

**Determinants of National Policy on Human Embryonic Stem Cell Research in Selected Countries: A Comparative Study**

by

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## **Abstract**

Embryonic stem cells have remained a polarizing issue around the globe. The plethora of potential applications and technologies are unfamiliar to most of society. Politicians and policy analysts continually work to pass laws acceptable to a public with diverse cultural, educational, and religious backgrounds. In this comparative study, fifty countries are analyzed regarding their stem cell policy, type and size of government, literacy rate, age, religiosity, and public and private research funding. Using binary logistic regression, religiosity demonstrated a significant inverse relationship, and public funding demonstrated a direct significant relationship on permissive ESC policies. As religiosity increased permissive policies decreased; whereas, when public funding increased permissive policies increased. There was no relationship found with age of predominant citizen, literacy, private funding, type of government, or size of government on ESC policy. In the realm of comparative policy theory, culture impacted a country's position on ESC policy in the form of religion and a pro-science culture evidenced by both public and private funding for ESC research. Future studies should consider using a mixed methods approach in correlating frequency of religious activities and age with opinions on ESC research. Annual funding for research from both public and private sources should also be pursued. The addition of the scientific literacy rate to future studies would also be beneficial in assessing the general understanding of stem cells in the public sphere and how well it correlates with current and future policy on ESC research. The trajectory of ESC research is dependent on both policy

and funding. Culture will continue to be a formidable factor in elucidating the nexus between moral issues and advances in stem cell research.

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## Table of Contents

|  |     |
|--|-----|
| Abstract.....  | ii  |
| Acknowledgments.....   | iv  |
| List of Tables.....  | vi  |
| List of Figures.....   | vii |
| Chapter I: Introduction.....   | 1   |
| Chapter II: Embryonic Stem Cell Research and Funding.....            | 22  |
| Chapter III: Literature Review.....                                  | 99  |
| Chapter IV: Methodology, Data Analysis, and Findings.....            | 119 |
| Chapter V: Discussion and Limitations of Study.....                  | 129 |
| Chapter VI: Conclusion and Recommendations for further Research..... | 146 |
| References.....  | 151 |
| Appendix.....  | 168 |

## List of Tables

|   |     |
|---|-----|
| Table 1. Binary Logistic Regression Analysis..... | 127 |
| Table 2. Study Data.....                          | 168 |
| Table 3. Collinearity Statistics.....             | 170 |
| Table 4. Public and Private Funding Data.....     | 171 |

## List of Figures

|   |     |
|---|-----|
| Figure 1. Catholic States and Funding.....                  | 173 |
| Figure 2. Non-Catholic States and Funding.....              | 174 |
| Figure 3. Three Tiered Model for evaluating ESC Policy..... | 175 |

## Chapter I Introduction

### **Science as National Policy**

History has shown that science can impart great benefits to society as well as great harm (Burke et al, 1985). The discovery of vaccines eradicated smallpox and prevented numerous other disease outbreaks on a global scale. On the other hand, the atomic bomb and poisonous gas led to innumerable deaths during WWII. It is this dichotomy that requires government officials to formulate policies carefully when discoveries are made. Of the thousands of research studies published annually in scientific journals very few of them necessitate or lead to the implementation of a national policy.

Examples of science policies that have been passed and implemented by governments due to a palpable medical threat include those related to transmissible diseases like smallpox, bubonic plague, and the Human Immunodeficiency Virus (HIV). Growing fears of a pandemic generally prompt immediate action by health and government officials to safeguard the public. Some scientific discoveries appear to have great potential to improve lives but raise questions with regard to religious tenets or morals. In vitro fertilization (IVF), reproductive cloning, and the subject of this study, embryonic stem cell (ESC) research, are prime examples. In addition, unethical scientific and medical research have been the impetus for both policies and laws to oversee and regulate research misconduct by scientists and physicians. The unethical medical experiments conducted during WWII in German concentration camps led to the World Medical Association Declaration of Helsinki in 1964, and syphilis studies conducted on black men in Tuskegee, AL led to passage of the National Research Act of 1974 both aimed at protecting



human subjects in research studies. This study examines factors that affect the development of ESC policy in fifty countries using binary logistic regression. The countries are Albania, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chili, China, Costa Rica, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Hong Kong, Iceland, Israel, Italy, Ireland, Japan, Latvia, Lebanon, Lithuania, Malta, Mexico, Morocco, New Zealand, Norway, Poland, Peru, Portugal, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, The Netherlands, Trinidad and Tobago, Tunisia, United Kingdom (UK), United States (US), Uruguay, and Vietnam. The criteria for selection of countries is 1) the legislature has passed a law on ESC research policy, and 2) the legislatures are characterized as unicameral or bicameral. The research question for this study is what factors influence the development of national ESC policy in most countries around the world. The factors being investigated are religiosity, literacy, age, type and size of government, and type of funding. The purpose of the study is to determine the reasons for national differences in attitudes (permissive or non-permissive) regarding ESC policy. Chapter I introduces the theoretical framework and the key methodological approach for this study.

### *Moral Status of an Embryo*

The major concern surrounding the use of human embryos in research is the moral imperative. Two moral principles that are highly valued in society are the duty to alleviate or prevent suffering and the duty to respect human life (Hug, 2006). When harvesting ESCs the latter duty is violated when in the process the embryo dies (Doerflinger, 1999). There are many

salient issues worthy of discourse and discussion surrounding the moral status of an embryo. These may include the relationship between humans and their environment, mental faculties in a comatose adult versus a developing human embryo, etc... For this dissertation I am going to focus on the question of when life begins. Most people believe life begins at conception (Nisbet, 2004). The majority of religions not only preach this tenet but also that all human life is sacred because it is created in God's image. This presents a major obstacle for scientists as billions of people in the world belong to religions that oppose ESC research. Embryonic stem cell research presents a unique ethical dilemma. Society is being asked to allow the killing of a life so that society can benefit in the future by proven treatments. How have people responded and what factors influence their opinion? There are many factors that play a role and many circumstances that influence a citizen's position on ESC research. Factors such as a family member with an incurable disease, political party platform, profession, or religion may impact the public's policy preference.

Some religious leaders are very absolute in their beliefs while some are willing to concede to other sides of the issue. The Roman Catholic Church and conservative Protestants are absolute in their belief that personhood begins with the zygote but would allow research on existing stem cell lines as they have already been created (Walters, 2004). More liberal Protestants concede the fact that although all life is sacred this must be weighed against potential benefits to society, and they are willing to consider factors such as when major organs are formed as a basis for determining partial person status. The central nervous system and beating heart are much more convincing than a clump of cells when assigning personhood. There are

many different churches characterized as being Protestant (e.g., the Church of England, the United Methodist Church (UMC), the United Church of Christ). Each of these may hold different beliefs on ESC research contributing to the varying views across the world. In the US two world leaders who happened to be Protestant had a major impact on ESC policy. Former President George W. Bush is a member of the UMC and opposed ESC research. President Barach Obama is a member of the United Church of Christ and favors ESC research. The differing views on ESC research among Protestants are likely the result of a central body, like the Vatican, not taking a unified stand on the issue and the multitude of Protestant churches with different views.

In Judaism, the human fetus less than 40 days old does not have human status. Further, activities that facilitate advancements in the world are not looked upon as deliberate contradictions to divine decrees, as God is the architect for the creation of new technologies (Lampman, 2001). With advances in science and changes in attitudes, people have the opportunity to consider what is known regarding the embryo. People with an incurable disease or an afflicted family member are especially motivated to gather all information available on treatment options.

While most people agree that a fertilized egg deserves protection based on the potential to become a person, most also agree that pre-implantation embryos do not have the psychological, physiological, emotional or intellectual characteristics associated with personhood (Rickard, 2002). Moreover, many people have accepted that a human embryo becomes worthy of protection at day 14 post fertilization. Most worldwide policies on ESC research incorporate this

time frame for the following reasons: the embryo can no longer divide to form twins after 14 days, and the central nervous system is not formed until after 14 days. Without a central nervous system the embryo cannot feel pain. The predicament of whether to allow scientific research that violates moral ethos, but which could be beneficial to many will not be solved in the near future. As more research studies are published, public opinion may shift depending on the outcome, interpretation, and applications of these studies.

Embryonic stem cell research has generated tremendous excitement in the scientific world as every new study published contributes to our understanding of the functionality of ESC cells and their potential in medicine (Thomson, 1998, Kehat et al, 2001, Tachibana et al 2013). The political sphere has embraced these discoveries with equal fervor. Politicians who support ESC research speak enthusiastically about the great potential of stem cells while their legislative opponents mobilize religious groups and other pro-life entities to highlight the negative aspects of stem cell research using embryos. In democratic societies the goal of public policy is to provide the maximum benefit for the greatest number of people; however, viewpoints differ on what constitutes the greater good and on the means to achieve it. Politicians may be torn between their own goals and fulfilling their representative legislative function. Their own goals may be dependent on tenure of office, coalitions, or loyalties to parties. For example, a member of parliament belonging to a party which is pro-life and against ESC research would be more apt to vote along party lines even if he or she saw value in stem cells to secure re-election or remain committed to their party platform. The repercussions of voting for a law which contradicts the party platform are palpable; and often results in lack of funding and support for re-election, lack

of support for a bill the politician sponsors, or being removed from a committee to name a few. In 2006 republican senator Bob Bennett of Utah voted for the 2006 Stem Cell Enhancement Act which allowed for experimentation on human ESCs. In 2010 Bennett voted for the bank bailouts and was voted out of office that same year, losing a senate seat he had held for eighteen years (Miller, 2012).

Democracy is better served when the goals of constituents take precedence. In countries such as Sweden, the UK, and Belgium, to name a few, where the majority of the population support ESC research, members of parliament have represented and honored their oath in carrying out the will of the people regarding stem cell policy. Societal influences may direct a person on how to think or which policy to favor over another. Citizens communicate their policy preferences to their political representatives with the hope that their voices will be heard and votes will be cast accordingly.

#### *Civic Action as an Instrument for Change*

Countries such as Norway have utilized civic action to change the law on ESC research. While civic action is not a variable in this study, it is prudent to provide a foundation of civic action as a venerable tool for impacting policies on ESC research that all people and cultures may utilize in attaining laws that best matches their values. Public policy driven by community support may be dependent on access to civic groups and citizens propensity to engage in dialogue (Dalton, 2004). The idea of democracy is binary; it provides both civil and political rights, entitling people to freedom of choice in their public and private actions (Dahl, 1973); the

majority preference on an issue is translated into law by their state or local representative(s). This idea was more tenable, according to Dewey, when the public participated more in their local communities. As Dewey states in *The Public and its Problems*, for democracy to be realized it must “affect all modes of human association:” (Dewey 1940, 40) that is, schools, churches, neighborhood communities, recreation venues, industry, work, libraries, and other community oriented facilities. The public is comprised of individuals, each with his or her own interests and beliefs, allowing them to become members of multiple groups in the community in which they live or work. These groups interact with other groups to promote more public discourse. Human association is an organic phenomenon; people are social beings and creatures of habit. It is through habit that the community interacts and groups grow in function and in number. Habit in this sense refers to being taught at a young age to participate in social activity. As adults, we are accustomed to continuing this activity in satisfying social needs and being involved in the community. Aristotle believed all communities were like parts of the political community whose goal is to seek that which is advantageous for the whole of life or society. He placed the community above the individual in the city-state. Society thrives when people with similar needs and goals are able to communicate in solving problems. Communication originating from social inquiry is equivalent to the formation of public opinion (Dewey, 1927). According to Dewey, the problem for the public is to improve the methods and conditions of debate, discussion and persuasion.

There are many examples of civic action effecting change in policy. With regard to ESC research policy, citizens of Norway called for change in 2004. Prior to 2004, Norway had one of

the strictest laws involving ESC research. Embryos could not be used for research because their use would violate evolving human rights. In 2004, there was a salient community campaign to loosen these restrictions. It involved a six- year-old Norwegian boy, Mehmet Yildiz. Mehmet was diagnosed with an inherited blood disorder called thalassemia. The campaign sparked a political crisis. Utilizing community outlets (e.g. media, medical experts, neighbors) the Yildiz family lobbied for prenatal genetic diagnosis (PGD) so that embryos could be tested for the abnormal gene linked to thalassemia and Mehmet could receive a stem cell transplant from a normal embryo. Through the use of media outlets, Mehmet generated huge sympathy among Norwegians, which ultimately eclipsed political opposition in Parliament.

Imagery is a powerful medium and often produces a long-lasting effect on people that conjures up emotions. In one television program viewers could see the painstaking process Mehmet and his parents went through in frequent visits to the hospital when Mehmet needed a transfusion. The significant factor of civic action in this case was the original intent to allow PGD, which is quite different from ESC research and all of its potential applications. Because the public became engaged, the law in Norway was changed in 2008 despite opposing views of some politicians. Research is now allowed on surplus or left-over embryos as long as the goal of the research project is to cure disease. Some of the opposition included the Prime Minister Kjell Magne Bondevik, a priest in Norway's Lutheran state church and a member of the Christian People's Party; he viewed research on embryos as scientists playing God by using spare parts for diseased siblings. The Mehmet case illustrates how one citizen's predicament can galvanize a community to change a country's law, even in the face of political opposition.

## *Social Capital*

The change in law on the heels of the Mehmet case can be viewed as an example of social capital. Social capital can be defined as networks, norms, and values that individuals or groups mobilize in formal or informal relationships to achieve a common goal. Communal orientations create social capital, and this is reflected in volunteer groups and trust among citizens (Putnam, 2002). Social capital has changed and become more pervasive with societal modernization; that is, the shift from agrarian to industrial and post-industrial society. Whether the result of secular trends in secondary and higher education, changes in the workplace and mass communications, or a more informed public, people are poised to come together for better policies. In agrarian societies, slaves and peasants labored for land owners. In the Industrial Age people were essentially cogs in a wheel and controlled by powerful employers until the advent of Trade and Labor Unions in the 18<sup>th</sup> century. Attitudes began to change in the post-industrial age as people became more expressive and independent in forming their own opinions on pertinent issues. People were empowered from the successes of Unions in improving pay and working conditions; they were now challenging political elites and bypassing the laissez faire mentality.

Communication is a prerequisite for civic action. It may be achieved in face-to-face meetings, formal or informal gatherings of friends, neighbors, or people with common interests in the group function. Depending on the composition of the groups, people may network with other people in other groups which may lead to further development of the cause; for example, if a member of a volunteer group happens to be a politician or have experience in legislative



proceedings, he or she may lead the charge in the state or national legislature to garner support for policy change. These social forces may channel collective actions toward political outcomes (Inglehart and Welzel, 2008) and be independent of party alignment (Dalton and Watterberg, 2000).

In Denmark, universities and professional societies sponsor “Science Theatres” (Arnason et al, 2007, 14) to encourage public debate and discussion on stem cell research. Discussion is also encouraged in most primary and secondary schools in Denmark where pupils aged 14 and above are taught the basic principles of stem cell research. In 2005 the European Commission (EC) provided funding to the European Federation for Neurological Disorders for a one-day conference on all aspects of stem cell research with a special emphasis on patients. The Conference was entitled “Stem Cells: European Patients Debate the Issues.” Approximately 500 European Union (EU) citizens discussed and debated present and future aspects of stem cell research. Professional groups included physicians, bioethicists, journalists, and scientists. Conference proceedings were made available via radio and television, websites, journals, newsletters, and on CD-ROM. The event was held in Brussels with free registration. The conference served as a testament to the EU’s dedication to involving all citizens and stakeholders in determining the best path forward for member states of the EU and their citizens.

Persons taking stock in social capital is paramount to success of policy formulation and implementation. For example, Germany’s policy on ESC research allows scientists to perform research only on imported ESC lines with date restrictions. This importation policy has not been

liberalized to allow research on surplus embryos in Germany since its time of enactment in 2002. What are the reasons for this? The public accepts the compromise of importation in consideration of Germany's history of unethical medical experiments and scientific accomplishments. Catholics, the Green Party, and women's groups keep pressure on the German parliament through the media and their supporters to allow the policy to go forward without allowing changes that violate their tenets. The policy is successful in the eyes of many Germans because scientists are still allowed to perform research and publish their findings. If however, families with diseased children thought there was a credible chance such research and treatments could provide a cure the situation might be different. The families would be the ones to mobilize supportive groups in society counteracting religious and other opposing groups in an effort to change the law.

### *Political Party Alignment*

Throughout history, the creation of political parties made it easier for representatives and activists to accomplish things relevant to their ideological platform. Aggregation of issues and subsequent strategic packaging to voters was commonplace. Members of parties made decisions on societal issues largely from information the party organization machine provided. The modernization process has resulted in individuals moving away from political party alignments on a variety of issues. These include gender equality, reproductive rights, environmental issues, and lifestyle choices (Inglehart 1990). Embryonic stem cell policy can also be included. In 2002 when debating the Stem Cell Act, Peter Hintze and Wolfgang Schäuble who are members of the

CDU (Christian Democratic Union) in the German Bundestag not only supported unrestricted importation of ESCs but also the notion of German researchers creating their own ESC lines (Reiter, 2002). The actions of Hintze and Schäuble clearly demonstrate a break in party alignment on the stem cell issue in Germany. The political platform of both the CDU and CSU (Christian Socialist Union) are steadfastly against ESC research. The reasons for Hintze's stance may stem from his background in Protestant theology as he holds a degree from Rheinische Friedrich-Wilhelms University of Bonn and University of Wuppertal Church. Protestants are typically more accepting toward ESC research in comparison with Catholics. Another example is former Chancellor Gerhard Schröder and the former President of Germany, Johannes Rau. Both officials were members of the social democrats, whose platform was more accepting of ESC research than the CDU and CSU parties. Schroder believed that gene technology would bring new jobs and opportunities for Germany, while Rau was adamant that ESC research was no different than Nazi eugenics (Cohen, 2001). These two examples demonstrate that ESC research is a divisive issue within political parties.

Taking a position that counters the platform of a members political party has weakened and in some instances helped to dismantle the saliency theory proposed by Budge and Farlie (1983), which said that when political parties compete against one another they do so on the basis of policy drawing support from the people who favor their position on issues. This theory was less porous in the 20<sup>th</sup> century when a political party owned and campaigned successfully on select issues. Party materials distributed to the public were not questioned as they are today. Party leadership must alter their marketing strategies to the current societal barometer and

espouse what the public wants to hear to remain viable. People are more educated today and value independent thinking on issues that concern them. The internet has replaced the political party leaflet enabling people to make up their own mind on issues and finding their own reference material. In advanced industrial societies a partisan dealignment theory has been postulated by Dalton. Individual and systemic factors have influenced dealignment where members of a party no longer support part of the party platform. Higher educational levels have resulted in more citizens developing their own opinions on issues and becoming self-sufficient in the political sphere (Dalton, 1984). The explosion of mass and social media venues and public interest groups has to an extent replaced political parties as the source of information on issues.

### *Comparative Policy Theory*

A wide range of societal questions can be answered in comparing one country to another or multiple countries using analytical tools and a subject of study (Lim, 2010). Comparisons may be made on political, economic, cultural, and social issues.

Four types of comparative theory are the rationale, structural, partisan, and cultural positions. The rationale position focuses on the behavior of the individual and the decisions and actions taken given their environment and circumstances. Brams (1992) posits that individuals will weigh a set of alternatives over the status quo as to ponder costs and benefits of a particular action. There are many examples that can be presented here. When Adolf Hitler came to power in 1933 and laws were passed reclassifying German citizenship, those people and families who were now classified as non-citizens based on non-Aryan heritage pondered their alternatives to

the status quo. The rationale choice is focused on the individual and their circumstances. That is, discrimination under a dictatorship (status quo) or emigration to another country (alternative). The degree of self-interest or egocentrism will depend on the environment as far as what rationale choice is made (Little, 1991). Consider parents of a child diagnosed with leukemia. If the only hope for their child's survival was a stem cell transplant but such an intervention was against their religion, they may rationalize in favor of saving their child over religious restrictions.

In contrast, structural theory is based on relationships and networks in society. Lim suggests structural forces are susceptible to change. Change may be dependent on social tensions as they relate to the structure. For example, feudalism survived and thrived for centuries throughout Europe until social unrest grew strong enough to change the structural force or economic system of Medieval Europe. Structure as it relates to comparative studies can also be applied to government (UCL, 1998). In Japan, for example, a revolt ensued in 1993 over scandals surrounding the Liberal Democratic Party (LDP) which has dominated the Diet since 1955. The LDP perfected the art of winning elections by soft campaign promises, fierce interparty competition, and *koenkai* factions (O'neil et al, 2010). This ultimately led to prominent members of the LDP bolting and forming new parties and LDP coalitions. Most governments today have either a unicameral or bicameral legislature, with the former being in the majority. Throughout history there have been changes regarding government structure. In the 20<sup>th</sup> century, Germany moved from a bicameral government to a dictatorship back to bicameral. Denmark moved from a bicameral government to a unicameral government. The reasons for this change in

structure vary from state to state but are primarily based on characteristics of bicameral and unicameral structures. Bicameral legislatures have more checks and balances and the opportunity for brinkmanship, where unicameral legislatures are thought to be more efficient, albeit less democratic, with possibly more policy output. Regarding structure, this study will examine the effect of type of government and size of government on ESC research policy in fifty countries. A more detailed comparison of unicameral versus bicameral can be found in Chapter III.

Partisan theory can be described as party composition of government effecting public policy that is, a 'parties do matter' philosophy (Hibbs, 1992). Most of the empirical studies have involved Organization for Economic Cooperation and Development (OECD) countries. These countries have two-party or multiple party systems allowing for ideological polarization and evolution and/or changes to party platforms over time. Most of the studies published in the literature involve public revenues, welfare, and other social policies expenditures tied to a leftist party majority. Researchers have delineated parties toward the left-right or left-center-right spectrum quantitating number of leftist majority seats in parliament or the cabinet, with correlations to social program expenditures. Cameron (1978) examined the role of partisanship in expanding public revenues by studying 18 capitalist nations after 1960. Large nations like Germany and Great Britain demonstrated more partisanship than smaller countries. Non-leftist parties controlling government in both Germany and Britain exhibited modest increases in the public economy compared to majority leftist parties. In contrast, smaller countries like Denmark and Norway showed no difference in advancing public economies whether the government was controlled by social democrats or conservative parties. Countries with more open economies

(e.g. Belgium, Ireland) were also more diligent in increasing public expenditures independent of partisanship. Cameron posits the maturation of the welfare state has led governments to play an active role in the public economy by raising taxes and controlling activities of major industries and financial institutions. Cameron found that left-Right partisanship was more evident in larger countries with closed economies compared to smaller countries with open economies.

In regard to the left-center-right trichotomy, Blais et al (1993) analyzed fifteen liberal democracies from 1960 to 1987 analyzing total public spending as a percentage of GDP and parties of the cabinet characterized as left, center, and right. They found that a majority government controlled by the left increased domestic spending. Addition of center parties introduces an aspect of variation situating centrist parties between the extreme poles of left and conservative tendencies. One of the criticisms surrounding this theory is changes in party platform on social issues, such as the leftist parties in the majority supporting a bill which cuts social programs (Schmidt, 1996). Such changes may be difficult to predict leading to unexpected results of empirical studies.

It is clear that the partisan theory model consumes economic issues. However, one study by Fink (2008) analyzing strictness of ESC policy in OECD countries did find a significant relationship between Christian Democratic parties and strict laws regarding ESC research policy. Christian democratic parties led to strict laws regarding ESC research in countries like Italy, Austria, and Germany. Partisan theory is discussed here as it is a staple of comparative studies. It

is not measured in this study, however, given the selection of countries having single party as well as multiparty parliaments.

Culture theory in comparative politics is highly complex and prolifically defined in the literature. A British anthropologist, Edward Burnett Tylor (1871), posited culture is that complex whole which includes knowledge, belief, art, morals, custom, and any and all other capabilities and habits acquired by men and women as members of society. According to Dahl (2006) culture is a learned, symbolic system of values and beliefs; it is shared, arbitrary, internalized, patterned, and mutually constructed. Culture is the pattern of beliefs, behaviors, and values maintained by groups of interacting people (Holvikivi, 2007). Schein (2010:18) defines culture as “a pattern of shared basic assumptions learned by a group as it solved its problems of external adaptation and internal integration, which has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems”. Schein further delineates culture into organizational, microculture, subcultures, and macrocultures. Organizational cultures comprise private, public, nonprofit, and government entities; microculture refers to microsystems outside or within organizations such as an operating room within a hospital. Subcultures are occupational groups inside organizations such as sales personnel inside pharmaceutical companies, and macrocultures refers to national, ethnic, and religious groups. Schein also differentiates social reality from individual reality. In the former, Schein describes phenomenon that are not testable and therefore must be determined by group consensus such as when an embryo is considered a human being; in the latter, a personal experience may impact positions on issues. Reaching a consensus within a group



becomes more difficult with increased cultural diversity and personnel experiences related to issues of discourse.

Culture is learned through repetitive activities, written communication, and verbal communication, transmitting knowledge from one generation to the next. Values and beliefs may be taught through religious practices, schools, organizations, and also in the family unit. These values may be unique to one culture or common to all. In Arab culture it is acceptable to practice polygamy; in all cultures, trade of goods is practiced in one form or another. People belonging to a culture share and exchange ideas on a regular basis. This serves to strengthen unity and beliefs, while leaving the door open for change. Intersubjective representations approach to culture examines the separation of an individuals' knowledge about their culture and their personal beliefs (Wan, 2012). Keesing (1974) posited that the structure of a culture is shaped by individual minds and brains; "cultures must be thinkable and learnable, as well as livable" (Keesing, 1974, 86). A culture that is not livable, where people are discouraged from thinking, learning, and adapting to positive change, will eventually be extinguished, i.e. Nazism, by other countries who perceive a culture as a threat to their own values and self-determination.

Culture has also been described as a *virtual onion* where each individual contains unique layers of cultural experiences and identity, like layers of an onion, which can shift in certain circumstances (Straub et al, 2002; Gallivan and Srite, 2003). In the realm of ESC research education, religiosity, family health history, ideology may represent separate layers and influence

a person's position on policy. Persons of a group engaged in conversation share certain beliefs of their culture; however, that is not to say that change in beliefs or practices never occurs.

Invention is one instrument for change. In the time of hunters and gatherers, the spear was used to hunt game. When the bow and arrow was invented, it replaced the spear because it was more effective. The sail replaced the paddle for sea travel, and the automobile replaced the horse and buggy. The comparisons are endless. Inventions and innovation precipitate change in culture aided by the knowledge and ingenuity of both scientists and engineers in the community (Layton, 1974). History has shown that cultures are not static; they change when a new idea overpowers conformity. Change can also occur when one culture sees how another culture is doing something they are unfamiliar with; that is, diffusion of an idea from one culture to another. Diffusion may be direct or forced. In the former, one culture is in close proximity to another precipitating exchange of ideas; in the latter, people belonging to one culture defeats people belonging to another culture via conflict or war and may force them to take on their cultural ways of life.

