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Researchers', Stakeholders', and Investors' Perceptions of U.S. Stem Cell Research Policy

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2017

Abstract

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by

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MBA, University of Phoenix, 2007

BS, Kennesaw State University, 2004

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Policy and Administration

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Abstract

Federal support and funding for human embryonic stem cell (hESC) research in the United States lags behind stem cell programs in many countries because of the divisive debate over hESC research and the continually evolving federal policies that have hindered research efforts. The purpose of this phenomenological study was to explore the perceptions of stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and their recommendations to improve stem cell research policy in the United States. Rogers's diffusion of innovation theory and Kingdon's agenda-setting theory served as the theoretical frameworks for this study. Data were collected through telephonic semistructured interviews with a snowball sample of 21 participants. Data were analyzed using Attride-Stirling's 6 steps of thematic coding. Findings indicated the need to educate laypersons and legislators, involve the public in the stem cell research policy debate, increase federal funding, and exclude religious considerations from political discussions. The implications for positive social change are directed at stem cell policymakers to focus attention and resources on creating a cohesive federal hESC funding policy to ensure that stem cell research improves in the United States with the goal of developing treatments for conditions that are currently untreatable.

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Dedication

This dissertation is dedicated to my mom who suffered a massive heart attack in 2007 and to my dad who passed away in 2016 at the age of 91 due to complications from Alzheimer's. To my big sister who passed away in 2015 due to a massive heart attack and who made numerous sacrifices for me to visit New York City every summer. To my eight remaining sisters and brothers; thanks for keeping me grounded. With all my ambition, you all still remind me that I am the daughter of a sharecropper who had very limited education and that although I am the first to graduate with a degree and achieve my PhD, all of you have a stake in my success. Even though I did not work as a cotton or corn picker, through your pain, you all allowed me to go to school with very limited interferences. To my boys, thanks for always letting me know that your support would always be felt and instrumental in my results.

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First, I must give thanks to my Lord and Savior Jesus Christ for his undivided attention and mercy that he professes in my life. Second, I would also like to thank my family and colleagues for their ongoing support. My deepest appreciation goes to my husband, Michael, who has been my greatest supporter. My husband was my rock and motivator. When I was ready to throw in the towel, he showed me another way of using it and for that I say thank you. Thanks to mom and dad who believed that I could do anything, and raised me to be tenacious and committed to achieving. I know you are both smiling from above. I appreciate the encouragement that I received from my classmates and my colleagues who understand what it feels like to hit a wall, get up, and keep moving.

Third, I would like to thank my editor, Dr. Carolyn Rose-Smith, and my previous chair, Dr. Ian Birdsall, who is no longer with us. I would like to posthumously thank him for his generous contribution. Thank you to Dr. Eliesh O'Neil Lane, who was my committee member, and when Dr. Birdsall was no longer there, she honorably stepped in to become my committee chair; thank you so much. Thank you to my current committee member, Dr. Hector Antunez, for stepping in so that I could accomplish my doctoral journey. Special thanks to my university research reviewer, Dr. Tanya Settles.

Finally, I want to sincerely thank those participants who volunteered and took time out of their busy schedules to share their knowledge, time, and thoughts about this topic with me. Your interests and responses have provided valuable insight that can help address and possibly heal those who suffer from chronic illnesses in the near future.

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Chapter 1: Introduction to the Study

The uncertain stem cell policies in the United States have been a great challenge for stem cell researchers, especially for those who work with human embryonic stem cells (hESCs; Levine, 2011). Levine (2011) reported that in 1995, President Clinton banned federal funding for research that would destroy human embryos. In 2001, the Bush administration's restriction resulted in only 21 viable lines that could be used in federally funded research. However, in 2009, President Obama issued an executive order (EO) with the goal of strengthening hESC research in the United States (Levine, 2011; Nature Cell Biology, 2010). President Obama's new stem cell policy, however, did not approve the 21 hESC lines that were eligible under the Bush administration (Levine, 2011). Nature Cell Biology (2010) reported that hESC lines have to meet the National Institutes of Health (NIH) strict ethical policies. According to the NIH (2015a), applicant institutions proposing research using hESCs derived from embryos donated in the United States should be derived from human embryos that were created using in vitro fertilization (IVF) for reproductive purposes and were no longer needed for this purpose. In addition, the hESCs should be donated by individuals who sought reproductive treatment and gave voluntary written consent for the human embryos to be used for research purposes. Therefore, it is still not possible to create new hESC lines from viable embryos using federal funds, and verifying that the hESC lines were derived from donors who had given their informed consent has been very time-consuming for researchers (Nature Cell Biology, 2010). Questions still remain as to whether U.S. stem cell researchers have really benefited from President Obama's more relaxed funding policies.

The use of hESCs in stem cell research has been a very divisive and controversial issue (Levine, 2011; Mintrom, 2013). Mintrom (2013) discussed morality politics that are associated with hESC research. Mintrom noted that hESC research is controversial because it raises questions about what counts as human life and who gets to make that decision. Sano (2013) argued that for hESC research to flourish in the United States, a cohesive federal hESC public financing policy is needed. In this phenomenological study, I explored the perceptions of 21 stem cell researchers, stakeholders, and investors in the United States regarding the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. Stem cell researchers are scientists who study the biological properties of stem cells and the potential use and effect of stem cells in treating diseases (NIH, 2009). Stakeholders are "individuals whose collective actions are guided by or directly serve the mandate of an overarching organizational framework" (Downey & Geransar, 2008, p. 70). Stakeholders play a major role in the stem cell debate as well as in stem cell research and policy development, such as patient groups in alignment with the medical community (Downey & Geransar, 2008). Investors are individuals who invest in stem cell research with the intent on making a profit (Zucchi, 2015).

This study was significant because findings may encourage stem cell policymakers to focus attention and resources on creating a cohesive, bipartisan federal hESC funding policy to ensure that stem cell research succeeds in the United States. Having a unified federal hESC funding policy may lead to positive social change in the

health care field. Chapter 1 includes the background of the study, statement of the problem, purpose of the study, research questions, theoretical framework, nature of the study, definition of terms, assumptions, scope and delimitations, limitations, significance of the study, and a summary.

Background of the Study

In the late 1990s, breakthroughs in the cloning of mammals and the isolation of hESC lines resulted in science policy debates at the national and state levels (Levine, Lacy, & Hearn, 2013). Levine et al. (2013) indicated that these debates tend to focus on hope and controversy of these scientific breakthroughs. Levine et al. noted that most scientists believe that hESC research offers great promise in understanding human disease and developing treatments for conditions that are currently untreatable. Other researchers have noted that hESC research may provide advances in treatment of numerous diseases and may provide stem-cell-based therapies for a number of conditions such as strokes, spinal cord injuries, Alzheimer's disease, and Parkinson's disease (California Institute for Regenerative Medicine [CIRM], 2015b; Holland, Lebacqz, & Zoloth, 2001; Mason & Manzotti, 2010).

However, hESC research is controversial because it involves the use and destruction of early human embryos (Levine, 2011; Levine et al., 2013; Mintrom, 2013). Levine et al. (2013) reported that for hESC research to reach its highest potential, cloning technology may be needed to create embryos that are genetically matched to potential patients, which is also called therapeutic cloning. Levine et al. reported that although this

technique has been performed only in animals, it creates controversy because it is viewed as creating an opportunity for the cloning of humans for reproductive purposes.

Due to these scientific advances, President Clinton banned the use of federal funds for human cloning (Levine et al., 2013). With the successful isolation of hESCs in 1998, a legal review was conducted by the National Bioethics Advisory Committee (NBAC) in 1999, which indicated that the federal government could legally fund hESC research; however, funds could not be used for derivation of stem cell lines (Levine et al., 2013; Walter, 2001). Levine et al. (2013) reported that in 2000, the Clinton administration issued guidelines supporting research in the stem cell field, and the NIH invited scientists to apply for research funding. However, before the Clinton administration guidelines could be adopted and the first grant meeting could take place, President Bush was elected. Levine et al. noted that in 2001, President Bush restricted federal funds for hESC research on existing stem cell lines. In 2009, the Obama administration relaxed some of the Bush administration's restrictions on federal funding for hESC research, such as authorizing the use of federal funds on ethically derived hESC lines despite the date of derivation; however, the implementation of this policy has been hindered by legal challenges (Levine, 2011; Levine et al., 2013; Nature Cell Biology, 2010). For example, the Dickey-Wicker Amendment (the amendment) was the response of the Republican-controlled House and Senate to ethical concerns surrounding federal funding for research involving human embryos. Since 1996, the amendment has been attached to appropriations bills for the Department of Health and Human Services, Labor, and Education (Kearl, 2015). Therefore, uncertainty persists about the future of federal

funding for hESC research (Couch, Lane, & Black, 2012; Levine, 2011; Levine et al., 2013).

Due to the divisiveness of the hESC research debate, a cohesive or bipartisan federal ESC public financing policy is still uncertain (Levine, 2011; Levine et al., 2013; Mintrom, 2013; Sano, 2013). As a result, hESC researchers face continued policy fluctuations, legal challenges, and other hurdles to their future research (Levine, 2011; Levine et al., 2013; Mintrom, 2013; Sano, 2013). A review of literature indicated that there is a gap in stem cell research that focuses on U.S. stem cell researchers', stakeholders', and investors' perceptions regarding the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States; in this phenomenological study, I addressed that gap. This study was needed to encourage policymakers to focus attention and resources on creating a consistent federal hESC funding policy to ensure that stem cell research succeeds in the United States.

Statement of the Problem

On March 9, 2009, President Obama issued EO 13505, *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, which changed the way the NIH can support and conduct human stem cell research (NIH, 2011). The EO removed limitations on scientific inquiry and expanded the NIH support for the exploration of stem cell research, with the purpose of enhancing the contributions of U.S. scientists to make important discoveries and create new therapies for the benefit of humanity (Obama, 2009). However, despite President Obama's reversal of some of the barriers to hESC

research, questions remain about the extent to which U.S. stem cell researchers have benefited from this more relaxed federal funding policy (Nature Cell Biology, 2010; Wolinsky, 2009).

The problem is that despite the new federal stem cell policy, federal support and funding for hESC research in the United States are still behind stem cell programs in many countries, and the evolving federal policies have hindered research efforts (Nature Cell Biology, 2010). Nature Cell Biology (2010) reported that although federal funds can now be used for research on any hESC line that is found to meet the NIH's strict ethical policies, creating new hESC lines from viable embryos using federal funds is still not possible. Mintrom (2013) noted that hESC research is controversial because consideration has to be given to what counts as human life and who gets to make that decision. In addition, Nature Cell Biology related that an essential element of NIH approval is verifying that hESC lines were derived from donors who provided informed consent, and this has proven to be extremely time-consuming. As of July 2010, 64 hESC lines were eligible for use in research supported by U.S. federal funds. In contrast, 120 hESC lines are available in the United Kingdom (UK) Stem Cell Bank registry, and new hESC lines can be created in the UK, which are subject to licensing by the Human Fertilization and Embryology Authority. China, Japan, and some European countries such as Belgium and Sweden have similarly liberal policies regarding the creation of new hESC lines.

