

# National Determinants of Human Embryonic Stem Cell Research Policy in Select Countries

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**Abstract** The policies which dictate the scope of embryonic stem cell research around the world are diverse reflecting primarily the country's culture and posture on the status of a human embryo and beneficent duty in healing persons afflicted with disease. In this retrospective comparative study utilizing logistic regression six national factors were analyzed for their effect on permissive or restrictive human embryonic stem cell policies in fifty countries. These are literacy, age of citizens, type and size of government, religion, and funding. It was hypothesized that a high literacy rate, younger age of citizens, public funding, lower number of legislators, and unicameral government would favor a permissive policy whereas a higher percentage of Catholics, older age of citizens, private funding, greater number of legislators, bicameral government, and low literacy rate would favor a restrictive policy. The variables which were found to be statistically significant ( $P < .05$ ) were funding and Catholicism. Results indicated public funding had a direct effect on permissive policies and percentage of Catholics in each country had an inverse effect on permissive policies surrounding embryonic stem cell research utilizing logistic regression. Culture will continue to influence the trajectory of embryonic stem cell policy navigating between the moral imperative of protection of the human embryo and curing those afflicted with disease.

**Keywords:** stem cell, embryo, logistic regression, culture

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## 1. Introduction

History has shown that science can impart great benefits to society as well as great harm [1]. 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.

Examples of science policies that have been 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 paper, 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 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.

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 categorized into three groups: 1) ESCs, 2) somatic (adult) stem cells, and 3) induced pluripotent stem (iPS) cells. Embryonic stem cells are derived from pre-implanted early human embryos. They are pluripotent, and capable of complete differentiation, giving rise to all tissues in the adult human. These stem cells 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 a 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. These cells are genetically identical to the patient alleviating the problems associated with 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. Somatic stem cells, referred to as adult stem cells provided an alternative to policy makers who oppose use of ESCs. These cells are easier to acquire and less controversial in the realm of research ethics. Sources of adult stem cells 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 the former for moral reasons lean toward adult stem cell research as a viable alternative. However, when Thomson's discovery was published [2] 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).

This paper examines factors that affect the development of ESC policy in fifty countries using logistic regression. The selected 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 countries were selected for this retrospective study based upon having a law in place regarding ESC research during the study period of 2000 to 2012.

### 1.1. Countries with Permissive Laws

A country was categorized as having a permissive policy if the policy stipulated research on ESCs was allowed, including therapeutic cloning. These included Australia, Belgium, Brazil, Bulgaria, Canada, China, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hong Kong, Hungary, Israel, Japan, Mexico, The Netherlands, Norway, New Zealand, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, UK, and the US.

**Australia.** *The Prohibition of Cloning Act and the Research Involving Human Embryos Act* was passed in 2002 prohibiting reproductive human cloning and allowing research on surplus human embryos, that is embryos left over from IVF procedures. In 2005, a review committee was formed to revisit the policy and offer recommendations. As a result, therapeutic cloning, creation of a national stem cell bank as well as a national register of donated excess surplus embryos were all inserted as an amendment to the law. 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 throughout Australia. Other sources of public

funding include the Australian Stem Cell Center and the Australian Research Center.

**Belgium.** *The Act Regarding Research on Embryos in Vitro* was passed in 2003. Research is allowed on human embryos not older than 14 days after fertilization as well as therapeutic cloning. Reproductive cloning, however is prohibited. Each study must be approved by an ethics committee of the respective academic institution as well as the Federal Commission for Medical and Scientific Research on Embryos. Public funding is provided by INNOVIRIS, the Scientific Research Foundation, the Special Research Fund, and the Funds for Scientific Research.

**Brazil.** 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. Brazil is characterized as a predominantly Catholic country. Prior to passage of the bill Catholics and Evangelicals formed a caucus in the lower house with the goal of blocking the bill. In the senate, however, experts in science testified on the issue of how many human embryos are being discarded diverting the question of when life begins and instead focused on continuing the cycle of life by using human embryos to save lives [3]. This argument swayed both houses of government becoming law in 2005. Public funding agencies in Brazil for science research include the National Fund of Scientific and Technological Development, the Ministry of Science and Technology, and Brazil's science council, CNPq. Private agencies include the WisdomTree Trust and Intel Capital Brazil Technology Fund.

**Bulgaria.** Research on human embryos is permitted under the *Bulgarian Health Act of 2004* and the *Law on Transplantation of Organs, Tissues, and Cells of 2003*. Reproductive cloning and therapeutic cloning are prohibited. The agency that oversees research on human embryos is the Bulgarian Central Ethics Commission and the Ministry of Health. The primary public agency that funds research is the Bulgarian National Science Fund.

**Canada.** Research is permitted on human embryos through the *Assisted Human Reproduction Act of 2004* as long as they are not older than 14 days and the study has been reviewed by an appropriate ethics board. Human cloning and therapeutic cloning are prohibited. Public funding agencies for science include the Canadian Institutes of Health Research and the Natural Sciences and Engineering Research Council.