Cultural theory is applicable to ESC research policy on multiple levels and may include diffusion of policies on ESC research and exchange of new ideas. In the former, the UK was one of the first countries after James Thomson's discovery to pass a permissive law on ESC research. Many countries have followed the UK's lead specifically in regard to the time limit of 14-day development of the embryo. Technology has also precipitated change. Like the discovery of IVF treatment, ESC research offers a potential benefit that was not possible before. If most cultures

believe in providing the greatest good for the greatest number of people and minimizing human suffering, (Bentham, 1789) it is plausible that people would support such research based upon what has been published in the literature, as long as it did not contradict societal mores. Factors analyzed in this study such as age, literacy rate, religion, and funding also relate to culture. In certain cultures young people may be encouraged to think independently compared to other cultures and be more open to technology. The elderly may be less interested in technological advances that pervade society and less willing to change beliefs on controversial issues. Literacy rates relates to how much emphasis cultures place on education. Religion in culture places an emphasis on moral values, religious beliefs, deity, and religious practices. Funding may influence a scientific culture, as posited by Feuer et al (2002) where researchers in the community are free to practice their trade by studies that are supported by the general public and/or private enterprise, consistent with the mission of public agencies and private foundations. For example the Bill and Melinda Gates Foundation, which strives to improve the health of people through research initiatives in developing countries, has pledged \$50 million for development of drugs and vaccines to combat the Ebola crisis of 2014-15.

The theories outlined in this chapter provide a general foundation for ESC research policy formulation in the fifty countries studied. This research will provide an analysis of what national factors influence a permissive or non-permissive policy on ESC research. This research is significant because it is a quantitative study in the realm of ESC public policy and examines a number of other national factors that influence national ESC policy. It would also be quite interesting to know if in fact a bicameral government is more associated with restrictive policies

because of a more rigorous legislative process compared to a one chamber legislature. Other factors examined include religiosity, age, size of parliament or congress, literacy rate, and funding. These factors and methodology will be discussed in detail in Chapters III and IV.

## Chapter II Embryonic Stem Cell Research Policy and Funding

This chapter discusses the basic characterization of stem cells, ESC policies, type of legislature, and private and public funding agencies. Specific issues regarding a country's policy on ESC research will also be discussed where applicable.

### **Classification of Stem Cells**

Stem cells are characterized as undifferentiated cells capable of self-renewal. They represent a potential therapeutic modality for many diseases for which there is no cure. Stem cells can be divided into three general groups: 1) ESCs, 2) somatic (adult) stem cells, and 3) induced pluripotent stem (iPS) cells. ESCs are derived from pre-implanted early human embryos. They are pluripotent, and therefore capable of complete differentiation, giving rise to all tissues in the adult human. Human ESCs can be acquired using surplus embryos left over from IVF procedures or through a process known as SCNT (somatic cell nuclear transfer) also referred to as therapeutic cloning. This is a procedure used to create ESCs that are genetically identical to a specific individual. Briefly, a nucleus from a patient cell is placed into an human egg cell that has had its nucleus removed; once stimulated it grows into a blastocyst and is manipulated using various proteins where specific cell types can be injected into the patient. A blastocyst can be described as a five to six day embryo. These cells are genetically identical to the patient alleviating the problem of graft rejection. James Thomson from the University of Wisconsin is credited with developing the first human ESC line using human embryos left over from IVF

procedures. This work was viewed as a medical break-through around the world; scientists and healthcare providers were eager to join and support the ensuing stem cell race.

Somatic stem cells, referred to as ‘adult’ stem cells, provided an alternative to policy makers who oppose ESC research. These cells are easier to acquire and less controversial in the realm of research ethics. Sources include umbilical cord blood, peripheral blood, bone marrow, heart, brain, and other tissues. They are devoid of the plasticity seen with ESCs and therefore are characterized as multipotential stem cells. Where ESCs can form nearly any cell in the body, adult stem cells are more limited in their differentiation capacity. Many politicians who are opposed to ESC research for moral reasons lean toward adult stem cell research as a viable alternative. Transplants using stem cells from peripheral blood and umbilical cord blood have been successful in patients encompassing a variety of disease states (Rocha, 2004, Bensinger 2012). However, when Thomson’s discovery was published scientists began to theorize what was possible beyond the limitations of adult stem cells and how patients could benefit. Finally, iPCs are adult cells which have been manipulated in the laboratory to act like ESCs; that is, these cells can develop into any tissue in the body (Okano, 2013) just as Thomson showed in his seminal study using human embryos. The importance of iPCs for the purposes of this study is use of these cells are devoid of the moral controversy associated with human ESCs, and such an argument can be used by policy makers opposed to ESC research using human embryos.

## ESC Policy and Funding in Select Countries

The countries chosen for this study are Albania, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chili, China, Costa Rica, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Hong Kong, Iceland, Israel, Italy, Ireland, Japan, Latvia, Lebanon, Lithuania, Malta, Mexico, Morocco, New Zealand, Norway, Poland, Peru, Portugal, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, The Netherlands, Trinidad and Tobago, Tunisia, UK, US, Uruguay, and Vietnam. As mentioned in chapter I these countries were selected based on the type of legislature and having a bill or law on ESC research policy. A non-permissive policy on ESC research can be defined as prohibiting all research on human embryos or only allowing research on imported human ESC lines. A permissive policy can be defined as allowing research on surplus human embryos left over from IVF techniques and/or allowing therapeutic cloning. For the purposes of this chapter surplus human embryos will be used to describe those human embryos that were created by IVF techniques. The laws for each of the fifty countries concerning ESC research are described below, as well as any perceived issues with policy, where applicable.

**Albania.** Albania has a unicameral legislature (*Kuvendi i Shqipërisë*). Research using human embryos is prohibited from any commercial, industrial, or experimental purpose in the 2002 *Law on Reproductive Health*. The law does not place unreasonable stress on the woman but it is clear that the Ministry of Health regulates all aspects of the law. Contraceptive devices and

fertility services are available for those couples that need them. Albania's abortion law is liberal and couples are free to decide if they want to start a family, and the government provides many resources to that end.

Research using adult stem cells, however, is thriving in Albania. In 2011, a conference was held at Hygeia Hospital Tirana entitled "Stem Cells: The Future of Medicine." Service to the citizens of Albania was emphasized in the hope of cures for people afflicted with disease. Physicians from Greece met with their Albanian counterparts and shared their knowledge of cord blood banking which would provide a rich source of adult stem cells for research and clinical use. The CEO of Hygeia Hospital Tirana emphasized the significance of the stem cell bank describing it as "a novelty in medicine" (Hygeia Group, 2011). It is clear that Albania, while formally against ESC research, is pursuing a path that will provide hope to families who are afflicted with disease while at the same time respecting societal values.

Public funding is available through the Agency of Research, Technology, and Innovation (ARTI), Ministry of Education and Science (MOES), and the Albanian Science Academy (ASA). ARTI was established in 2010 to strengthen science and research integrated with higher education in Albania. The MOES is the state authority which monitors and oversees higher education in Albania. It supports both public research and private sector endeavors. Biotechnology is one of six national programs to address scientific activity in the country. The ASA was founded in 1972 and is characterized as an institution with organizational autonomy and scientific independence. It is made up of distinguished scientists and academics who develop



and participate in scientific activities at various institutions. Members also coordinate activities with other academies, both regionally and internationally.

*Australia.* Australia has a bicameral legislature (*Senate and the House of Representatives*). The law in Australia regulating ESC research was first passed in 2002. *The Prohibition of Cloning Act and the Research Involving Human Embryos Act* prohibits reproductive human cloning and allows research on surplus human embryos. A Legislation Review Committee was formed in 2005 to revisit the 2002 law and offer recommendations. Members consisted of a clinical ethicist, a physician and community advocate, a lawyer and ethicist, a clinical neurologist, and a neuroscientist. Recommendations included allowing therapeutic cloning, creation of a national stem cell bank, and a national register of donated excess surplus embryos. Inspectors would be given the authority to enter the premises of licensed and non-licensed facilities to ensure personnel were acting in compliance with law. Guidelines for egg donation with special reference to the circumstance of embryos being deemed unsuitable for reproductive purposes were also inserted as related to results of the PGD test. Creation of hybrid embryos, where an animal is fertilized by a human sperm, would also be permitted. The committee consulted with State and Territory Government representatives and heard oral views from 109 people across every State in Australia. The Committee Chair stated “The Committee believes it is important for Australia to maintain its role as a leader in the advancement of high quality and ethically sound scientific research and medical practices” (Legislative Review Committee, 2005). All recommendations were included in the amended law. The National Health and Medical Research Council (NHMRC) must maintain a database comprised of

researchers who were granted licenses, how human embryos were used, conditions of the license, date of issue, and time period of license; this database must be accessible to the public. Australia has employed the democratic process in derivation and amendments to their laws regulating ESC research. Leaders and scientists are poised to keep pace with advancements in the field supported by a regulated but permissive law and tremendous resources.

In 2011 the Department of Innovation, Industry, Science and Research and the Treasury Department announced a research and development (US\$) 1.9 billion tax credit to boost biotech companies innovation activities. This move has cross party support and expected to increase intellectual property production and launch the start of clinical trials allowing products to enter the market sooner than predicted. Other sources of public funding are the Australian Stem Cell Center (ASCC) and the Australian Research Council (ARC). The ASCC is located in the Australian Biotechnology Centre of Excellence at Monash University. Its mission is to be a resource hub of academics, scientists, and industry leading to therapeutic modalities for millions of Australians suffering from disease. In 2011 the Australian government allocated 21 million dollars for a period of seven years to the ARC to be used for funding approved research projects.

***Austria.*** Austria has a bicameral legislature (*Federal Council and the National Council*). Embryonic stem cell research, therapeutic cloning, and reproductive human cloning are banned. The *Forschung an Humanen Embryonalen Stammzellen* (Research on Human Embryonic Stem cells) under the Reproductive Medicine Act of 2004 and the Medicinal Products Import Act of 2002 mandates that viable cells may not be used for purposes other than medically assisted

reproduction and further that the procurement of human ESC lines from the inner cell mass of a fertilized egg is prohibited because such an act would constitute a processing of a viable cell for purposes other than inducing a pregnancy. However, importation of ESCs is not illegal under the law. A loophole exists in Austria's policy allowing ESCs from abroad or imported to be used in research. Therefore, under the Reproductive Medicine Act procurement of cells from an embryo is prohibited, however, research using imported stem cell lines is not. Further, the *Medicinal Products Import Act* only specifies therapeutic products; imported ESCs are not considered therapeutic products.

Public funding for scientific research in Austria comes mainly from the Funds for Promotion of Scientific Research or *Wissenschaftsfonds* (FWF). The mission of the FWF is the advancement of the science of high international standard. It contributes to the cultural development, and the expansion of the knowledge throughout society, and seeks to increase value and wealth in Austria. There are twenty-five members from all areas of science which made up the Board of Trustees. It is this body that decides on which projects are funded. Another public source of funding is the Vienna Science and Technology Fund or WWTF (Wiener Wissenschafts-, Forschungs- und Technologiefonds), established in 2001. The WWTF funds major scientific projects in basic research that offer the prospect of economic or social benefits. Funding ranges from (US\$) 263,000 to 1.3 million. It is clear that the research infrastructure in Austria encourages collaboration between universities and biotechnology firms.

**Belgium.** Belgium has a bicameral legislature (*Senate and Chamber of Representatives*). *The Act Regarding Research on Embryos in Vitro* was supported by the Flemish and French speaking liberals as well as the Green party, while opposed by the Christian party. The bill regulates research using human embryos. Established in 2003, the law had three important goals: 1) to determine conditions in which research using embryos may be performed, 2) to prohibit eugenic practices, and 3) to prohibit reproductive cloning (Pennings, 2003). Research is allowed on surplus human embryos within 14 days of fertilization. This is subject to the condition that therapeutic goals are pursued with the research and that insights are gained into the prevention or treatment of disease. The obtaining of new insights in the areas of fertility, sterility, and organ/tissue transplantation also constitutes grounds for conducting research on embryos in vitro, if no other research methods promise results of equivalent quality. The creation of embryos purely for research purposes or therapeutic cloning is generally prohibited, although permitted if the available surplus embryos do not meet the needs of the research project. Adhering to the tenets of the law reproductive cloning is prohibited. Each research project on human embryos must be approved by an ethics committee of the academic institute that is involved and the Federal Commission for medical and scientific research on embryos. Informed consent must be secured from the parents.

The Federal Commission reports to the legislative chambers on an annual basis and the Commission decides whether the research project should commence by a two-thirds majority. The Commission is made up of four physicians, four doctors in fields of science, two lawyers, and four experts in the social sciences and ethics. Restrictions on the law include human embryos

may not be implanted in animals and work cannot be performed on embryos past 14 days of fertilization. Embryos on which research has been performed may not be placed into the woman's reproductive system unless it involves a therapeutic goal for the embryo or an observational method where the structural integrity of the embryo is not harmed. An example of an observational method is examining microscopically for irregularities in the blastocyst. Sex selection of the fetus may not be carried out for nonmedical reasons as well as the genetic makeup of the fetus may not be manipulated for nonmedical reasons (eugenics). One problem with the law is approving and monitoring requests for creation of human embryos when surplus human embryos are not available. What type of documentation would the researcher need to provide to make the case that surplus embryos are not available. These points would likely be determined by the Federal Commission.

Public research funding agencies include INNOVIRIS, the Scientific Research Foundation or FWO (*Fonds Wetenschappelijk Onderzoek*), the Special Research Fund or BOF (*Bezonder Onderzoekfonds*), and the Funds for Scientific Research or FNRS (*Fonds de la Recherche Scientifique*).

INNOVIRUS was created in 2003 and known as the Brussels Institute for Research and Innovation. Its mission is to promote and support technological innovation through the funding of research and development projects developed by companies in the Brussels area.

INNOVIRUS offers co-financing to companies who have received funding from other sources

based on how large the enterprise is and the percentage of funding they have received from other sources. It also offers 100 percent of funding to research institutes and universities.

The FWO started in 1928 as the National Fund for Scientific Research or NFWO (*Nationaal Fonds Voor Wetenschappelijk Onderzoek*) following a call from King Albert I to increase funding for scientific research. This fund financed the stratosphere flights of Professor Jean Picard in 1934. Funding throughout the 20<sup>th</sup> century came from government subsidies and donations until 1981 when the community provided the main source of funding. The mission of the FWO is to stimulate and support groundbreaking fundamental research in all areas of science at the universities in the Flemish community, including collaboration agreements between Flemish universities and other research institutes. Funding is awarded on the basis of interuniversity selection with the only criterion being scientific excellence regardless of scientific discipline, host institute, gender, politics or religious persuasion. A central tenet of the FWO is that basic research facilitates innovation leading to economic growth, welfare, and well-being.

The BOF was created in 2000 and funds university projects focusing on quality and innovation and those that further new research directions and are monitored by the Research Council. The tasks of the Research Council are to scientifically assess research project applications and applications for fellowships. The BOF adds 12 percent to government contributions of approved research projects.

The FNRS was established in the 1930s and promotes the production and development of knowledge supporting individuals and research teams in universities of the Federation Wallonia-

Brussels. Monetary awards include scholarships and fixed term contracts for research projects which precede permanent employment by a university.

**Brazil.** Brazil has a bicameral legislature (*Federal Senate and Chamber of Deputies*). The *Biosafety Law* was passed in 2005 allowing research on surplus human embryos provided that the embryos have been frozen for three years or more. Human cloning and therapeutic cloning are prohibited. Parental consent is required and researchers must have their proposals approved by the National Biosafety Technical Commission. Multiple disciplines are well represented on the Commission whose mission is to monitor the development and technical and scientific progress on biosafety, biotechnology, and bioethics as well as approve research projects. Prior to the passage of the bill, Catholics and Evangelicals formed a caucus in the lower house (Chamber of Deputies) to try and block the bill. The newly formed caucus focused on the beginning of life argument. This resulted in changes to the bill to the effect of banning all types of ESC research. In the senate, however, science experts testified brilliantly and effectively, by diverting the question of when life begins to how to address the abundance of surplus embryos that are being discarded. Dr. Drauzio Varella, an oncologist, testified that “no one knows what happens to the embryos” (Cesarino, 2011, 234), indicating that a great many embryos may be discarded. Dr. Patricia Pranke, a stem cell researcher, suggested a more noble destiny, “to save lives”. Dr. Mayana Zatz, a stem cell supporter, injected the circle of life reference, “many scientists think life has no beginning and no end, that life is a cycle, so...if we keep the embryo frozen, if we don’t use it, the cycle comes to a halt. If we use the embryo’s cells to save a life, we’ll be resuming the cycle of life.” This is an example of creatively and effectively framing a

contentious issue; Brazilian experts were able put forth the notion of blastocysts being interchangeable with patients. Most of the Catholics and Evangelicals in the Senate were swayed by the testimony. Senator Osmar Dias, proclaimed “I am a Catholic, I am not contradicting my biblical principle because I’ve read in the Bible that we should protect life, and life in this case means to provide the conditions so that cells which are not yet life can be used for research that can save lives.” The bill passed the senate as rewritten allowing ESC research and then passed the lower house in 2005 and was signed into law.

After the bill became law the constitutionality of the law was swiftly challenged by Claudio Fonteles, who was the attorney general at the time. Fonteles argued that the Biosafety law violated the right to life and dignity of the human person. Six of eleven judges voted to uphold the law, and nearly all of them bypassed the question of when life begins. They focused on Brazilians who could benefit from the research and using surplus embryos in research is more dignified than throwing them away. Of those that did address the life question, one position put forth was that only those [embryos] inside the womb have constitutional value (Cesarino, 2011). Brazil is an interesting case because of being a predominant Catholic nation and yet they were able to frame the ESC research issue in favor of a permissive law. It is likely however, that Catholic leaders will continue to challenge the law.

Public funding agencies in Brazil include the National Fund of Scientific and Technological Development (Fundo Nacional de Desenvolvimento Cientifico e Tecnologico (FNDCT), the Ministry of Science and Technology (MCT), and Brazil’s science council, CNPq.



Private companies that fund research in Brazil are the WisdomTree Trust and Intel Capital Brazil Technology Fund.

**Bulgaria.** Bulgaria has a unicameral legislature (*National Assembly*). ESC research is regulated through the *Bulgarian Health Act* (2004) and the *Law on Transplantation of Organs, Tissues, and Cells* (2003). Under the Bulgarian Health Act surplus human embryos donated following IVF treatment can be used for research purposes with informed consent of the donor. Reproductive cloning and therapeutic cloning are prohibited. The Bulgarian Central Ethics Commission (CEC) oversees medical research on human subjects and reports to the Ministry of Health. Additionally, local ethics boards in hospitals report to the CEC on an annual basis regarding research activity.

The major public funding agency is the Bulgarian National Science Fund (BNSF). In 2012, *Nature* published an article describing protests by scientists against the BNSF for corrupt practices (Abbott, 2012). It was alleged that cronyism was rewarded over scientific merit. Those scientists with close ties to the agency were funded. This is coupled with a decrease in university budgets and that of the Bulgarian Academy of Sciences. In 2012, it was reported that (US\$) 9.8 million was allocated for research (Abbott, 2012). While these entities are still the key source of public funding in Bulgaria, there are obvious improvements needed in administration of funding for Bulgaria to be competitive in the research arena.

**Canada.** Canada has a bicameral legislature (*Senate and House of Commons*). Research using embryos is regulated through the *Assisted Human Reproduction Act (AHRA)* of 2004. The

AHRA allows for surplus human embryos created for fertility treatments to be used in research if they are not older than 14 days and donor approval is granted. Researchers must have approval from the Research Ethics Board and research may not involve any type of genetic alteration of human gametes or embryos. There are a number of other restrictions in this law. First and foremost, human cloning and therapeutic cloning are prohibited. Human gametes may not be purchased nor may there be any type of advertising for purchase of human gametes and a human embryo may not be maintained outside of the female body for more than 14 days (Knowles, 2008). Support for allowing ESC research was documented in Canada's working group which identified the human embryo as having less status of personhood than that of a child or an adult (Discussion Group on Embryo Research, 1995).

The ISI Essential Science Indicator ranked Canada second in ESC research using the number of publications and works cited in the realm of stem cell research. In addition, the University of Toronto ranked second in ESC research institutions, just behind Harvard University (Reicin and McMahon, 2005). The Stem Cell Network brings together eighty scientists, clinicians, ethicists, and engineers so that collaboration is heightened among hospitals, universities, and research institutions. Public funding for ESC research is possible through the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council (NSERC). The CIHR has mandated that any public funds that were used to develop human ESC lines must be listed in the national ESC Registry, and the cells made available to other academic researchers. The NSERC supports research projects of university students as well as facilitates collaboration with the private sector encouraging Canadian

companies to invest in postsecondary research projects. Research projects that are not acceptable for public funds include creating embryos to use in the derivation of stem cells, research involving therapeutic cloning, research involving the direct donation of stem cell lines to individuals or combining non-human cells with a human embryo.

*Chile.* Chile has a bicameral legislature (*Senate and Chamber of Deputies*). The 2006 *Law on Scientific Research in Humans, the Genome, and Prohibited Human Cloning* places high emphasis on protection of human life from the moment of conception. Human cloning is prohibited. The law also states clearly that no human embryo may be destroyed to obtain stem cells. The National Commission on Bioethics is charged with advising government on ethical issues as related to scientific and technological advances in biomedicine.

Chile's National Commission for Scientific and Technological Research (CONICYT) provides funding for University of California Berkeley and Chilean researchers for early stage collaborative projects. The maximum award is (US\$) 30,000 and the possibility of long term collaboration is a criterion for consideration. Another public funding outlet is the National Fund for Scientific and Technological Research (FONDECYT). Funding has increased from (US\$) 71 million in 2007 to 160 million in 2012. FONDECYT has funded over 13,000 research projects since 1981 with the aim of strengthening national scientific and technological applications while at the same time boosting the economic climate.

*China.* China has a unicameral legislature (*National Peoples Congress*). China allows surplus human embryos up to 14 days of life to be used in research as well as therapeutic

cloning; additionally, imported cell lines and fetal cells may be used from spontaneous or induced abortion. The law is governed by the 2003 *Ethical Guiding Principles on Human ESC Research* and enforced by the ministry of Science and Technology (MOST). Informed consent from the donors must be granted and selling of embryos is prohibited. China's one-child policy, which was recently amended in 2013 (Areddy, 2013) allows couples to have two children if one parent was an only child. An abundant supply of frozen embryos creates a favorable foundation for productive ESC research. If a couple undergoes fertility treatment it is likely there will be surplus embryos available given the one-child law as they would be prohibited from using surplus embryos after one successful implantation. Moreover, it is forbidden for couples to donate their embryos to other childless couples (Heng, 2009). The Chinese culture and religious backdrop have likely contributed to permissive policies. Confucianism, Taoism, and Buddhism do not view human embryos as persons. Heng (2009) contends that childless couples are more afraid of surplus embryos being donated to other couples than to research. The special attachment of biological kinship, the one child policy, and religious and culture beliefs position China in a favorable and prolific environment for ESC research.

The major public funding resource in China is the National Natural Science Foundation (NNSF). This organization was founded in 1986 with the goal of advancing basic and applied research. Other resources for research funding include the Ministry of Education (MOE) and the Ministry of Science and Technology (MOST). In 2011, Bill Gates met with Minister Wan Gang to explore cooperative initiatives between the Bill and Melinda Gates Foundation and MOST

involving research into global health problems. The Bill and Melinda Gates Foundation has funded Chinese researchers in projects involving ESCs (Cai et al, 2007).

**Costa Rica.** Costa Rica has a unicameral legislature (*Legislative Assembly*). *The Regulation of Assisted Reproduction and IVF* law passed in 2000 prohibits research of any variety on the human embryo in addition to banning IVF therapy. In 2001 nine infertile couples petitioned the Inter-American Commission on Human Rights (IACHR) claiming their rights to start a family and right to privacy had been violated. Until 2013 Costa Rica was the only country to place a ban on IVF therapy. The IACHR ruled in 2013 that an embryo is not a person and that life begins at implantation not fertilization and that couples must be granted access to fertility treatment as infertility is considered a disease by the World Health Organization (Blackburn-Starza, 2013). Government officials have said they would comply with the ruling but have not yet passed any specific legislation or any caveats regarding ESC research leaving the 2000 law on prohibiting research on embryos viable.

Regarding human cloning, Costa Rica presented a proposal to the United Nations in 2003 banning all forms of human cloning. The reasons given for the proposal were to protect the dignity of life and fundamental rights of human beings in the face of threatening cloning experiments. The proposal included making it a crime for performing human cloning and developing a legal framework for the crime, a mandate to adopt strategies to stop human cloning experiments, and international cooperation between police and judicial authorities in bringing to justice those individuals violating the law. These actions taken by the Costa Rican government

and ban on ART reflect stern opposition to all types of ESC research placing human dignity and right to life above science.

Public funding for research is available through the Ministry of Health (MOH), Costa Rican Social Security Fund (CRSSF), and National Council for Scientific and Technology Research (CONICIT). Costa Rica is characterized as a developing country which results in prioritization of funds more stringently than some other countries. Costa Rica is concerned with improving the health of its citizens in an area that is endemic for a number of diseases (e.g. dengue fever). Biotechnology and work with stem cells will likely come second to areas such as HIV/AIDS, mental health, transmissible diseases, and nutritional safety. Private companies such as the Institute of Pediatric Research, ICC Neeman Institute, and CRUSA (Costa Rica – United States Foundation for Cooperation) provide funding for research projects.

**Czech Republic.** The Czech Republic has a bicameral legislature (*Senate and Chamber of Deputies*). Embryonic stem cell research in the Czech Republic is regulated by the *Act on Research on Human Embryonic Stem Cells and Related Activities* enacted in 2006. Embryonic stem cell research may be conducted on imported cell lines or surplus human embryos. The one limitation, however, is research may not be conducted on human embryos older than 7 days. In addition, donor consent is required as well as acquisition of a license from the government to conduct research aimed at advancing scientific or medical knowledge that potentially leads to cures and new treatments for disease. A bioethics committee was established in 1997 to advise all aspects of research and effects on human health and society.

Funding for scientific research in the Czech Republic is available through the Grant Agency of the Czech Republic-Czech Science Foundation. The agency provides grants in the amount of approximately (US\$) 74 million a year from the state budget. Historically, there have been between 1600 and 1800 grant applications per year, with an average award of approximately \$650,000 per project. Projects may be funded in the fields of medical and biological sciences, natural sciences, mechanical engineering, and social sciences. The Academy of Sciences of the Czech Republic also funds research projects in a wide range of disciplines. Its mission is to conduct basic research in a wide range of natural, technical, and social sciences and the humanities. It consists of 54 public research institutes with a strong emphasis of collaboration in the international community. In 2011, the Czech Republic established partnerships with Norway where researchers in the Czech Republic may apply for research grants from Norway. The impetus for this partnership was meeting the EU goal of 3 percent spending of GDP on research and development in the Czech Republic. Funds will be available that approximate (US\$) 16.2 million. The Ministry of Education, Youth, and Sport of the Czech Republic also funds research. The Ministry of Education, Youth, and Sport, established in 1918, is responsible for the administration of the school system, determines the content of education and is responsible for public research. It evaluates research plans and activities of universities and institutes and approves funding for research projects. Private funding is available from the Open Society Fund which funds projects related to healthcare and overall improvements toward democratic societies. Partners of the Open Society Fund include Ceska Sporitelna Foundation, Accenture, Cesky Telecom, and the Hyundai Endowment Fund.