Although it is unavoidable that each state government will set restrictive policies for stem cell research within their borders (and several states have already done so), a

liberal policy at the federal level could soften the tone of the hESC debate and promote greater acceptance of such research within the United States (Nature Cell Biology, 2010). From a policy perspective, more remains to be done to ensure that stem cell research flourishes in the United States. A qualitative phenomenological study was needed to explore the perceptions of stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States.

Purpose of the Study

The purpose of this phenomenological study was to explore the perceptions of 21 stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. There are many different types of stem cells, each with different potential to treat disease (CIRM, 2013). The CIRM (2013) reported that adult stem cells come from any organ, are the source of new cells throughout the life of the organism, and are also called tissue stem cells. "The pluripotent cells, which have the ability to form all cells in the body, can be either embryonic or induced pluripotent stem (iPS) cells" (CIRM, 2013, para. 1).

Stem cell researchers, biotechnology companies, and laboratories are highly mobile actors who have the ability to relocate in response to liberal regulatory environments and public funding offers (Marzotto & Alt, 2012). According to Marzotto

and Alt (2012), commercial companies have created active research programs to develop stem cell technologies and therapies. Due to electoral politics and federal restrictions on publicly funded stem cell research, some states have provided their own legislation and significant public funding to promote stem cell research. However, controversies over hESC research continue, especially during tough economic times where there are concerns about losing jobs to other states or countries.

Research Questions

To explore the perceptions of 21 U.S. stem cell researchers, stakeholders, and investors about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States, I asked the following research questions:

1. What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States?
2. What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research?
3. What do U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States?

Theoretical Framework

Rogers's (1962) diffusion of innovation (DOI) theory and Kingdon's (1995) agenda-setting theory served as the theoretical framework for this study. A brief

overview of the theories is provided in this section with a more detailed explanation provided in Chapter 2. This section is organized in the following subsections: diffusion of innovation theory and Kingdon's agenda-setting theory.

Diffusion of Innovation Theory

DOI theory refers to the process of how and why innovation of new ideas and technology are communicated to a culture or social system as well as the rate at which they spread (Rogers, 2003). There are four main elements in the DOI theory: innovation, communication channels, time, and social systems (Rogers, 2003, Sahin, 2006). According to Rogers (2003), innovation refers to an idea, practice, or object that an individual perceives to be new. Communication channels refer to the ways in which messages travel from one person to another. Time refers to the innovation-decision period, which is the length of time that is needed to pass through the innovation-decision process. Time also refers to the rate of adoption, which is the speed an innovation is adopted by members of a social system. Social systems refer to a set of interrelated units that are engaged in joint problem solving to accomplish a common goal.

The innovation decision process consists of five stages of adoption: knowledge, persuasion, decision, implementation, and confirmation (Rogers, 2003). Sahin (2006) noted that in the knowledge stage, individuals learn about the existence of innovation and seek information about the innovation. In the persuasion stage, individuals have negative or positive attitudes toward the innovation; however, this does not always lead to an adoption or rejection of the innovation. In the decision stage, individuals choose to adopt or reject the innovation. In the implementation stage, the innovation is put into practice.

Finally, in the confirmation stage, the innovation decision has been made, but individuals seek support for their decision. Dresser (2010) indicated that the debate over stem cell research offers an opportunity to examine a variety of ethical and policy issues raised by biomedical innovation.

Kingdon's Agenda-Setting Theory

Kingdon's agenda-setting theory refers to how agenda setting affects the policy process in the planning stages and how it shapes the behavior of others (Kingdon, 1995). Kingdon (2003) argued that governmental agenda pertains to subjects that people in and around government are giving serious attention. Kingdon described the policymaking process around three streams and a policy window (Soroka, 1999). Soroka (1999) reported that the three streams or processes are problems, policies, and politics. Kingdon (1995) described the problem stream as the process of convincing policy decision-makers to overlook one problem for another. Chayabunjonglerd (2012) observed that for public officials to create policies, there must first be problems that they can address through policymaking. For example, with the successful isolation of hESCs in 1998, problems with hESC research arose. The policy stream represents the process by which policy proposals are created, discussed, revised, and adopted for serious consideration (Kingdon, 1995). Chayabunjonglerd noted that since 1998, many officials and interest groups have considered alternative policies on hESC issues. In 2001, these ideas were formulated into proposals, such as the Responsible Stem Cell Research Act of 2001. The open policy window provided the policy stream with different possible solutions.

In the politics stream, politics are political factors that influence agendas, such as changes in elected officials, political climate or mood (e.g., conservative, tax averse), and the voices of advocacy or opposition groups (Kingdon, 1995). Chayabunjonglerd (2012) reported that due to the opening of the policy window and the general public support of hESC research, intense political activity took place in Congress. Chayabunjonglerd noted that the majority of Democrats and moderate Republicans argued in support of hESC research. On the other hand, the majority of conservatives opposed hESC research. All three streams, plus the opening of the policy window, resulted in the issue of public funding for hESC being placed on the decision agenda. The possibility of change is at its greatest when all three streams come together (Soroka, 1999).

Nature of the Study

In this phenomenological study, I explored the perceptions of 21 stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. I chose a phenomenological design to explore participants' experiences to obtain rich descriptions of a reaction to an event or phenomenon (see Creswell & Miller, 2000). This design allowed me to understand and reveal multiple facets of the issue (see Creswell & Miller, 2000). A phenomenological design provides an understanding of a phenomenon by revealing the meaning that underpins participants' perceptions (Moustakas, 1994; Waters, 2016; Waugh & Waugh, 2004).

Data were collected for this study through in-depth telephonic semistructured interviews with 21 stem cell researchers, stakeholders, and investors in the United States. The relationship between saturation and sample size was sufficient in this study because through the use of snowball sampling, I recruited 21 participants to obtain the richest data possible. Individual telephonic interviews were conducted at a time that was convenient for each participant. Using snowball sampling, which is a subset of purposive sampling, I recruited seven stem cell researchers, seven stem cell stakeholders, and seven stem cell investors to participate in the study. I contacted potential participants by e-mail or telephone. Selection criteria included men or women who were researchers at a government organization, private company, or university; faculty members at a univeristy where stem cell research was being conducted; or investors who worked for a government organization or private company that invests in stem cell research in the United States. Prospective participants were sent an invitation letter to participate in the study and were asked to recommend other stem cell researchers, stakeholders, or investors who met the selection criteria (see Appendix A). I transcribed the interviews, managed the data with NVivo, and analyzed the data using Attride-Stirling's (2001) six steps of thematic coding. The study was conducted in accordance with Walden University's Institutional Review Board (IRB) guidelines to ensure the ethical protection of research participants. The nature of the study is discussed in further detail in Chapter 3.

Definition of Terms

Adopters: Individuals who adopt an innovation (Rogers, 2003).

Adult stem cells: Found in the various tissues and organs of the human body and thought to exist in most organs where they are the source of new cells throughout the life of the organism (CIRM, 2015a). They replace cells lost to natural turnover or to damage or disease (CIRM, 2015a).

Bioethics: "Bioethics is the application of ethics to the field of medicine and healthcare" (Center for Practical Bioethics, 2015, para. 1).

Diffusion: "The process in which an innovation is communicated through certain channels over time among the members of a social system" (Rogers, 2003, p. 5).

Diffusion of innovation (DOI) theory: The process of how and why innovation of new ideas and technology are communicated to a culture or social system as well as the rate in which they spread (Rogers, 2003).

Embryonic stem cells (ESCs): Come from pluripotent cells, which exist only at the earliest stages of embryonic development and in humans, do not exist after about 5 days of development (CIRM, 2015a). When isolated from the embryo and grown in a lab dish, pluripotent cells can continue dividing indefinitely.

Groupthink: Groupthink occurs when a homogenous highly cohesive group is so concerned with maintaining unanimity that they fail to evaluate their alternatives and options (Janis, 1972).

Innovation: An idea, practice, or object that a person perceives as new (Rogers, 2003).

Investors: In this study, individuals who invest in stem cell research with the intent on making a profit (Zucchi, 2015).

In vitro: Embryos that have developed from eggs that have been fertilized outside of the body (Small & Doherty, 2011).

Kingdon's agenda-setting theory: How agenda setting affects the policy process in the planning stages and how it shapes the behavior of others (Kingdon, 1995).

Pluripotent cells: Pluripotent means many potentials, and "these cells have the potential of taking on many fates in the body, including all of the more than 200 different cell types" (CIRM, 2015a, para. 3). ESCs and induced pluripotent stem (iPS) cells (reprogrammed from adult tissues) are pluripotent cells (CIRM, 2005).

Stakeholders: In this study, "individuals whose collective actions are guided by or directly serve the mandate of an overarching organizational framework" (Downey & Geransar, 2008, p. 70). Stakeholders play a major role in the stem cell debate as well as in stem cell research and policy development, such as patient groups in alignment with the medical community (Downey & Geransar, 2008).

Stem cell researchers: Scientists who study the biological properties of stem cells and the potential use and effect of stem cells in treating diseases (NIH, 2009).

Stem cells: "Have the ability to divide and create an identical copy of themselves, a process called self-renewal" (CIRM, 2015a, para. 2). In addition, stem cells "can also divide to form cells that mature into cells that make up every type of tissue and organ in the body" (CIRM, 2015a, para. 2).

Assumptions

Assumptions made for this study were as follows:

- Stem cell researchers, stakeholders, and investors had experience with the stem cell research process.
- Stem cell researchers, stakeholders, and investors would be willing to take part in the study because of its significance to focus attention and resources on creating a consistent federal hESC funding policy to ensure that stem cell research succeeds in the United States.
- The in-depth telephonic semistructured interviews would be appropriate to explore U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States.
- The in-depth semistructured interview questions were worded so that the participants could understand the questions being asked.
- The participants would honestly and openly answer the interview questions by sharing their perceptions about the questions asked.
- The results of the study would lead to positive social change as findings are directed at stem cell policymakers to focus attention and resources on creating a consistent federal hESC funding policy to ensure that stem cell research succeeds in the United States.

Scope and Delimitations

The study's participants included 21 stem cell researchers, stakeholders, and investors in the United States. I focused on participants' perceptions about the effects of

the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. I excluded stem cell researchers, stakeholders, and investors from other countries. I did not include anyone with whom I had a personal relationship, which included family members, friends, coworkers, or professional and personal associates. This prevented perceived coercion to participate due to any existing or expected relationship between the participants and me. However, I asked personal and personal associates if they knew individuals who fit the study criteria to get snowball sampling going.

Limitations

There were several limitations in this study. First, findings were limited by the snowball sample of seven stem cell researchers, seven stem cell stakeholders, and seven stem cell investors; each category of participants contained a smaller number than the overall sample of 21. Due to the small sample size for each category of participant, caution has to be taken in transferring the findings to similar populations of U.S. stem cell researchers, stakeholders, and investors. In addition, the results of the study may not be transferrable to other populations or countries. As a result, in future research, the sample population for each type of participant could be increased to achieve a broader understanding of their stem cell research policy experiences. In future studies, a different sampling strategy could also be used, such as random sampling.

Second, social desirability bias was considered as stem cell researchers, stakeholders, and investors may have wanted to be perceived positively, so they may not

have responded honestly to the interview questions. However, I assumed that participants would honestly and openly answer the interview questions by sharing their perceptions about the phenomenon. Third, there were limitations with self-reported data as participants may not have accurately or fully evaluated themselves. However, I assumed that participants accurately and fully self-evaluated.