**China.** China allows research on human embryos up to 14 days post fertilization as well as therapeutic cloning governed by the 2003 law (*Ethical Guiding Principles on Human ESC Research*). One of the cultural issues that likely helps to promote ESC research in China is prohibiting couples from donating embryos to other couples, leading to donating them to research instead. Moreover, the law only allowing couples to have one or two children creates a favorable foundation for prolific ESC research especially with those couples who have undergone fertility treatment [4]. The Chinese culture and religious backdrop have also contributed to a permissive policy. Confucianism, Taoism, and Buddhism all view embryos as persons [5]. Public funding agencies in China for science research includes the National Natural Science

Foundation, the Ministry of Education, and the Ministry of Science and Technology. In the private sector, the Bill and Melinda Gates Foundation has funded Chinese scientists in projects using ESCs [6].

**Czech Republic.** Research is allowed on human embryos not older than 7 days post fertilization regulated by the *Act on Research on Human Embryonic Stem Cells and Related Activities* of 2006. Stipulated in the law is that human embryos may be used that have either been imported or in surplus from IVF treatments. Public funding is available for scientists through the Grant Agency of the Czech Republic-Czech Science Foundation and the Academy of Sciences of the Czech Republic. Private funding is available from the Open Society Fund and the Ceska Sportelna Foundation.

**Denmark.** Research on human embryos was initially banned under the *Act on the Establishment of an Ethical Council and the Regulation of Certain Forms of Biomedical Experiments* of 1987. In 1992 however, the *Act on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects* allowed research on human embryos if the study advanced assisted reproduction techniques and the embryos were not older than 14 days. That law was amended in 1997 to include studies geared toward curing disease. Public agencies which fund research include the Danish Council for Strategic Research, the Danish National Research Foundation, and the Danish National Advanced Technology Foundation which partners with private industry to advance research initiatives. Private agencies include the Novo Nordisk Foundation which help to create the Danish Stem Cell Centre in 2011.

**Estonia.** Research is allowed on human embryos up to 14 days post fertilization through the *Artificial Insemination and Embryo Protection Act of 1997 and 2003*. An embryo may be frozen for up to 7 years and if not used for reproduction may be used for research. Therapeutic cloning and reproductive cloning are prohibited in Estonia. Public funding for research is available from the Ministry of Education and Research, the Estonian Science Foundation, the Archimedes Foundation, and the Estonian Research Council.

**Finland.** Research is allowed on human embryos up to 14 days post fertilization as is therapeutic cloning if the study is geared toward curing disease. Research is regulated under the *Medical Research Act of 1999* and embryos may be frozen for up to 15 years. Public funding for research is available from the Academy of Finland, Finnish Funding Agency for Technology and Innovation and the Finnish Innovation Fund. Private funding agencies include the Sigrid Jusellius Stiftelse Foundation, Finnish Diabetes Foundation, Finnish Neurological Foundation, and Ylppo Foundation.

**France.** In 2004, the *Research on the Embryo and Embryonic Cells Law* was passed allowing research on human embryos if a study is geared toward great therapeutic progress and has been approved by the French Agency of Biomedicine. The law was amended in 2013 where therapeutic progress was replaced with scientific relevance [7]. Public funding agencies include the France-Canada Research Fund and the French National Research Agency. A notable private organization, the French Muscular Dystrophy Association, has been conducting

telethons since 1987 with the 23rd telethon held in 2012 to generate funds for ESC research.

**Greece.** The *Medically Assisted Human Reproduction Act of 2002* prohibits therapeutic cloning and reproductive cloning but allows research on surplus human embryos up to 14 days. Human embryos not used for implantation can be frozen for up to 5 years, and after that time may be used for research. Public funds are available from the General Secretariat for Research and Technology and the Ministry of Education, Life Long Learning and Religious Affairs.

**Hong Kong.** Human embryos may be used for research as long as those embryos show no appearance of the primitive streak as promulgated by the *Human Reproductive Technology Ordinance of 2000*. Therapeutic cloning and reproductive cloning are prohibited. Public funding for research is available from the Innovation and Technology Fund and Research Grants Council. Private funds are available from the Croucher Foundation.

**Hungary.** 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 after fertilization. Therapeutic cloning and reproductive cloning is prohibited. Public funding is available from the Hungarian Scientific Research Fund and the Hungarian Academy of Sciences. Private funding is available from the Magyary Zoltan Foundation.

**Israel.** The *Prohibition of Genetic Intervention* law regulates research on human embryos. Research may be performed on human embryos up to 14 days of life and therapeutic cloning is also permitted. Israel's position of stem cell research can be attributed to Judaism and a Zionist duty to advance science and technology and a pro-natalism culture. Moreover, Judaism does not ascribe dignity to the embryo outside the womb regarding the structure as water for the first 40 days of gestation [8]. Public funding is available from the Israel Science Foundation and Research Funds of Chief Scientists in Government Ministries. Private funding agencies include the Geron Corporation, Legacy Heritage Foundation, and the Leona and Harry Helmsley Trust.

**Japan.** Therapeutic cloning as well as research on human embryos is permitted under the *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques* as long as the embryos are not older than 14 days. Projects must be approved by the Ministry of Education, Culture, Sports, Science, and Technology. Japan was praised by the ingenuity of one of its scientists, Shinya Yamanaka in 2006. Yamanaka was the first to successfully produce iPSCs in mice and humans [9] procuring a salient alternative to the moral controversy associated with ESCs. As a result, the Japanese government pledged (US\$) 100 million for five years toward perfecting and applying iPSC technologies [10]. Japan's scientific community was stunned however when in 2014, a scientist from the Riken Research Institute, Haruko Obokata, published fraudulent data in *Nature* [11].