**Denmark.** Denmark has a unicameral legislature (*Folketing*). The *Act on the Establishment of an Ethical Council and the Regulation of Certain Forms of Biomedical Experiments* was adopted by the Danish Parliament in June 1987. Under this Act, research using embryos was banned as well as reproductive cloning or the creation of genetically identical human beings. In 1992, the *Act on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects* allowed research on embryos for the purpose of improving techniques of assisted reproduction as long as the embryos were no older than 14 days and informed consent of the donating couple was secured. In 1997 the law was amended where ESC research is still allowed up to 14 days with a maximum storage time of five years. Applications of research were broadened from improving IVF methods to developing cures for human diseases and PGD. Issues with the Denmark law involve which human diseases studied would qualify for research awards which may be contingent on what percentage of society is inflicted with disease. This would likely be decided by the Committee on Biomedical Research Projects.

Public funding agencies for scientific research include the Danish Council for Strategic Research, the Danish National Research Foundation, and the Danish National Advanced Technology Foundation. Goals of the Danish Council for Strategic Research are to strengthen interdisciplinary research, facilitate collaboration between research environments, including international collaboration and to foster cooperation between private and public enterprises. Research that is funded is expected to contribute to society, be of high quality and basis for innovation and economic growth. A board of nine individuals from various disciplines is charged with approving or disapproving research proposals. In 2012, the Council awarded (US\$) 102.6



million in research grants. The Danish National Research Foundation was created in 1991. Its mission is to strengthen Denmark's development of research capacity by funding excellent research at an international level. Eighty-eight Centers of Excellence have been created across Denmark since the inception of the Danish National Research Foundation. Their strategy is to fund a Center for five years, encouraging global competitiveness and converging all of the natural sciences, social sciences, and humanities under one roof. In this scheme, research funding and opportunity are less fragmented and more cohesive. A board is appointed to manage the Foundation consisting of nine members with outstanding research credentials. Peer reviews of research proposals are performed by both national and international experts in the related field. Lastly, the Danish National Advanced Technology Foundation, started in 2008, offers private companies and universities the funds and framework for developing new and salient technologies. The foundation utilizes a total budget of (US\$) 923 million with a fifty-fifty split of financing between the foundation and private industry. Its mission is to enhance growth and strengthen employment by supporting strategic and advanced technological priorities within the areas of research and innovation. It also has a board comprised of nine members which monitor and manage activities of the foundation.

The Danish Stem Cell Centre (DanStem) was created in 2011 with funds from the Novo Nordisk Foundation and the Danish Council for Strategic Research. It is located at the University of Copenhagen. DanStem focuses on both basic research and translational research in diseases such as cancer and diabetes.

*Estonia.* Estonia has a unicameral legislature (*Riigikogu*). *The Artificial Insemination and Embryo Protection Act* (1997, 2003) indicates that an embryo is a fetus in its very early stage of development and an embryo exists from the moment of fertilization. On the 15<sup>th</sup> day after fertilization an embryo obtains human dignity. Frozen Embryos may be used in Estonia for research only if they were acquired from IVF procedures and donors have given consent. An embryo may be preserved/frozen for 7 years, and if it was not used for implantation it may be used for scientific research. This length of preservation changed from 5 years to 7 years in 2003. Therapeutic cloning and reproductive cloning are prohibited in Estonia.

Research in Estonia is funded under the guise of the Ministry of Education and Research, the Estonian Science Foundation (ETF), the Archimedes Foundation, and the Estonian Research Council. Nearly all basic research in Estonia is conducted in the public sector, whereas the private sector focuses mainly on product development. The Estonian Science Foundation was created in 1990 by the Estonian Government and is located in Estonian's capital, Tallinn. Its mission is to support the most promising research initiatives in all fields of basic and applied research. Proposals are peer-reviewed and awarded to both individuals and research groups. The ETF uses budget appropriations for awards. The Archimedes Foundation was established in 1997 and also located in Tallinn. Its mission is to create an environment that helps to ensure the competitiveness of Estonian education and research on a global scale. Key areas are education, research and development, and youth civic action. A Board of Directors manages and monitors the activities of the Foundation and members are appointed by the Minister of Education and Science. The Estonian Research Council, established in 2012, has a number of funding

opportunities. One program, EEA/Norway, encourages collaboration between Estonian Researchers and colleagues from Norway, Iceland and Liechtenstein. In 2007 ten out of thirty-one proposals were funded.

Research in the university setting is very active; two-thirds of Estonian undergraduates attend public universities and more than half of the research and development is done at the University of Tartu, accounting for more than 50 percent of Estonia's scientific publications. Other public universities include Tallinn University of Technology, Tallinn University and the Estonian University of Life Sciences. Additionally, Estonia has created 7 Centres of Excellence (CoEs) designed to strengthen cooperation in the field of research and linking Estonia researchers to top scientific research areas. The CoEs include Frontiers in Biodiversity Research (FIBIR) (University of Tartu), CoE in Genomics (Estonian Biocentre), CoE for Translational Medicine (University of Tartu), CoE in Computer Science (Tallinn University of Technology), CoE in Chemical Biology (University of Tartu), CoE in Cultural Theory (University of Tartu), and Centre for Integrated Electronic Systems and Biomedical Engineering (Tallinn University of Technology). Estonia researchers also collaborate with their international counterparts by participating in Framework Programmes (FP) Projects funded by the European Commission (EC). The majority of R&D funding comes from governmental and EU sources. Funding from the private sector is possible, but limited.

***Finland.*** Finland has a unicameral legislature (*Eduskunta*). *The Medical Research Act of 1999* allows surplus human embryos use in research for up to 14 days after fertilization. Embryos

may also be frozen for up to 15 years. Therapeutic cloning is banned unless it is thought the research is geared toward finding new cures and treatments for serious diseases. The Finnish National Advisory Board on Research Ethics was created in 1991. Its mission is to advise the government and inform the public about any ethical issues regarding science and technology. The researcher must be granted a license by the board in order to conduct the research.

Public sources of funding in Finland include the Academy of Finland, Finnish Funding Agency for Technology and Innovation (TEKES), and the Finnish Innovation Fund (SITRA). The Academy of Finland funds primarily basic research and supports international research cooperation. The TEKES and SITRA funds applied research and technology. Finland has a large base of private funding entities. These include Sigrid Jusellius Stiftelse Foundation, Finnish Diabetes Foundation, Finnish Neurological Foundation, and Ylppo Foundation.

**France.** France has a bicameral legislature (*Senate and National Assembly*). There has been much discourse in France regarding human embryos and research. Discourse is typically more associated with bicameral legislatures where a bill has passed two chambers instead of one before it can become a law. In France, however, discourse may result from disproportionate legislative power between the two chambers. The upper chamber or Senate legislative powers are limited to delaying legislation passed by the lower house or National Assembly. Moreover, a bill that has passed the lower chamber can become law over objection from the Senate rendering the upper chamber somewhat obsolete in the realm of public policy (O'Neil et al, 2010).

A 1994 bioethics law prohibited experimentation on human embryos and creation of embryos for research purposes. However, research could be performed on imported stem cell lines. With importation being the only viable option to perform ESC research scientists had a difficult time acquiring imported human ESC cell lines because of French government red tape. For example, scientists in Montpellier were delayed two years because of difficulty in obtaining cells from the US. Science is a discipline where being first matters. A delay in starting research opens the door for another group to publish similar studies first. In November of 2000, during the annual meeting of Bioethicists the French Prime Minister proposed to authorize human ESC research. The law proposed had two purposes: research to improve artificial reproductive technologies and to advance ESC research. After input from the Council of Ministers and Parliament, the law changed in 2004 with passage of *Research on the Embryo and Embryonic Cells*. The law prohibits creation of embryos for research purposes. The law technically forbids research on embryos with exception. Research may be conducted only when the couple agrees to donate the embryo and only if there is the potential for great therapeutic progress and further, must be approved by the France Agency of Biomedicine. In addition, the scientist must offer support that no other source of cells could be employed. This law was seen as a compromise between those wishing to protect the embryo and those who favored medical progress. The law was renewed in 2011 maintaining this compromise. In July 2013, the French National Assembly approved a new law that is thought to ease regulation of research involving embryos and stem cells. This law must satisfy four criteria: 1) research must have scientific relevance, 2) performed

toward a medical end, 3) cannot be done without using embryos or ESCs, and 4) respects ethical principles (Pain, 2013).

Public organizations that fund scientific research in France include the France-Canada Research Fund (FCRF) and the French National Research Agency (ANR). The FCRF fund supports the development of scientific exchanges between France and Canada in a variety of disciplines. The FCRF was created in 2000 and receives funding from Canadian universities and private sector contributions. Projects are funded between French and Canadian research teams with a range of (US\$) 8,000 and 15,000 depending on project needs. The ANR was created by the French Government in 2005 to fund research projects. It aims to bridge the gap between the French Research System and the French economy by fostering private-public collaborations. The ANR is organized into 8 programs. These are Environment and Biological Resources, Sustainable Energy, Health and Biology, Engineering, Social Sciences and Humanities, and Communication Technologies. Moreover, the ANR implemented the “Investments for the Future” program in 2009 which serves to transform higher education, research, and innovation and sustain long-term competitiveness.

The French Muscular Dystrophy Association (AFM) is a private organization that funds embryonic stem cell research largely through telethons. The 23<sup>rd</sup> telethon was held in 2012 generating (US\$) 5.4 million. It has been in operation since 1958 with the first telethon conducted in 1987. It funds the I-Stem project which is a collaboration between INSERM (National Institute for Health and Medical Research) and the Institute of National Health and

Medical Research. I-Stem represents the largest French research laboratory for research and development dedicated to human pluripotent stem cells and ESCs. It is also part of the Biotherapy Institute for Rare Diseases.

**Germany.** Germany has a bicameral legislature (*Bundesrat and Bundestag*).

Reproductive cloning and therapeutic cloning are explicitly banned. ESC research is restricted to surplus embryos created before May 2007 in another country that can be imported. The first law to address research on human embryos was the *Embryo Protection Act* which was passed in 1991. This law prohibited the production of an embryo “for any purpose other than the bringing about of a pregnancy.” (*Embryonenschutzgesetz* 1990, 1.2) The Act makes it punishable to cause “artificially a human embryo to develop with the same genetic material as another embryo, fetus, or deceased person.” (Sec 5.1) The Act bans the creation of embryos for research purposes. The next law passed regarding research on human embryos was the *Stem Cell Act of 2002*. Under this Act importation of human ESCs was admissible only if derived before January 1<sup>st</sup> 2002 in the country of origin and subject to specific conditions. No stem cell lines could be imported from another country if not in existence at that time and the material must have originated from IVF embryos, as opposed to embryos created via therapeutic cloning. The rationale for the set time frame is to negate the impression that a German researcher is ordering human ESCs on demand and it obviates the process of extracting cells from an embryo destined for implantation. By setting a time frame, the cell line is already in existence. Another issue with the law is criminal liability. The law states “any person who imports or uses ESCs without approval pursuant to §6(1) shall be liable to imprisonment of up to three years or to a fine” (SCA 2002, sec 6). It was

unclear whether the word ‘uses’ referred to research performed in Germany only, or whether it applied to German researchers who collaborated or performed research outside of Germany. Further, the German Federal Ministry of Education and Research mandated that German scientists would be committing a crime if they advised a colleague in another country regarding harvesting of ESCs (Paarlberg, 2005). The vagueness of the law was corrected in April 2008 when an amendment was passed extending the time frame from which ESC lines could be imported. Cell lines could now be imported if created before May 1, 2007 and criminal liability would only be pursued if a researcher *in Germany* used imported ESC lines without formal approval. This amendment provided more opportunities for collaboration outside Germany.

One of the problems with Germany’s policy is because the law sets a date for using embryonic stem cell lines created before a certain time the law will continuously have to be amended due to lack of availability of quality cell lines. This will open the door for politicians and factions that oppose current policy to mount a campaign to change the law in their favor. Based on the tremendous activity in this research area in Germany, it is likely parliament will continue to renew the policy but extend the date so that ample quality ESC lines are available to scientists.

Opposition to ESC research in Germany comes from antiabortion religious groups, anti-science Green Party, and women’s groups labeling this research as “continuations of Nazi eugenics” (Paarlberg, 2005, 45). Green Party officials have also stated that “we Germans, in light of experiences during the years 1933 through 1945, should be sensitive, even supersensitive to



the possible abuse of embryo research” (p 46). It is evident that the German parliament is working to satisfy all elements of society utilizing the democratic process. Scientists must be approved for research and go through necessary channels with importation but work with ESCs can still be performed. Oliver Brüstle, a German scientist and Director of the Institute for Reconstructive Neurobiology at Bonn University applied for a patent for a technique that transformed stem cells into brain cells. In 2011, the European court of justice ruled that procedures that utilize human ESCs could not be patented. This ruling created the perception among many scientists and investment firms in Europe that salient discoveries, in the realm of ESC research would have difficulty transitioning to the market given the decision by the court. Greenpeace, a global environmental organization who filed suit against Brüstle, proclaiming that using ESCs represents immoral industrial use of human embryos (Sample, 2011).

Stem cell treatments were carried out in Dusseldorf by the company XCell-Center from 2007 to 2011. It closed its doors when a story broke in the UK’s *The Sunday Telegraph* revealing the death of an 18-month-old boy from Romania after receiving treatment at the center (Mendick & Hall, 2011). The boy was injected with bone marrow stem cells into his brain. A 10-year-old boy from Azerbakjan almost died from the same procedure. The company was able to perform unproven treatments to patients all over the world via a loophole in the German law. Each patient was charged approximately (US\$) 26,000 per treatment. The Center was given approval to practice for a transitional period because it was already in operation when a law came into force in 2009 banning the commercial exploitation of unproven stem cell treatments. The Center treated about 25 patients a year. In countries like the US and the UK, stem cell treatments are

medicines; this means that for a procedure to be licensed it must undergo rigorous clinical trials before being made available to the public. An EU regulation passed in 2007 defines stem cell transplantation as a medicine in Germany. The company could not show its modalities were effective but was able to operate because regulations were not enforced. While the XCell Center did not involve ESCs it brings to light that even with a controversial history of medical ethics, physicians chose to perform unproven experiments on vulnerable patients at will from all over the world.

Public funding for scientific research in Germany includes the Academies of Science and Humanities, Humboldt Foundation, German Academic Exchange Service (DAAD), German Research Foundation (DFG), Fraunhofer-Gesellschaft, Helmholtz Association, and Max Planck Society. The Academies of Science and Humanities provide funding for long-term projects of basic research to postdoctoral and junior researchers. The Alexander von Humboldt Foundation promotes research collaborations between foreign and German investigators. It awards over 800 research scholarships and research awards every year. The headquarters of the Foundation is located in Bonn. It has an annual budget of approximately (US\$) 132 million with most funding procured from federal sources. The largest provider of research scholarships, including those for postdoctoral students, is the DAAD. The DAAD is a joint organization of German institutions of higher education and the world's largest funding organization for the international exchange of students and researchers. One of the goals of the DAAD is to strengthen the international networking of German higher education institutions increasing their appeal to the global research landscape. Offices of the DAAD are located in Berlin and Bonn. The budget for the DAAD

comes largely from federal funds. These may include the Federal Foreign Office, the Federal Ministry of Education and Research (BMBF), the Federal Ministry for Economic Cooperation and Development (BMZ), and the EU. The annual budget is approximately (US\$) 502 million. The Fraunhofer-Gesellschaft, based in Munich, funds postdoctoral researchers in developing their own working groups and encourages research in Germany. It is the largest organization for applied research in Europe having more than 80 research institutes. It has an annual budget of approximately (US\$) 2.3 billion. Funding is procured from the Federal Government, contract research, and industry. The Helmholtz Association, located in Bonn, funds long term research with goals that benefit society and state as a whole. There are 18 Helmholtz Centers where scientists conduct research involving health, environment, and energy. It has an annual budget of approximately (US\$) 4.4 billion which is supported by the Federal Government and private sector. Finally, the Max Planck Society located in Munich funds postdoctoral students and research groups whose work is thought to benefit the public. Fields of research include natural sciences, life sciences, social sciences and the humanities. It has an annual budget of approximately (US\$) 1.9 billion procured from the Federal and State (Länder) governments.

Private funds for research in Germany is available thru the Hertie Foundation. This organization, based in Frankfurt, began in 1974 with the mission to carry on the work of its founder Georg Karg, owner of the Hertie Waren und Kaufhaus (department stores). Projects are funded that promote science and education and is based in Frankfurt. Annual funding is (US\$) 30 to 40 million. The Volkswagen Foundation also provides private funds for research in the areas of humanities, social sciences, science, and technology. It was established in 1961 as a non-profit

organization with no connection to the car company. It has funded approximately 30,000 projects totaling (US\$) 5 billion since its inception. Other private companies that fund stem cell research include Oligene in Berlin and Cell Genix in Freiburg.

**Greece.** Greece has a unicameral legislature (*Parliament*). The *Medically Assisted Human Reproduction of 2002* prohibits therapeutic cloning and reproductive cloning but allows research on surplus human embryos within 14 days post fertilization. Human embryos not used for IVF can be frozen for up to 5 years. After 5 years they are destroyed or used for research. Donor consent is required. Acceptability of research projects is regulated by the Hellenic National Bioethics Commission.

Regarding current funding options, scientists were hit hard by austerity measures in 2011 and 2012. Direct funding to universities was cut by 20 percent and faculty pay was cut by 10 percent (Abbott, 2011). Typically funding is available through the General Secretariat for Research and Technology (GSRT) and the Ministry of Education, Life Long Learning and Religious Affairs. For the time being it is likely the EU FPs will be a more feasible option for funding given the dismal fiscal climate in Greece. Private funding is available through the Stavros Niarchos Foundation.

**Hong Kong.** Hong Kong has a unicameral legislature (*Legislative Council*). Regulation of ESC research in Hong Kong is mandated through the *Human Reproductive Technology*

*Ordinance of 2000.* Therapeutic cloning and reproductive cloning are prohibited; no human embryo may be used for research after the appearance of the primitive streak, which is in line with the 14 day post-fertilization threshold. In addition, embryos cannot be commercialized.

Public funding agencies in Hong Kong include the Innovation and Technology Fund (ITF) and the Research Grants Council (RGC). The ITC is more dedicated to industry than universities in increasing productivity and competitiveness where the RGC operates under the University Grants Committee addressing needs of higher education as related to research activity and funding. Private funding is available through the Croucher Foundation dedicated to technology, medicine, and the natural sciences in Hong Kong.

**Hungary.** Hungary has a unicameral legislature (*National Assembly*). Research on human embryos is regulated under the *Sandor Judit Medical Law* of 2003. Research can be performed on surplus human embryos within 14 days post fertilization. Reproductive cloning and therapeutic cloning are prohibited. The Hungarian Reproduction Commission must approve all research projects.

Research funding is available through the Hungarian Scientific Research Fund or OTKA (*Országos Tudományos Kutatási Alapprogramok*). Established in 1986, this fund is an independent and not-for-profit organization. By government mandate it is charged with supporting scientific activities and infrastructure funding projects on a competitive basis. Funds are provided within the annual budget of parliament. It has supported over 15,000 projects spending over (US\$) 292 million. The Hungarian Academy of Sciences also funds student

research projects in an effort to halt the emigration of young researchers. The overall climate for research activity is favorable in Hungary. In 2010, the Hungarian Ministry for National Economy bolstered small and medium enterprises (SMEs) by unveiling the New Szechenyi Development Plan allocating (US\$) 4.5 billion aimed at new jobs and innovation across all industries including biotech. Private funding sources include the Magyary Zoltan Foundation.

***Iceland.*** Iceland has a unicameral legislature (*Althing*). Research using embryos is regulated by the *Law on Artificial Fertilization of 1997*. Any research on surplus human embryos is prohibited unless it is geared toward advancing fertilization techniques and the embryo is less than 14 days old. An embryo may never be created for research purposes and reproductive cloning is prohibited. Health officials in Iceland have been active in supporting public discussions on stem cell research concerns. In 2002 the Icelandic Association of Healthcare Professionals held the first meeting on ethical issues; a year later the University of Iceland Center for Ethics aided by the National Director of Health held another public meeting. In 2005, the Icelandic Research foundation arranged for a geneticist and a moral philosopher to engage in dialogue as part of a popular event called Science Café's. These events were televised with excerpts printed in newspapers. In 2006 the National Bioethics Committee and the Icelandic Society of Biologists held similar public forums. In 2010, a Eurobarometer poll indicated that 70 percent of residents thought that ESC research should not be forbidden (Eurobarometer, 2010).

Officials in Iceland are making a great effort to involve the public on an area of science that is still in its infancy and intertwined with moral dilemmas.

Public funding is available through the Icelandic Research Fund and Technology Development Fund under guidelines of the Science and Technology Policy Council (STPC). Sources of private funding include the Sigurour Jonsson and Helga Siguroardottir Fund for Research on Human and Animal Pathology and the Helga Jonsdottir and Siguourlioi Kristjansson Commemoration Fund for Studies in Engineering and Natural Sciences.

***Ireland.*** Ireland has a bicameral legislature (*Oireachtas and Dáil Éireann*). In 2008 the *Stem-Cell Research bill* was presented to parliament and proposed to regulate stem cell research by prohibiting embryo destructive research and related activities. These activities may include creation of human embryos, human clones or human-animal hybrids for research purposes. In 2009 the Irish Medical Council banned medical practitioners from creating embryos for research purposes. In early 2010 the Irish Council for Bioethics dissolved due to budget cuts. This was right before a law on stem cells was to be presented to parliament. This provided an opportunity to delay legislation as ethics of stem cell research could not be clarified without the Council (Abbott, 2009).

The Eighth Amendment of the Constitution guarantees “right to life of the unborn, and with due regard to the equal right to life of the mother” (Art 40, II), and therefore is deeply ingrained in Irish society. The fact that the bill was not passed gives credence to the bicameralism-brinkmanship theory, that two chambers, are one too many when it comes to

passing legislation. As is often times the case there is more to the story. The Ireland Supreme Court ruled in 2009 against a woman who wished to implant her frozen embryos against the wishes of her estranged spouse. Referring back to the Eighth Amendment the Judge ruled an embryo in storage does not constitute the unborn. With that said, it would seem that parliament would have backing, by the Supreme Court ruling, to allow research on surplus embryos as they do not come under the heading of the unborn and are not guaranteed right to life. The Science Foundation Ireland and the Health Research Board decided not to consider grant applications for projects using human ESC lines in 2010. Ireland is restricting ESC research on the authority of the Medical Council.

Public funding is available through the Irish Research Council with a wide range of stages from postdoctoral fellowships to advanced scholars. The Science Foundation Ireland provides funding to academics and research teams in the areas of biotechnology, information and communications, and efficient energies. Private sources of funding include the Christina Noble Foundation and the Shad Ireland Foundation.

*Israel.* Israel has a unicameral legislature (*Knesset*). Research using surplus embryos less than 14 days old as well as therapeutic cloning is permitted. Human cloning is prohibited through the *Prohibition of Genetic Intervention* (Human Cloning and Genetic Manipulation of Reproductive Cells) law. In 1998, this law passed the *Knesset* or Israeli parliament unanimously. It mandated a 5-year moratorium on human cloning and germ line therapy. An advisory



committee was entrusted with following up on scientific, medical, and biotechnological developments in the field of genetic experimentation on human beings and reporting to the Ministry of Health on a yearly basis (Prainsack, 2006). In 2004 the moratorium was extended another 5 years. The moratorium is quite unique as most countries have banned reproductive cloning permanently. This action can be interpreted as not closing the book entirely on reproductive cloning but allowing time for more information regarding safety to surface. Israel's permissive policy on embryos in research can be attributed to Judaism, the majority religion in the country, a Zionist duty to advance science and technology, and pro-natalism culture. In 2001 the Bioethics Advisory Committee of the Israeli Academy of Sciences and Humanities was created to issue a report on the ethical implications of stem cell research. The committee concluded that the use of surplus human embryos and therapeutic cloning was ethically permissible. Regarding reproductive cloning, the report indicated that technology may be safe in the future with medical implications. Other bodies that have oversight into regulations are the Helsinki Committee for Genetic Medical Experiments on Humans and the Public-Professional-Interdisciplinary Committee to Examine the Status of the Human Embryo in Medical Science.

Judaism does not ascribe dignity to an embryo outside the womb and deriving stem cells from embryos outside of the body presents no moral dilemma. In addition during the first forty days of gestation any embryo material is regarded as water. Saving lives is also a central tenet of Judaism. Any improvement of nature and life of humans is a *mitzvah* or duty to God. Another important aspect regarding Israel's permissive policy is pro-natalism. Procreation is a priority in Israel and supported by having the largest number of IVF clinics per capita in the world and

covering IVF therapy under the state health system (Heyd, 1993). Procreation is also consistent with Jewish doctrine facilitating an alignment between scientists and Jewish orthodoxy to continuously work on improvements in IVF therapy so that infertile couples can start a family. Regarding public opinion, Israeli's trust the decisions made by the *Knessett* (Simonstein, 2008). There does not appear to be any organized public effort for or against ESC research to change the law. An obvious issue in the future concerning the Israeli stance on ESC research is leaving the door open for reproductive cloning. If the law was ever amended allowing human cloning, Israel would likely be condemned in the media and perhaps sanctioned by the major world powers.

Public research funds in Israel include the Israel Science Foundation (ISF), Bi-national and International Funds, Research Funds of Chief Scientists in Government Ministries, and Research Centers. The ISF has an annual budget of (US\$) 60 million awarding grants in humanities and social sciences, life sciences and medicine, and science and technology. Israel is a global leader in innovation and export of technology. It is fourth in the world in the number of patents per capita (Horn, 2011). Moreover, the Tel Aviv Stock Exchange (TASE) has allowed young enterprises to seek public funding despite not having regulatory approval or sales. There are many sources of private funding available to scientists in Israel and many are in the US. These include Geron Corporation, Leona and Harry Helmsley Trust, and Legacy Heritage Foundation.

*Italy.* Italy has a bicameral legislature (*Senate of the Republic and Chamber of Deputies*). The 2004 law (*Law 40*) on ART prohibits research on human embryos or experimentation. According to this law, the embryo is deserving of respect from the moment of fertilization. While the law deals mostly with IVF procedures, it does mandate that cryopreservation or freezing of embryos is forbidden placing a cap on that number of embryos allowed to be produced, which is three. How to address the embryos that were frozen before 2004 was also discussed in the law and there were no guidelines or indication that those embryos could be used for research. Instead, the donors would be notified and if not claimed the embryos would be transported to a central repository in Milan. Therapeutic cloning, reproductive cloning, and genetic manipulation of embryos is forbidden. Before the passage of *Law 40* there were many heated debates between supporters and critics of ESC research. The conservative majority in parliament was successful in attracting Catholic votes in enacting a conservative law on IVF and ESC research (Boggio, 2005). In the jargon of Italian politics this crossing of party lines is referred to as a *traversal party*, where provisions of the bill were perfectly aligned with not only the Vatican but the Roman Catholic community. The Vatican was reported to informally endorse the bill allowing certain forms of IVF. The view held by the Vatican in 1997 was that IVF and reproductive cloning are horrid aberrations driven by science and representing malaise of society (Pontificia Academia Pro Vita, 1997)

Division was also noted in the Italian Bioethics Committee. The Chairman and one Catholic member publicly endorsed the new bill on several occasions. Six other members called the regulations harsh and that the bill breaches the constitutional clause of separation of church

and state. Like Brazil, Italy's law made its way to the Constitutional Court for a review of the law and ban on ESC research. The court ruled that a referendum be held in 2005 on certain aspects of the law, but essentially allowed research on surplus embryos. The referendum failed as the total votes did not eclipse 50 percent of the Italian electorate. The influence of the Vatican played a major role in passing a restrictive law on ESC research. One of the problems with Law 40 is the use of imported ESCs is not addressed nor is there any mention of the use of surplus embryos before Law 40 was enforced in 2004 (Fрати, 2014) invoking a loophole in the law. Italy is not the only predominantly Catholic country in this study but is unique in that the Roman Catholic base had a significant influence on policy; the same cannot be said for Brazil or Spain.