Significance of the Study

Policy entrepreneurs, who are political figures who seek policy changes to existing areas of public policy, have faced significant opposition to government funding and favorable regulations to advance hESC research due to morality issues (Mintrom, 2013). The most restrictive stem cell laws are in countries where Roman Catholicism is the dominant religion or Christian democratic parties are on the rise (Fink, 2008; Mintrom, 2013). Mintrom (2013) reported that the UK has a permissive approach to hESC research regulation and that it is correlated with the low percentage of adults who identify with the Roman Catholic faith (9%) in the UK. Mintrom noted that in the UK, moral issues have been widely investigated and extensively debated; however, they have not inhibited scientific research.

Unlike in the UK and other permissive countries, hESC research in the United States is divisive and controversial, which has resulted in stem cell policy uncertainty (Levine, 2011; Levine et al., 2013; Mintrom, 2013). In 2010, 24% of Americans identified with the Roman Catholic faith (Pew Research Center, 2013, para. 11). There is no consistent federal hESC funding policy, which impedes the United States from being a leading country in the advancement of hESC research (Mintrom, 2013; Sano, 2013). U.S.

hESC researchers continue to face policy fluctuations, legal challenges, and other hurdles to their research (Levine, 2011; Levine et al., 2013; Mintrom, 2013; Sano, 2013). There is a gap in stem cell research regarding U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. In this study, I addressed this gap by making an original contribution to the public policy and administration literature on this topic. Individuals working in public policy and administration, including the fields of biology and regenerative medicine and agencies such as the CIRM and the NIH, may be interested in the findings.

Findings may encourage policymakers to focus attention and resources on creating a cohesive federal hESC funding policy to ensure that stem cell research succeeds in the United States. Implementation of a bipartisan federal hESC funding policy may lead to positive social change in the health care field as hESCs can be used for cell-based therapies to replace ailing or destroyed tissues resulting from macular degeneration, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis (NIH, 2015b). In addition, hESCs can be used to treat Alzheimer's and Parkinson's disease; however, the need for transplantable tissues and organs far outweighs the available supply (CIRM, 2015b; NIH, 2015b).

Summary

I explored seven U.S. stem cell researchers', seven U.S. stakeholders', and seven U.S. investors' perceptions about the effects of the current federal stem cell policy on

stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. Data were collected using in-depth telephonic semistructured interviews. Using snowball sampling, I recruited 21 participants for the study. Findings may encourage stem cell policymakers to focus attention and resources on creating a more unified federal hESC funding policy to ensure that stem cell research succeeds in the United States. A cohesive federal hESC funding policy may lead to positive social change in the health care field by creating cell-based therapies to replace ailing or destroyed tissues.

In Chapter 1, I included the introduction, background of the study, statement of the problem, purpose of the study, research questions, theoretical framework, nature of the study, definitions of terms, assumptions, scope and delimitations, limitations, significance of the study, and a summary. In Chapter 2, I include the introduction, literature search strategy, theoretical foundation, Dickey-Wicker Amendment, United States national policies, international communities' stem cell policies, bioethics and the moral debate, embryonic stem cell research, and a summary and conclusions. In Chapter 3, I include the research design and rationale, role of the researcher, methodology, issues of trustworthiness, and a summary. In Chapter 4, I include the introduction, setting, demographics, data collection, data analysis, evidence of trustworthiness, results, and a summary. In Chapter 5, I include the introduction, interpretation of findings, limitations of the study, recommendations, implications, and a conclusion.

Chapter 2: Literature Review

In Chapter 2, I provide a review of relevant and current scholarly resources related to my study on the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. The literature review includes the introduction, literature search strategy, theoretical foundation, Dickey-Wicker Amendment, U.S. policies, international communities' policies, bioethics and morality debate, embryonic stem cell research, and a summary and conclusions. According to Rogers (2003), innovation is adopted through a five-step process (i.e. relative change, compatibility, complexity, trialability, and observability). The problem is with constant change from one administration to the next, too much change hinders policy growth and development.

Literature Search Strategy

I searched all Walden University library databases including ProQuest and EBSCOhost databases such as Academic Search Complete, Health and Medical Complete, LexisNexis Academic, and PubMed. In addition, I searched Gwinnett County Public Library databases. Search terms included *public policy and human embryonic stem cell*, *public policy funding for stem cells*, *historical innovation on stem cells*, *U.S. policy on stem cell development*, *Obama policy on stem cells*, *Bush policy on stem cell research*, and *legislative policies or statutes on stem cells*. I examined additional articles after reviewing the reference section from each article and dissertation. Furthermore, I

examined relevant organizational websites such as the NIH and placed emphasis on the most recent literature.

Theoretical Foundation

Rogers's (1962) DOI theory and Kingdon's (1995) agenda-setting theory served as the theoretical foundation of this phenomenological study. This section is organized in the following subsections: diffusion of innovation theory and Kingdon's agenda-setting theory.

Diffusion of Innovation Theory

Rogers's (1962) DOI theory is used to explain how an idea or product gains momentum and diffuses through a specific population or social system. According to Rogers (1995), the goal of diffusion is for people who are part of a social system to adopt a new idea, behavior, or product as new or innovative. Rogers reported that the DOI theory addresses how policy and agendas are set, how policy moves through the political process, and the effect of policy once it is created. The purpose of diffusion is to create a dialogue with those who are against change.

What is learned from previous innovations results in more advanced innovations being created and adopted (Rogers, 1995). Rogers (1995) related that the success of an innovation determines the rate of adoption for a similar innovation. Rogers noted that groupthink tends to limit the spread of innovation. Leaders of a group exert influence over the behaviors and beliefs of individuals and adopters in their networks (Anderson, 2006; Janis, 1989; Rogers, 1983). Limiting the spread of innovation also slows down

growth (Amidon, 2005). According to Amidon (2005), individuals in political or social settings tend to accept groupthink as a form of solidarity and unanimity.

Groupthink, diffusion, innovation, and adopter are important terms in DOI theory. Groupthink was first introduced by Janis in 1972 to explain why groups sometimes make poor decisions. According to Kretchmar (2009), groupthink comes from the application of those who were part of a political advisory group to four U.S. presidents. Groupthink is often used when one cannot explain a phenomenon, and is often seen in consensus seeking and when evidence is not readily available. Diffusion is the means of how information is shared among a group of people in a network. Diffusion may impede a new product, idea, or practice from being accepted by others of a particular culture or network (Rogers, 1995). Rogers (1995) noted that innovation is a new product or service being introduced to potential adopters. Adopters are those who are affected by the new product, and adopters' behavior may be influenced by the opinion of a leader.

Diffusion of innovation is connected to an individual's perception of a new product or service, while invention is new (Therin, 2012). Therin (2012) noted that with the perception of newness, there must be knowledge about the service or product; otherwise, that perception is not relevant. In addition, any new innovation must be known among the targeted population of potential adopters, and a clear perception should be established. Once the knowledge about the product and service has been conveyed, there should be a theoretical framework in place to rate the adoption of the new innovation. According to Rogers (2003), there are five factors that influence the adoption of innovation probability rate: (a) relative advantage, (b) compatibility, (c) complexity, (d)

trialability, and (e) observability. These factors can be seen in Figure 1 under the persuasion stage, which is one of the five innovation-decision processes: (a) knowledge, (b) persuasion, (c) decision, (d) implementation, and (e) confirmation.

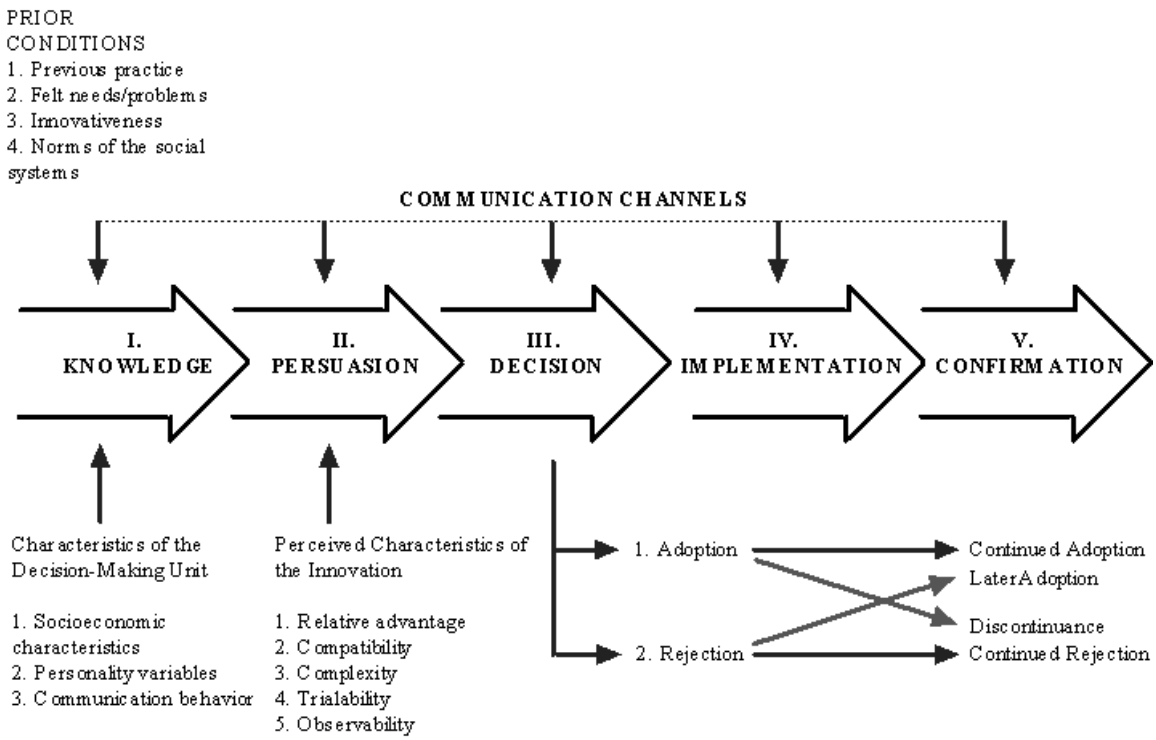

Figure 1. Five stages of Rogers's (2003) innovation-decision process model. Reprinted from *Diffusion of innovations* (5th ed.), by E. Rogers, 2003: New York, NY: The Free Press. Copyright 2003 by the Free Press. This source was taken from Creative Commons 3.0.

Relative advantage is defined as the degree to which an innovation is perceived as better than available products or services (Therin, 2012). Therin (2012) reported that this can be measured in terms of quality, satisfaction, or social status. Compatibility is determined by the acceptability of social or religious norms in the country, which may forbid certain practices, attitudes, or behaviors. Complexity pertains to the perception of

the difficulty of understanding, implementing, integrating, and using an innovation. Trialability is the possibility of experimenting with an innovation before adopting it. Observability is the degree to which the results of the implementation of an innovation are visible. If potential adopters can witness what happens after an innovation is implemented, they will be reassured about other factors and potential concerns about health and safety.