**Mexico.** Therapeutic cloning and research on human embryos is permitted under the *General Health Law of 1997*. Then President Vicente spearheaded the INMEGEN center in Mexico City which focuses on stem cell research for curing disease. Public funds for research are available through the National Council of Science and Technology



and private funding is available through the MacArthur Foundation and Kellogg Foundation.

**New Zealand.** Research on human embryos is permitted under the 2004 *Human Assisted Reproductive Technologies Act* as long as the embryos are not older than 14 days and they are left over from IVF treatments. Research on imported ESCs is also permitted. Public funds for research are available through the New Zealand Aid Programme and the Royal Society of New Zealand.

**Norway.** Norway's position of ESCs changed significantly in 2007 when the entire country rallied around a young boy diagnosed with an incurable disease. Mehmet Yildiz was diagnosed with thalassemia in 2004. His community utilized the media, medical experts, and neighbors to lobby for prenatal genetic diagnosis (PGD) so that embryos could be tested for the abnormal gene linked to thalassemia possibly procuring a stem cell transplant for Mehmet from a normal embryo.

This campaign led to a complete reversal of the restrictive law in place at the time (*Act on Artificial Fertilisation of 1987*). According to the new law, enacted in 2007, research on surplus human embryos may be used as long as goals of the research include improving IVF procedures, developing techniques for PGD and adding to the body of knowledge regarding incurable disease. Reproductive cloning and therapeutic cloning, however, are banned. The Norwegian Center for Stem Cell Research and the Research Council of Norway provide funding for ESC research.

**Singapore.** The *Human Cloning and Other Prohibited Practices Act of 2004* regulates research on human embryos. Research on human embryos is permitted as long as the embryos are not older than 14 days; therapeutic cloning is also permitted. Public funding is available through the Agency for Science Technology and Research and private funds from ES Cell International. Between 2001 and 2010 the government invested more than (US\$) 4 billion to advance biomedical science [12].

**South Africa.** The *National Health Bill of 2003* prohibits reproductive cloning but allows therapeutic cloning and research on human embryos. The first bill drafted actually banned all types of research on human embryos insisting that such research would only exploit poor South African women [13]. However, medical experts and a pro stem cell lobby eventually persuaded members of parliament to rewrite the bill favoring a more permissive law. Between 2004 and 2007 (US\$) 58 million was allocated by the government to advance stem cell research.

**South Korea.** Research on human embryos, including therapeutic cloning, is permitted in South Korea under the *Bill on the Prohibition of Human Cloning and Stem Cell Research* which passed in 2003. South Korea, like Japan, had to endure a national scandal involving egregious breaches in ethics. Professor Woo-Suk Hwang published fraudulent data in 2004 and 2005, which has since been retracted by *Science*. Breaches included proclaiming to have created a cell line via therapeutic cloning, female members of his research team donating their eggs, and adding a government officials name to the author listing of his paper in an effort to thank him for funding his research. Baylis portends that part of the ethical breaches lie in the Korean culture of Confucianism and filial relations from

the standpoint of duties from child to parent, subject to monarch, etc...[14] This could certainly translate into duties, ethical or not from employee to employer. Hwang is quoted as saying he had gotten "too much preoccupied with work and achievement" to keep ethics in mind [15]. The South Korean government responded to these breaches by suspending all stem cell research for a period of three years. Public funding is available through the Korean Research Foundation under the guidance of the Ministry of Culture and Tourism, the National Research Foundation, and the 21st Century Frontier. Private funding companies include the Takeda Foundation and Samsung.

**Spain.** Spain took a very incremental approach on its stem cell policies. From 1988 to 2003 the *Techniques of Assisted Reproduction Law* only permitted research on embryos which were non-viable. The law was amended in 2003 to address the overflow of embryos which had been frozen. Couples could donate the embryos in storage for research. In 2006, the law was again amended giving couples the choice of donating their embryos to other couples, keeping them in frozen storage, donating them for research, or discarding them. In 2007, the law was amended to allow therapeutic cloning for studies aimed at curing disease. Public funding for research is available through the Carlos III Health Institute. Private sources of funding include the ESADE and the Carlos Crespo Banchemo Foundation.

**Sweden.** Research on human embryos is permitted up to 14 days after fertilization under the 2005 *Genetic Integrity Act*; therapeutic cloning is also permitted. Couples undergoing IVF treatment cannot donate surplus embryos to other couples; they must be discarded if not used for research. The debates in parliament were quite vociferous in passing the 2005 law being played out in the media daily. The issue of when life begins versus the potential of research involving ESCs kept the bill on the political agenda. Members of the Social Democratic Party had the majority of votes for passage of the bill, while efforts to repeal the law were cogent, the law remains today. Public funding is available from the Swedish Research Council and private funding from the Swedish Cancer Society, NovaNordisk, and the Swedish Diabetes Foundation.

**Switzerland.** All types of cloning are prohibited in Switzerland under the Federal Constitution of the Swiss Confederation and any form of commercialization of human embryos is prohibited. The *Loi federale relative a la recherche sur les cellules souches embryonnaires* (Federal Act of Research involving human ESCs) allows surplus human embryos to be used for research with the stipulation that the embryos shall not be older than 7 days post-fertilization. Research proposals involving the use of human embryos must be approved by the Research Office and the Commission of Competent Ethics. Public sources of funding include the Swiss National Science Foundation and the Commission of Technology and Innovation. Private sources of funding include the Latsis Foundation, Maecenas Foundation, and the Louis-Jeantet Foundation.