Public funding for research comes from the Ministry of University and Research (MIUR) with four major national funds: 1) Research Projects of National Interest (PRIN), 2) Fund for Basic Research Investments (FIRB), 3) Fund for Applied Research (FAR), and 4) Special Integrative Fund for Research (FISR). Funds are also available from the National Research Council (CNR) and the National Agency for New Technologies, Energy and Environment (ENEA).

**Japan.** Japan has a bicameral legislature (*House of Councilors and House of Representatives*). A bill was passed in 2000 to prohibit human cloning and allow research on surplus human embryos. The *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques* also prohibited therapeutic cloning. The surplus

human embryo must not be needed or suitable for implantation and must be no older than 14 days. An expert panel was formed meeting more than twenty times in three years deciding that therapeutic cloning should be permitted but only for intractable diseases. The moratorium on therapeutic cloning was lifted in 2008. Guidelines for research is provided by the Ministry of Education, Culture, Sports, Science, and Technology. The approval process for research projects is two-tiered; that is projects must be approved at the researchers institution and also through the Ministry. This process has been met with much criticism from the science community claiming it makes for excessive bureaucracy (Kawakami et al, 2010).

A Japan researcher was the first to report production of iPS cells in 2006 in mice and a year later in humans (Takahashi and Yamanaka, 2006). This study was viewed as a scientific achievement across the world and leaders in Japan were quick to capitalize on Yamanaka's work. The Prime Minister, Yasuo Fukuda, stated in the Council for Science and Technology Policy (CSTP) "I want the CSTP to quickly create an environment in which this science, including clinical research can move forward smoothly" (Cyranoski, 2008, 4). Strategies were put forth to pledge (US\$) 100 million over next five years. (US\$) 1 million was pledged to Yamanaka in 2008 fiscal year and another (US\$) 4 million in infrastructure (Cyranoski, 2008). A similarity can be made between the US and Japan regarding capitalizing on a landmark publication in their country, and investment of funds; however, in the US it was the private sector that led the charge and put forth capital, while in Japan national funding was the driving force. Inferences can be made that Japan is much more nationalistic and less divided politically in this regard. In 2014, however, Japan's reputation in the stem cell world was severely tarnished

when Haruko Obokata, a scientist at Riken Research Institute in Japan, was found guilty of scientific misconduct by the Riken investigative committee in two instances. The committee found that Obokata published non-credible images from her doctoral dissertation to illustrate her findings regarding STAP (Stimulus-Triggered Acquisition of Pluripotency) stem cells. These images did not reflect the STAP experiments and her findings have yet to be replicated by other scientists (Takenaka, 2014). The committee and stem cell scientists around the world have called for the retraction of two papers published in January in *Nature*.

**Latvia.** Latvia has a unicameral legislature (*Saiema*). Stem cell research is regulated by the 2002 *Law on Sexual and Reproductive Health*. The policy stipulates embryos may not be exported or imported and may not be obtained for scientific or for commercial reasons. Human cloning is prohibited. It also stipulated in the law that after ten years of storage, gametes are to be destroyed.

Public funding is limited in Latvia. After breaking away from the Soviet Union in 1990 it took time to allocate funds for research as there were many other priorities. Most scientists relied on EU funds. Only about .02 percent of GDP goes toward actual research (Tatolovic, 2013). As a result many scientists are forced to leave Latvia for better employment and funding. Private funding is possible through the Baltic Innovation Fund.

**Lebanon.** Lebanon has a unicameral legislature (*Chamber of Deputies*). Lebanon prohibits reproductive cloning and therapeutic cloning in Law No. 625 regarding human genetic testing. The *Law on Assisted Human Reproductive Techniques* prohibits research on embryos or

commercialization thereof. Muslims believe that the Qur'an is the word of God. Regarding ethical behavior in Lebanon and other Arab states, a publication by UNESCO points out that the Qur'an does not offer definite solutions to problems humans face. It instead attempts to prompt man to look upon himself and the world to find solutions together based upon human rationality (UNESCO, 2011). However, Lebanon is not purely Muslim. The Lebanese parliament is made up of Christians and Muslims and practices a system of confessionalism. Confessionalism is designed to deter sectarian violence and conflict and fairly represent all peoples securing a peaceful co-existence of diverse ethnic and religious communities. Lebanon's law is restrictive and likely the result of that diversity.

The main funding source in Lebanon is the National Council for Scientific Research (CNRS). The Economic and Social Research Council (ESRC) in the UK also provides funding for Lebanese scientists. The CNRS awards grants in diverse fields of study related to sustainable development with a direct impact on the environment, public health, and human development. The ESRC was established by Royal Charter in 1965 and supports high quality research that is thought to have an impact on the public sector. The Al Waleed bin Talal Foundation provides private funding for scientists in Lebanon.

***Lithuania.*** Lithuania has a unicameral legislature (*Seimas*). The law on ESC research is regulated by the *Law on Ethics of Biomedical Research*. This law was enacted in 2000 and amended in 2007. This law is very restrictive where embryo use in research is limited to clinical observation. Importation and exportation of human embryos, or tissues thereof, is also

prohibited. Regulatory oversight is provided by the Lithuania Bioethics Committee, established in 1995, with the goal of promoting and protecting human rights and dignity. From the standpoint of research it protects patient rights in biomedical research and reviews ethical impacts of research studies.

The Research Council of Lithuania or LMT (*Lietuvos Mokslo Taryba*) provides public funding for research. This body was established in 1991 and is comprised of two committees: 1) humanities and social sciences, and 2) natural and technical sciences. The LMT has input in formulating science policy and also is involved in legislative issues regarding the Lithuania science and studies system. It has designed competitive research programs in Lithuania and in 2010 became a member of the European Science Foundation. It is viewed as the authority on research projects, policy, and funding by the Lithuanian government in building a viable and continuous research platform for the scientific community aligned with national interests and international collaboration. The Research Council has an annual budget of approximately (US\$) 35.2 million. Private funds for research are available through the Juozas Kazickas foundation. Established in 1998 this family foundation provides funding for education, culture, healthcare, and universities.

**Malta.** Malta has a unicameral legislature (*House of Representatives*). Malta is an island country in the Mediterranean Sea south of Sicily. The *Embryo Protection Law of 2012* prohibits all research on human embryos as well as donation of embryos. In 2012 the Maltese government opposed the EC plans to fund research projects on ESCs or cells that were derived via the



destruction of human embryos. It argued that the EC program Horizon 2020 does not protect human embryos in research and is not capitalizing on therapeutic potential adult stem cells (Vella, 2012). Maltese Bishops also protested the EC FP7 programmes in 2006. Archbishop Joseph Mercieca stated that in no situation can the Church agree to fund research on human embryos (Micaleff, 2006). This is one of the problems that surface from time to time with member countries in the EU. Policies of the EU do not always align with policies of the member states.

Public funding is available through the Malta Council for Science and Technology. This body is responsible for research policy, promoting research, and serves as the contact point for the EU Framework Programmes.

**Mexico.** Mexico has a bicameral legislature (*Senate and Chamber of Deputies*). Mexico allows therapeutic cloning and research on surplus human embryos but prohibits reproductive cloning. The *General Health Law of 1997* originally forbid any type of research on human embryos or fetal tissue, however, this was reversed in 2004. Also in 2004, President Vicente approved funds for the INMEGEN center in Mexico City which focuses on disease susceptibilities among Mexico indigenous populations (Bosch, 2004). Ricardo Tapla, emeritus professor at the National Autonomous University of Mexico stated after the reversal “we believe that such a ban would have set a dire precedent and led inexorably to a total prohibition on ESC research throughout Mexico” (Orellana, 2004, 656). Tapla participated in the lobbying campaign holding seminars on the potential of ESC research and the parliament took notice. There was

opposition however, to the parliaments vote by conservative and Catholic groups but their efforts did not prove fruitful.

Public funding is available through the National Council of Science and Technology (CONACYT) aimed at supporting private sector research toward commercial productivity. The Mexican government has increased funding from 2012 to 2013 from US\$ 150 million to 230 million (Rosen, 2013). As a result of private companies working with universities, 180 patents have been awarded since 2009 through this program. Private funding is available through the MacArthur Foundation and Kellogg Foundation.

**Morocco.** Morocco has a bicameral legislature (*House of Councilors and House of Representatives*). According to Law No. 16-98 (2003) concerning the removal, donation, and transplant of organs and tissues it is not permissible to use surplus embryos for research. In contrast to Lebanon which has equal representation of Christians and Muslims in parliament, the Moroccan government is led by the Justice and Development Party which is Islamic. In addition, the constitutionally established religion in Morocco is Islam; in Lebanon, people are free to practice the religion of their choosing. This disparity, however, has not impacted ESC research policy as both countries passed non-permissive laws.

Public funding is available through the Morocco Foundation for Advanced Science, Innovation, and Research. Its mission is to provide support and funding in the fields of health, natural resources, energy, and the environment. Morocco also has a Biotechnology Center which serves as a hub for world class scientific expertise utilizing state of the art research laboratories.

*New Zealand.* New Zealand has a unicameral legislature (*House of Representatives*). Research using surplus embryos is allowed under the 2004 *HART (Human Assisted Reproductive Technologies) Act*. Embryos left over from IVF procedures must be no older than 14 days to be used for research. The donor must give consent and can receive no payment for the embryo. The project must be approved by the Ethics Committee on Assisted Reproductive Technology (ECART). Imported cell lines are also permissible under *HART*. Any genetically modified cell or tissue must be approved by the Environmental Risk Management Authority (ERMA) under the *Hazardous Substances and New Organisms (HSNO) Act* of 2003. The policy in New Zealand ascribes limited moral status to the embryo; this is supported by their law allowing research on surplus embryos within the 14 day time limit. In a 2001 survey of New Zealanders, 64 percent of respondents believed couples should donate surplus embryos to research rather than destroying them; 23 percent disagreed. Sixty-six percent agreed that scientists should use ESCs to treat incurable disease, and forty-four percent of New Zealanders approved of therapeutic cloning (Reuters, 2001).

Public funding is available through the New Zealand Aid Programme and the Royal Society of New Zealand. The former funds postgraduate level projects aiming to support developing professionals in New Zealand. The Royal Society of New Zealand provides numerous funds for research through the Bayer Primary School Science Fund, Benson Fund, Centres of Research Excellence (CoREs), Charles Fleming Fund, and Hunton Fund to name a few. Most stem cell research is being done at Auckland University, University of Canterbury,

University of Otago and the Malaghan Institute of Medical Research.

*Norway.* Norway has a unicameral legislature (*Storting*). Research on embryos was banned under the *Act on Artificial Fertilisation of 1987*. The Norwegian Ethics Committee emphatically supported this prohibition. An amendment to this act was made in 2002 which reaffirmed not only that research using embryos was banned but that research on more developed embryos and stem cells derived from them were banned. In January 2007, a proposal to lift the ban was proposed because of a campaign in support of a boy with an inherited disease as discussed in Chapter I. According to the new law, research on surplus embryos may be used as long as the research has the goal of improving IVF procedures, developing techniques for PGD, and/or add to the body of knowledge in curing disease. Reproductive and therapeutic cloning are banned, and embryos cannot be used older than 14 days post fertilization. The couple of the embryo must give informed consent and the study must be approved by an ethics committee.

Research on adult stem cells became a major focus in 2002. The Norwegian Center for Stem Cell Research (NCS) was established in 2003. The mission of the NCS was to join the Nordic and Baltic researchers together in collaborative projects. During the years 2002 to 2013 the Research Council of Norway awarded US\$ 29.4 million to scientists. This was followed by US\$ 520 thousand in 2010 for six new projects. The Stem Cell Research Program which started in 2008 established the National Centre for Stem Cell Research and was given (US\$) 4.8 million

over a five year period. Projects supported by the center focus on patient welfare and stem cells as a form of medicinal treatment.

NordForsk has funded stem cell research through the ScanBalt stem cell research network since 2005. The network is coordinated from Norway and includes members from Sweden, Denmark, Finland, Iceland, Estonia, Lithuania, Russia, Poland, and Germany. Lundbeck Foundation funds projects in Denmark and Sweden. The Norwegian Center for Stem Cell Research and the Research Council of Norway provides funding for ESC research.

*Peru.* Peru has a unicameral legislature (*Congress*). The *General Health Law of 1997*, amended in 2009, prohibits research using the human embryo for anything other than procreation and forbids human cloning and therapeutic cloning. Many patients who are suffering from incurable disease are flocking to Peru to have procedures done in Lima at the Clinica San Felipe. These procedures involve use of adult stem cells. This trend is known as *stem cell tourism* where unproven treatments are performed in countries like Peru and Mexico because they have no national regulation on these stem cell procedures. Regarding the law it seems that while Peru prohibits ESC research it does not regulate unproven medical treatments regarding adult stem cells.

Public funding for research in Peru is available from the Ministry of Health and the State and the National Council of Science and Technology. However, as indicated by Caceres and Mendoza funding falls short of demand prompting the government to accept a loan from the Inter-American Development Bank to fund scientific research. Caceres and Mendoza (2009)

suggest there is a disconnect between researchers and policy makers in research ideology; policy makers tend to accept research as primarily a knowledge based activity as opposed to applications of research that could aid Peruvians. An example of misguided priorities is the major cause of premature death being traffic accidents. Yet no research funds have been allocated to study the magnitude of the problem so that solutions could be contemplated. This suggests that the administrative policies of research funding are in need of revision at the highest levels so that funding can be allocated effectively. Private funding is available through the Schlumberger Foundation and Tinker Foundation.

**Poland.** Poland has a bicameral legislature (*Senate and Sejm*). The law concerning ESC research in Poland is vague and perceived to be forbidden based upon the Law on *Family Planning of Human Fetuses and Conditions under which Pregnancy Termination is Permissible* and the *Medical Profession Act of 1996*. According to the former every human being has a natural right to life from the time of conception, and further the life and health of the child shall be placed under the protection of the law from the time of conception. In the 1996 law it states that “conceived children cannot participate in research experiments” (*zawód medyczny Ustawa z 1996 r*). As a response to the debates in the EU whether to fund research using human embryos the Sejm passed a resolution in July 2006 declaring that human ESC research is not consistent with Polish law (Schultz, 2006). This was in reference to the Polish Constitution which ensures “legal protection of the life of every human being” (*Dziennik Ustaw, 1997*). The Sejm resolution states that human embryo experimentation violates article 157 of the Polish Penal Code in which human life is protected from the point of conception. A pro-life advocate, Bogna Bialecka stated

that the public is confused over the meaning of the term “embryonic stem cell research” and the country needs more effective pro-life education. “Poland is a solidly Catholic nation with strong pro-life policies,” said Bialecka (Schultz 2006, 52). It is unlikely importation of ESCs will occur in Poland given the strong pro-life rhetoric and laws in place. It is also significant how quickly the Sejm acted after the EU passed the funding proposal. The Sejm resolution passed in July 2006 and the EU proposal passed June 15, 2006.

Organizations that provide funding for scientific research in Poland include the Polish Agency for Enterprise Development (PARP), Foundation for Polish Science (FNP), the Polpharm Scientific Foundation, the National Centre for Research and Development, and the Polish Academy of Sciences (PAN).

The PARP is a government agency that funds entrepreneurs in competitive and innovative projects. It was created in 2003 and one of its main tenets is to help small companies network with foreign companies in exporting their products. The Enterprise Europe Network allows companies to publish their profile in a European database containing over 600 companies. The funding scheme of PARP includes support from the EU and state budget. The FNP was established in 1991 and provides funding through private industry. Individual researchers and research teams may apply for funding for projects which foster Polish science development. It also funds the FNP Award which is considered the most prestigious award in Poland. Polpharma also provides private funds for research. It was established in 2001 and is the largest Polish manufacturer of generic drugs and pharmaceutical substances. With a slogan of *We Help People*

*of Science*, its mission is to support the development of pharmaceutical and medical science by financing scientific research. Individual researchers, organizations, and institutions may apply for funding. Polpharma has adopted a framework of knowledge transfer between representatives of industry, and scientific and social foundations, both domestic and foreign.

The National Centre for Research and Development was established in 2007 with a platform of creating programs and funding applied research. It is the implementing agency of the Minister of Science and Higher Education. One of its programs is INNOTECH. This program funds companies for research involving modern technologies and conversion to the market. The Centre works with companies on both the national and international level. Lastly, PAN was founded in 1952 and recognized as one of the most significant scientific institutions in Poland. Its roots date back to 1800 when the Warsaw Learned Society was established on the initiative of the Stanislaw Staszic – an outstanding personage in Polish scientific life. The PAN has more than 350 elected members, 79 research institutes and is divided into 7 territorial branches (Gdansk, Katowice, Krakow, Lublin, Lodz, Poznan, and Wroclaw). The branch representatives create dialogue with local communities in advancing science. It receives funding from the State budget via the Ministry of Science and Higher Education.

***Portugal.*** Portugal has a unicameral legislature (*Assembly of the Republic*). The *Medically Assisted Reproduction law of 2006* permits only surplus human embryos that have severe genetic abnormalities and cannot be implanted to be used for research. Therapeutic cloning and reproductive cloning are prohibited. The National Council for Medically Assisted



Reproduction must approve all research projects. In addition, the purchase or sale of embryos or any other biological material derived from such IVF technology is forbidden.

Portugal is home to Europe's second largest cord blood stem cell bank, Crioestaminal. A Portuguese company invested (US\$) 1 million to expand the labs storage capacity from 50,000 to 300,000 samples. Crioestaminal is a private stem cell bank. Portugal also has a public stem cell bank but falls short of the space and resources that Crioestaminal possesses. The presence of two stem cell banks in Portugal supports the notion that the Portuguese are heavily invested in adult stem cells and more work with ESCs is possible by current law.

Public funding is available through the Foundation for Science and Technology (FCT) which funds not only individual and group research but also provides funding for infrastructure that supports research and technological development. Private funding is available through the Gulbenkian Foundation and Champalimaud Foundation. Higher education has improved regarding PhD degrees; at one time students were forced to pursue their educational goals outside of Portugal. There are now more PhD programs so that researchers can be home grown.

***Singapore.*** Singapore has a unicameral legislature (*Parliament*). Stem cell research is regulated under the *Human Cloning and Other Prohibited Practices Act of 2004*. Human cloning is prohibited and research using human embryos is permissible as long as they are less than 14 days old. Therapeutic cloning is also permissible. Singapore is heavily invested in stem cell research creating an infrastructure that links research institutes, universities, and industry toward product development.

In 2000 the Singaporean government created the Agency for Science Technology and Research (A\*STAR). Between 2001 and 2010 it invested more than (US\$) 4 billion in infrastructural and operational support for existing and fourteen new research institutes in the biomedical sciences (Colman, 2008). Singapore also established its first start-up company involved in stem cells in 2000 called ES Cell International (ESI). There are approximately forty research groups located in hospitals, universities, and research institutes involved in multiple facets of stem cell research. For the long term Singapore hopes to develop cell-based therapies to treat a wide range of diseases becoming a major international hub for patients seeking therapy.

In 2007 the A\*STAR Singapore Institute of Clinical Sciences (SICS) opened its doors serving as a training institution for clinician-scientists as well as a bridge linking basic research conducted at A\*STAR universities and research institutes with clinical research programs in hospitals. Moreover, the Duke University-National University of Singapore Graduate Medical School trains local medical graduates in translational research. Singapore has also been successful in recruiting experts in the stem cell field. Davor Solter, who headed the Max Planck Institute of Immunobiology in Germany has joined the Institute of Medical Biology in Singapore. There are over five thousand PhDs working in Singapore; more than half are from other countries. The major public funding agency in Singapore is A\*STAR. Private funds are available from EC International.

**Slovakia.** Slovakia has a unicameral legislature (*National Council*). *Law No. 277/1994 on Health Care* forbids limits research on human embryos to fertility treatments and prohibits

therapeutic cloning and reproductive cloning. The Slovakian Penal Code (Law No. 140/1961) assigns imprisonment for 3 to 8 years, to persons engaging in reproductive cloning. The Central Ethics Committee of the Ministry of Health oversees all research activities. Researchers in Slovakia are able to apply for EEA grants and Norway grants which provide more than (US\$) 1.2 million for project in the fields of nanotechnologies, biotechnology and food, sustainable development, and renewable energy. These grants represent the contribution of Iceland, Liechtenstein, and Norway aimed at improving economic conditions and social disparities as well as strengthening bilateral relations with 15 EU countries in Central and Southern Europe. Recently, scientists in Slovakia protested against a decision the Slovakian government made to divert (US\$) 161 million in research funds from the EU into a road construction program. These funds were allocated to Slovakia as part of the FP7 Programme which runs from 2007 to 2013. Slovakia spending on science and research amounts to only 0.48 percent of GDP, which is far below the EC threshold of 3 percent (Stafford, 2011). These dubious government practices will have a detrimental effect on future research in Slovakia.

***Slovenia.*** Slovenia has a bicameral legislature (*National Council and National Assembly*). The *Biomedically Assisted Fertilization* law enacted in 2000 allows surplus human embryos to be used for research as long as they are no older than 14 days and they are deemed unsuitable for reproductive purposes. Reproductive cloning and therapeutic cloning are prohibited. The aim of research should include improving human health and not just advancement of science. Written consent of the donors is required. In 2012 seventy scientists gathered in Kranjska Gora, Slovenia to discuss the latest advances in stem cell research and

funding from the EU's perspective. Arnd Hoeveler from the EC indicated that future funding will be prioritized toward translational research instead of basic research.

The Slovenian Research Agency was created in 2003 and is responsible for funding research projects as well as promoting research both internationally and domestically. A Scientific Council, made up of diverse disciplines, works within the agency to approve or disapprove projects. Slovenia also proposed a Research and Innovation Strategy for 2011-20 to increase the number of researchers and doctors of science, and to strengthen qualifications of researchers in Slovenia. The Slovenia Science Foundation also provides grants and stipends for doctoral candidates. To enhance collaboration between doctoral training and industry the Young Researchers in the Economy Programme grants funding to doctoral students employed in the private sector while pursuing a PhD. Mentoring is procured by both the company and the university. Private funding is available through the CF of Pomurje, CF Vincenc Draksler of Gorenjska, CF Planota of goriska, and CF of Posavje.

**South Africa.** South Africa has a bicameral legislature (*National Council of Provinces and National Assembly*). The *National Health Bill of 2003* prohibits human cloning but allows therapeutic cloning and research using surplus human embryos no older than 14 days with donor consent. Manipulation of genetic material is prohibited and export or import of ESCs must be approved by the Minister of Health. The Minister of Health must approve all projects and no embryonic material may be exported without approval. The draft bill actually banned all types of ESC research. Reasons given for the ban at the time included exploitation of poor South African

women. According to Dr. Eddie Mhlanga, Chief of the Maternal, Child and Women's Health in the National Health Department posited that ESC research targeted a vulnerable population in which Western companies would exploit women by harvesting stem cell lines and ship them elsewhere for research purposes. He further asserted that South Africa would never see any remuneration from the cell lines sold to Western nations describing his homeland as just a petri dish for Western physicians (Schuklenk, 2002). It did not take long for the pro-stem cell lobby to dispute Mhlanga's premonitions. Taking into consideration ethical boards and guidelines that are embedded in nearly every country with a stem cell law or an ART law, the bill was revised and passed in 2003.

In 2006 the government established the Biotechnology Regional Innovation Centers (BBICs) to fund research and promote the biotech industry in an area of the world isolated at the tip of Africa. Between 2004 and 2007 the National Biotechnology Strategy earmarked (US\$) 58 million in public funding for biotech development. Other public sources of funding include the Innovation Fund and the Technology and Human Resources for Industry Program.

**South Korea.** South Korea has a unicameral legislature (*National Assembly*). Research using surplus embryos and therapeutic cloning is permissible under the law. Human cloning is prohibited. Surplus embryos are frozen for a period of 5 years and if not used for implantation may be used for research with donor consent. While the law does not indicate a 14 day period, it does state that the surplus embryo may only be used before the appearance of the primitive

streak. Therapeutic cloning may only be performed if the project is geared toward curing rare or incurable diseases.

South Korea's standing in the stem cell research community was severely tainted by Professor Woo-Suk Hwang, once hailed for cloning the country's first mammal in 1999 (a cow named Chini), but who proceeded to publish fraudulent data in 2004 and 2005 (Hwang et al, 2004; Hwang et al, 2005). These articles have been retracted by *Science*. Before charges of fraud were proven South Korea celebrated Hwang's accomplishment by issuing a special postage stamp commemorating his stem cell breakthrough of creating stem cell lines via therapeutic cloning. In addition, Korean stocks of biotech companies rose threefold putting investors into a frenzy. Hwang was investigated by a committee from the Seoul National University. Not only had Hwang paid women for their oocytes but some of the donors were members of his research team and the stem cell line purportedly created by therapeutic cloning never existed. Hwang was banned from holding a public position for five years as well as being charged with embezzlement of (US\$) 2.91 million. As a result of Hwang's egregious acts, the National Bioethics Committee placed a moratorium on all stem cell research for a period of three years.

Baylis (2009) argues that part of the ethical breaches may lie in the Korean culture of Confucianism and filial relations. That is, Confucian ethics implicates duties from child to parent, subject to monarch, younger sibling to older sibling, etc... Hwang had a very prestigious reputation in South Korea and was well funded. South Koreans viewed Hwang as holding the hopes of the world; to further Hwang's research was to advance South Korea's standing in the

world. (Scanlon, 2006) Hwang is quoted as saying he had gotten “too much preoccupied with work and achievement” to keep ethics in mind (Carmichael, 2005).

Gottweis & Triendl (2006) offer a more systemic view of the breach of ethics. The South Korean government failed to provide adequate regulations and oversight fueled by ambition and thoughts of world greatness in science. Transparency, regulations, financial and political responsibility were lacking in the realm of science research opening the door for corruption, cronyism, and misconduct. A prime example was the addition to the author list on the fraudulent 2004 *Science* publication of Park Ky Young who was the advisor to the South Korean President for Science and Technology. According to Gottweis & Triendl adding Young’s name was a gesture of thanks to those in the political sphere for funding his research.

The bid for national legislation on ESCs came in 2000 after Hwang’s cloning experiment. The Ministry of Science and Technology created the Korean Bioethics Advisory Commission with the goal of drafting a law on bioethics. It was conceived by twenty members to allow ESC research on surplus embryos but to prohibit therapeutic cloning and human cloning. The draft legislation was rejected by the National Assembly. Another bill was drafted in 2002 called the *Bill on the Prohibition of Human Cloning and Stem Cell Research*. This bill promoted biotechnology research and meshed with another bill written by the Ministry of Health and Welfare regarding protection of human subjects in research. Both bills merged into the Act on Bioethics and passed the National Assembly December 2003, taking effect in 2005. The law established the National Bioethics Committee which regulates stem cell research. The World

Stem Cell Hub at Seoul National University published guidelines on the management of stem cells and the Ministry of Health and Welfare grants permission to scientists to conduct research. Unlike countries like the UK and the US that passed legislation before any potential suspect research could be conducted, South Korea chose to place scientific achievement above scientific oversight and is now credited with the worst case of scientific misconduct of the 21<sup>st</sup> century.