The persuasion stage occurs when individuals interested in the innovation actively seek information about the innovation (Rogers, 2003). The other four innovation-decision process stages include knowledge, decision, implementation, and confirmation. According to Rogers (2003), in the knowledge stage individuals are first exposed to an innovation, but they do not have information about it. In the decision stage, individuals consider the advantages and disadvantages of using the innovation and make decisions about whether to use or reject it. In the implementation stage, individuals use the innovation at different degrees depending on the situation. In the confirmation stage, individuals make final decisions about whether to continue to use the innovation.

According to Rogers (1995), there are six steps in the innovation-development process:

1. Recognizing a problem or need: Research and development activities are started to address a problem or need, and scientists seek to produce research to find a solution to an issue.
2. Basic and applied research: Research is conducted to determine whether there is a need for more in-depth investigation. Basic research leads to applied

research, which provides a more scientific process to help eradicate practical problems. If this does not work, a new technology is designed to address the problem.

3. Development: The development process involves new ideas designed to meet the needs of a particular audience. During the development phase, there is a high rate of uncertainty about the innovation while trying to meet the needs of its adopters. With regard to policy, regulation, and competitor's perspective, the system of information exchange about technological innovation is a pervasive issue that can have an unwavering effect on the outcome. A new industry may be developed around a radical innovation.
4. Commercialization: The product is ready for manufacturing, marketing, packaging, and distribution. The end product at the time of commercialization may include two or more innovations to facilitate a more widely acceptable product to potential adopters.
5. Diffusion and adoption: This is the most difficult step in the innovation-development process, which involves diffusing the product to potential adopters. As with all new products, there is pressure to move it to market due to the problem and need being high priority. Sometimes public funds are used until there is a positive outcome that will be beneficial to potential adopters. The move to market is when scientists seem to have the greatest concern around innovation, which includes unveiling the product and putting it into practice.

6. Consequences: In this stage, the innovation addressed or did not address the original need or problem.

Hematology inventions spread rapidly, and factors that affect the introduction, international diffusion, and durability of innovation use are not well understood (Gratwohl et al., 2010). Gratwohl et al. (2010) used the DOI theory as the theoretical foundation in their study. The researchers used 251,106 hematopoietic stem cell transplants from 591 teams in 36 European countries. Gratwohl et al. analyzed the increase and decrease in such transplants for breast cancer and chronic myeloid leukemia and the replacement of bone marrow by peripheral blood as the source of stem cells as processes of diffusion. The results indicated that gross national income per capita, World Bank category, team density, team distribution, team size, team experience, and team innovator status were all significantly associated with some or all of the changes. The researchers concluded that adoption of any new medical technology and its diffusion correlate with four main elements: economics, evidence, external regulations, and expectations. These four factors may form the basis for any process of diffusion.

In the debate over ESC research, ethical and policy issues should be considered (Dresser, 2010). Dresser (2010) suggested that many of the ethical and policy issues that stem cell research presents apply to biomedical research in general, such as questions about appropriate research priorities and allocation of limited resources for research and health care. Dresser argued that the debate over stem cell research offers an opportunity to examine a variety of ethical and policy issues raised by biomedical innovation. Ethical considerations sometimes justify setting limits on scientific innovation (Dresser 2010).

Dresser noted that some individuals believe that there should be severe limits on research involving early human embryos, while others disagree. Dresser claimed that these disagreements cannot be settled by science because they are value conflicts. In struggling with these conflicts, Dresser suggested that individuals should maintain respect for those holding differing views and should look for policies that are consistent with as many of those views as possible.

Kingdon's Agenda-Setting Theory

Kingdon's agenda-setting theory pertains to how agenda setting affects the policy process in the planning stages and how it shapes the behavior of others (Kingdon, 1995). According to Kingdon (1995), setting an agenda is the main step in the policy process. At this stage, the policy agenda is set up with a list of issues or problems that need to be reviewed by various government officials before their session for the year has ended. As the agenda is set and reviewed, a government official may decide to make changes to the order in which it is reviewed based on the priority assigned.

Kingdon (1995) described the policymaking process around three streams and a policy window. The three streams or processes are problems, policies, and politics (Kingdon, 1995). Kingdon described the three streams as follows:

1. Problems: The process of convincing policymakers to overlook one problem for another. A particular policy proposal's chance of rising on the agenda is much greater if the associated problem is perceived as serious. Problem recognition can be influenced by how problems are described through data, indicators, crisis events like a disaster, and

constituent feedback. Budget crises are a special consideration in problem recognition as they often override other problems.

2. Policies or proposals: This stream represents the process by which policy proposals are created, discussed, revised, and adopted for serious consideration. Proposals can be attached to the same problem, and getting a proposal on the short list typically takes time and the willingness to pursue it by using many tactics. Proposals tend to be more successful if they are seen as technically feasible, compatible with decision-maker values, reasonable in cost, and appealing to the public.
3. Politics: In this stream, politics are political factors that influence agendas, such as changes in elected officials, political climate or mood (e.g., conservative, tax averse), and the voices of advocacy or opposition groups.

When all three streams come together, policy initiation or change is at its greatest (Soroka, 1999). Kingdon (1995) noted that the three streams operate parallel in a policy area until one or more of the streams meet in a window of opportunity that represents a possibility that policy may develop or change. Similarly, Soroka (1999) related that the combination of streams can result in a policy window due to changes in the problem or political streams. Windows can predictably or unpredictably appear due to events such as election results or a sudden crisis, respectively (Kingdon, 1995).

In the United States, the stem cell controversy opens a window to a larger moral problem (Dresser, 2010). According to Dresser (2010), the social justice inquiry about what justifies the United States substantial investment in biomedical innovation, when millions of people in the United States and abroad are denied access to proven medical interventions, raises questions about the priority that stem cell and other basic science studies should have in the competition for limited resources. Dresser argued that if government officials and health advocates want to help patients, meaningful help would also come from a system that supplied adequate health care to more people, both across the nation and worldwide.

In regard to Kingdon's (1995) three streams (problems, policies, and politics), problems with hESC began with the 1998 discovery, which introduced new possibilities (Chayabunjonglerd, 2012). Chayabunjonglerd (2012) reported that scientists sought to gain more funding through governmental sponsorship and argued that the Dickey-Wicker Amendment that banned the use of human embryos in federally funded projects hindered significant advances in health care. The author noted that the issue of federal funding of hESC research raised the important question of whether the government should and can fund hESC research. Chayabunjonglerd (2012) claimed that President Bush's inauguration represented significant change in the political stream, which opened a policy window for him to push forward his solution on hESC research. This resulted in the policy stream, where President Bush issued a Presidential Statement in 2001 that limited federal funding of research involving hESCs (Chayabunjonglerd, 2012; Obama, 2009).

Kingdon's agenda-setting theory served as the theoretical foundation in Fukushima's (2013) study of chemical biology as part of postgenomic research agenda. Specifically, Fukushima analyzed how three different levels, laboratory practices, community of scientists, and policy processes, are mutually important. In addition, Fukushima analyzed Japanese scientists' and policy makers' belief that chemical biology is important in science and policy. Findings indicated that the three levels have developed in parallel by joining different theoretical traditions. In addition, different elements beyond the laboratory and policy process facilitated or accelerated these developments: the character of policy entrepreneurs, the international environment, and the cultural mood, which promoted parallel developments.

Dickey-Wicker Amendment

The amendment, authored by Representative Jay Dickey of Arkansas and Roger Wicker of Mississippi, was created as a response to the 1994 recommendations of the NIH Embryo Research Panel (the Panel; Kearl, 2015). According to Kearl (2015), the Panel consisted of ethicists, public policy analysts, and patient advocates who evaluated when and under what circumstances human embryo research should be federally funded. They also assessed what moral and ethical controversies would be raised by this research and compiled their findings in a report on September 27, 1994, titled, *Report of the Human Embryo Research Panel*. The Panel recommended that research on unused gametes and embryos from fertility procedures like IVF should be allowed with the informed consent of the donor. The Panel also approved the creation of embryos for

research purposes; however, President Clinton immediately rejected this part of the proposal.

Since 1996, the amendment has been attached to appropriations bills for the Department of Health and Human Services, Labor, and Education (Kearl, 2015). Kearl (2015) reported that the amendment was the response of the Republican-controlled House and Senate to ethical concerns surrounding federal funding for any research involving human embryos. Kearl related that this amendment restricts the use of federal funds for creating, destroying, or knowingly injuring human embryos. However, the amendment only prohibited federal funding for experimentation using human embryos. Thomson, researcher from the University of Wisconsin, created the first human stem cell line using private funds in 1998. As a result of Thomson's discovery, Rabb, a lawyer at the Department of Health and Human Services, argued that experimentation with the lines derived using private funds could receive federal funding. Rabb's legal interpretation was endorsed by the Clinton administration and revised guidelines were created in August 2000 for when federal funds could be provided to researchers. However, in 2001, President Bush withdrew the Clinton administration's guidelines. On March 9, 2009, President Obama EO 13505, *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, lifted restrictions to federally funded stem cell research. Kearl noted that the amendment was renewed on March 11, 2009 in the 2009 Omnibus Appropriations Act, Pub. L. 188-8, and remains the only legal obstacle to the federal funding of experimentation on human embryos.

United States National Policies

This section discusses the United States' stem cell policies. It is organized in the following subsections: United States' stem cell policy and adoption of new policy guidelines.

United States' Stem Cell Policy

In this subsection, the U.S. stem cell policy will be discussed in further detail. According to Keiper and Levin (2010), in 1999, the Clinton administration's Department of Health General Counsel noted its support to fund stem cell research with hESCs that were discarded, destroyed, injured, or at risk. However, the funds could not be used to destroy the embryos. The authors noted that the Clinton administration may have sent the wrong message to scientists by allowing them to destroy embryos with private funding and then use federal funds to conduct further research. However, President Clinton's policy did not take effect because his second term ended before funds were released.

In 2001, the Bush administration decreased the number of hESC lines that could be funded by the federal government (Keiper & Levin, 2010). Keiper and Levin (2010) noted that further constraints were placed on stem cell development in the United States. Researchers were given permission to work on approximately 60 to 78 hESC lines. President Obama overturned President Bush's policy on ESC research. He instructed the NIH to create guidelines that would allow researchers to receive federal funding while working on stem cell lines that were created from extra embryos frozen in IVF clinics, with parents' permission.

The continuous changes in the policy by each President have been a source of great concern for representatives of states such as California, who support hESC research (Adelson & Weinberg, 2010). Adelson and Weinberg (2010) related that in some states, additional revenue was added to the budget to further stem cell research programs. For example, in 2004, after President Bush's policy denied the use of federal funds to further research, California officials created the California Research Cures Initiatives to continue with their research after law was passed to stop federal funding to support stem cell research and to ban those who continued their study on stem cells from using laboratories and facilities that were supported by federal funds. California went on to create the CIRM to provide oversight and created funding for all research in their state. The CIRM agreed to contribute $3 billion over a decade and create another $3 billion through the sale of public bonds and the state general fund to aid in the study of stem cells.

Adoption of New Policy Guidelines

Policy uncertainty affects researchers' plans more significantly than temporary funding bans (Levine, 2011). In 2009, President Obama reversed previous decisions of his predecessor to move forward with a more vigorous program to increase stem cell research (Wolinsky, 2009). According to Wolinsky (2009), the policy put in place by the previous president has been removed, but researchers that are involved in stem cell research taken from human embryos are still fighting red tape and are not able to gain access to federal funds for ESC research.