**The Netherlands.** Research is permitted on human embryos under the *Embryos Law of 2002* if they are not older than 14 days post-fertilization and the research project has been approved by the Central Commission. Public sources of funding include the Netherlands

Organization for Scientific Research and the Dutch Funding Agency for Applied University Research. Private funding agencies include the Netherland Chest Foundation and Nederlandse hartstichting.

**UK.** The UK was one of the first countries to address national policy regarding research on human embryos given the accomplishments of Patrick Steptoe and Robert Edwards in successfully delivering the first test tube baby, Louise Brown in 1978. This scientific breakthrough opened the door for a new technology where parents with fertility issues had a viable option for bearing a child via in vitro fertilization (IVF). Inherent in this technology is the possibility of surplus human embryos and controversy of what to do with them. In 1996, Dolly the sheep was born through a process known as SCNT conducted by Ian Wilmut and Keith Campbell. Shortly after Louise Brown was born the Warnock Committee was formed to address the social, ethical, and legal implications of human embryos in research. It was chaired by Baroness Mary Warnock. The time period of 14 days was recommended by the British Medical Association wherein research could not be done on human embryos older than 14 days. At the time there was no law in place granting right to life to an embryo. Most of the committee members agreed that a central body would have to issue licenses for research involving human embryos and that criminal charges would be brought against those scientists that breached that requirement. While there was a minority of dissenters who felt it was wrong to create an embryo with a purpose of destroying it, in the end Mary Warnock concluded “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” [16]. Today research on human embryos as well as therapeutic cloning is permitted under the *Human Fertilisation and Embryology Act* (HFEA) of 1990 as long as the embryos are not older than 14 days. Reproductive cloning, however, is prohibited under the *Human Reproductive Cloning Act of 2001*. Public funding is available from the Medical Research Council and the Biotechnology and Biological Sciences Research Council. Private funding is available from the Diabetes UK, The Wellcome Trust, and the Parkinson’s Disease Society.

**US.** The drive toward national policy on human ESC research began on the heels of the *Roe v. Wade* Supreme Court landmark decision which legalized abortion in 1973. A moratorium was placed on federal funds supporting research on human embryos by Congress in 1974. In 1975 the moratorium was lifted and an Ethics Advisory Board was assembled to discuss the implications of research. In 1979, the EAB approved federal funding for research using IVF and embryo transfer up to 14 days. However, the EAB dissolved in 1980 which precipitated the formation of the Human Fetal Tissue Transplantation Research Panel at the National Institutes of Health (NIH) in 1987. In 1990 Congress passed a bill lifting the moratorium set by Secretary Sullivan in 1987 prohibiting any federal funds to be used for human ESC research, however, President George H.W. Bush vetoed it. In 1993 President Clinton lifted the moratorium. This act was short lived because in 1994 both the Senate and the House

banned federal funds in 1995 when the Republican Party was in the majority. In 2001, President George W. Bush allowed federal funds to be used for research on existing ESC lines vetoing the *Stem Cell Enhancement Act* twice (2005, 2007) which permitted federal funding on newly created ESC lines. In 2009, by way of Executive Order 13505 *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, President Barack Obama mandated federal funds could be used for research involving surplus human embryos. Federal funds cannot be used to advance reproductive or therapeutic cloning. The path of research involving human embryos in the US is not significant in that it follows party lines. It is unique however, how the federalist system changed the trajectory of stem cell research in the US. During the George W. Bush administration when federal funds could only be used for existing ESCs, states like California, Maryland, and Massachusetts to name a few passed their own laws not only allowing research on human embryos but also procuring funds for it. The premier public funding agency in the US is the NIH. Private funds can be procured from the Christopher Reeves Foundation, Michael J. Fox Foundation, and the Bill and Melinda Gates Foundation.

## 1.2. Countries with Restrictive Laws

Countries with restrictive 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.

**Albania.** Research using human embryos is prohibited under the Law on Reproductive Health (2002). Research on adult stem cells, however, is allowed with the goal of helping families afflicted with disease while at the same time respecting societal values. Public funding for research is available through the Agency of Research, Technology, and Innovation, Ministry of Education and Science, and the Albanian Science Academy.

**Austria.** Research on human embryos as well as therapeutic and reproductive cloning are banned under 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*. Viable cells may not be used for purposes other than medically assisted reproduction, however research may be performed on imported stem cell lines. Public funding is available from the Funds for Promotion of Scientific Research or *Wissenschaftsfonds* and the Vienna Science and Technology Fund.

**Chile.** The *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 and no human embryo may be destroyed to obtain stem cells. Public funding for research is available through the National Commission for Scientific and Technological Research and the National Fund for Scientific and Technological Research.

**Costa Rica.** The *Regulation of Assisted Reproduction and IVF* law passed in 2000 prohibits research of any kind on the human embryo as well as IVF therapy. Public funding for research is available from the Ministry of

Health, Costa Rican Social Security Fund, and the National Council for Scientific and Technology Research. Private companies which provide funding are the Institute for Pediatric Research and Costa Rica – United States Foundation for Cooperation.