Public funding is available through the Korean Research Foundation under the guidance of the Ministry of Culture and Tourism providing support for advancement of a number of science disciplines as well as Korean culture. The National Research Foundation also provides grants in all areas of academic initiatives with an emphasis on R& D collaboration. The 21<sup>st</sup> Century Frontier R&D Program launched in 1999 has funded 23 projects of (US\$) 1 million each toward development of core technology and commercial potential in bioscience, nanotechnology, and space technology. This endeavor has resulted in 7061 patents in 2007 alone. Private funding is available through the Takeda Foundation and Samsung.

*Spain.* Spain has a bicameral legislature (*Senate and Congress of Deputies*). Spain can be characterized as a very Catholic country with a tradition and culture consistent with the idiom *slow but secure* (Cervera and Stojkovic, 2009). From 1988 to 2003 the *Techniques of Assisted Reproduction Law* only permitted research on non-viable embryos. To address the overflow of IVF embryos not implanted the law was amended in 2003 permitting embryos which had been frozen prior to that date to be donated for research as well as limiting the number of embryos per couple. The law was amended a third time in 2006. Couples could now decide the destiny of the



unused embryos: 1) keep them frozen for their future use, 2) donate them to other couples, 3) donate them for research, or 4) discard them. In 2007 new legislation was passed allowing therapeutic cloning in the Spanish Law on Biomedical Research. Lawmakers in Spain strive to combine support for research with stringent regulations for ethical limits. The law stipulates safe procedures that are respectful of society in maximizing health of citizens. The law is explicit in that therapeutic cloning should only be undertaken in combating incurable diseases. The Guarantees Commission for the Donation and Use of Human Tissues and Cells is responsible for assessing the feasibility and safety of the research project. Informed consent of the parents or oocyte donor is also required. The scientist must first receive permission for the project from the research committee at their institution and, if approved, acceptance by the Commission of Guarantees. Spain's position on ESC research has been gradual; utilizing existing laws and implementing new laws based on scientific achievements and public opinion.

Public funding is available through the Carlos III Health Institute (ISCIII) which focuses on the promotion and support of research and technological development in biomedicine, health science research, and regenerative medicine. It is funded by the Spanish government. The General Subdirectorate for Cell Therapy Research and Regenerative Medicine manages the National Stem Cell Banks in Barcelona, Granada, and Valencia as well as promoting evaluating, coordinating, and monitoring research involving regenerative medicine and cellular therapy. Private sources of funding include ESADE and the Carles Crespo Banchoero foundation.

*Sweden.* Sweden has a unicameral legislature (*Riksdag*). Sweden is unique in that every spring the Nobel Laureates are announced creating a positive atmosphere for science and research. It is no surprise that Sweden is a country heavily invested in ESC research. Therapeutic cloning and research using surplus human embryos up to 14 days after fertilization is permissible in Sweden under the *2005 Genetic Integrity Act*. It is not legal for couples undergoing IVF therapy to donate their embryos to other couples, the only options are to discard the spare embryos or donate them for research. The embryos are only allowed to be frozen for five years. In a study done in 2001, 92 percent of couples agreed to donate their spare embryos for research from one IVF clinic (Bjuresten and Hovatta, 2003). In 2001 the parliamentary debates were quite vociferous with daily coverage in the morning and evening newspapers. Debated discussions included therapeutic cloning, research using surplus embryos and when life actually begins. Political leaders of the Social Democratic Party went head to head with leaders of the Christian Democrats. Because the debate was covered in the media the issue remained on the political agenda. The two opposing positions were the great potential of stem cells supported by advocacy groups and protecting the dignity of a potential being. It wasn't until April 2005 that the law permitting therapeutic cloning and research using surplus human embryos came into effect. Debates were once again revived with similar arguments by politicians, however, those opposed to the law were not successful in repealing it.

Sweden is home to top ranked universities in Uppsala, Lund, and Stockholm, and the Karolinska Institute. The government body responsible for the framework of research and higher education is the Ministry of Education and Research. Every four years a bill is presented to

parliament with proposed allocations to universities and research councils for acceptable projects. The Swedish Research Council (SRC) operating under the guise of the Ministry provides approximately (US\$) 335 million per year for research (Schreck, 2009). Grant funding decisions lie with three scientific councils (Humanities and Social Sciences, Medicine, and Natural/Engineering) and two committees (Education Science and Research Infrastructure). Private funds are available through the Swedish Cancer Society, the Knut and Alice Wallenberg Foundation, NovaNordisk, and the Swedish Diabetes Foundation to name a few.

**Switzerland.** Switzerland has a bicameral legislature (*Council of States and National Council*). Under the Federal Constitution of the Swiss Confederation all forms of cloning are prohibited. Additionally commercialization of embryos or material from embryos is prohibited. Under the *Loi federale relative a la recherche sur les cellules souches embryonnaires* (Federal Act of Research involving Human ESCs) of 2004 surplus human embryos may be used for research with parent consent and the embryos may not be older than 7 days. This law was ratified when 66 percent of voters approved legislation via referendum held November 28, 2004 (Fitzli, 2005). Therapeutic cloning and human cloning are prohibited. Research projects as well as the export or import of ESC lines must have approval of the Research Office and the Commission of Competent Ethics. Additionally, the researcher must defend why the research could not be conducted using another method or source, other than ESCs.

Public sources of funding are available from the Swiss National Science Foundation which supports projects in biology, medicine, nanosciences, and the humanities. The commission

of Technology and Innovation (CTI) provides funding for market-oriented R&D projects, start-up companies, and technology transfer programs. Private foundations which fund research include the Latsis Foundation, Maecenas Foundation, and the Louis-Jeantet Foundation.

***The Netherlands.*** The Netherlands has a bicameral legislature (*Senate and House of Representatives*). Research using embryos is regulated by the *Embryos Law of 2002*. Surplus human embryos no older than 14 days may be used for research with donor consent and approval of the Central Commission. The law defines an embryo as a cell or complex of cells with the capacity to develop into a human being. The research must be intended to lead to significant medical advances carried out by experts in the field and no other alternative protocol is available. Therapeutic cloning was given a five year moratorium that was renewed in 2007 and human cloning is prohibited. The Netherlands began discussing policy regarding embryos in research about the same time as the UK, in the mid-1980s. The Dutch Health Council required a license for select IVF clinics to operate and decided that embryos had intrinsic value and should not be instrumentalized in research. A report was submitted to parliament by the Health Council in 1986. The Christian Democrats firmly opposed any research on human embryos claiming they are deserving of protection from the moment of fertilization (Kirejczyk, 1999). Both the Social Democrats and Liberal party agreed that more discussion was needed regarding what type of experimentation was acceptable. As early as 1988 the government proposed to allow research on embryos if the research was beneficial to public health. It also decided to leave the door open for modifications in future legislation. It was obvious the parties were treading slowly and opting for legislation acceptable to all. Unlike the UK, the Dutch political scene represents a large number

of parties with varying degrees of positions on the issue. Physician groups also tread lightly on the issue. Fearing a complete ban of research if they called for therapeutic cloning to be permitted, they were relatively silent on the issue until a law allowing research on surplus embryos was passed with the opportunity for modifications in the future, which came to fruition in 2002.

Public sources of funding include the Netherlands Organization for Scientific Research or NWO (*Nederland Organisatie voor Wetenschappelijk Onderzoek*) under the auspices of the Dutch Ministry of Education, Culture, and Science. The NWO has annual budget of (US\$) 840 million and manages eight research institutes so that funding can be channeled through a variety of disciplines. The Dutch funding agency for applied university research or STW (*Stichting Technische Wetenschappen*) also provides funding from the Ministry of Economic Affairs and the Ministry of Science and Education. Private sources of funding include the Netherland Chest Foundation and Nederlandse hartstichting.

***Trinidad and Tobago.*** Trinidad and Tobago has a bicameral legislature (*Senate and House of Representatives*). Trinidad and Tobago is a nation in the West Indies northeast of Venezuela. *An Act Respecting Human Reproductive Technologies and Commercial Transactions* Relating to Human Reproduction was passed by parliament in 1999. The law prohibits reproductive cloning, cross breeding of animals and humans, genetic alterations of embryos, maintenance of an embryo outside the body, fertilization of ova outside the body for the purpose of research, and commercialization of human embryos.

Public funding is available through the University of West Indies Trinidad and Tobago Research Development Impact Fund in areas of public health, environmental issues, entrepreneurship, and technology. The government plans to invest (US\$) 5 million dollars on health related projects and papers in an effort to reduce the amount of revisits at area hospitals (MOH, 2013).

**Tunisia.** Tunisia has a unicameral legislature (*Constituent Assembly*). Research using surplus embryos is prohibited by *Law 01-93 The Medicine of Reproduction*. Therapeutic cloning and human cloning is also prohibited. Any cryopreservation of surplus embryos is strictly for reproductive purposes. Import and export of ESCs is also prohibited. In 2002 the Tunisian National Committee of Medical Ethics proposed adult stem cells as an alternative to using human embryos or cells thereof in research.

The constitution of Tunisia provides for freedom of religion with the predominant religion being Muslim. The government is led by multiple political parties which posit a social democratic and secularist ideology. Like Morocco and Lebanon, Tunisia has adopted a non-permissive policy on ESC research. While these countries have Muslim populations they have not embraced ESC research as other Muslim countries such as Iran. Islam is supportive of ESC research up to 14 days after fertilization as discussed in Chapter III.

Tunisia has established a program to promote science and research via an EU grant of 12 million euros (US\$ 16.4 million) for the years 2011 to 2014 (Bournedjout, 2011). Funding will provide for an infrastructure of research centers and laboratories. The idea is to enhance

collaboration between Tunisian researchers and counterparts in EU states encouraging joint projects. Specific research projects will focus on healthcare, renewable energy, and water.

***United Kingdom.*** The UK has a bicameral legislature (*House of Lords and House of Commons*), and one of the most permissive policies on ESCs in the world. This is not surprising when considering the pioneering scientific achievements in the fields of IVF and cloning. On July 25, 1978 Louise Joy Brown was hailed as the first test tube baby by the efforts of Dr. Robert Edwards and Dr. Patrick Steptoe. Dr. Edwards was a physiologist at Cambridge University and Dr. Steptoe a gynecologist at Oldham General Hospital. Together they were successful in fertilizing an egg outside a woman's body and opening the door for millions of couples to have a child through IVF. Then in 1996 Dolly the Sheep was born and represented the first mammal to be cloned from an adult somatic cell of a Finn-Dorset sheep and an egg of a Scottish Blackface sheep. Ian Wilmut and Keith Campbell of the University of Edinburgh conducted the experiment. Dolly lived a short life, succumbing to disease in 2003, but planted the seed for the possibility [and fear] of human cloning.

Four years after Louise Brown was born the Warnock committee was formed to evaluate the social, ethical, and legal implications of human embryos in research and other issues concerning IVF therapy. It was chaired by Baroness Mary Warnock and made up of physicians, professors, social workers, and lawyers. Among the issues the Warnock committee was charged with examining were the scope of infertility treatment and the use of human embryos in research. For the purposes of this study discussion will focus on the latter. The Warnock report includes

details on the development of the embryo which includes mention of the primitive streak structure which is indicative of the beginnings of the central nervous system. Before this structure appears, it was asserted, the developing embryo cannot feel pain and research at this stage would be acceptable. The Royal College of Obstetricians and Gynaecologists suggested a time limit of seventeen days but the British Medical Association was more in favor of fourteen days if human embryos were to be used for research. The committee also examined current and historical laws regarding protection of the embryo and found in the UK there was no legislation that afforded the embryo with equal rights of a child or an adult; in addition, there was no law that states an embryo has a right to life. *The Congenital Disabilities Act of 1976* allows damages to be recovered if an embryo or fetus is injured in utero through negligence of a third party but this would not apply to ESC research as these embryos are not implanted for reproductive purposes. The majority of the committee members agreed that the embryo of the human species should be afforded protection and addressed this recommendation by mandating stringent controls and regulations in the research application process. A license would be required for the scientist to conduct research and criminal charges would be brought against persons who breached license requirements. Another requirement is that informed consent of the parents is required for using their embryos in research. It should be noted that even though the final report of the Warnock committee ultimately allowed research using human embryos there was dissent by four members who argued the question of when life begins and the special status of the embryo. They surmised that the question of when life begins could not be answered on fact, but on moral principles. On special status they felt it was wrong to create something with the



potential of becoming a human person and then deliberately destroy it, concluding that research on human embryos should not be permitted (Warnock, 1984). Mary Warnock's concluding remarks were "The majority of us held that the sanctity of human life in general can be upheld even if the very earliest and least developed embryos were used in research. But not everyone agrees. In the end it must be for Parliament to come to a decision about which value to place higher"(Warnock, 1984, 99). The Warnock Report was presented to the British Parliament and led to the passing of The Human *Fertilisation and Embryology Act (HFEA) of 1990*.

The *HFEA* allows therapeutic cloning and research on surplus embryos up to 14 days post fertilization. In the legislative process the House of Lords Select Committee on Stem Cell Research proposed creation of a national stem cell bank as a custodian of stem cell lines and requiring any stem cell line created in the UK be deposited in the stem cell bank. Further, the committee proposed that embryos should not be created explicitly for research unless there was a shortage of surplus embryos. As a result the government funding provided (US\$) 3.1 million for an IVF-stem cell infrastructure so that researchers could procure high quality surplus embryos for research. An additional (US\$) 1.5 million was allocated to upgrade five IVF clinics to comply with current good manufacturing practices for derivation of clinical grade ESCs appropriate for therapeutic applications (Ehrich, 2010).

The *Human Reproductive cloning Act of 2001* prohibits reproductive cloning. Research using embryos must promote advances in the treatment of infertility, increase knowledge regarding inheritable diseases, increase knowledge regarding miscarriages, develop more

effective techniques of contraception, develop methods for detection of chromosomal aberrations, or increase knowledge regarding development of embryos, hastening the transition from basic research to clinical trials. In addition, the scientist must apply for a license through the HFEA which may last for three years. If a license is granted the research process is inspected by HFEA on a regular basis inquiring how embryos are used and the progress of the research.

It is clear the evolution of the UK's policies in ESC research was thorough and painstaking. The permissive policy adopted by the UK was not devoid of contentious debates in parliament. Members of parliament presented their case in committees on why human embryos should not be used in research and why they should be. The Medical Research Council (MRC) is a significant funding organization in the UK for scientific research and funded the UK Stem Cell Bank. The MRC is also part of the *Stem Cells for Safer Medicines Initiative* where government, research centers, and industry maximize resources to encourage early drug discovery using stem cells.

The UK Stem Cell Center opened in 2004 and has the full backing of the UK government. It is a repository for human embryonic, adult, and fetal stem cell lines. These cells are available to scientists from all over the world placing the UK at the forefront of potential stem cell discoveries. It provides education and training to scientists by qualified staff so that the stem cell lines produced and stored are of the highest quality. It strives to exhibit a transparent and accountable organization free of conflicts of interest and involvement in commercial product development (Healy, 2005). The House of Lords Steering Committee oversees the operation of

the Bank. The Biotechnology and Biological Sciences Research Council (BBSRC) is the principal funder of basic and strategic research in the medical, healthcare, agricultural, veterinary, and food disciplines. It receives funding from the Department of Innovation, Universities and Skills (DIUS). The BBSRC spends approximately (US\$) 12 million annually on stem cell research. It also co-funds the UK Stem Cell Center along with the MRC. The Scottish Stem Cell Network was created in 2003 and is funded by the Scottish Enterprise Edinburgh and Lothian (SEEL). This organization supports interdisciplinary exchanges so that basic research may translate to clinical studies and patient benefit, as well as economic incentives.

The British Heart Foundation is a private charitable organization strictly reliant on donations from the public. Approximately (US\$) 67 million is spent annually on cardiovascular research. The stem cell connection lies in replacing damaged tissue in persons with heart disease. Cancer Research UK claims to be the world's largest non-governmental organization dedicated to cancer research and largest single funder of cancer research in the UK. It is also the largest producer of anti-cancer drugs in Europe. Diabetes UK and the Parkinson's Disease Society are charitable organizations in the UK that provides funding to scientists researching these incurable diseases. The Wellcome Trust is also a charity in the UK providing funds for researchers to advance biomedicine. On an annual basis, approximately (US\$) 872 million is allocated for research. It is particularly focused on how stem cells can differentiate into any type of cell in the human body.

*United States.* The US has a bicameral legislature (*Senate and House of Representatives*). The legislative discourse regarding the use of human embryos in research began after the Supreme Court's decision on the landmark case *Roe v Wade* (1973). The Department of Health, Education and Welfare (now Department of Health and Human Services) placed a moratorium on research using living embryos. One year later Congress placed a moratorium on federal funds being used for research on embryos until a national committee could generate ethical guidelines. In 1975 the now Department of Health and Human Services (DHHS) lifted the moratorium and adopted guidelines of the Ethics Advisory Board (EAB) so that basic, non-therapeutic research was possible. In 1979 the EAB approved federal funding for research using IVF and embryo transfer up to 14 days. In 1980, the EAB dissolved leaving a void in the research protocol approval process. The National Institutes of Health (NIH) formed the Human Fetal Tissue Transplantation Research Panel after an application for fetal research was received in 1987. Secretary Sullivan extended the moratorium indefinitely on the use of fetal tissue or embryos. In 1990 Congress passed a bill to lift the moratorium, however, President George H.W. Bush vetoed the bill. In 1993, President Clinton lifted the moratorium. After midterm elections in 1994 the Democrats lost the majority in the House and Senate and Congress banned federal funding for research on human embryos in 1995. The *Dickey-Wicker Amendment*, which prohibited NIH funding on creation of embryos for research or destruction of an embryo, has been attached to all congressional appropriation bills for the DHHS since 1996. In 2001, President George W. Bush compromised by allowing public funding on existing ESC lines only. In 2005, the *Stem Cell Enhancement Act* providing federal funds for research using surplus human embryos was passed

by the House, and the Senate a year later. President Bush vetoed the bill. It was passed by both houses again in 2007 and again vetoed by President Bush. Finally in 2009 by Executive Order 13505 *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells* President Barack Obama mandated federal funding could be available for research involving surplus embryos from IVF procedures. The research projects are regulated by the NIH under guidelines that stipulate such research must have scientific merit and informed consent from the embryo donor (parent) is secured. In addition, embryos that have undergone PGD may be used for research. Therapeutic cloning and reproductive cloning research cannot be funded by the federal government.

It can be discerned that the stem cell issue in the US is decided along party lines with the Republicans claiming such research violates moral ethics and the Democrats leaning more toward curing disease and advancing medical science and technology. However, there are exceptions to towing the party line. Moderate Republicans, like the late Arlen Specter (R-PA), Mike Castle (R-PA), and Orin Hatch (R-UT) have all lent support for ESC research based on it being the best option for curing diseases and improving patient's lives. In addition, four conservative Republican Court of Appeal judges ruled in favor of the NIH in lifting an injunction put in place by a federal judge after two scientists challenged the NIH guidelines (Annas, 2011). With the tenable presence of tea party Republicans seemingly poised to unseat their moderate counterparts it is unlikely a law will be passed codifying President Obama's executive order. At this juncture, however, given the tremendous outpour of public and private funding in California and the private sector, is federal funding really an issue? Glenn McGee, editor of the American

Journal of Bioethics, commented “I think that ship has sailed” (Wolinsky, 2010,924). That is, in the US stem cell research will continue to thrive irrespective of who is in the White House or what party holds the majority.

The states that have passed permissive laws on ESC research are California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Missouri, New Jersey, and Rhode Island. States that have passed laws prohibiting stem cell research include Arkansas, Indiana, Louisiana, Michigan, North Dakota, and South Dakota. Because federal funds could not be used for research during the George W. Bush Administration, unless stem cell lines were already in existence, states had to procure their own funding and it was California that took the lead. In 2004 voters in California passed *Proposition 71* (the California Research and Cures Initiative) amending the Constitution to render stem cell research a state right and creating the California Institute for Regenerative Medicine (CIRM). The most populace state had full endorsement from their republican Governor Arnold Schwarzenegger and twenty Nobel laureates. Three billion dollars was procured for the stem cell program via sale of public bonds; the CIRM funds, facilitates, and regulates stem cell research in California. California has positioned itself as a global mecca of stem cell research attracting world class scientists and awarding more than 500 million in research grants (Adelson and Weinberg, 2010). When examining the multitude of papers published by American scientists involving ESC research, the CIRM was only second to the NIH in top funding agencies. In the realm of stem cell research, the federalist system of the US has allowed states to write, pass, fund, and implement their own policies. No other country

with a prohibitive policy has seen individual states pass their own laws and procure their own funding so that research activity can continue.

As mentioned the major source of federal funds is the NIH. Private sources of funding include the Christopher Reeves Foundation, Michael J. Fox Foundation, Bill and Melinda Gates Foundation, and Juvenile Diabetes Research Foundation to name a few. The US has a definite advantage in ESC research because of numerous funding outlets, ability of scientists to apply for patents, and collaboration between research institutes, universities, and the biotech sector. Notable research institutes are the NIH, Mayo Clinic, California Institute for Regenerative Medicine, Dana-Farber Cancer Institute, New York Blood Center, and the Howard Hughes Medical Institute.

*Uruguay.* Uruguay has a bicameral legislature (*Chamber of Senators and Chamber of Deputies*). Research on human embryos, therapeutic cloning, and reproductive cloning is prohibited in Uruguay according to the *Human Assisted Reproduction Law of 2003*. Additionally, according to the Code of Ethics of the Uruguayan Union of Doctors “the human embryo may never be the subject of experimentation, nor the raw materials for drugs, cosmetics, or other products” (Montano, PJ, 179).

Public funding includes the National Research and Innovation Agency (ANII), the Directorate of Innovation, Science, and Technology for Development (DICYT) of the Ministry of Education and Culture, CONICYT, and CSIC of the University of the Republic. Private funding is provided by the Manual Perez Foundation, the Programme for Technological

Development (PDT), the Clemente Estable Fund (FCE), and the National Institute for Agricultural Resources. Most research is conducted at the School of Medicine at the University of the Republic in Montevideo.

**Vietnam.** Vietnam has a unicameral legislature (*National Assembly*). The *Law on Childbirth by Scientific Methods* enacted in 2003 forbids human cloning and use of human embryos for research purposes unless they are explicitly designed to aid fertilization. The Health ministry is the regulating body for overseeing any experiments on embryos as well as IVF techniques. Vietnam is a newcomer to biomedical techniques. At the same time James Thomson used human ESCs to grow tissue in mice, the first baby was born using IVF technology in Vietnam. The country's gingerly approach to IVF therapy may provide some insight into society's views on human embryo research. Sociocultural values and pressures are related to infertility as women are viewed as the only means for carrying on the patriline via birth of a son. The woman is said to have a sentiment (*Tinh cam*) or close and intimate relationship with her child not only after birth, but also in utero where exchange of blood and nutrients is the foundation for life long intimacy (Pashigian, 2012). Donating an embryo to another couple, surrogacy, and IVF therapy for unmarried women is prohibited. Given that it stands to reason the human embryo is treated with great respect and not suitable for stem cell research unless it improves fertility treatment.

Public funding is scarce in Vietnam and limited to university students with little potential for significant scientific development. Alternatively, the International Foundation for Science



(IFS) has provided funding in Vietnam since 1980. The IFS can be described as a research council with international cooperations to support science and technology in a wide variety of fields. Other sources of funding include the Kids with Cancer Foundation, Lin Center for Community Development, the Spirit of Enterprise, and Southeast Asia's Children's Fund.

This chapter discussed ESC policies and funding mechanisms in the fifty countries chosen for this study. For such geographical diversity, there are common themes. Most countries allow research on surplus human embryos using the 14 day threshold, with the exception of the Czech Republic and Switzerland mandating a 7 day threshold. Nearly all countries are absolute in prohibiting human cloning, with only Israel using incremental moratoriums on this issue. Israel has placed five-year moratoriums on reproductive cloning in 1998, 2004, and 2009 (Cook, 2009). A handful of countries are permissive of therapeutic cloning. These are Australia, Belgium, China, Finland, Israel, Japan, Mexico, Singapore, South Africa, South Korea, Spain, Sweden, and the UK. Countries with non-permissive laws include Albania, Austria, Chile, Costa Rica, Germany, Iceland, Ireland, Italy, Latvia, Lebanon, Lithuania, Malta, Morocco, Peru, Poland, Portugal, Slovakia, Slovenia, Trinidad and Tobago, Tunisia, Uruguay, and Vietnam. The next chapter will present related literature and construction of hypotheses.

### Chapter III Literature Review

This study is exploring differences in national policy regarding ESC research by examining factors in each country. To that end, this chapter will review the literature and construct hypotheses regarding religiosity, literacy, age, funding, type of government, and size of government which are the predictor variables selected for this study. There are no studies to date that have included type of government, funding characteristics, or literacy rate as independent variables in similar studies.

#### **Religiosity**

Opposition to ESC research stems largely from religious views and tightly held principles of the sanctity of life. The majority of countries studied practice Catholicism or another Christian religion. Christian and other religious leaders have voiced opposition to ESC research because in the process of acquiring ESC's the embryo is killed, and therefore, a potential human life is lost. The embryo is a human person from the moment of conception who should neither be produced for other means, killed, or instrumentalized for medical benefits or therapeutic products (Rigaud, 2008). This belief is most accepted by conservative Christians. The influence of the Roman Catholic Church and the Vatican is most palpable in Italy, Germany, Ireland, Austria, and Poland. In this setting the utilitarian view on ESC research is quelled by lawmakers in parliament with strict Catholic views.

The Vatican strongly and unequivocally opposes ESC research because embryos are destroyed in the process. In 2011, Pope Benedict XVI said “the destruction of even one human life can never be justified in terms of the benefit it might conceivably bring to another” (Wooden, 2011, 1). Opponents of ESC research have numerous examples, in both the Old and New Testament, of religious views protecting the sanctity of life. The Scripture contains many passages that reflect the Christian view of life and when it begins. The book of Genesis states, “in the beginning God created the heavens and the earth” and “God created mankind in his image” (New Jerusalem Bible, Gen 1.1, 1.27). The creation account clearly depicts that all life, where life includes mankind, is sacred because all life was created by God. Another writing, the *Donum Vitae* (1987), provides the moral foundation for the official Roman Catholic position on ESC research. As this passage states “the fruit of human generation, from the first moment of its existence, that is to say, from the moment the zygote has formed, demands the unconditional respect that is morally due to the human being in his bodily and spiritual totality “ (Ratzinger, 1987, 6). Unconditional respect can be viewed as absolute protection of the embryo and preservation of human life. When stem cells are extracted from the embryo, the potential for human life is extinguished. The message of life and the sanctity of life is a stapled tradition in the Christian religion. In contrast to a country’s constitution which is interpreted as society changes, the Christian religion is tightly bound to its historical tenets; the *what ifs* are not part of the conversation where the Holy Scripture is concerned.

The Lutheran church has not taken a firm stand on ESC research. Leaders of the church have offered individual opinions based upon tenets of the church doctrine. Ted Peters, a

theologian, refers to a parable in which a Jew is beaten by robbers and left to die; a non-Jew passes by to come to his aid. Peters argues that by deciding to help a life may be saved. Ignoring the beaten man by walking on the other side of the street is comparable, according to Peters, to ignoring the potential use of ESCs from an early embryo as these cells also may save a life (Peters, 2001).