New guidelines for research initiatives were introduced in 2009; 9 weeks after President Obama took office (Wolinsky, 2009). Wolinksky (2009) related that President

Obama asked Congress to develop new legislation that would coincide with the new bill to support the use of federal funding since public support had increased and had been unprecedented in recent years. Wadman (2009) reported that while President Obama changed the ESC funding policies of his predecessors, U.S. Representatives Diana Degette of Colorado and Mike Castle of Delaware, urged Congress to support and fund stem cell lines, where parental permission was given for the use of embryos leftover at infertility clinics. Levine (2011) noted that a legal challenge, which claimed that Obama's policy violated the Dickey-Wicker Amendment, was filed following the Obama administration's stem cell policy and this resulted in uncertainty in the field. U.S. District Court Judge Royce Lamberth granted a preliminary injunction, which prevented the implementation of the Obama administration's policy. However, the Obama administration appealed and on April 29, 2011, the U.S. Court of Appeal for the District of Columbia allowed the NIH to resume funding hESC research while the case proceeded. On July 27, 2011, Federal District Court Judge Lamberth dismissed the plaintiff's suit, which was in line with decision of the U.S. Court of Appeal panel (Association of American Medical Colleges [AAMC], 2015a).

There is renewed interest in stem cell research to treat numerous diseases, but U.S. regulations and restrictions have had a negative effect on ESC research efforts (Cyranoski, 2013). Cyranoski (2013) related that stem cell researchers are frustrated with the policy surrounding stem cells as it places universities at risk because they struggle to locate funding from private sources. Kington (2011) related that researchers were concerned about NIH published draft guidelines for research involving hESCs that gave

proponents of stem cell research an opportunity to become beneficiaries of hESC funding due to an existing patent. Therefore, this would result in insufficient funding for research under the established guidelines that offered financial gains to donors, where policies were not directly established. Biomedical scientists are struggling to continue their research as funds are limited and organizations have considered merging to hold on to the research that they have completed.

International Communities' Stem Cell Policies

Differences in national regulatory approaches have generated competition to implement stem cell programs that will give countries an edge in the global knowledge economy (Gottweis, Salter, & Waldby, 2009). Countries such as China, India, South Korea, and Singapore have been identified as emerging biotech powers (Wahlberg, 2012). This section briefly examines stem cell policies in China, Singapore, UK, Australia, India, and Canada, who are all members of the International Stem Cell Forum (ISCF, 2016). The ISCF was founded in January 2003 to encourage international collaboration and funding support for stem cell research, with the overall aim of promoting global good practice and accelerating progress in this area of biomedical science (ISCF, 2016).

China's Stem Cell Policy

Biotechnologies such as stem cell science, genetic testing, and reproductive medicine are being examined by scholars (Wahlberg, 2012). The author noted that China has moved in an aggressive manner to become a super power in biotechnology. In a 2009 workshop, the leader of the Chinese biomedical program displayed in bold print a map

that aggressively moves toward being recognized as a major party in the exploration of ESC research. China policy on ESC research is permissive, which has allowed them to be competitive by building an infrastructure that attracts scientist from various countries (Lysaght & Capps, 2012). State-led investment programs have lured young researchers from Europe and the United States to China (Wahlberg, 2012). In addition, Wahlberg (2012) claimed that political mobilization around biotechnology as a source of economic growth, aspiration in the global race to be the first, and biosecurity risk anxieties, have all been highlighted as facilitators of Asia's rising science and technology strength.

Singapore's Stem Cell Policy

Singapore is another Asian country that has adopted research-friendly stem cell policies to secure a competitive edge in the global marketplace (Lysaght & Capps, 2012). Lysaght and Capps (2012) noted that Singapore's approach has attracted scientists from other countries and has resulted in the development of local industries in stem cell science. Singapore's approach included the establishment of a national funding body called the Agency of Science, Technology, and Research, and strategic plans to compete in the global bioeconomy. The strategic plans include provision of taxation incentives and venture capital schemes to encourage public and private partnerships as well as the creation of highly educated workers through the use of university scholarships and graduate placements under international renowned scientists. Other important strategies included technological infrastructure and the development of science parks and the creation of national ethical boards.

United Kingdom's Stem Cell Policy

The UK has in place a comprehensive regulatory framework for stem cell research (Small & Doherty, 2011). According to Small and Doherty (2011), the Human Fertilization and Embryology Authority is responsible for granting licenses for stem cell research. Research can only take place on embryos created in vitro; thus, embryos that have developed from eggs that have been fertilized outside of the body. The majority of embryos used in the UK for stem cell research is obtained from embryos that were originally created for fertility treatment, but were not used. The surplus IVF embryos have to be donated with parental consent for use in stem cell research. The UK made hESC research a priority and set aside $556 million for stem cell research (Nature Cell Biology, 2010). Gough (2013) related that hESC approval in the UK is based on the needs of the people and the policy is transparent and supported by evidence that demonstrates a level of critical appraisal and willingness to review and amend in light of progress.

Australia's Stem Cell Policy

Stem cell research conducted by Australian scientists adds knowledge to the field of human stem cells and the application of stem cell technologies (Australia Law Reform Commission, 2015). The Australian Law Reform Commission (2015) reported that publicly funded organizations and companies are involved in adult and ESC research in Australia. Waldby and Carrol (2012) related that human embryos and oocytes or eggs have become the focus of intense scientific research. Both are key tissues in regenerative medicine with the aim to treat degenerative conditions through in vivo tissue growth

instead of organ transplant. The researchers noted that "oocytes are essential elements in a type of stem cell research termed somatic cell nuclear transfer (SCNT), sometimes called therapeutic cloning" (Waldby & Carol, 2012, p. 513). Australia has a permissive legislation in place for SCNT, but has a conservative approach to research donation regulation. Australia's Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 legislation allows the practice of SCNT. However, unlike the UK, Australia's legislation does not allow for the use of animal oocytes for experimental purposes. In addition, in contrast to the United States, Australia's legislation also does not permit the development of a reproductive oocyte market. In Australia, strict regulated gifting is used to transfer oocytes from donor to recipient.

India's Stem Cell Policy

India has introduced policies that are designed to improve their global competitive position in the stem cell research field (Mittal, 2013). Mittal (2013) reported that India has ethical guidelines for biomedical research that was published by the Indian Council for Medical Research (ICMR); however, limited boundaries for hESC research is used. India's IVF clinics are noted to be an established source of embryos for research and foreign scientists visit these clinics for supplies. Due to negative publicity, India's government announced that they would take steps to counter the international view of India as "an embryo surplus nation" (Mittal, 2013, p. 106). However, due to a lack of legal backing for the ICMR ethical guidelines for biomedical research, India's stem cell scientists make their own decisions. Mudur (2005) found that in the absence of any

powers of enforcement, only 40 of India's 179 institutional ethics committees followed the principles noted in the document.

Canada's Stem Cell Policy

Canada did not have any laws, guidelines, research ethics boards, or funding agencies to govern stem cell research until March 2002 (Canadian Institutes of Health Research [CIHR], 2014). The CIRC (2014) reported that this urgent need was recognized and they announced guidelines for stem cell research in March 2002. The federal granting agencies, the CIHR, the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC) adopted the measures and agreed that no stem cell research would be funded without the prior review and approval of the Stem Cell Oversight Committee (SCOC), which conforms the CIHR guidelines. Canada's federal government also worked on legislation on assisted human reproduction, which included the use of human embryos for research. In March 2004, the Act called, *Respecting Assisted Human Reproduction and Related Research*, became law. The Act pertains to the derivation of stem cells from human embryos. With the guidelines in place, Canadian researchers have moved forward and remained at the forefront of their field while conducting their research according to explicit ethical standards.

Bioethics and the Moral Debate

The ethical and moral disagreement on hESC research and the destruction of embryos continues between religion and science (Doerflinger, 2010). Stem cell research remains highly controversial as there are still unresolved questions about human cloning, therapeutic abortions, and reproductive rights (Adelson & Weinberg, 2010). Lysaght and

Campbell (2012) reported that there are still concerns over the last decade that has generated political and public bioethical issues. Fadel (2012) discussed the issue of ethics in stem cell research and noted that it remains a lengthy and heated debate in the scientific literature, religious circles, and the political arena. The author noted that the debate includes the need to protect human life from the time of inception versus curing many debilitating diseases.

There are 220 original hESCs (Fadel, 2012). Aznar and Navarro-Illana (2014) related that much of the controversy surrounding stem cells focus on pluripotent, ESCs, which are destroyed at 5 to 6 days old. According to Mintrom (2013), the question of what constitutes independent life is at the center of the debate about the use of hESCs in research and research-based therapies. Thus, there are questions about whether life begins at conception when the human egg is fertilized or at some later stage of development. In addition, the researcher noted that there are questions about the point in development of the embryo or fetus when human rights and other legal protections should be assigned. Thus, hESC research is controversial as consideration must be given to what counts as human life and who makes that decision.

Some religious groups, such as representatives of the Roman Catholic Church and other Christian traditions, have argued that human life begins at conception; therefore, the embryo or fetus should be given the full respect and rights as a human being (Mintrom, 2013). Therefore, destruction of the embryo is immoral (Mintrom, 2013). Fink (2008) found that the most restrictive stem cell laws are in countries where Roman Catholicism is a dominant religion or Christian democratic parties have been on the rise. On the other

hand, Mintron (2013) reported that those who support hESC research have argued that eggs are often fertilized but they do not implant in the uterus. Even though a fertilized egg has the potential for human life, proponents argue that it cannot be considered equal to a human being until it has been successfully implanted in a woman's uterus. Furthermore, some supporters also consider hESC research justifiable for the advancement of scientific knowledge.

There is also the possibility that there might be an extensive growth in markets that trade human eggs (Mintrom, 2013). As a result, Mintrom (2013) noted that women may be incentivized to produce and sell eggs that would then be fertilized to create embryos for the purpose of destroying them at the blastocyst stage (5 to 7 days after fertilization) in order to harvest the stem cells. Withrow (2007) pointed out that trading of human eggs is a common response to the demands of infertile couples who want to gain access to donor eggs to make a baby. In treating infertility, Mintrom (2013) reported that more eggs are produced than are used to create viable embryos. Thus, surplus of eggs are stored, discarded, or donated to research. As a result, those in support of hESC research have argued that it is morally permissible to use surplus embryos for biomedical research that may save many lives. However, those who oppose hESC research do not agree with this argument and have argued that such research would still support the destruction of embryos. Levine (2011) related that due to the divisiveness of the hESC research debate and the history of policymaking in other morally charged areas, policy certainty will continue to prove difficult. Hence, some degree of uncertainty may be unavoidable and as

a result, hESC researchers should prepare for continued policy changes, legal challenges, and other challenges to their research.

Embryonic Stem Cell Research

This section discusses effective procedures that should be used when conducting biomedical research, ESCs in relation to regenerative medicine, and possible ways to improve stem cell research policy in the United States. It is organized in the following subsections: improvements in biomedical research, embryonic stem cell and regenerative medicine, and improving stem cell research in the United States.