**Germany.** Research on human embryos is restricted to surplus embryos created before May 2007 that can be imported from another country. Germany's path has been long coming to grips with a past which included novel medical achievements and horrific medical atrocities. The Embryo Protection Act of 1991 prohibited production of an embryo "for any purpose other than the bringing about of a pregnancy" (*Embryonenschutzgesetz* 1990, 1.2). The next law to be passed was the *Stem Cell Act of 2002*. Under this law human embryos may be imported if they were derived before January 1<sup>st</sup> 2002 as long as the embryos originated from IVF treatment and not therapeutic cloning. The law also mandates prison time for any person violating the tenets of the policy. In April 2008, the date of procurement of human embryos was extended to May 1, 2007. By setting a date upon which human embryos may be procured the law will continuously have to be amended which may open the door for politicians who oppose policy to mount a campaign to change the law toward their point of view. Opposition to ESC research in Germany comes from antiabortion religious groups, antiscience Green Party, and women's groups labeling this type of research as "continuations of Nazi eugenics" (Paarlberg, 2005, 45). It is evident that the German parliament is working to satisfy all elements of society. However, this injects a moral duplicity because under this law scientists are still conducting research on human embryos funded by the government. The one caveat is they are not embryos that originated from Germany. Public funding is available through the Academies of Science and Humanities, Humboldt Foundation, German Academic Exchange Service, Germany Research Foundation, Fraunhofer-Gesellschaft, and Max Planck Society. Private funding is available through the Hertie Foundation and the Volkswagen Foundation.

**Iceland.** Research on human embryos may never be created for research and reproductive cloning is prohibited under the *Law on Artificial Fertilization of 1997*. Any research on surplus human embryos is prohibited unless it is geared toward advancing fertilization techniques only. Iceland hosts Science Café's periodically which are televised so that the public can keep informed and offer comment on the latest scientific discoveries. In 2010, a Eurobarometer poll indicated that 70 percent of residents thought that ESC research should not be forbidden [17]. Public funding for research is available through the Icelandic Research Fund and Technology Development Fund. Private funding sources include Sigurour Jonsson and Helga Siguroardottir Fund for Research on Human and Animal Pathology.

**Ireland.** Ireland's position on ESC research stems from its large Catholic populace. In 2008 the *Stem-Cell Research Bill* was presented to parliament prohibiting ESC research. In 2009 the Irish Medical Council banned medical practitioners from creating embryos for research purposes. In 2010 the Irish Council for Bioethics dissolved due to budget cuts. Without this body no research projects involving morally questionable studies

could be approved. 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 there is deeply ingrained in Irish Society. Both parliament and the Medical Council have closed the door on any ESC research activity in Ireland.

**Italy.** The 2004 law (*Law 40*) on ART (Artificial Reproductive Technology) prohibits research on human embryos or experimentation thereof. The embryo is deserving of respect from the moment of fertilization according to this law and there is a cap of 3 on the number of embryos which can be produced from IVF procedures. Additionally, therapeutic cloning, reproductive cloning, and genetic manipulation of embryos is prohibited. Provisions of the bill were aligned with both the Vatican and the Roman Catholic Community. Division was palpable in the Italian Bioethics Committee where six members thought the bill breached separation of church and state. A referendum held in 2005 failed the majority of the populace which would if allowed research on human embryos. Importation of ESC lines is a loophole in the law. Public funding is available from the Ministry of University and Research and the National Research Council as well as the National Agency for New Technologies, Energy, and Environment.

**Latvia.** Stem cell research in Latvia is regulated under the Law on Sexual and Reproductive Health passed in 2002. Human embryonic stem cells may not be exported or imported and may not be created for scientific or commercial purposes. Further, human cloning is prohibited. For Public funding scientists apply for grants from the EU. Private funding for research is available from the Baltic Innovation Fund.

**Lebanon.** The Law on Assisted Human Reproductive Techniques prohibits research on embryos or commercialization. Reproductive and therapeutic cloning is prohibited. Lebanon is made up of both Christians and Muslims practicing a system of confessionalism where all peoples are fairly represented and diversity is encouraged. Lebanon's policy on ESC research is likely a result of diverse religious and ethnic communities. Public funds for research is available from the National Council for Scientific Research and the Economic and Social Research Council. Private funding is available from the Al Waleed bin Talal Foundation.

**Lithuania.** The Law on Ethics of Biomedical Research passed in 2000 and amended in 2007 mandates that ESC research is limited to clinical observation. Importation and exportation of human ESCs is prohibited. The Lithuania Bioethics Committee was created in 1995 and regulates all research activity and ethics thereof. Public funding is available from the Research Council of Lithuania with an annual budget of 35 million (US\$). Private funding is available from the Juozas Kazickas Foundation.

**Malta.** Embryonic stem cell research is prohibited through the Embryo Protection Law of 2012. In 2012 the Maltese government opposed the EC decision to fund projects involving human ESCs via the Horizon 2020 program arguing that the EC is not capitalizing on the therapeutic potential of adult stem cells (Vella, 2012). In response to the EU FP7 research program allocating funds for ESC research Archbishop Joseph Merceica stated in no situation can the Church agree to fund research involving



human embryos [18]. While Malta is a member of the EU, clearly the Maltese people and Catholic base does not always agree with EU decisions. Public funding for scientific research is available from the Malta Council for Science and Technology.