Nissen (2006) references the writings of Lutheran theologian and Pastor Dietrich Bonhoeffer in arriving at a position on ESC research. Bonhoeffer was born in 1906 in Breslau (Germany). In 1933 when Hitler came to power he was a minister in the Lutheran church and used the radio medium to voice opposition to the Nazi party. From 1935 to 1939 he was the leader of an underground seminary and then fled to the US for a short time. He returned to Germany because he felt he was needed by the people of Germany given the war time and oppressive circumstances. He was imprisoned in Berlin and executed in 1945 for complicity in a plot to assassinate Hitler. While in prison he wrote what many consider to be his greatest contribution to theology *Ethics* from 1940 to 1943. In Bonhoeffer's *Ethics* he discusses elements happening in the world around him such as the problem of evil but also contrasts natural life with unnatural life. According to Bonhoeffer natural is inclusive of the human Christ and unnatural is devoid of Christ in daily life. The unnatural distorts and is contrary to life; all that lies outside of the natural or will of God is doomed to failure. Bonhoeffer also talked about the protection of bodily life and believed that all life is deserving of preservation. The developing life has a right to life and the deliberate ending of life is simply murder. Nissen believes the Lutheran church has a position on ethics however when considering all of the traditions of the Lutheran church in

attempting to decide on an issue like ESCs there is ambiguity. For Nissen's part, as inspired by Bonhoeffer, he cannot support ESC research because it is contrary to natural life. Peters and Nissen's opposing views on ESC research are evidence that the Lutheran Church has not taken a firm stand on supporting or opposing ESC research. Discussions and debates are likely to continue by both theologians and parishioners on the contentious issue of ESC research.

The Protestant view is generally more flexible than Catholicism. Theologians have supported embryo research through the fourteenth day of development, while others have emphatically condemned therapeutic cloning, and others have rejected any type of research that leads to the destruction of embryos. For example in France, the French Protestant Federation believes research for worthy causes should be allowed as long as women are not exploited and give their consent. (Federation protestant de France, 2000). They also have stated that embryos with no plan for adoption or care by biological parents are not whole human beings leaving other alternatives on the table for their destiny. The Church of England is in favor of research on human embryos up to 14 days development, but against therapeutic cloning; believing up to 14 days the moral status is not equal to a child or adult. Protestants tend to look at the whole spectrum of gestational age from early cells to a formed fetus being more lenient toward the former in benefiting medicine and society.

The Greek Orthodox Church also condemns ESC research but comes out in favor of stem cell research using adult stem cells. Like the Catholic Church, the Greek Orthodox Church believes life begins at conception giving the human embryo the same moral status as a human

entity. In this view it is immaterial whether the embryos are in surplus, slated for destruction or research, their right to life is violated. Likewise, the use of ESC lines is tainted due to the fact that the immoral act of killing the embryo has already been committed. In other words, using ESCs is in effect condoning their destruction.

In contrast to the Greek Orthodox Church and other Christian denominations, the rules of the Jewish culture are shaped by both religious text and rabbinical law (Knowles, 2008). Orthodox Jews believe that embryos do not have the same moral status as human persons. Under Jewish law embryos created by IVF have no moral or legal status. The fetus gains human status when its head emerges from the womb. The human embryo is described as water during the first 40 days of its development (Tendler, 2000). In addition, the Jewish culture places great emphasis on preventing and alleviating suffering, which is in line with the pursuit of medical research. Where in the Christian religion the moral imperative rests with protecting life from the time of conception, the Jewish faith places the moral imperative on alleviating human pain and suffering. This viewpoint is evident in Laurie Zoloth's writing,

“The task of healing in Judaism is not only permitted, it is mandated. This is supported and directed not only in early biblical passages (you shall not stand idly by the blood of your neighbor, and you shall surely return what is lost to your neighbor) but in numerous rabbinic texts as well. The general thrust of Jewish response to medical advances has been positive, even optimistic, linked to the notion that advanced scientific inquiry is a part of tikkum olam, the mandate to be an active partner in the world's repair and perfection” (Zoloth 1999, 22)

Islam is similar to Judaism in that life is ascribed to later stages of the embryo, according both to the Qur'an and tradition. The Qur'an does not address moral status of the fetus or embryo, allowing the jurist to render the distinction between embryo and human. The embryo is not considered human when it attaches to the womb or exhibits involuntary movement (Sachedina, 2000). In 2002, the Legal Committee of the Majelis Ulama Indonesia (Islamic Religious Council) stated the following: "The Fatwa Committee rules that the opinion of the Bioethics Advisory Committee to use stem cells from embryos below 14 days for the purpose of research, which will benefit mankind is allowed in Islam. This is with the condition that it is not misused for the purpose of human reproductive cloning, which would result in contamination of progeny and loss of human dignity" (Fadel, 2007, citation Muslim World League, 2003).

The basic tenet of Buddhism is not to harm or kill any being on earth and to exhibit compassion for all beings. Those that practice Buddhism are not against research that aims to benefit human kind and regard such research as ethical; if on the other hand, research has egregious or unethical goals, they would be against it. The Buddhist principle of *ahimsa* posits that no harm should come to any animal or human. Because the human embryo dies upon extraction of ESCs Buddhist are against ESC research (Keown, 2004). Barua (2005) states Buddhists would be against human cloning from the aspect of untoward motivations of scientists and the fear that such experiments are outside of the natural order of things. For example, cloned embryos may undergo mutations with untoward effects and values of love and human procreation would be missing in the act of cloning a human. Furthermore, humans would be playing the role of God and potentially placing society in disarray if the clone was designed with

deliberate traits toward a nefarious end. Schleiter (2004) posits human cloning could also be problematic with regard to emotional issues of the cloned child, being devoid of biological parents. The child may have feelings of isolation or being a misfit in society. Schleiter's points are tenable, it seems, if the child has knowledge how they were created. As no human to date has been cloned, these questions can only be pondered and debated by interested actors in society until more research becomes available.

In Taoist religion, all life is valued and saving life is the highest virtue. While embryonic stem cell research does aim to benefit humankind, Taoism is not supportive of research that involves taking the life of another, e.g. using embryos for research. In contrast,

Simon Fink (2008) demonstrated that religion does matter in the realm of ESC research by conducting an ordinary least squares regression study. Fink references the term *biopolicies* (Rothmayr and Varone, 2004) to refer to public policies that regulate controversial biological issues. These may include stem cell and embryo research, genetic, and reproductive engineering. Fink analyzed biopolicies in Germany, Spain, Norway, Austria, France, Sweden, Denmark, Great Britain, Finland, Australia, Greece, Netherlands, Belgium, New Zealand, Canada Italy, and Switzerland with the goal of trying to explain the variation in embryo research laws using theories of comparative public policy. A restrictive policy index was calculated based upon what procedures the country allows. This index served as the dependent variable or outcome variable. Independent variables included the strength of Christian democratic and left parties, veto players, strength of pharmaceutical companies, and Catholicism. The results of Fink's study were as



follows: predominantly Catholic countries have stricter laws on ESC research, countries with strong Christian democratic countries also have stricter laws on ESC research, countries with a strong pharmaceutical industry do not have more permissive laws, and the number of veto players does not impact ESC research laws.

Fink also found that the strength of Christian democracy parties was significant in that this entity is associated with strict research laws regarding the embryo. Specific examples include Germany and Austria. Fink ascertains that left-leaning governments only influenced permissive laws after 1997 and that this dichotomy was due to the promise of economical benefits from ESC research; prior to 1997 leftist governments passed liberal as well as strict laws (Mulkey, 1997). The effect of veto players in the analysis was not significant and Fink's reconciled this finding by stating that ESC research is an area that can bring together multiparty coalitions. For example, in Belgium a coalition consisting of five parties led to one of the most liberal biopolicies in Europe (Schiffinoi & Varone, 2004). Regarding the strength of the pharmaceutical industry, Fink determined there was no systematic relationship between the strength of the pharmaceutical industry and permissive ESC laws. The United Kingdom has a strong pharmaceutical base yet a permissive law; in contrast both Germany and Italy have a strong pharmaceutical base yet strict laws. A robust pharmaceutical industry does not always sway lawmakers toward permissive policies.

The Catholicism variable was significant using percentages of Catholics in each country. Catholic societies have stricter laws on research involving embryos, in comparison to Protestant societies. A salient example is Italy. Even though a secular government ruled Italy in the 1990's the Church was a coherent political actor by its powerful influence on the Christian Democratic Party. In addition, many members of center-left government were devout Catholics. In 2001, the Christian Democrats aided by a center-right coalition won elections in 2001 leading to one of the strictest laws on ESC research in Europe. Fink's conclusion was that religion matters in the realm of embryo research laws and can be used to explain differences in public policy. A strong religious base can counteract the influence of economics in devising liberal laws. The present study differs from Fink's on many levels. It utilizes a larger sample size, and age, literacy rate, type and size of government, and funding as predictor variables. It also selects countries based upon type of government, unicameral or bicameral where Fink limited his selection to OECD countries.

Blendon et al (2011) presents data from the United States and Europe on public attitudes toward stem cell research. Iceland, Norway, Sweden, and the UK indicated that ESC research should not be forbidden. This is in contrast to Austria, Luxembourg, Greece, Slovenia, Germany, Slovakia, Latvia, and Turkey who were against ESC research. Respondents were also asked about their religious practices. They were categorized into attending religious services less than once per year, monthly or yearly, and weekly or more. Of fifty percent of respondents who did not forbid ESC research 57 percent attended a religious service less than once per year and 64 percent were categorized as atheists or non-believers. Of 39 percent who forbid ESC research 49

percent attended religious services weekly or more which was the highest percentage in the attendance category. According to this Eurobarometer poll more religious practicing people were associated with prohibiting ESC research and those that were either non-believers or exhibited low attendance were associated with permissive ESC research in Europe. Clearly, religiosity is a formidable factor on the issue of ESC research and will be analyzed as a variable in this research utilizing the percentages of Catholics in each country.

Thomas Banchoff (2008) compared the United States and Germany regarding ESC policies. Providing more insight into the German policy on ESC research, Banchoff (2008) wrote that the amendment to the German Stem Cell Act of 2002 where the cutoff date for acquiring embryonic stem cell lines was extended was the result of advances in science, fissure surrounding the Church, and shifts in public opinion. Regarding the Church, while Catholic officials remained opposed to ESC research the Lutheran Church began to soften its position. The Evangelical Church of Germany (EKD) President Bishop Wolfgang Huber voiced support for an amendment to extend the cutoff date one time influencing German Protestants toward a less restrictive law (EKD, 2008). The EKD is a federation of Lutheran, Reformed Calvinist, and Union Protestant Churches. Banchoff remains steadfastly committed to the notion that Germany's cautious approach to ESC research to date has links to the long shadow of the Nazi past. Both secular and religious regions echo a gingerly approach to ESC research in Germany.

These studies demonstrate that religiosity influences public policy in the realm of ESC research with Catholicism serving as the most polarizing denomination. A significant part of that

influence stems from the fact that only in Catholicism do you have a sovereign central authority revered by most of practicing Catholics. Statements made by the current and past Popes, supported by scripture, in opposing ESC research have influenced the public and pro-life groups to campaign for a policy which restricts research on human embryos. Catholicism is the religion that is most polarizing to ESC research compared to other denominations leading to non-permissive policies. The **REL** variable is continuous, utilizing the percentages of Catholics in each country.

*Hypothesis 1. Predominantly Catholic countries are more likely to favor non-permissive ESC policies and research while non-Catholic countries are more likely to favor permissive policies and research.*

## **Literacy Rate**

Literacy is defined as the ability to read and write, with understanding a statement related to someone's daily life (Azariadis and Drazen, 1990). The adult literacy rate includes an age range of persons sampled. The most utilized age range on a global scale is 15 years and over. The literacy rate has been linked to human capital proxy in that to be involved in social issues that perpetuate positive changes people need to be able to read the newspaper and reports on the internet, or newsletters of a community organization. International law has codified literacy as a right. The 1948 Universal Declaration of Human Rights recognizes the right to education. That right is stated International Bill of Human Rights promulgated by the United Nations. Literacy has the potential to satisfy vital needs and stimulate social, cultural, political, and economical

participation for all people (UNESCO, 1997). Hirabayashi and Khatib (1958) studied five rural villages in Menoufia (Egypt) to assess literacy and political knowledge among 146 people. The literacy rate in Menoufia when interviews were conducted was 20 percent. Interviewees were asked if they read the newspaper and listened to the radio. They were also asked to distinguish between political terms, such as *election* and *plebiscite*. Only persons who were previously characterized as being literate could make the distinction. Additionally, one-third of newspaper readers were able to adequately differentiate terms compared to only 10 percent of non-newspaper readers.

Darden and Gryzmalla-Busse (2006) demonstrated that countries which firmly established widespread literacy via mass schooling before communist rule were more successful in voting out the communist party in the first free elections. Hungary, Poland, and the Czech Republic were among those countries with pre-communist high literacy rates (70 percent) compared to Albania, Bosnia, and Macedonia (30 percent). Once free elections were held people who had established mass schooling had sufficient social capital to vote out communist incumbents in parliament swiftly ending communist rule in their country. Literacy increases political knowledge and activism toward significant social change eliciting a positive aura that is renewable each every time something new is revealed through reading. People are most apt to participate in community gatherings when they feel comfortable in social situations. Studies have shown literacy correlates with high self-esteem. Egbo (2000) compared non-literate women to literate women in Nigeria. Utilizing focus groups and individual interviews of 36 women from rural areas she found literate women espoused confidence when participating in community

meetings, were more self-reliant and knew their rights. In contrast, illiterate women were uncomfortable in the community setting in others thinking they lacked knowledge.

Literacy is paramount to political engagement. Repetitive activities toward that end perpetuate a fundamental interest in the myriad of issues surrounding public policy. In studying Chile, Columbia, Portugal, and the US Torney-Purta and Amadeo, (2004) found that among 15,000 students, those with more years of life experiences and formal education (17 year olds vs 14 year olds) performed better on civic knowledge exams suggesting that political knowledge is additive. Factors linked to an interest in political and social activism as adults included a conducive learning environment, confidence in class discussions, and activities involving community problem solving. Human beings at any age are social creatures and like to be involved in issues which concern them. It is clear illiteracy is a venerable obstacle in community engagement and severely limits an individuals potential to effect change in society.

The literacy rate is accessible in a great number of countries; it is a measurement that is feasible to generate and has value in society. It is hypothesized that countries with higher literacy rates will more likely favor permissive policies on ESC research in possessing the skills to read the latest advances reinforced by community involvement.

*Hypothesis 2. The higher the literacy rate the more likely a country will favor a permissive ESC research policy.*

## Age

In public opinion polls, it is commonplace to survey individuals that represent a large range in age of the sampled population (Esomar, 2009). This can be helpful when deciding on strategies utilized by political groups and factions toward achieving their policy goals. In the realm of ESC research older individuals tend to be more disciplined toward their religion than younger individuals and steadfast in their beliefs. As described above, religion is connected to ESC policy based on moral beliefs and tenets of respective religions. Considering that most people in the countries studied practice some form of Christian religion and older individuals are less accepting of modern technology and science than younger people (Eurobarometer, 2005), the latter are more apt to approve of ESC research compared to older individuals.

The Internet is also a formidable factor when considering the age differential. Most young people have access to the internet. The internet allows the individual or group to delve deeper into topics that interest them. Information can also be found inadvertently. For example, just by browsing a news website or a social network that posts an article they may happen to see a scientific discovery or significant update on stem cells and click on the report. Not all older individuals have access to the internet (Eurobarometer, 2008) or have interest in learning how to navigate it. Daily or weekly use of the internet may influence a person's views on science and technology by frequent use. The generation most associated with frequent use of the internet is the younger generation.

Krones et al (2006) ascertained opinions of ESC research of ethicists, physicians, scientists, and couples undergoing IVF therapy in Germany. The study was conducted at the University of Marburg, University of Giessen, Heidelberg, Berlin and Leipzig as part of the German Human Genome Project and evaluation of social attitudes toward *reprogenetics*. Pediatricians, human geneticists and obstetricians considered production of ESC from human surplus embryos as morally acceptable. The majority of IVF couples, obstetricians, and human geneticists were in favor of techniques like blastocyst culture which is thought to improve implantation rates; ethicists were against it. Half of couples were willing to donate embryos for research but less willing to donate embryos to other couples. One third of couples would donate embryos for research in exchange for free fertility services. Couples aged 38 years and older were less willing to donate embryos for research indicating older age individuals tend to be more apprehensive in embryo research than younger age persons. Interestingly, strength of religious beliefs had a significant effect on donating eggs or embryos to other couples but not on donating embryos for research. It was important to most couples that their child be genetically related to them. This study is different from Krone's as it uses logistic regression and not a survey format and analyzes national determinants of fifty countries including Germany.

In this study five age groups are studied: 0-14, 15-24, 25-54, 55-64, and 65 and older. My hypothesis is that the younger age ranges will favor permissive policies on ESC research compared to the elderly age group. The time period is 2011-2012.



*Hypothesis 3. Younger people are more likely to favor permissive policies on ESC policy and research while older people are more likely to favor non-permissive ESC policies and research.*

## **Funding**

A detailed discussion of funding opportunities for ESC research was discussed in Chapter II. Adequate funding is essential for both basic and applied research in all areas of science. The public and private agencies will be tabulated that specifically awarded grants to scientists performing ESC research using human embryos or cells derived from human embryos. Public funding is allocated via legislative appropriations bounded by strict procedures of applying for funds and carrying out research. Private funding tends to be less restrictive but not as financially rewarding compared to public agencies. It is commonplace for a scientist to list both public and private funding agencies in their published paper. There are notable differences between smaller and larger countries, and between developed and underdeveloped countries when it comes to scientific research. If a smaller country that is devoid of a biotechnology presence and private funding wishes to pursue a path of scientific productivity in ESC research then the government could allocate public funding to support that path. On the other hand, as was the case in the US during the George W. Bush administration, if a country has a strong biotechnology base yet restricted public funds then it is likely the private sector will step up and offer funding for research if the research is supported by citizens.

Charles Lindblom lamented in *Politics and Markets* (1977) that “not all interest and participants in incrementalist politics were equal; that some had considerably more power than others. Businesses and large corporations exercise a powerful influence over the policy making process” (Lindblom, 1977). Large corporations, which may be biotech firms providing funds to scientists, could sway politicians, city council members, and members of parliament with the help of other factions toward permissive policies regarding stem cells. A country with a robust biotechnology presence may be successful in moving the pendulum toward prolific research activity in the presence of fierce opposition. The US is the best example. By virtue of its federalist system, states like California were able to utilize all viable resources to pass a law in which the people of California and the US could benefit from. The **FUNDING** variable is the ratio of **PUBLIC** grants to **PRIVATE** grants. The time period for these variables is 2000 to 2012.

*Hypothesis 4. Countries with predominantly private funding are more likely to have a non-permissive ESC policy and research; while countries with predominantly public funding are more likely to have a permissive ESC policy and research.*

### **Type and Size of Government**

Just over half of the countries analyzed in this study have a one chamber or unicameral legislative system. While most political scientists would agree the two chamber or bicameral

system is more representative of democracy, others prefer a unicameral government for its simplicity and lack of brinksmanship. One of the great proponents of unicameralism was Jeremy Bentham. Bentham was a British philosopher and honorary citizen of France. His views on unicameralism are likely the result of the time period in which he lived, the 18<sup>th</sup> century. Bentham thought the aim of the “greatest happiness for the greatest number” (Rockow 1928, 579) was achieved via universal suffrage. There was no justification for a second chamber and such a body would represent special interests leading to mischievous activities. He had little regard for tradition and believed England’s decision to use two chambers was more due to social stratification than social welfare. Moreover, those countries with a monarch or aristocracy might utilize the second chamber for special favors. Further, Bentham believed a second chamber would align the aristocracy with the monarch leaving the citizens misrepresented. In the realm of passing laws, having two chambers required double the amount of effort. In the unicameral system, rule of the majority is secured immediately according to Bentham (Rockow, 1928).

In contrast, British historian Viscount Bryce who was regarded as the father of constitutional science, supported bicameralism because it was the best check on the power of the popular assembly; the second chamber can criticize, amend, and/or reject bills passed by the first chamber (Ali, 1995). A bicameral system provides greater representation of the masses so that bills passed or rejected, or amended hopefully reflect more completely the will of the people.

Another advantage of the bicameral system is the opportunity for innovative ideas by policy entrepreneurs. Consider a House of Representatives in country A and a House of

Representatives and Senate in country *B*. In the former the one chamber system is engaged in debate and committees regarding a bill that has been introduced in parliament. In the latter while representatives of one chamber are working on activities before voting, the senate may be writing and working on other bills resulting in greater legislative activity by the end of the legislative session. (Rogers, 2003). Rogers belief has validity in that the more people or lawmakers the greater the opportunity for ideas to surface on any particular issue. This point is ever more cogent when the people that make up the chamber have diverse cultural and educational backgrounds injecting an element of expertise concerning a selection of bills.

Today second chambers are in the minority. There are approximately 112 countries with a unicameral government. Throughout history, there have been countries that have never had a second chamber and countries that have transitioned from a bicameral to a unicameral system. Denmark falls into the second category. Just before German occupation, in 1939, a vote was put to the people on reform of their bicameral system. One chamber would be elected directly by the people and the second chamber would be elected from parliament members and national party lists. The reform bill did not pass. After World War II, in 1953, the Danish people voted for a unicameral system with safeguards in place, including the institution of an ombudsman. The function of the ombudsman was to protect individuals against injustice from administrative executives in an appellate capacity. New Zealand and Iceland also switched from a bicameral to a unicameral system in 1950 and 1991, respectively (Jackson, 1991). Because a bicameral system is more representative of the democratic process and more actors to participate in debate and committees [with possible brinksmanship] it is thought this system would be associated with

non-permissive policies on ESC research. In contrast, countries with a unicameral system would favor a permissive policy on ESC research due to, at least in most countries, fewer legislators participating in passing laws and fewer debates. The size of government is also analyzed in the number of members of parliament. A larger government may invoke more partisanship in general session and in committees compared to smaller governments (Francis, 1982). With increased size there is the potential for more diverse perspectives on issues and political rancor. The **GOVT** variable is a binary variable with codes of 0 for bicameral or 1 for unicameral. The **MP** variable represents the total number of members in parliament in each country. The time period for this variable is 2011 to 2013.

*Hypothesis 5. Countries with a bicameral system are more likely to have a non-permissive policy on ESC policy; while countries with a unicameral system are more likely to have a permissive policy.*

*Hypothesis 6. The greater number of legislators in parliament the more likely a country will favor a non-permissive policy*

## Chapter IV Methodology, Data Analysis, and Findings

The research statistic employed in this study is binary logistic regression with country serving as the unit of analysis. Binary logistic regression was chosen because it can predict an outcome using a dichotomous dependent variable from a set of predictor variables that may be dichotomous, categorical, or continuous. In this study, we are trying to determine if predictor variables religion, literacy, age, type and size of government, or funding affects the dependent variable ESC policy. The countries chosen for this study are Albania, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Costa Rica, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Lebanon, Malta, Mexico, Morocco, The Netherlands, Norway, New Zealand, Peru, Poland, Portugal, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Trinidad and Tobago, Tunisia, UK, US, Uruguay, and Vietnam. The countries were chosen with the following criteria: 1) countries with a law or bill that could be categorized as permissive or non-permissive on ESC research policy, and 2) representative number of countries with a unicameral or bicameral legislature.

### *Methodology*

The statistic chosen for this study is binary logistic regression because the dependent variable is dichotomous taking on only two possible outcomes "0" or "1" (0 = non-permissive policy or 1 = permissive policy). Logistic regression is used in statistics to ascertain the explanatory power of an independent variable on a dependent variable. Studies using regression

must consist of at least one dependent variable and one independent variable. The dependent variable can be viewed as the outcome or effect and the independent variable as the predictor variable selected to explain the outcome. Binary logistic regression is employed when the dependent variable is dichotomous or nominal having only two possible outcomes and the researcher wishes to examine the association of that dependent variable with one or more predictor variables. The independent variables may be categorical or continuous (scale) (Campbell, 2008).

Binary logistic regression can be applied in a variety of different settings. These may include medical studies where a researcher simply defines the dependent variable as a disease or condition being present or absent (Frank et al, 2004; Blaser MJ et al, 1995), and using independent variables to predict the disease. In political science and international studies binary logistic regression is used to try and explain a particular policy, voting behavior of politicians, or investigate what factors influence a country's decision to go to war (King & Zeng, 2001). In all of these cases the dependent variable is dichotomous where a value of "0" or "1" is assigned to the outcome variable.

Using binary logistic regression the probability ( $p$ ) of "1" or "0" is determined, i.e. the  $p$  is the event associated with one group (1 or 0) over another where "1" represents a permissive policy and "0" a non-permissive policy. The ultimate goal of binary logistic regression is to determine the probability of a case belonging to the "1" category of the dependent variable given a set of independent variables. The assumptions of this model include: 1) logistic regression does

not assume a linear relationship between the dependent variable and the independent variables, 2) the dependent variable must be dichotomous, 3) the independent variables can be categorical or continuous, 4) the independent variables do not have to be linearly related or normally distributed, and 4) a case can only be in one group, “1” or “0”. Probability ( $p$ ) is calculated as follows:

$$p = \frac{\exp^{(a+b_1x_1+b_2x_2+b_3x_3\dots)}}{1+\exp^{(a+b_1x_1+b_2x_2+b_3x_3\dots)}}$$

where,  $p$  = probability that a case is in a particular category,  $\exp = 2.71828182845904$ ,  $a$  = constant of the equation, and  $b$  = coefficient of the IV or the slope. The expression  $\exp$  stands for exponent and can be defined as the power to which a given number is to be raised. The constant represents the log-odds of dependent variable = 1 vs dependent variable = 0 when the independent variables values are zero. The slope can be interpreted as the rate of change in the log odds as  $X$  changes.

Because the outcome variable can only have two possible values, “0” or “1”, it is impossible to graph a straight line as is typically done in linear regression. The solution is to transform data into predicted probabilities which yields an *s*-shaped curve allowing the researcher to deduce if increasing values of  $X$  are associated with a  $Y$  value of “1”. Using the log transformation of  $p$  values the logit ( $p$ ) can be calculated using the following formula:

$$\text{Logit}(p) = \log[p/(1-p)] = \ln[p/(1-p)]$$



The  $\text{logit}(p)$  is the log (to base  $e$ ) of the odds ratio (OR) or likelihood ratio that the dependent variable is equal to 1. Where  $p$  can only equal “0” or “1”, determination of the  $\text{logit}(p)$  creates a range of values from negative infinity to positive infinity making it possible to not only graph data but to visualize increasing or decreasing strength of the predictor variables. The logistic equation can be expressed as:

$$\text{Logit } [p(x)] = \log [p(x)/1-p(x)] = a + b_1x_1 + b_2x_2 + b_3x_3 \dots$$

The logits (log odds) are the  $b$  coefficients (slope values) of the regression equation. The slope can be interpreted as a change in the average value of  $Y$  from one unit of change in  $X$ . The odds value can range from 0 to infinity and indicates how much more likely an observation is a member of the “0” or “1” group. For a dichotomous variable the odds of membership of the target group are equal to the  $p$  of membership in target group divided by  $p$  of membership in the other group. An odds ratio (OR) can also be calculated which estimates the change in the odds of membership in the target group for a one unit increase in the predictor variable. An OR of 1 indicates the same probability of the event occurring between two situations. For example, consider a study where the researcher is investigating whether students that graduate from a private college have a better chance of being accepted to medical school than students from public colleges. The dependent variable is coded as “0” for not being accepted to medical school or “1” for acceptance into medical school. The predictor variable is coded as “0” for public

college or “1” for private college. An OR of 1 would indicate the probability of being accepted to medical school is the same for both private and public college graduates. An OR >1 indicates the probability of event occurring increases with a one unit increase in the independent variable; an OR <1 represents the probability of event occurring decreases with a one unit increase in the independent variable.