Improvements in Biomedical Research

To develop future innovations in health care and prevention, research is needed across a wide range of biomedical science (AAMC, 2015b). The AAMC (2015b) related that this includes basic and translational research, which would be used to implement science and comparative effectiveness research. Maintaining a valid and sound foundation for credible research with an enriched mission statement is needed to provide long-term healthcare outcomes, maintain a patient-centered environment, and minimize health disparities. Further, the AAMC reported that they work to ensure that integrity, privacy, and confidentiality remain an important part of innovation and improvement in research. Partners in improving research include the NIH, Agency for Healthcare Research and Quality (AHRQ), and the Department of Veterans Affairs (VA).

Another measure used to improve research is working with medical colleges and teaching hospitals to reduce conflict of interest and to gain insight on how effective programs instituted are working (AAMC, 2015b). The AAMC (2015b) related that

information on annual aggregate data about conflict of interest systems, disclosures submitted by investigators to institutions, and financial conflict of interest are reported to the appropriate federal agency to help improve research metrics and transparency initiatives. The NIH developed strict policies and procedures that must be followed when providing quality research (National Institute of Neurological Disorders and Stroke [NINDS], 2014). According to NINDS (2014), several committees have been developed to oversee appropriate unit and site set-up for clinical trials in progress. The following steps are used to ensure research remains safe and ethical, and these steps often lead to new products and innovation for new procedures:

1. Establish a manual of operating procedures (MOP) and ensure that clinics and labs use the same examination procedures.
2. Use data analysis to track errors and omissions.
3. Specify quality control measures.
4. Put metrics in place to keep information confidential.
5. Obtain a signed informed consent form.
6. Practice due diligence for eligibility.
7. Communicate the plan to all involved in the research process.
8. Keep a staff roster.
9. Implement training.
10. Track participant retention, where necessary.

Embryonic Stem Cell and Regenerative Medicine

The study of regenerative medicine has been around for more than 20 years (Mason & Manzotti, 2010). Mason and Manzotti (2010) reported that the cell-based therapy industry has manufactured over 675,000 units of therapy and cured more than 323,000 patients. The CIRM (2015b) discussed the potential of stem cells to treat many diseases. The CIRM reported that in stem cell transplant, ESCs are specialized into the necessary adult cell type and those mature cells replace damage tissue that is diseased or injured. Other types of treatment include the replacing of neurons damaged due to a spinal cord injury, stroke, Alzheimer's disease, and Parkinson's disease or other neurological problems. In addition, this type of treatment could be used to produce insulin to treat people with diabetes and heart muscle cells after a heart attack. Furthermore, studying stem cells could help in understanding how to induce heart muscle to repair itself after a heart attack as well as studying disease, identifying new drugs, or screening drugs for toxic side effects. Thus, there is the potential for researchers to make breakthroughs in any disease. Clinical trials for ESC-based therapies are currently underway.

Improving Stem Cell Research in the United States

Although the controversy over embryo destruction continues, two developments have helped the proponents' public debate over hESC research (Hyun, 2010). Hyun (2010) related that first is the creation of human induced pluripotent stem (iPS) cells, which are genetically engineered to act like hESCs and second is the Obama administration's friendlier stance toward hESC research. The researcher noted that the

main bioethical considerations now focuses more on how stem cell research should be conducted instead of whether it should be conducted. Those who oppose hESC research applauded the iPS cell revolution, which they hoped would end ESC research. However, most stem cell researchers believe that iPS or other alternative source of stem cells do not take away the need for ongoing hESC research.

Summary and Conclusions

Scientists have noted the potential of stems cells to treat a wide range of diseases, such as spinal cord injury, stoke, Alzheimer's disease, and Parkinson's disease (CIRM, 2015b). Liberal stem cell policies in many countries, such as in the UK, China, Japan, Belgium, and Sweden, have resulted in these countries making further progress in hESC research by producing more stem cell lines (Nature Cell Biology, 2010). On the other hand, policy uncertainty has affected hESC in the United States (Levine, 2011). As a result, Levine (2011) recommended that lawmakers who are supportive of hESC research should work to create policies that reduce the uncertainty facing stem cell scientists. Nature Cell Biology (2010) related that each state government will create restrictive policies for stem cell research within their borders, where several states have already done so, but a liberal policy at the federal level also softens the tone of hESC debate and promote greater acceptance of such research within the United States. As a result, from a policy perspective, more remains to be done to ensure that stem cell research flourishes in the United States.

Due to the problem that federal support and funding for hESC research in the United States are still behind stem cell programs in many countries, the divisiveness of

the debate over hESC research, and the continually evolving federal policies that have further hindered research efforts (Levine, 2011; Mintron, 2013; Nature Cell Biology, 2010), in this phenomenological research study, I explored the perceptions of stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States. I also explored the moral disagreement with stem cell research and participants' recommendations to improve stem cell research policy in the United States. Rogers's (1962) DOI theory and Kingdon's (1995) agenda-setting theory served as the theoretical foundation of this study. Dresser (2010) related that the debate over stem cell research offers an opportunity to examine a variety of ethical and policy issues raised by biomedical innovation. Kingdon's problem, policy, and politics streams, plus the opening of the policy window, resulted in the issue of public funding for hESC being placed on the decision agenda. Thus, the possibility of change is at its greatest when all three streams come together (Soroka, 1999).

In Chapter 2, I included the introduction, literature search strategy, theoretical foundation, Dickey-Wicker Amendment, United States national policies, international communities' stem cell policies, bioethics and the moral debate, embryonic stem cell research, and a summary and conclusions. In Chapter 3, I include the introduction, research design and rationale, role of the researcher, methodology, issues of trustworthiness, and a summary. In Chapter 4, I include the introduction, setting, demographics, data collection, data analysis, evidence of trustworthiness, results, and a

summary. In Chapter 5, I include the introduction, interpretation of findings, limitations of the study, recommendations, implications, and a conclusion.

Chapter 3: Research Method

In this study, seven U.S. stem cell researchers', seven U.S. stakeholders', and seven U.S. investors' perceptions were explored about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. Using snowball sampling, I collected data using telephonic semistructured interviews. Transcribed interview data were managed with NVivo, and data were analyzed using Attride-Stirling's (2001) six steps of thematic coding. The study was conducted in accordance with the parameters established by Walden University's IRB to ensure the ethical protection of participants. The IRB approval number was 06-16-16-0073123. Chapter 3 includes the research design and rationale, role of the researcher, methodology, issues of trustworthiness, and a summary.

Research Design and Rationale

This section contains the research questions and phenomenological design rationale.

Research Questions

To explore the perceptions of 21 U.S. stem cell researchers, stakeholders, and investors about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States, I asked the following research questions:

1. What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States?
2. What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research?
3. What do U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States?

Phenomenological Research Design Rationale

A phenomenological design was used to explore stem cell researchers', stakeholders', and investors' perceptions. Through the use of this design, the meaning, structure, and essence (Dalberg, 2006) of participants' experiences in dealing with policy issues around stem cell research were examined. Purposive sampling, specifically snowball sampling, was used to collect data through in-depth semistructured interviews with 21 stem cell researchers, stakeholders, and investors in the United States. Data were analyzed using Attride-Stirling's (2001) six steps of thematic coding.

A quantitative research method was not used for this study because subjective behaviors, beliefs, and opinions cannot be measured with standardized instruments. Instead, a qualitative research method was used because it allowed for the understanding of the complex and holistic picture of participants' experiences. Patton (2002) reported that qualitative research is used to explore and understand social conditions or problems faced by individuals and groups. In this study, the qualitative research method was used to explore the effects of the current federal stem cell policy on stem cell research in the

United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States.

Five qualitative designs considered for this study included narrative research, phenomenology, grounded theory, ethnography, and case study (McCaslin & Scott, 2003). After an extensive review of the five designs, I chose the phenomenological design. Phenomenological research designs are used when the researcher is trying to understand the essence of experiences about a phenomenon (Moustakas, 1994), such as the current federal stem cell policy on stem cell research in the United States. Moustakas (1994) reported that the use of a phenomenological design help researchers to gain a unified vision of the essence of a phenomenon or experience.

Role of the Researcher

I served as a participant-observer during the in-depth semistructured interviews. I had direct contact with participants as I recruited them by e-mail and telephone. I collected interview data, which I transcribed, coded, analyzed, and interpreted. No personal or professional relationships existed between research participants and me. Therefore, I had no power over potential participants, and they participated without feeling coerced or obligated to take part in the study. In addition, I had no bias against potential participants, and I respected their rights and did not exploit them. All participants' perceptions were considered, and there were no conflicts of interest in the study. Upon successful completion of this study, I will e-mail each participant a summary of the findings.

Methodology

This section contains the following subsections: participant selection and sampling strategy, instrumentation and data collection, procedures, and data analysis plan.

Participant Selection and Sampling Strategy

Snowball sampling is a subset of purposive sampling, where the researcher begins by identifying someone who meets the criteria for inclusion in the study and then asks the individual to recommend others whom they know meet the study's criteria (Trochim, 2006a). Snowball sampling was used to identify participants with expertise in the field of stem cell research. Seven stem cell researchers, seven stem cell stakeholders, and seven stem cell investors in the United States were used in the study. Mason (2010) reported that the sample size in qualitative studies is normally small in comparison to quantitative studies. For phenomenological studies, Klenke (2008) reported that the sample size might range from two to 25 participants, while Morse (1994) recommended at least six. For the current study, 21 participants were used to explore experiences regarding stem cell research. Saturation is the point in data collection when the collection of new data does not shed any further light on the issue under investigation (Glaser, Strauss, & Strutzel, 1968). The relationship between saturation and sample size was sufficient in this study because through the use of snowball sampling, I included 21 participants to obtain the richest data possible. Saturation was reached with 21 participants. Potential participants were recruited using the snowball sampling strategy, and included 122 men and women who met the selection criteria of being a current stem cell researcher who worked at a

government organization, private company, or university; a stem cell stakeholder who was a faculty member at a university where stem cell research was being conducted; or an investor who worked for a government organization or private company that invested in stem cell research in the United States. Potential participants were sent an invitation letter to participate in the study and were asked to recommend other stem cell researchers, stakeholders, or investors who met the selection criteria (see Appendix A).

Instrumentation and Data Collection

I used a 45-minute researcher-developed interview questionnaire to collect data about perceptions of stem cell research in the United States. The questionnaire was structured to elicit stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States and the moral disagreement with stem cell research. Additionally, participants were asked about their recommendations to improve stem cell research policy in the United States. The interview guide contained an introduction, welcome, discussion purpose, discussion guidelines, general instructions, possible probes, interviews questions, and a conclusion (see Appendix B). The interview questions were open ended to provide for a deep exploration of the stem cell topic. Through the use of open-ended questions, participants were able to provide detail, and I was able to probe deeper to gain a better understanding of the responses (see Turner, 2010).

Procedures

I completed the NIH Office of Extramural Research Human Research Protections training (see Appendix C). I also complied with all federal and state regulations such as

the Georgia Department of Public Health's (2015) directive to obtain legal informed consent from potential participants or their legal representative prior to their participation in the study. After I received Walden University's IRB approval to conduct the study, I contacted potential participants by e-mail or telephone who were known to meet the selection criteria. Contact information for stem cell researchers, stakeholders, and investors was obtained from personal contacts and public information available online. I did not include anyone with whom I had a personal relationship, including family members, friends, coworkers, or professional and personal associates, to prevent perceived coercion to participate. I asked professional and personal associates if they knew individuals who met the study's criteria to get snowball sampling going. I also used public information available online through organizations such as Microbot Medical Inc. (2017) and Cell Therapy Foundation (2014) to obtain information about those involved in stem cell research. I looked up their public contact information from individual companies' websites. I also used the NIH (2015c) stem cell information about organizations, advocacy groups, professional associations, federal government sites, and others involved in stem cell research. I reviewed those resources and found public contact information for potential participants.