**Morocco.** Research involving human embryos is prohibited through Law No. 16-98 passed in 2003. The government in Morocco is led by the Justice and Development Party which is Islamic. Islam is the constitutionally established religion in Morocco. The Qur'an does not address ESC research. It prompts man to look upon himself and the world to find solutions based on human rationality [19]. Other Islam countries such as Saudi Arabia do not oppose ESC research. Public funding is available through the Morocco Foundation for Advanced Science, Innovation, and Research.

**Peru.** The General Health Law was passed in 1997 and amended in 2009 prohibits research using human embryos for any activity except for procreation. Human and therapeutic cloning are prohibited. Public funding is available from the Ministry of Health and National Council for Science and Technology. Private funding is available from the Schlumberger Foundation and Tinker Foundation.

**Poland.** Laws that govern ESC research include the Law on Family Planning of Human Fetuses and Conditions under which Pregnancy Termination is Permissible and the Medical Profession Act of 1996. Embedded in these laws is the tenet that every human being has a natural right to life from the time of conception and that conceived children cannot participate in research experiments. In July 2006 the Sejm passed a resolution declaring that human ESC research is in contradiction to Polish Law as the constitution states that every human life is afforded legal protection [20]. Public funding is available from the Polish Agency for Enterprise Development, the Foundation for Polish Science, the Polpharm Scientific Foundation, the National Centre for Research and Development, and the Polish Academy of Sciences. Poland is predominantly Catholic which most likely accounts for their restrictive policies involving human ESCs.

**Portugal.** The Medically Assisted Reproduction Law of 2006 is restrictive in that only embryonic stem cells with genetic abnormalities to be used for research. Therapeutic and reproductive cloning are prohibited. Public funding is available from the Foundation for Science and Technology and private funding from the Gulbenkian Foundation and Champalimaud Foundation. Portugal is home to the Crioestaminal cord blood stem cell bank which is a private stem cell bank indicating that Portugal is supportive of adult stem cell research.

**Slovakia.** Law No. 227/1994 on Healthcare limits research on human embryos to fertility treatments as well as prohibiting therapeutic and reproductive cloning. Further, anyone that attempts reproductive cloning can be imprisoned for up to 8 years under Slovakia's penal code. Scientists in Slovakia can apply for EEA grants and Norway grants providing more than 1.2 million (US\$) in a variety of fields including biotechnology. These grants represent the contributions 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. Slovakia

spending on science and research amounts to only 0.48 percent of GDP, which is far below the EC threshold of 3 percent [21].

**Slovenia.** The Biomedically Assisted Fertilization Law passed in 2000 allows surplus embryos to be used for research with the stipulation that they are unsuitable for reproduction and no older than 14 days. Reproductive and therapeutic cloning is prohibited. Public funding includes the Slovenia Research Agency and Slovenia Science Foundation. Private funding is available from the CF of Pomurje, CF Vincenc Draksler of Gorenjska, CF Planota of Goriska, and CF of Posavje.

**Trinidad and Tobago.** The Act Respecting Human Reproductive Technologies and Commercial Transactions relating to Human Reproduction prohibits reproductive cloning, crossbreeding of animals and humans, genetic alterations of embryos, fertilization of ova outside the body for the purpose of research and commercialization of embryos. This law was passed in 1999. Public funding for science research is available from the University of West Indies Trinidad and Tobago Research Development Impact Fund.

**Tunisia.** Research involving human embryos is prohibited under Law 01-93 The Medicine of Reproduction. Therapeutic and reproductive cloning is also prohibited. In 2002 the Tunisia National Committee for Medical Ethics proposed adult stem cells as an alternative to embryonic stem cells. Embryonic stem cells may neither be imported nor exported. Like Morocco and Lebanon, Tunisia has a substantial Muslim population that has decided on a restrictive policy regarding ESC research. Tunisia does support other science research as 16 million (US\$) was allocated through an EU grant to establish research centers and laboratories throughout Tunisia enhanced collaboration with other EU researchers [22].

**Uruguay.** Uruguay has a restrictive policy via Human Assisted Reproduction Law of 2003. This law prohibits research on human embryos, therapeutic cloning, and reproductive cloning. Moreover, the Code of Ethics of the Uruguayan Union of Doctors stated that "the human embryo may never be the subject of experimentation, nor the raw materials for drugs, cosmetics, or other products" [23]. Public funding is available from the National Research and Innovation Agency, the Directorate of Innovation, Science, and Technology for Development of the Ministry of Education and Culture, and the University of the Republic. Private funding agencies include Perez Foundation, Programme for Technological Development, and the Clemente Estable Fund.

**Vietnam.** The Law on Childbirth by Scientific Methods forbids human cloning and use of ESCs for research unless they are being used for fertilization. This law was passed in 2003. Vietnam is a latecomer to embracing IVF techniques; at the same time James Thomson published his seminal article on human ESCs the first test tube baby was born in Vietnam. Women in Vietnam are thought to have a sentiment (Tinh cam) or intimate relationship with their baby and that the exchange of blood in utero is the foundation of that closeness [24]. Donating an embryo to another couple is strictly prohibited as it would cross a cultural tenet regarding the mother-child intimacy. This is likely the rationale for Vietnam's restrictive policy on ESC research. Public funding for research includes the

International Foundation for Science, Lin Center for Community Development, and Kids with Cancer Foundation.