Using the reference of Burns and Burns (2008) each predictor variable will be analyzed against 50 cases. The Wald statistic is used to test the significance of coefficients in the model calculated as the square of the coefficient divided by SE. Inherent in this formula is a low SE with a high Wald statistic. The Wald statistic is named after Abraham Wald, a statistician from Transylvania (Harrell, 2001). Collinearity may be defined as two or more predictor variables which are highly correlated, such as political party and ideology. Collinearity of predictor variables will be assessed using the tolerance and variance inflation factor (VIF) parameters in SPSS using thresholds of <0.2 and >5, respectively. An  $R^2$  will also be determined giving an indication to the strength of the model regarding variance of data.

Logistic regression requires a larger sample size than with linear regression or a comparison of means analysis. The statistical analysis will be performed using SPSS (IBM SPSS Statistics v 21.0, IBM Corp. Amronk, NY). The parameters derived are OR, *p* value (set at .05), beta weight, Wald Statistic, and standard error (SE). The dependent variable is ESC research policy. The country is coded “0” having a non-permissive policy on ESC research or “1” for having a permissive policy. The decision to assign a “1” or “0” to each of the countries studied

was derived from the laws on ESC research representative of the study period of 2012. A non-permissive policy was defined as not allowing ESC research or only allowing importation of ESC lines created from surplus embryos. A permissive policy was defined as allowing ESC research in the country of origin either using therapeutic cloning and/or surplus embryos.

The independent variables are religiosity, literacy rate, type of government, size of parliament, funding, and age. The religiosity [**REL**] variable represents the percentage of Catholics in each country. Data was accessed from the CIA World Facts Book (CIA, 2013-14) latest figures. The Literacy Rate [**LIT**] variable is expressed as a percentage of the population that can read and write with understanding. Data was accessed from the CIA World Facts Book and the World Bank database. All countries studied use an age range of 15 years and over. The variable that represents whether a country has a unicameral or bicameral government will be denoted as **GOVT**. Data was accessed from the each country's legislative website and coded as "0" for bicameral or "1" for unicameral. The **MP** variable denotes the size of parliament of each country studied. Data was accessed from each country's government website. The time period for **GOVT** and **MP** is 2011 to 2013 as national election time tables vary from country to country. The **AGE** variable represents five age ranges (0-14), (15-24), (25-54), (55-64), and 65 and older. Data for these ranges was accessed from the CIA World Facts Book and coded as "1" for 0-14, "2" for 15-24, "3" for 25-54, "4" for 55-64, and "5" for 65 and older. The largest percentage group was used as the data point for the respective country. The variable **FUNDING** represents the ratio of public to private research grants. Data was compiled using the PubMed (NIH, Bethesda MD) website. The time frame examined was 2000 to 2012. The rationale for a broad

study period is to maximize the chance of a country utilizing public or private funds for ESC research. Utilizing the advanced search option on PubMed the search term “human embryonic stem cells” AND “country” AND “year” was entered. The output generated was analyzed for research that used human embryos or human ESCs in the time frame specified. The *Acknowledgements* section of the paper was examined for funding agencies if the paper satisfied the criteria of utilizing human embryos or ESCs. The funding source(s) was documented in a hardbound notebook and categorized as public or private by entering the name of the agency on the internet (Google) and analyzing the agency’s portfolio. This process was followed for all fifty countries. If the research article was not accessible on PubMed, databases from the Auburn University library were used. If the article could not be accessed using these two sources, an interlibrary loan form was completed on the Auburn University website (ILIAD) with subsequent electronic delivery of the article within two to three days to an email account.

Variables were first defined in SPSS so that data could be entered. The first variable entered was **COUNTRY**. The dependent variable and independent variables were defined in SPSS as described above. For the analysis, binary logistic regression was selected and the **POLICY** variable was entered as the dependent variable. The independent variables were entered as single entities in the covariate block. A p value of 0.05 was selected.

A major change occurred with the **AGE** variable when performing the analysis. Since the dominant age in all countries was in the 25-54 range, no association could be made by SPSS between permissive or non-permissive policies. The analysis was instead run using three age

groups representative of youth (0-14) and (15-24), and elderly populations (65 and over). Every statistical test has limitations and with logistic regression there must be ample variability with the independent variable to establish a relationship with the dependent variable. Nonetheless, the two most polarizing groups (youth and elderly) regarding ESC research were analyzed successfully using “1” for 0-14, “2” for 15-24, and “3” for 65 and over.

Upon performing the binary logistic regression analysis significance was found with the **REL** and **FUNDING** variables (Table 1). **REL** had a p value of .015, a coefficient of -.053, a Wald statistic of 5.9, and an OR of .948. This can be interpreted as the odds of a country having a permissive law are decreased by a factor of .958 with a one unit increase in the percentage of Catholics. The negative coefficient indicates an inverse relationship; that is, increases in Catholics associated with non-permissive policies. **FUNDING** had a p value of .017, a coefficient of 0.913, a Wald statistic of 5.7, and an OR of 2.5. This can be interpreted as the odds of a country having a permissive law is increased by a factor of 2.5 with a one unit increase in the ratio of public grants to private grants. In contrast to the REL variable, the FUNDING variable had a positive beta coefficient reflecting a direct relationship, as opposed to an inverse relationship. Public funding and not private funding had a significant effect on the outcome variable because the majority of the data points reflected a ratio of >1 (public grants to private grants). The Wald statistic was increased for both of these variables. A large Wald statistic is generally associated with significant p values (Warder et al, 2002), as was the case in this study.

The R<sup>2</sup> statistic reveals that the model explains 70 percent of the variance of the response variable around its mean. In general, the higher the R<sup>2</sup> the better the model fits the data. Study data is depicted in Table 2 in the appendix. Utilizing the Tolerance and VIF parameter, none of the predictor variables demonstrated collinearity. Collinearity statistics can be found in the appendix (Table 3).

**Table 1. Binary Logistic Regression Analysis**

| Variable | B      | SE    | Wald  | Sig          | Exp(B) |
|----------|--------|-------|-------|--------------|--------|
| REL      | -.053  | .022  | 5.899 | <b>.015*</b> | .948   |
| MP       | .001   | .002  | .363  | .547         | 1.001  |
| GOVT     | -.863  | 1.212 | .508  | .476         | .422   |
| AGE(1)   | -1.368 | 1.097 | 1.555 | .212         | .255   |
| AGE(2)   | 1.883  | 1.747 | 1.161 | .281         | 6.573  |
| FUNDING  | .913   | .382  | 5.723 | <b>.017*</b> | 2.492  |
| LITERACY | .053   | .079  | .449  | .503         | 1.054  |
| CONSTANT | -3.842 | 7.795 | .243  | .622         | .021   |

R<sup>2</sup> = 0.7, Exp(B) = odds ratio, \*p<.05

This chapter discussed the methodology, analysis, and findings. There was an inverse relationship found with the predictor variable religiosity and a direct relationship found with public funding; both of these variables were significant. There was no relationship found with type of government, size of government, private funding, literacy rate, or age. The binary logistic regression model corroborated the hypotheses regarding religiosity and public funding; it did not,

however, corroborate the hypotheses concerning literacy, type of government, size of government, private funding, or age. The next chapter will discuss these findings in the context of other published work.

## Chapter V Discussion and Limitations of Study

This study analyzed six national determinants in an effort to ascertain their relationship to ESC policy in fifty countries. Of the six variables selected, only religiosity and public funding were shown to have an effect. The results depicted in Table 1 indicated that high percentages of Catholics had an inverse relationship where public funding had a direct relationship on permissive ESC laws. The countries were selected based on having a law in place and being categorized as either unicameral or bicameral. The results of this study demonstrated that neither unicameralism nor bicameralism had an effect on ESC policy. Moreover, the size of government, i.e. number of legislators, also had no effect measured by the total number of seats in the legislature. This places an emphasis on cultural factors over structural factors in the realm of comparative policy theory. There are no similar studies published that have used type of government as a covariable in binary logistic regression in the analysis of stem cell policy. There were twenty-six countries with a unicameral legislature and twenty-four countries with a bicameral legislature. Fourteen unicameral and fourteen bicameral countries had permissive policies on ESC research. Type of government did not have an effect ESC policy as was hypothesized, suggesting that other factors may play a role in the legislative process.

The number of committees, size of committees, whether the public is permitted to present oral evidence for a bill, length of session, number of bills introduced, and size of the upper chamber compared to the lower chamber are exigencies that may affect passage of bills. If parliamentary sessions are open to the public, then opinions of citizens regarding ESC research



may have an impact on the parliamentarians by presenting a point of view or information not yet heard. The size of committees may also affect a bill becoming law. Larger committees may be associated with more partisanship than smaller committees and may open the door for external costs such as repercussions for decisions made that were not unanimous. According to Francis (1982) these repercussions may be in the form retaliation on other bills, verbal harassment and delay, or legal challenges in the courts. Moreover, the time and energy expended on bargaining with other committee members to procure majority support is also increased in large committees, these decision costs as described by Francis infer a linear relationship to committee size.

Whether the parliament has a single party, coalition minority, or majority can affect speed of passage of bills. In Denmark, for example, there is a long history of coalition governments and politicians are sensitized to the process of brokering deals on policy. In contrast, when New Zealand operated within the coalition of National/New Zealand First government the platforms were aligned and resembled a single party majority (UCL, 1998). Most of the countries studied had multiple party systems injecting many platforms into the equation on whether a party supports or opposes ESC research. These factors all may have played a role in a legislature passing [or not passing] a law on ESC research.

Crain (1979) posits that when bicameral legislative bodies have near equal proportions in the both chambers there is more legislative output. Legislators undergo the same process of legislative proposals but may differ in the number of committees [and subcommittees] and size

of committees. However, even given differences in the size of the chambers this differential can be offset by the degree of specialization in each chamber.

Crain also suggests legislative output can also be affected by length of legislative sessions and how committee members are appointed. These will vary from country to country. He suggests that a shorter session may yield more legislative output compared to longer sessions. In a long session legislators may make arrangements for outside interests or even outside work. In a shorter session, they may be more focused knowing their time is limited for completing the work at hand.

This was the first study analyzing type and size of government in relation to ESC research policy and selecting countries based upon that premise. More research is needed in this area given the proportion of unicameral and bicameral states and plethora of laws that exist. For ESC research policy, a relationship was not evident, but the model may be affected by confounding, suppressor, or interactive covariates such as length of legislative session, size of upper and lower chamber, existence of coalition governments, or number of bills introduced.

Literacy was not a significant variable in this study. As in type of government no studies have analyzed literacy in relation to ESC research policy. The reason for lack of effect is most likely literacy rates were close in value as to whether the country had a permissive law or non-permissive law. The only outliers were Morocco and Tunisia with average rates in the high 60s

and 70s, respectively. Lack of variation in the literacy rate likely influenced the finding of no effect on the dependent variable. This pattern is not likely to change in the near future. A more robust parameter would be the scientific literacy rate (SLR). The SLR has been measured by posing questions to a sample of the population regarding the scientific process and concepts in earth, physical, and life sciences, and calculating the percent of questions answered correctly by participants (Miller, 2006). This has been carried out by OECD PISA (Program for International Student Assessment), PEW Research Center (Monmaney, 2013), Jon Miller (1983, 2006), and also by the EU (Eurobarometer, 2005). Miller (2006) has framed his studies toward civic scientific literacy defined as the level of understanding necessary to follow and comprehend public policy issues involving science and technology. He contends that for society to flourish voters must possess a general understanding of issues they are being asked to vote on. Public policy in the 21st century has included issues on fracking, genetically modified foods, ESCs and health related issues.

Scientific issues will continue to fill the dockets in legislative sessions necessitating a well-informed public. Certainly, the SLR should be investigated in future studies as such a measurement would provide insight to the researcher on the public's ability to understand scientific policies. Government officials should find the resources to measure scientific literacy in select age groups so that citizens may be better equipped to vote and express educated opinions on science policy.

Age was also not a significant variable in this study. Unlike the literacy rate, there was variability in the youth and elderly percentages across fifty countries. However, no effect could be established in youth being more in favor of permissive policies, as hypothesized. Studies have been done to ascertain which age groups support ESC research and many have indicated that the youth would be more in favor in ESC research compared to the elderly. However, many of those studies involved focus groups and smaller numbers of respondents (Eurobarometer, 2005, 2008; Solo and Pressberg, 2007). This study employed three age groups, 0-14, 15-24, and 65 and older. The first two can be described as youth and third as elderly. The study design originally included all age groups, however given that adult ranges, 25-54 and 55-64, predominated in all countries studied the logistic regression analysis could not find a solution. Thus, the adult ranges were deleted from the study design. There were actually more countries coded as elderly with permissive policies than coded as youth when utilizing the three age groups (see Table 2). This was an interesting finding.

Because the adult age groups are likely to dominate the other age groups in nearly all countries across the globe qualitative studies, i.e. focus groups may be the preferred method for ascertaining a relationship between age and ESC policy. If you have twenty-five people characterized as youth, twenty-five characterized as adult, and twenty-five characterized as elderly in each country being studied appropriate questions posed will provide information into which group(s) favors or opposes ESC research. Nonetheless, this study examined youth and elderly age ranges and found no relationship on favoring permissive or non-permissive policies.

Religiosity was a significant variable. As described in Chapter III, Fink (2008) also found a relationship using ordinary least squares regression between Catholicism and a restrictive policy index. In his study, the dependent variable represented an index of policy strictness based on which countries prohibited the following: therapeutic research, therapeutic sex selection, germline therapy, non-therapeutic research, embryo production for research purposes, ESC research, reproductive cloning, and therapeutic cloning. Germany, for example, had an index of 8 while the UK had an index of 2.5. For the Catholicism variable, he used the percentages of Catholics in each country. Fink claims that it is not Catholicism, per se, that affects policy but the degree of individual religiosity that is more pervasive. I agree with Fink that people who habitually pray the rosary, attend church, and practice other religious acts are more likely to follow the Catholic doctrine and oppose ESC research. Percentages of Catholics in a particular country provides no information on the degree of individual religiosity; this information can be obtained through the use of surveys and interviews.

The present study did not control for other factors related to a citizens religious practices, i.e. how often a person goes to church, prays the rosary, or receives communion; the variable simply listed the percentages of Catholics in each country, as Fink did. In explaining the **REL** variable results, the countries in this study can be divided up into four groups: 1) predominantly Catholic countries who have a permissive policy of ESC research, 2) predominantly Catholic countries that have a non-permissive policy, 3) non-Catholic countries that have a permissive policy, and 4) non-Catholic countries that have a non-permissive policy. Group 1 includes Belgium, Brazil, France, Mexico, Canada, and Spain. Group 2 includes Austria, Chile, Costa

Rica, Germany, Ireland, Italy, Lithuania, Malta, Peru, Poland, Portugal, Slovakia, Slovenia, and Uruguay. Group 3 includes Australia, Bulgaria, China, Czech Republic, Denmark, Estonia, Finland, Greece, Hong Kong, Hungary, Israel, Japan, The Netherlands, Norway, New Zealand, Singapore, South Africa, South Korea, Sweden, Switzerland, UK, and USA. Group 4 includes Albania, Iceland, Latvia, Lebanon, Morocco, Trinidad and Tobago, Tunisia, and Vietnam.

The factor common to countries in Group 1 is decreasing numbers of churchgoing Catholics or people who no longer characterize themselves as Catholics which may have contributed to permissive policies on ESC research. In Belgium, churchgoing among Catholics has decreased from 42.9 percent in 1967 to only 7 percent in 2006 (Cendrowicz, 2010). A large part of this decline is likely due to the rampant sexual abuse cases by Catholic clergy and the church turning a blind eye to the euthanasia law which is devoid of any age restrictions (McDonald-Gibson, 2014). A child of any age can be given a lethal injection if “deemed to be suffering beyond any medical help, terminally ill, or close to death” (McDonald-Gibson, 2014, 1) In addition, the loss in revenue from poorly attended mass and expenses from lawsuits has resulted in closed seminaries and nunneries (Anonimo, 2013). In Brazil, the Catholic population fell from 74 percent to 65 percent from 2000 to 2010, while the numbers of Protestants and agnostics has risen. This shift has largely been generational and geographical; the majority of Catholics are over 70 years of age living in rural areas, while the younger generation primarily make up the Protestant denomination inhabiting urban areas (Pew, 2013).

In France, 35 percent of the population and 63 percent of youth have indicated they belong to no religion. Only one in twenty Catholics attend mass which may have contributed to declines in other church services such as baptisms and marriages. The aging Priest population has necessitated clergy from other countries coming to France to hold mass, many of which are African, creating a language and cultural barrier to parishioners. (Ghosh, 2013). Mexicans are also leaving the Catholic Church in roves; four million left the church between 2000 and 2010 (Marin, 2011). It has been reported that only 15 percent of Spanish Catholics attend mass on a weekly basis and more than 60 percent rarely step inside a church; moreover, seminaries, monasteries, and nunneries are half-empty and in some cases closed (Tremlett, 2011).

The interesting observation regarding Group 2 countries is admixed among staunchly Catholic states like Poland, Italy, and Ireland is Germany whose law on ESC research allows importation of ESCs. Germany's situation is much more complicated because of their tumultuous history with Nazi eugenics and the breach of ethics by Nazi physicians during WWII. That being said it is ironic that Germany is placed alongside Poland and Austria where many of the experiments took place during that time period. The legislators in Germany have tried to balance their scientific genius and culture with their Nazi legacy by allowing scientists to practice and advance the field of ESC research using ESCs from other countries. It is unknown at this time whether Germany will liberalize their stem cell law in the future or retain the status quo; what is clear is even with a somewhat restricted law German scientists are active participants in ESC research via importation.

Group 3 is comprised of countries which are not predominantly Catholic; most are Protestant, Buddhist, Hindu, Muslim, or Jewish. It is expected these countries would have permissive policies on ESC research given the liberal view held by these denominations and the fact that the majority of these countries are active in scientific research. The Jewish faith is especially permissive of ESC research as discussed in Chapter II. Israel is the only country that has not placed a permanent ban on reproductive cloning.

The last group comprises non-Catholic countries with non-permissive policies on ESC research. A common element in this group of countries is lack of a scientific culture. None of these countries have the research infrastructure, that is biotechnology sectors and research institutes, that might promote scientific research including research involving ESCs. Thus, the non-permissive policy is likely not related to a religious denomination but rather to economic climate where scientific research is not a priority.

Evans and Hudson (2007) conducted over four thousand interviews in the US examining religious denomination and support or opposition to reproductive technologies. These technologies included pre-genetic testing, PGD, and human genetic engineering. Americans who identified themselves as Traditional Catholics, Evangelicals, and Fundamentalists were most opposed to reproductive technologies compared to liberal Protestants or liberal Catholics. This study used logistic regression where reproductive technologies constituted the dependent variable and religious demographics constituted the independent variable. The authors concluded that persons in the former group may believe that such technologies equate to playing



God and universal adoption of such technologies will lead to inequality. All technologies involve experimentation on human embryos and that in itself would breach the threshold of bioethics for most traditional Catholics. The inequality assertion offers another viable caveat that church members may support and rally behind. Some people may not be able to afford the technology or only certain patients may match the criteria for the technology. Equality is a common theme in most constitutions and violations thereof are not permitted.

Green (2008) posits the rally cry against research on embryos for Catholic leaders began after the *Roe v Wade* decision. This in part was due to a decreasing influx of Catholic immigrants in various countries and the need to stay relevant [and dominant] on national moral issues. If the Vatican and other Catholic leaders neglected to strategically voice positions of the church their base might continue to decrease or stagnate and become ambivalent on science-related moral issues. Green raises another interesting point. Why didn't the Catholic Church support research that would decrease the rate of stillbirths, given their pro-life position. Such an act would have little effect on mobilizing Catholics via limited visibility compared to morally questionable rulings or experiments. *Roe v Wade* was the impetus for an ethical-religious platform that kept abortion policy on the political agenda and strengthened the base of traditional Catholics as well as Christian and right-wing political parties. When Dolly was born and James Thomsons' paper was published the Catholic base was again strengthened fortuitously by church leaders issuing vociferous statements against these experiments. The significance found in Fink's study and this study can be explained by the powerful influence church leaders have on their parishioners (which may include political leaders), the versatility and variety of media outlets, and the number

of practicing Catholics in each country. This ethical-religious platform will likely remain robust on a plethora of issues, including ESC research. It is interesting that events such as scientific discoveries may on the one hand drive policy, while at the same time strengthen the Catholic Church if the Church regards the area of scientific research as possibly immoral.

More and more polls are indicating that Catholics are permissive of ESC research and this number is rising as time passes (Pressberg and Solo, 2007; Gardner, 2010). A US poll indicated sixty-nine percent of Catholics supported ESC research compared to sixteen percent who did not (Gardner, 2010). However, this is one poll in one country and citizens in Poland and Italy would likely poll differently. Such numbers, however, start the conversation so that ideas can be put forth and studies can be conducted to measure and attempt to explain the differences among predominantly Catholic nations that have adopted a permissive policy on ESC research and those that have not. I think that support for ESC research will continue to evolve among Catholics as efficacy of stem cell research becomes evident at both the basic and translational research level.

The **FUNDING** variable was significant and exhibited a direct relationship using the ratio of public grants to private grants. Results are interpreted in the context of the beta coefficient, p value, and OR (Table 1). The odds of a country having a permissive law are increased by a factor of 2.5 with a one unit increase in the ratio of public grants to private grants. It can be surmised that since the majority of the data points were  $>1$  public grants were more associated with permissive ESC policies more than private grants as depicted in Table 2. Twenty

out of twenty-three countries that had a permissive ESC research policy and were awarded grants had a ratio  $>1$ . These were Australia, Belgium, Brazil, Canada, China, Czech Republic, Estonia, Finland, France, Hong Kong, Hungary, Japan, New Zealand, Norway, The Netherlands, Singapore, South Korea, Spain, UK, and US. The three countries that were permissive and had a ratio  $<1$  included Denmark, Israel, and Sweden. Private grants exceeded public grants in those countries (Table 4). The countries with non-permissive policies with a ratio  $>1$  included Germany and Italy. This finding injects an element of hypocrisy and a moral duplicity in those countries by funding research projects involving human embryos under the guise of a restrictive law. Germany allows researchers to use imported ESCs and Italy has no regulation on using imported ESCs. Germany and Italy are both complicit in allowing and funding ESC research either via legal mandate or loophole via importation; Germany and Italy are only against ESC research, it seems, when the ESCs are home grown. Those countries with non-permissive laws and no funding included Albania, Austria, Chile, Costa Rica, Slovakia, Slovenia, Trinidad and Tobago, Tunisia, Uruguay, and Vietnam. In these countries, funding was not available for a research activity forbidden by law.

Another comparison that can be drawn regarding the funding variable is predominantly Catholic countries that had more public grants than private grants. Belgium, Brazil, France, Italy, Germany, Canada, and Spain are predominantly Catholic with a public to private grant ratio of  $>1$  (Figure 1). This finding suggests that Catholic groups in these countries have not deterred funding by the state for research involving ESCs. In contrast, predominantly Catholic countries with no grants (public or private) include Austria, Chile, Costa Rica, Ireland, Lithuania, Malta,

Mexico, Peru, Poland, Portugal, Slovakia, and Slovenia. The reason for lack of either public or private grants may be due to lack of a biotechnology and research presence as well as religiosity. Finally, there were no predominantly Catholic countries with more private grants than public grants. Only Israel, Sweden, and Denmark had a public to private grant ratio of  $<1$  (Figure 2).

It was not feasible to access yearly or cumulative funding from the hundreds of organizations in fifty countries that support ESC research. Instead, a novel methodical approach was utilized using journal articles which document the funding organization for studies over twelve years (2000-2012). Using this approach there was no uncertainty what organization or agency funded the research and that the research did involve human ESCs as opposed to mouse ESCs or adult stem cells. From a policy standpoint, if permissive policy is associated with decreases in private funding can it be posited that public funding must be more fluent negating the need for private funding? Possibly, but more studies would need to be done demonstrating this inverse relationship in the realm of ESC research. What is clear from the raw data is that of the 28 countries coded as permissive all but 3 (Denmark, Israel, and Sweden) had more public grants than private grants (Table 4). In that view, over a time period of 12 years from 2000 to 2012 private funding did not exceed public funding in the majority of countries coded as permissive.

Funding of research experiments has occurred throughout history. Galileo received funding from mostly wealthy people, including the Pope. Darwin was funded by the British Government for his *HMS Beagle* voyage to South America and Oceania. Interestingly, Robert

Edwards and Patrick Stepcoe were turned down by the prestigious UK MRC for their work which eventually led to the first test tube baby and were instead funded by the Oldham Health Authority (UK) and various US philanthropists. Even James Thomson's work was conducted entirely using non-public funding injecting the premise that non-public funding can serve as a nexus of allowing somewhat controversial studies to come to fruition. While the literature lacks any similar studies ascertaining the effect of public and private funding on ESC research it is prudent to discuss elements of both.

Public funding is associated with more regulations and oversight than private funding and generally has a higher monetary value. Arrow (1962) discussed public funding of scientific research in the realm of traditional market failure. Knowledge that is produced from research is non-rival and non-excludable. That is, knowledge is freely available to all people and all firms if they are so inclined to access it. When government funds are increased for research the pool of economically useful information is expanded potentially facilitating a positive feedback cycle. Public funding generates basic research which may transition into product development benefiting society. Firms may not feel compelled to use their own funds for research if they know a particular area of science is already funded by the government.

Callon (1994), however, disagrees that scientific knowledge is a public good and that all people can access it. He insists the appropriate educational background is a pre-requisite for understanding the knowledge generated. Moreover, the bulk of new knowledge is nestled inside of scientific journals which are not freely accessible to the public. People need to have access to

a library or databases to view a particular article but even then not all libraries can accommodate all patrons. Unlike the public good of national defense that is available to all of society regardless if a citizen understands what a DMZ (demilitarized zone) is or a LAW (light antitank weapon) knowledge may need to be transitioned to a product or procedure to come into the sphere of a public good. This transition is influenced by private funding and companies.

Fry-Revere and Elgin (2008) contend that private funding is much more practical than public funding and pose the question whether the latter is justified in the realm of the taxpayer. Feasible therapies can take decades to clear the development stage. Clinical trials can take years with no guarantee of success. The promise of lower health care costs and healthy biotechnology economy rests with primarily basic research. Should public funding continue to be allocated when the incurable diseases identified to be studied are still incurable sixteen years after Thomson's discovery? Fry-Revere and Elgin contend there is little risk research will go unfunded when biotechnology companies, philanthropic organizations, and individuals have given billions for stem cell research. They posit that public monies is wrought with politics, and politics can lead to delays in research. This was the case in California after Proposition 71 was passed. Philanthropists donated in excess of \$250 million to universities in California to conduct stem cell research when distribution of funds was delayed due to lawsuits challenging the constitutionality of Proposition 71. One of the most prudent ways to ensure advancement of stem cell research is to grow the private sector and ensure that appropriate regulations are maintained. Fry-Revere and Eglin make a good argument that private funding is not stymied in the face of

political strife. As research progresses and published results decrease the gap between basic and applied research, it is unlikely private funding will dissipate.