I sent potential participants an invitation letter and asked them to recommend other stem cell researchers, stakeholders, or investors who met the selection criteria by providing their personal contact information or public work contact information, but not their nonpublic work contact information (see Appendix A). Participants were informed that they could ask questions about the study by e-mail or telephone. Potential

participants were asked to complete the questions on the invitation letter and e-mail them back to me if they were interested in participating in the study. Their responses to the questions helped me ensure that they met the selection criteria. Once I received the e-mail responses to the questions asked on the invitation letter, I e-mailed prospective participants the consent form and requested their consent by asking them to reply to the e-mail with the words "I consent." Participants were also informed that they could ask questions before giving their consent and at any time during the interview process.

Once participants gave their consent, I contacted them by telephone or e-mail to set up an appointment to conduct individual semistructured interviews by telephone at a time that was convenient for them. Telephonic interviews were conducted because some participants resided in different states. Interviews were audio-taped and took approximately 45 minutes (see Appendix B). Before concluding the telephonic interviews, I asked participants if they had any questions or concerns. After all questions or concerns were addressed, I concluded the interviews and thanked participants for their participation. It was unlikely that participation would arouse discomfort; however, I provided participants with reasonable protection from psychological distress by informing them that they could seek counseling by calling the Substance Abuse and Mental Health Services Administration's (SAMHSA's, 2014) national helpline at 1-800-662-4357 should they experience any negative effects from taking part in this study.

After the interviews were transcribed, I e-mailed each transcript to the participant to review for accuracy. Transcription review is a quality control process that ensures the accuracy, credibility, and validity of what was recorded during the interviews (Harper &

Cole, 2012). I discussed the participants' feedback with them by telephone. The transcription review process took approximately 20 minutes. Once this study is completed, I will e-mail a summary report of the research findings to each participant. Data will be secured in a locked file cabinet and password-protected computer in my private home office. I am the only one with access to the records. Data will be kept for a period of at least 5 years, as required by Walden University. After that period, data will be properly destroyed using techniques such as shredding and demagnetizing.

Data Analysis Plan

To analyze the interview questions, I transcribed the interviews using WebEx audio playback. I then transferred the transcripts to NVivo analysis software, which assisted in managing the data. The next step was to analyze the data using the Attride-Stirling's method (2001), which outlines six steps or stages of thematic coding, which is discussed in further detail below. NVivo is a software program designed to facilitate qualitative data analysis (Zamawe, 2015). NVivo provided a way to manage and organize the interview transcripts so that I could logically identify thematic phrasing. NVivo allows the researcher to upload files such as transcripts, select parts of the document, and label them with particular descriptions (Zamawe, 2015). NVivo also produces word frequency counts, charts of the labels that are used most often, and text searches (Zamawe, 2015). The labels can be organized into categories, notes can be made about links between labels and concepts, and relationships can be created between labels and documents (Zamawe, 2015). Finally, for the results sections, tables can be created to present data and display the major and minor themes for each research question.

Coding and categorization of interview transcripts facilitated thematic analysis of the interview data. I followed Attride-Stirling's (2001) six steps on how to conduct a thematic analysis and the steps are modified to properly fit this specific research study's methodology:

1. Analysis stage A: The reduction or breakdown of text: Step 1. Coding of material: (a) devised a coding framework and (b) dissected or divided text into text segments using the coding framework in Step 1a. Step 2. Identifying of themes: (a) abstracted themes from coded text segments and (b) refined and edited themes. Step 3. Constructing of thematic networks: (a) arranged themes, (b) selected codes or the other essential perceptions of the participants, (c) rearranged into themes and codes (with the themes as the ones with the highest responses and the codes as the ones that followed), (d) illustrated as thematic networks or groups, and (e) verified and refined the networks.
2. Analysis stage B: Exploration of text: Step 4. Described and explored thematic networks or groups: (a) described the network or group and (b) explored the network or group. Step 5. Summarized thematic networks or groups.
3. Analysis stage C: Integration of exploration: Step 6. Interpreted the patterns.
4. During data analysis, I found no discrepant cases. Themes and subthemes emerged during the data analysis process, which are discussed later in the results section in this chapter.

I found no discrepant cases during data analysis. Themes and subthemes emerged during the data analysis process, which are discussed later in the results section in Chapter 4. Preliminary themes included ethical concerns, religious influence, funding shortages, end use of stem cells, and concerns about NIH guidelines. Table 2 in Chapter 4 provides the theories, preliminary themes, and subthemes based on my literature review and theoretical frameworks, which served as a starting point of my data analysis.

Issues of Trustworthiness

Qualitative research has richness to it and as such, data must be coded and interpreted correctly during the collection and evaluation process to ensure a level of trustworthiness (Moretti et al., 2011). This section is organized in the following subsections: validity and reliability of qualitative data and ethical procedures.

Validity and Reliability of Qualitative Data

In this qualitative phenomenological study, validity and reliability were established through credibility, transferability, dependability, and confirmability. According to Shenton (2004), credibility or internal validity is one of the most important factors in establishing trustworthiness and refers to how congruent the findings are with reality. In this study, credibility was established through transcription reviews. I e-mailed each participant the transcript of the interview and asked that they review the transcript for accuracy. I discussed participants' feedback with them by telephone or e-mail.

Transferability or external validity refers to the extent to which the study's findings can be applied to other situations (Shenton, 2004). Findings from this study might be applicable to similar stem cell researchers, stakeholders, and investors in the

United States who have had similar experiences. Merriam (2009) noted that rich, thick description in reference to the setting, the participants, and the findings of the study is one strategy that can be used to establish transferability. It is also the responsibility of the qualitative researcher to describe the context of the study and its participants in detail so that the possibility of replication exists. Hence, I provided a rich, thick description of the context of the study and the participants. I also supported the findings of this study through the use of direct quotes and summaries of participants' interview responses.

Dependability is the qualitative counterpart to reliability. According to Shenton (2004), the study's processes should be reported in detail, which enables future researchers to repeat the work. However, this does not necessarily mean that same result will be obtained. In this study, dependability was established through audit trails, which involves a thorough collection of documentation for all aspects of the research (Rodgers, 2008). Documentation that were used in this study included tape recorded interviews, transcriptions of those interviews, and transcription reviews; thus, data were authenticated by comparing these forms of data.

Confirmability is the qualitative counterpart to objectivity. Trochim (2006b) reported that confirmability is the degree to which the research results can be confirmed or corroborated by other researchers. Therefore, I ensured that the data and interpretations of the findings were not a figment of my imagination, but were clearly derived from the data (Tobin & Begley, 2004). In addition, I established confirmability through reflexivity, which is the process of reflecting critically on the self as researcher (Merriam, 2009). I used the strategy of reflexivity where I reflected on any biases that I may have about the

effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommended ways to improve stem cell research policy in the United States.

Ethical Procedures

The NIH human research protection training was completed (see Appendix C). I also complied with all federal and state regulations. The study was also conducted in accordance with the parameters established by Walden University's IRB to ensure the ethical protection of research participants. The data I collected present no greater than minimal risk and I followed Walden University's IRB guidelines to protect the data that were generated from the interview questions, such as the interview recordings and the transcriptions.

Before data collection began, all participants were e-mailed a consent form that had been approved by the Walden University IRB; thus, obtaining their permission to participate in the study. The consent form outlined participants' protections and ethical guidelines that were followed during the research study. These guidelines included the voluntary nature of the study and participants' right to withdraw at any time without fear of reprisal or penalty. The consent form also outlined any physical or psychological risks that participants might experience and indicated that participants were not obligated to complete any part of the study with which they were not comfortable. It was unlikely that participation in this study aroused any acute discomfort; however, participants were referred to the SAMHSA's national helpline at 1-800-662-4357 if they experienced any negative effects.

Participants were provided with my contact information and the contact information for my Dissertation Committee Chair in the event that they had any further questions or concerns about the research. Participants were provided with the contact information of the Walden University representative with whom they could talk privately about their rights as participants. I respected all participants during the research process and data collection stage. After data were collected, all identifiable data were eliminated; therefore, the interviews were numbered or coded to match the participant. This protected participants' identities; however, I knew the identity of the participants. Thus, all participants' identity were kept confidential.

Participants were informed that the interviews would be audio-taped and that a verbatim transcription would be made and analyzed later. I have kept all audio-recorded data secured, which I transcribed. Only my supervising committee had access to the data. All data are kept in a locked file cabinet and password protected computer in my personal home office for at least 5 years, as required by Walden University. Data will be properly destroyed after that time period using methods such as shredding and demagnetizing. Once this study is completed successfully, a summary report of the research findings will be e-mailed to each participant.

Summary

In this study, seven U.S. stem cell researchers', seven U.S. stakeholders', and seven U.S. investors' perceptions were explored about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the

United States. The in-depth semistructured interviews were transcribed and transcriptions were analyzed. Common words or phrases were grouped and labeled for coding across categories of inquiry. Once data were grouped, subsets were compared and contrasted. This allowed for the search of related codes and the making of inferences about these connections or patterns.

In Chapter 3, I included the introduction, research design and rationale, role of the researcher, methodology, issues of trustworthiness, and a summary. In Chapter 4, I include the introduction, setting, demographics, data collection, data analysis, evidence of trustworthiness, results, and a summary. In Chapter 5, I include the introduction, interpretation of findings, limitations of the study, recommendations, implications, and a conclusion.

Chapter 4: Results

The purpose of this qualitative phenomenological study was to explore the perceptions of 21 U.S. stem cell researchers, stakeholders, and investors about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. I conducted in-depth telephonic semistructured interviews with 21 stem cell researchers, stakeholders, and investors in the United States to answer three research questions: (a) What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States; (b) what are U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research; and (c) what do U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States? The interview transcripts were analyzed using Attride-Stirling's (2001) six steps of thematic analysis. In Chapter 4, I present themes according to their respective research questions. I also include the setting, participant demographics, data collection, data analysis, evidence of trustworthiness, and a summary.

Setting

I used snowball sampling in the Southeast, Northeast, Midwest, and West Coast regions of the United States. Telephonic interviews took place from July 6, 2016 to September 29, 2016. There were no personal or organizational circumstances that may

have influenced participants' experiences at the time of the study or that may have influenced my analysis of the data.

Demographics

From the 43 researchers, 47 stakeholders, and 32 investors who were initially contacted, I chose seven stem cell researchers, seven stem cell stakeholders, and seven stem cell investors in the United States to participate in the study. Thirteen out of 21 participants (62%) were female, and eight out of 21 participants (38%) were male. Stem cell researchers worked at a private company or university, stem cell stakeholders were faculty members at a univeristy where stem cell research was being conducted, and stem cell investors worked for a government organization or private company that invested in stem cell research in the United States. Eight female participants worked in the private sector, four at a university, and one in the government. Two male participants worked in the private sector, four at a university, and two in the government. Six female participants were researchers, four were investors, and three were stakeholders. One male participant was a researcher, three were investors, and four were stakeholders. The participant demographics are summarized in Table 1.