## 2. Methods

Logistic regression was performed using SPSS (v.24) in identifying national factors affecting ESC research policy in fifty countries; the unit of analysis was country. The dependent variable is ESC policy with 0 representing restrictive policies and 1 representing permissive policies on ESC research. A restrictive policy was defined as countries not allowing any type of research on human embryos or only allowing research on imported stem cell lines. A permissive policy was defined as allowing research on surplus embryos and/or therapeutic cloning. A country's law was reviewed and categorized as permissive or restrictive. All laws were accessed from the country's government website.

The independent variables are religion, literacy, age, funding, type of government and size of government. Religion is a continuous variable using the percentage of Catholics in each country from the CIA World Facts Book. Religion was chosen because it is embedded in culture toward moral values and religious beliefs. Catholicism was chosen because it is practiced across the globe though not a predominant religion in all countries included in this study. Further, Catholicism is the only religion with a central authority who can voice their opinion on controversial issues at will. The Pope has opposed research on human embryos however not all Catholics align with the Vatican on this issue.

*Hypothesis 1. Predominantly Catholic countries are more likely to favor restrictive policies on ESC research*

Literacy is defined as the ability to read and write with understanding a statement related to a person's daily life [25]. Most adult literacy rates are measured at 15 years of age and older. Data was accessed from the CIA World Facts Book. The reason literacy was included is it is essential to political discourse and the democratic process. If a voter cannot read or write they cannot in good faith vote in favor or oppose a policy. The variable is continuous using the percent literacy rate in each country.

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

Age was chosen as an independent variable because of generational gaps on various issues. In the realm of ESC research older individuals tend to be more disciplined toward their religion than younger persons and more steadfast in their beliefs. This could have a significant bearing on policy depending on their religious denomination. Likewise, younger persons may be more open to technological advances. The internet may also play a pivotal role. Younger people are much more likely to be computer savvy than older persons receiving information on a daily basis which may involve advances in stem cell research. Three age groups were utilized: 0-14, 15-24, and 65 and older. They were coded as 0, 1, and 2. Predominant age groups in each country were accessed from the CIA World Facts Book.

*Hypothesis 3. Younger people are more apt to favor permissive policies on ESC research and older persons are more apt to favor restrictive policies.*

Funding was chosen as an independent variable in this study because ESC research is dependent on funding from either public or private sources. Public funding is typically allocated via legislative appropriations bounded by strict procedures for applying for and carrying out research. Private funding tends to be less procedurally restrictive and less rewarding monetarily than public funds. Funding was a continuous variable and computed as the ratio of public to private grants. This ratio was derived by first tabulating how many grants were listed in the acknowledgement section of research papers in the literature that involved human ESC research. The years of study were from 2000 to 2012. Search terms were entered into Pub Med stipulating the year, country, and embryonic stem cells. All papers were reviewed for applicable grants and categorized as private or public by looking up the agency awarding the grant on the internet. This process was followed for all fifty countries.

*Hypothesis 4. Countries with predominantly private funding is more apt to favor restrictive policies, where countries with predominantly public funding is more apt to favor permissive policies.*

The type and size of government were chosen as variables in this study as many have theorized a unicameral government is associated with less brinkmanship than bicameral governments. The same can be said for a smaller number of congressman or ministers in the legislature. Larger governments may invoke more political rancor and iterative committee sessions. Type of government was coded 1 for unicameral and 0 for bicameral; size of government was a continuous variable accessed from the countries legislative website.

*Hypothesis 5. Countries with a bicameral system are more likely to favor restrictive policies where unicameral countries are more apt to favor permissive policies.*

*Hypothesis 6. The greater number of legislators the more likely the country will favor restrictive policies.*

## 3. Results

**Table 1. Logistic Regression Analysis using SPSS**

Variable	SE	B	OR	P
Religion	.022	-.053	.948	.015
Funding	.382	.913	2.5	.017
Govt	1.2	-.863	.422	.476
MP	.002	.001	1.0	.547
Literacy	.079	.053	1.0	.503
Age (1)	1.09	-1.36	.25	.212
Age (2)	1.74	1.88	6.5	.281
Constant	7.79	-3.84	.021	.622

SE = standard error, B = beta coefficient, OR = odds ratio.

The logistic regression analysis supported hypothesis 1 and 4 regarding religion and funding, respectively. Religion had a p value of .015 with a beta coefficient of -.053 and odds ratio of .948 representing an inverse relationship (Table 1). This can be interpreted as the odds of a country having a permissive law on ESC research are



decreased by a factor of .948 with a one percentage increase in the number of Catholics. The Funding variable had a p value of .017, a beta coefficient of .913 and an odds ratio of 2.5. This can be interpreted as the odds of a country having a permissive policy on ESC research are increased by a factor of 2.5 with a one unit increase in the ratio of public to private grants. Age, literacy rate, type and size of government were not significant variables in this study.

#### 4. Discussion

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 religion and public funding were shown to be significant using logistic regression. 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. This places an emphasis on cultural factors over structural factors in the realm of comparative policy theory. There are not similar studies published that have used type of government as a covariable in logistic regression in 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 nor size of government effected ESC policy.