The counter to Fry-Revere and Eglin's argument is the billions of dollars public funding has contributed to stem cell research all over the world. More funding, more resources, and more collaboration breeds more progress even when some public funding is delayed due to political strife. In scientific research, benefits are difficult to assess in the early stages. History has shown as in the case of vaccines and AIDS that public funding expended for research has benefited society; but the process of establishing a new standard of care for treatment of disease through research and clinical trials is long and offers no guarantee to tax payers. It is part of a country's dedication to science culture, expending funds for research to benefit the public who may be suffering from disease. Citizens can utilize the democratic process in supporting or opposing public funding for research.

Meyer-Krahmer and Schmoch (1998) postulate that public and private research systems complement each other, interlinked by common interests, institutional affiliations and personal connections (Meyer-Krahmer and Schmoch, 1998). Industry relies on publicly funded research for new ideas for marketable products. Imagine in the process of technological development if research studies were balls and placed into lottery machine for industry to draw from, the more balls added the more chances for product development. It can be surmised that publicly funded basic research stimulates R&D in industry propagating privately funded studies that are likely more focused based upon published studies (Klevorick et al, 1995).

## **Limitations of the Study**

The study limitations included the age variable and collection methods for research funding. Originally all age ranges representative of youth, adult, and the elderly were included in the data set. However, upon performing binary logistic regression it was evident that the coding of adults dominate the other age groups. With only one value for an independent variable, SPSS could not perform a binary logistic regression analysis because the independent variable has to associate with either a permissive policy or non-permissive policy; this is not possible with only one value for the predictor variable. As a result, only age ranges representative of the youth and elderly were examined. However, this is deemed acceptable when considering that it is these age groups which are the most polarizing on the issue of ESCs. It is unlikely the percentages of adults will decrease or fall below the other categories. Qualitative methods will need to be employed to ascertain differences among adults, youth, and elderly.

Another limitation involved the collection methods for funding, both public and private. If the author(s) did not include grant information in the published paper, where grants were awarded, the observed values may be less than the actual values. It is worth noting, however, that the data collected was in line with those countries one would expect to have few or no grants (Albania, Costa Rica) and those expected to have many grants (US, UK, China). Using the search term “human embryonic stem cells” and “country” in Pub Med output was generated that included review articles, mouse and other animal models, and policy articles. Only those articles that actually used human ESCs in the experiment were counted for the funding variable.



## Chapter VI Conclusion and Recommendations for Future Research

Many laws have been passed and amended since James Thomson's discovery in 1998 and the birth of the theory that human ESCs could be the solution to so many incurable diseases that afflict many. This study examined the laws and national determinants in fifty countries. There are multiple conclusions that can be drawn. First and foremost when all independent variables were regressed on the dependent variable only religiosity and public funding were significant at the .05 level. Second, type and size of government, literacy rate, private funding, and age had no effect on policy.

The fact that both religiosity and public funding were significant is highly reflective of the influence of culture in comparative policy theory. It is also worth noting that the finding that public funding was significant is new information in policy research. Religiosity will continue to be a factor on the issue of ESCs with Catholicism at the top of the list for most polarizing denomination. The discovery that adult stem cells can be manipulated to act as ESCs has not persuaded legislatures to repeal their permissive laws allowing research on surplus human embryos or therapeutic cloning. Pro-life groups, church leaders, and the Vatican will continue to voice their opposition regarding the moral imperatives associated with ESC research just as patient advocacy groups will continue to promote the great benefits of stem cells in saving lives. More discoveries will be made by scientists that may prompt a change in law regarding stem cells. Politicians will be asked to vote on behalf of their constituency in an ever challenging environment of party loyalty and impending future elections.

Religiosity was found to be significant utilizing percentages of Catholics in each country. While this finding added to the body of knowledge, especially regarding empirical studies, more work and data is needed to understand trends and future laws. Ideas for future research include a broadened examination of religiosity involving Catholicism, Protestants, Jews, Muslims, and Buddhists. This can be achieved perhaps by using a survey with questions designed to ascertain a citizens' religious practices across all denominations. Using a Likert scale, responses can be tabulated and statistically analyzed in the context of comparing frequency and diversity of religious practices to approval or disapproval of ESC research.

A second idea is to select countries that are consocial democracies, such as Belgium and The Netherlands, to ascertain if there is a difference in permissive policies in comparison to non-consocial democracies. A consocial democracy represents a political system based upon diversity in various groups (religious, ethnic, social) than on majority party rule. This diversity factor could have significant influence on ESC policy by providing a more proportional representation of all ethnic groups when voting on policy.

Public funding was significant in this study. This study provided a novel measurement for ascertaining the degree of public and private funding. Using the ratio of public to private grants a significant direct relationship was found with the former effecting permissive policies. As discussed in Chapter IV public funding exceeded private funding. For future studies it would be advantageous to track funding for human ESC research on an annual basis. This is not an easy task for either public or private entities. Many countries lack transparency in this arena. While

private foundations religiously publish annual reports for their stockholders, very few will delineate animal ESC research from human models or adult stem cells versus ESCs.

Nonetheless, this is data that is worth pursuing in future studies in correlating an actual monetary value to policy. It would likely involve a more detailed record of what type of studies were actually funded, i.e. those that actually used human ESCs as opposed to a collective category of all funding allocated to stem cell research irrespective of the source of stem cells.

It is also important to track changes in law over time. Many countries have moved from a non-permissive to a permissive law (i.e. France, Denmark, Norway, and Spain). Are more countries passing or making amendments toward more permissive laws or non-permissive laws and if there are trends in certain countries toward a specific geographical area, political system, or economic environment? Has there been an increase in the number of funding organizations or private ESC funding in the country? Also, a variable can be computed which figures in the proximity and number of research universities to biotech companies. As mentioned previously, even with adult stem cells capable of acting like ESCs (iPSCs), legislators are not repealing their permissive laws and research using ESCs will likely continue. Policy studies are needed to complement the democratic process in passing laws. The more information citizens have and understand, the better prepared they are to make decisions on an issue.

### **A Proposed Framework**

Many countries have implemented steps in educating the public and facilitating discussions on the issue of stem cell research. In building social capital, countries like Denmark

and Iceland are inviting communities to participate in public discussion on both the benefits and tribulations of stem cell research. The EU conducts public opinion polls on a regular basis. A three-tiered framework could easily be designed and implemented. Tier I would involve the high schools, Tier II the community, and Tier III the government (Figure 3). Embryonic stem cells are an appropriate topic for a high school biology course, STEM course, and also a civics course, the latter because it is a polarizing issue ideal for class debates, regional debates, and national debates at the high school level.

Young people can be given the opportunity to learn what stem cells are and what they can do but also be educated on the ethics associated with using them. Related high school clubs (i.e. debate club) can also be a venue for expressing opinions both for and against stem cells. The idea here is not to persuade or dissuade, but to educate and increase scientific literacy, and promote discussion so that the laws that are passed represent an informed public.

For Tier II, communities can hold gatherings on discussion of stem cells. Even in the digital age newspapers and flyers at the local grocery store and library still advertise when and where a particular group is meeting. Some of these groups may be for overcoming grief, alcoholism, or drug addiction. Support groups also include those people coping with medical issues, like breast cancer, Parkinson's disease, and Alzheimer's disease. Certainly, a discussion on a study that was done involving the latter and stem cells is possible if not probable and may be an eye opener for people who just had not the opportunity to be informed on the potential uses of stem cells. People from the community can also be asked to speak on the topic. Bioethicists,

high school biology teachers, clergy, and physicians can contribute their knowledge and lead discussions. These gatherings can take place in community centers, civic centers, libraries, schools, or someone's home.

For Tier III, at the government level, public opinion polls and scientific literacy tests can be conducted for age groups 15 and older to ascertain acceptance or opposition to stem cell research for both adult and ESCs. Once data is tabulated the politicians and policy analysts will have a better idea if the law(s) should be amended. This data can be presented in the legislative sessions as well as posted on government websites. These polls could be given every two years. This framework can be viewed as a continuous circle that starts with the youth and continues through adulthood. Needed changes to the law can be identified at the national level through public polling. This framework not only supports but in essence facilitates the democratic process through education and community involvement.

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Appendix

**Table 2. Study Data**

|           | <b>POLICY</b> | <b>FUNDING</b> | <b>AGE</b> | <b>REL (%)</b> | <b>MP</b> | <b>GOVT</b> | <b>LIT (%)</b> |
|-----------|---------------|----------------|------------|----------------|-----------|-------------|----------------|
| Albania   | 0             | 0              | 1          | 10.0           | 140       | 1           | 98.8           |
| Australia | 1             | 1.6            | 3          | 25.3           | 226       | 0           | 99.0           |
| Austria   | 0             | 0              | 3          | 73.6           | 245       | 0           | 98.0           |
| Belgium   | 1             | 5.3            | 3          | 75.0           | 221       | 0           | 99.0           |
| Brazil    | 1             | 2.0            | 1          | 64.6           | 594       | 0           | 90.4           |
| Bulgaria  | 1             | 0              | 3          | 1.0            | 240       | 1           | 98.4           |
| Canada    | 1             | 2.0            | 3          | 40.5           | 413       | 0           | 99.0           |
| Chile     | 0             | 0              | 1          | 66.7           | 158       | 0           | 98.6           |
| China     | 1             | 3.7            | 1          | 3.0            | 2987      | 1           | 95.1           |
| CostaRica | 0             | 0              | 1          | 76.3           | 57        | 1           | 96.3           |
| Czech R   | 1             | 36.0           | 3          | 10.4           | 281       | 0           | 99.0           |
| Denmark   | 1             | 0.6            | 3          | 1.0            | 175       | 1           | 99.0           |
| Estonia   | 1             | 1.5            | 3          | 2.0            | 101       | 1           | 99.8           |
| Finland   | 1             | 1.8            | 3          | 1.0            | 200       | 1           | 100            |
| France    | 1             | 4.9            | 3          | 88.0           | 925       | 0           | 99.0           |
| Germany   | 0             | 3.1            | 3          | 34.0           | 699       | 0           | 99.0           |

|             |   |      |   |      |     |   |      |
|-------------|---|------|---|------|-----|---|------|
| Greece      | 1 | 0    | 3 | 1.0  | 300 | 1 | 97.3 |
| HK          | 1 | 2.2  | 3 | 10.0 | 70  | 1 | 93.5 |
| Hungary     | 1 | 13.0 | 3 | 37.2 | 386 | 1 | 99   |
| Iceland     | 0 | 0    | 1 | 3.4  | 63  | 1 | 99   |
| Ireland     | 0 | 0    | 3 | 84.7 | 226 | 0 | 99   |
| Israel      | 1 | 0.7  | 2 | 2.0  | 120 | 1 | 97.1 |
| Italy       | 0 | 3.7  | 3 | 80.0 | 945 | 0 | 99   |
| Japan       | 1 | 4.0  | 3 | 2.0  | 722 | 0 | 99   |
| Latvia      | 0 | 0    | 3 | 1.0  | 100 | 1 | 99.8 |
| Lithuania   | 0 | 0    | 3 | 77.2 | 141 | 1 | 99.7 |
| Lebanon     | 0 | 0    | 1 | 6.0  | 128 | 1 | 89.6 |
| Malta       | 0 | 0    | 3 | 98.0 | 69  | 1 | 92.4 |
| Mexico      | 1 | 0    | 2 | 82.7 | 628 | 0 | 93.5 |
| Morocco     | 0 | 0    | 1 | 1.0  | 595 | 0 | 67.1 |
| Netherlands | 1 | 3.5  | 3 | 30.0 | 225 | 0 | 99   |
| Norway      | 1 | 3.0  | 3 | 1.8  | 169 | 1 | 100  |
| NZ          | 1 | 2.0  | 1 | 11.6 | 120 | 1 | 99   |
| Peru        | 0 | 0    | 1 | 81.3 | 130 | 1 | 89.6 |
| Poland      | 0 | 0    | 3 | 87.2 | 560 | 0 | 99.7 |
| Portugal    | 0 | 0    | 3 | 81.0 | 230 | 1 | 95.4 |



|             |   |      |   |      |      |   |      |
|-------------|---|------|---|------|------|---|------|
| Singapore   | 1 | 11.0 | 1 | 7.0  | 99   | 1 | 95.9 |
| Slovakia    | 0 | 0    | 3 | 53.0 | 150  | 1 | 99.6 |
| Slovenia    | 0 | 0    | 3 | 57.8 | 174  | 0 | 99.7 |
| S Africa    | 1 | 0    | 1 | 7.1  | 490  | 0 | 93   |
| S Korea     | 1 | 32.6 | 1 | 7.6  | 300  | 1 | 97.9 |
| Spain       | 1 | 5.0  | 3 | 94.0 | 614  | 0 | 97.7 |
| Sweden      | 1 | 0.8  | 3 | 8.0  | 349  | 1 | 99   |
| Switzerland | 1 | 0    | 3 | 38.2 | 246  | 0 | 99   |
| Trin/Tobago | 0 | 0    | 1 | 21.6 | 72   | 0 | 98.8 |
| Tunisia     | 0 | 0    | 1 | 1.0  | 217  | 1 | 79.1 |
| UK          | 1 | 1.1  | 3 | 32.0 | 1410 | 0 | 99   |
| US          | 1 | 1.1  | 3 | 23.9 | 535  | 0 | 99   |
| Uruguay     | 0 | 0    | 2 | 47.1 | 140  | 0 | 98.1 |
| Vietnam     | 0 | 0    | 1 | 6.7  | 500  | 1 | 93.4 |

**Table 3. Collinearity Statistics**

| <b>Variable</b> | <b>Tolerance</b> | <b>VIF</b> |
|-----------------|------------------|------------|
| MP              | .946             | 1.057      |
| GOVT            | .786             | 1.272      |
| LIT             | .740             | 1.351      |
| REL             | .797             | 1.254      |
| FUNDING         | .944             | 1.059      |
| AGE             | .713             | 1.403      |

**Table 4. Public and Private Funding Data**

| <b>Country</b> | <b>Public Grants</b> | <b>Private Grants</b> |
|----------------|----------------------|-----------------------|
| Albania        | 0                    | 0                     |
| Australia      | 72                   | 46                    |
| Austria        | 0                    | 0                     |
| Belgium        | 42                   | 8                     |
| Brazil         | 2                    | 0                     |
| Bulgaria       | 0                    | 0                     |
| Canada         | 89                   | 45                    |
| Chile          | 0                    | 0                     |
| China          | 225                  | 61                    |
| Costa Rica     | 0                    | 0                     |
| Czech Republic | 36                   | 0                     |
| Denmark        | 13                   | 20                    |
| Estonia        | 3                    | 2                     |
| Finland        | 39                   | 22                    |
| France         | 69                   | 14                    |
| Germany        | 50                   | 16                    |
| Greece         | 0                    | 0                     |
| Hong Kong      | 9                    | 4                     |
| Hungary        | 13                   | 1                     |
| Iceland        | 0                    | 0                     |
| Ireland        | 0                    | 0                     |
| Israel         | 84                   | 115                   |
| Italy          | 11                   | 3                     |
| Japan          | 97                   | 24                    |
| Latvia         | 0                    | 0                     |
| Lithuania      | 0                    | 0                     |
| Lebanon        | 0                    | 0                     |
| Malta          | 0                    | 0                     |
| Mexico         | 0                    | 0                     |
| Morocco        | 0                    | 0                     |
| Netherlands    | 39                   | 11                    |
| Norway         | 3                    | 0                     |
| New Zealand    | 2                    | 1                     |
| Peru           | 0                    | 0                     |
| Poland         | 0                    | 0                     |
| Portugal       | 0                    | 0                     |
| Singapore      | 66                   | 6                     |

|                 |     |     |
|-----------------|-----|-----|
| Slovakia        | 0   | 0   |
| Slovenia        | 0   | 0   |
| South Africa    | 0   | 0   |
| South Korea     | 163 | 5   |
| Spain           | 101 | 20  |
| Sweden          | 123 | 147 |
| Switzerland     | 0   | 0   |
| Trinidad/Tobago | 0   | 0   |
| Tunisia         | 0   | 0   |
| Vietnam         | 0   | 0   |
| UK              | 115 | 103 |
| US              | 822 | 729 |
| Uruguay         | 0   | 0   |

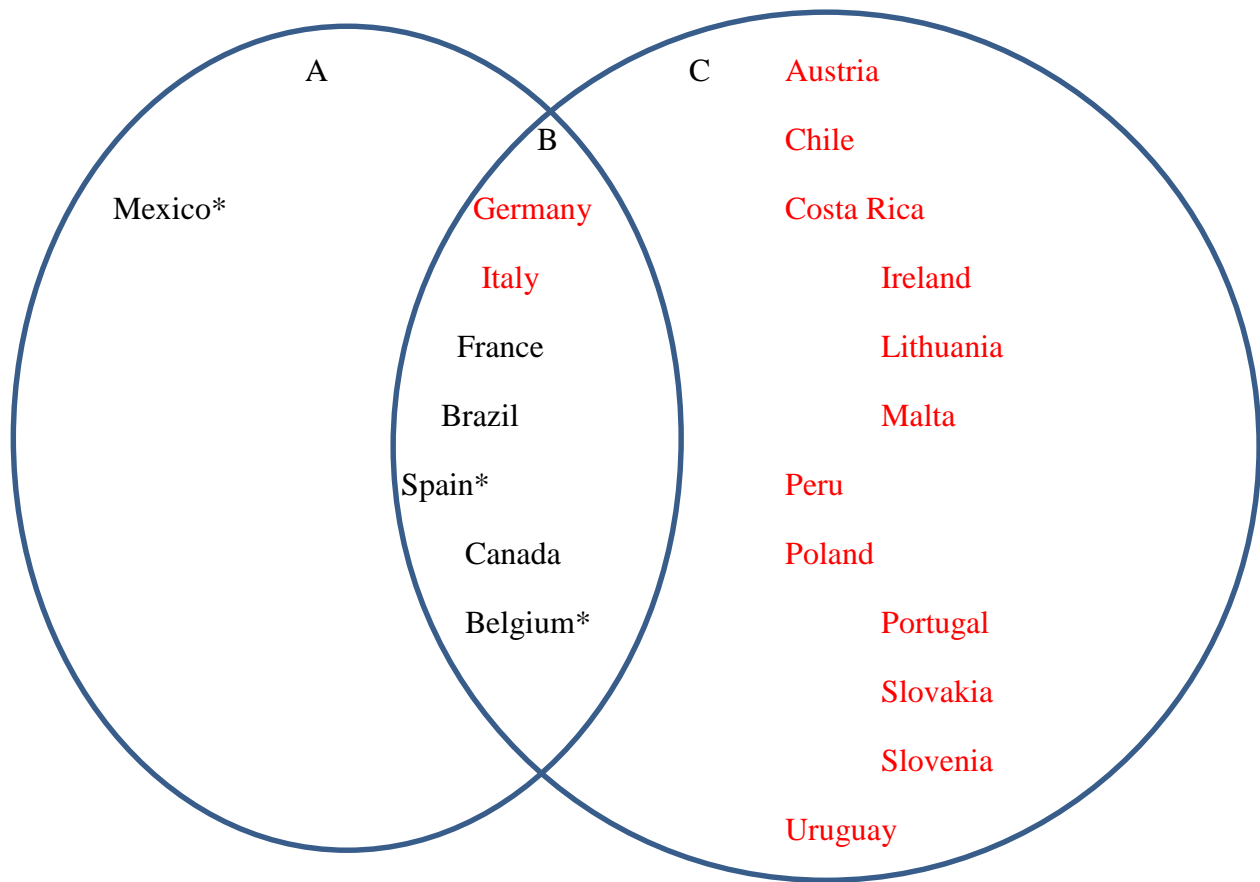


Figure 1. Predominantly Catholic States and Funding Venn Diagram. A = States with permissive policies, B = Non-permissive (red) and permissive (black) with more public grants than private grants, C = Non-permissive states (red) \*States that allow therapeutic cloning

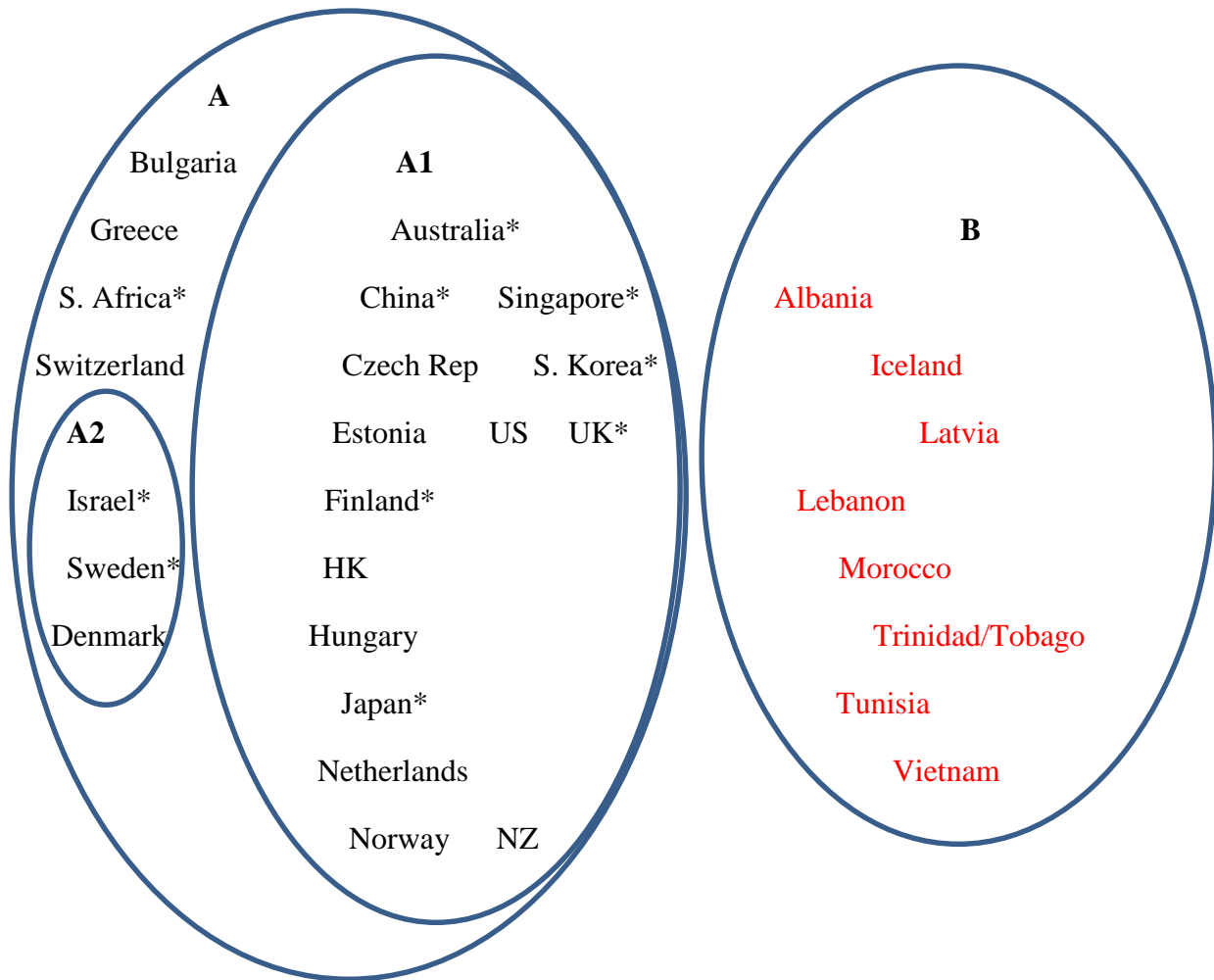


Figure 2. Non-Catholic States and Funding. A = States with permissive policies, A1 = States with permissive policies with more public grants than private, A2 = States with permissive policies and more private grants than public grants, B = States with non-permissive policies, \*allows therapeutic cloning. HK = Hong Kong, NZ = New Zealand, US = United States, UK = United Kingdom

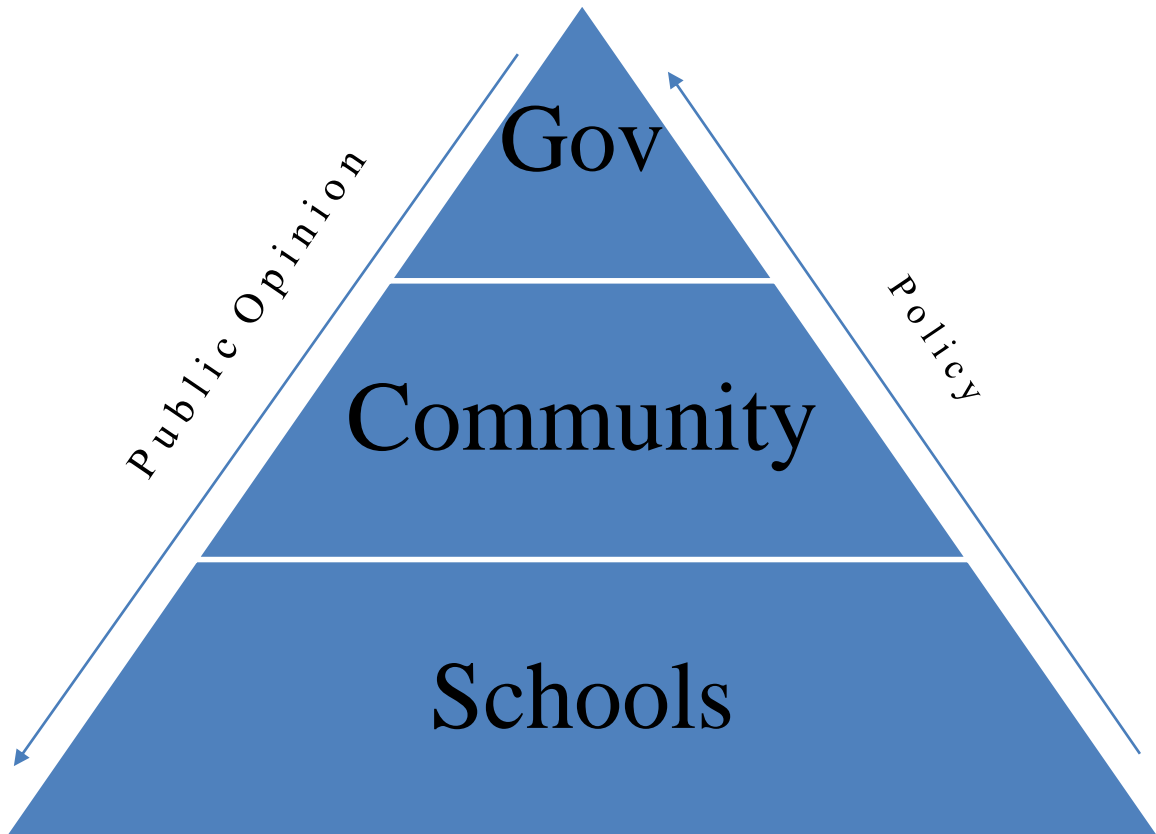


Figure 3. Three-Tiered Model for evaluating ESC research policy