Literacy was also not statistically significant. 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 restrictive law. The only outliers were Morocco and Tunisia with average rates in the high 60s and 70s, respectively. 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 [26]. This has been carried out by OECD PISA, PEW Research Center [27], Jon Miller [28], and also by the EU [29]. Miller 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. Certainly, the SLR should be studied in as such a measurement would provide insight into the publics ability to understand scientific policy. Age was also not significant. There was variability in the youth and elderly percentages across fifty countries. 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 the younger aged individuals are more permissive of research. However, many of those studies involved focus groups and smaller numbers of respondents [30].

Religion was a statistically significant variable. Fink also found a significant relationship using ordinary least squares regression between Catholicism and a restrictive policy index [31]. In his study the dependent variable represented an index of policy strictness based on which countries prohibited various biomedical applications. Germany had a high index and the UK a low index. He also 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. Of the fifty countries selected in this study four groups can be defined (Figure 1): 1) predominantly Catholic countries who have a permissive policy, 2) predominantly Catholic countries with a restrictive policy, 3) non-Catholic countries that have permissive policies, and 4) non-Catholic countries that have restrictive policies.

##### Catholic Countries with Permissive ESC Policies

- Belgium, Brazil, France, Mexico, Canada, Spain

##### Catholic Countries with Restrictive ESC Policies

- Austria, Chile, Costa Rica, Germany, Ireland, Italy, Lithuania, Malta, Peru, Poland, Portugal, Slovakia, Slovenia, Uruguay

##### non-Catholic Countries with Permissive ESC Policies

- Australia, Bulgaria, China, Czech Rep, Denmark, Estonia, Finland, Greece, HK, Hungary, Israel, Japan, The Netherlands, Norway, NZ, Singapore, South Africa, South Korea, Sweden, Switzerland, UK, US

##### non-Catholic Countries with Restrictive ESC Policies

- Albania, Iceland, Latvia, Lebanon, Morocco, Trinidad and Tobago, Tunisia, Vietnam

**Figure 1.** Delineation of Catholic and non-Catholic Countries relative to ESC Policy

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. In Belgium, churchgoing among Catholics has decreased from 42.9 percent in 1967 to only 7 percent in 2006 [32]. In Brazil, the Catholic population fell from 74 percent to 65 percent from 2000 to 2010 while 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 [33]. The interesting observation regarding Group 2 is admixed among staunchly Catholic states like Poland, Italy, and Ireland is Germany whose law on ESC research allows importation of ESCs. Germanys situation is much more complicated because of their tumultuous history with Nazi eugenics and breach of ethics by Nazi physicians during WWII. While legislators in Germany have tried to balance the past and present allowing importation of ESCs suggests a moral duplicity; research on embryos is allowed as long as they are not home grown. Group 3 is comprised of countries which are not predominantly Catholic; most are Protestant, Buddhist, Hindu, Muslim, or Jewish. It is not surprising these countries have permissive policies given liberal view held by these denominations as well as backdrop of technological infrastructure in these countries.

The last group of countries are non-Catholic with restrictive policies. A common element in this group is lack of a scientific culture and infrastructure. The restrictive policy may be more related to those factors than tied to religion.

The Funding variable was also statistically significant and exhibited a direct relationship using the ratio of public grants to private grants. Those countries with a ratio greater than one 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. These countries were all characterized as having permissive policies. The only exceptions were Denmark, Israel, and Sweden who had more private than public grants but had permissive policies. The countries with restrictive policies and ratios greater than one included Germany and Italy. The countries with restrictive policies and no funding grants included Albania, Austria, Chile, Costa Rica, Slovakia, Slovenia, Trinidad and Tobago, Tunisia, Uruguay, and Vietnam. In those countries one can assert funding was not available by private means for an activity forbidden by law. Moreover, another comparison that can be drawn regarding the funding variable is predominantly Catholic countries that had more public grants than private. Belgium, Brazil, France, Italy, Germany, Canada, and Spain are predominantly Catholic with a public to private grant ratio of >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. There were no predominantly Catholic countries with more private grants than public grants.

A limitation of this study is the possibility of researchers not including funding information in research articles utilized in tabulating public and private grants. The inclusion of funding information is customary worldwide when writing a research paper and many funding agencies require it. The occurrence of research papers being devoid of grant information is likely negligible.

## 5. Conclusion

This study analyzed ESC research policy in fifty countries respective of funding, religion, type and size of government, literacy, and age. Employing logistic regression it was established that public funding was directly related to permissive ESC research policy and Catholicism was inversely related to ESC research policy; both variables were statistically significant. Public funding represents a governments posture on various policies which are supported by and large by the citizenry and voted for by elected representatives in countries which are classified as democracies. Catholicism has been a formidable institution dating back nearly 2000 years that unequivocally indoctrinates the sanctity of life from the time of conception rendering research on human embryos prohibitory. The moral status of human embryos will continue to be a flash point for discourse on science policy.

Factions will continue to articulate their perspective on ESC research, and laws will continue to be drafted, passed, and amended. In the sphere of democratic nations, the decision to have a permissive or restrictive law lies with the voters in democracies amid a dynamic environment of competing ideologies, political action groups, lobbies, culture, and the media. While not every country included in this study may be viewed as a democratic country, the overwhelming majority are democratic. Future studies should include the SLR as an independent variable in regression studies, and given the discovery of iPSCs researchers should investigate whether there has been a decrease in the use of human embryos in stem cell research that have precipitated changes to ESC policy across nations.

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