Table 1

Participants' Demographics

Participants	Gender	Classification	Work sector	Acronym
1	Female	Researcher	Private	FRP
2	Male	Investor	Government	MIG
3	Male	Stakeholder	University	MSU
4	Male	Researcher	Private	MRP
5	Male	Investor	Government	MIG
6	Female	Investor	Private	FIP
7	Male	Stakeholder	University	MSU
8	Female	Investor	Private	FIP
9	Female	Stakeholder	University	FSU
10	Female	Investor	Private	FIP
11	Female	Stakeholder	University	FSU
12	Male	Stakeholder	University	MSU
13	Female	Researcher	University	FRP
14	Female	Investor	Government	FIG
15	Female	Stakeholder	University	FSU
16	Female	Researcher	Private	FRP
17	Female	Researcher	Private	FRP
18	Female	Researcher	Private	FRP
19	Female	Researcher	Private	FPR
20	Male	Stakeholder	University	MSU
21	Male	Investor	Private	MIP

Data Collection

I developed an interview guide to collect data about participants' perceptions of stem cell research in the United States. The interview questions were used to explore participants' perceptions of (a) the effects of the current federal stem cell policy on stem cell research in the United States; (b) the NIH ethical policies regarding human ESC research and their effect on stem cell research in the United States; (c) whether U.S. stem cell researchers have benefited from President Obama's more relaxed funding policies;

(d) how the Dickey-Wicker Amendment restricts the use of federal funds for creating, destroying, or knowingly injuring human embryos; (e) how the U.S. stem cell policy has diminished or improved U.S. stem cell research competitiveness with other countries; (f) how the U.S. can become more competitive with other countries that they lag behind in relation to stem cell research; (g) the moral disagreement with stem cell research; (h) how stem cell proponents and opponents can compromise on stem cell research; and (i) recommendations to improve stem cell research policy in the United States. Interviews were audio-taped and took approximately 45 minutes. After the interviews were transcribed, I e-mailed each participant the transcript and asked him or her to review it for accuracy. The transcription review process took approximately 20 minutes. I incorporated participants' feedback in the transcriptions, and no participants' feedback altered the original responses in any way.

Data Analysis

Recorded interviews were transcribed, data were managed with NVivo, and data were analyzed using Attride-Stirling's (2001) six steps of thematic analysis. The steps were modified to fit the current study's methodology. Table 2 depicts the preliminary themes and subthemes that served as a starting point for the data analysis, along with their theoretical backgrounds.

Table 2

Theoretical Origins of Preliminary Themes and Subthemes

Theories	Preliminary themes	Subthemes
Agenda-setting theory	Policy stream	• NIH guidelines • Dickey-Wicker Amendment • Political orientation of the executive branch • Political orientation of the legislature
Agenda-setting theory	Politics stream	• Ethical considerations • Religious influences • Funding shortages • International competition
Diffusion of innovations	Persuasion stage	• Religious influences • Medical value of research • Misconceptions about research, including perceived link to abortion
Diffusion of innovations	Knowledge stage	• Shifts in public perception • Advances in knowledge (e.g. iPSCs)

1. Analysis Stage A: The reduction or breakdown of text. In Step 1, I devised a coding framework and dissected or divided text into text segments using the coding framework. In Step 2, I abstracted themes from coded text segments and refined and edited themes. In Step 3, I arranged themes, selected codes or other essential perceptions of the participants, rearranged codes into themes (with the themes as the ones with the highest responses and the codes as the ones that followed), illustrated as thematic networks or groups, and verified and refined the networks.
2. Analysis Stage B: Exploration of text. In Step 4, I described the network or group and explored the network or group. In Step 5, I summarized thematic networks or groups.
3. Analysis Stage C: Integration of exploration. In Step 6, I interpreted the patterns.

During the data analysis phase, no discrepant data were found. Table 3 presents the number and percentages of the themes that emerged during data analysis in relation to stem cell researchers', stakeholders', and investors' perceptions. Number of occurrences refers to the number of times a theme occurred in the interview transcripts. Percent of occurrences is the total number of occurrences of the theme divided by the total number of occurrences of all themes in the interview transcripts.

Table 3

Theme Occurrences and Percentages for Stem Cell Researchers', Stakeholders', and Investors' Perceptions

Themes	No. of occurrences	% of occurrences
Perceptions of federal policy	142	65%
Perceptions of moral disagreement	44	20%
Policy recommendations	34	15%
Total	220	100%

Evidence of Trustworthiness

In this qualitative phenomenological study, I established validity and reliability through credibility, transferability, dependability, and confirmability. I established credibility through transcript reviews. I e-mailed each participant the transcript of the interview and asked that he or she review the transcript for accuracy. I discussed participants' feedback with them by telephone or e-mail. I ensured transferability by providing a rich, thick description of the context of the study and the participants. I also supported the findings of this study through direct quotes and summaries of participants' interview responses. I established dependability through the use of audit trails, where I included documentation for all aspects of the study. Documentation included tape-recorded interviews, transcripts of interviews, and transcript reviews; data were authenticated by comparing these documents. I established confirmability by ensuring that the data and interpretations of the findings were not a figment of my imagination, but were clearly derived from the data. In addition, I established confirmability through

reflexivity by reflecting on any biases that I had about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommended ways to improve stem cell research policy in the United States.

Results

Based on the data analysis, three overarching themes and 14 subthemes emerged. The research questions served as the basis for each overarching theme. Thematic analysis Step 1 or categorization of text appears in Appendix D, which shows all of the participants' responses that corresponded with each overarching theme and subtheme. In the following section, the themes and subthemes are presented according to their corresponding research question.

Research Question 1

What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States? One overarching theme and five subthemes emerged to answer this research question. Participants' perceptions of U.S. federal stem cell policy varied widely. Some participants perceived the policy as beneficial, others perceived it as irrelevant, and some perceived it as a constraint on stem cell research. Participants who perceived the federal stem cell policy as beneficial to U.S. stem cell research expressed their approval, stating that the Obama administration's comparatively relaxed funding policy was more advantageous to stem cell researchers than the Bush administration's restrictions, although the Obama administration's policy was not necessarily optimal. Other

participants reported that funding restrictions, which only affected research conducted on hESCs, had lost much of their significance with the increasing prevalence of research involving iPS cells and adult stem cells. Six participants (29%) indicated that current funding restrictions prescribed by the Dickey-Wicker Amendment were invalidated by their reliance on justifications that were perceived as irrational, and 13 participants (62%) agreed with the amendment. Almost all participants, however, agreed with the NIH ethical policy, with 17 of the 21 participants (81%) describing the policy as a valuable means of promoting ethical science.

In regard to the context of each research setting, 92% of all participants believed that the Obama administration's more relaxed stem cell policy was as a positive step in the right direction. Researchers' perception on the effects of the Obama administration's federal stem cell policy is that it is restrictive but they are moving forward by doing research in other countries, using less hESC research, and engaging more in adult stem cell research. Investors' and stakeholders' perceptions were closely aligned in how they perceived the Obama administration policy, where they noted that it is not very restrictive, but federal funding on new lines of hESC research is still restrictive; thus, research can continue with private donations. Most researchers agreed with the NIH policy as they understood the need for strict supervision. Five of the seven investors (71%) agreed with the NIH policy and noted that it was necessary to protect donors, while three out of seven stakeholders (43%) agreed with the NIH policy. Researchers, investors, and stakeholders who did not agree with the NIH policy described the policy as confusing because it did not provide clear differences between hESCs and adult stem

cells and their uses for research. Stakeholder and investors who disagreed with the Dickey-Wicker Amendment described it as a religious agenda. On the other hand, researchers discussed the limited scope of the amendment, but emphasized the legislation's negative effect on research. Participants agreed that stem cell policy changes from each administration made it challenging to compete with other countries. Researchers emphasized that the best way to be more competitive was to educate people, increase funding, and do more clinical trials. Table 4 depicts the occurrences and percentages for perceptions of the effects of Obama administration's federal stem cell policy theme and subthemes.

Theme 1: Perceptions of the effects of the Obama administration's federal stem cell policy. This theme has five subthemes, which are as follows: (a) overall perceptions; (b) perceptions of the Obama administration's funding policy, which is the policy that was created to inform applicants and grantees of the conditions that must be met in order for the NIH to fund stem cell research; (c) perceptions of the NIH's ethical policy, which was developed based on President Obama's EO 13505 to ensure researchers were informed of the new processes needed to conduct human stem cell research; (d) perceptions of the Dickey-Wicker Amendment, is an amendment attached to the appropriation bills ensuring that no federal funds get used for creating, destroying or knowingly injuring human embryos; and (e) perceptions of competition between the United States and other countries. Participants' responses are categorized in the five subthemes below.

Table 4

Subtheme Occurrences and Percentages for Perceptions of the Effects of Current Federal Stem Cell Policy

Theme	Subthemes	No. of occurrences	% of occurrences
Perceptions of the effects of the current federal stem cell policy	Overall perceptions	24	17%
	Funding policy	28	20%
	NIH ethical policy	24	17%
	Dickey-Wicker Amendment	24	17%
	Competition with other countries	42	29%
	Total	142	100%

Subtheme 1: Overall perceptions. Participants' perceptions of U.S. federal policy on stem cell research varied considerably. Only a few participants expressed approval of the Obama administrations' policy. Participant 12 (MSU) stated, "I do believe the current federal policy is for the betterment of science research and will have positive long-term effects on disease and disease treatment." Participant 13 (FRU) discussed the difference between the policies of the Bush and Obama administrations, noting that the "current federal stem cell policy has certainly boosted stem cell research considerably over the last 7 years." Participant 13 also stated:

> [The Obama administration's policy] has allowed stem cell researchers more flexibility in choosing cell lines of interest. In addition, there has been more investment in stem cell research, which has resulted in significant milestones

being achieved in stem cell research in the United States. Importantly, multiple clinical trials have been initiated for stem cell therapy of degenerative diseases.

Participant 21 (MIP) indicated that the current stem cell policy is permissive because it does not limit scientists' abilities to address interesting and important questions. On the other hand, Participant 7 (MSU) related that despite the thoughtfulness of the current stem cell policy, it is still restrictive in terms of access to carry out research. Participant 6 (FIP) related that while the current stem cell policy makes it easier to do more research, funding is still slow due to past policies and restrictions. Participants 1, 14, 15, and 20 described the policy as a significant constraint. Participant 1 (FRP) noted that despite all the testing that is taking place, the benefit from stem cell is still not fully realized. Participant 14 (FIG) pointed out that restrictive policies could have a negative effect on the international standing of U.S. stem cell research because major research companies move their stem cell research division to "other countries where scientists are permitted to conduct research without any restriction." Participant 15 (FSU) perceived the policy as negatively affecting medical research due to limiting ESC research as well as rapid advancement in therapeutic approaches and applications. Participant 15 also noted that the federal stem cell policy does not affect her research and that progress has been made despite how strict the policy may be. Similarly, Participants 15 and 20 reported that while the policy does limit ongoing research, its effects are limited due to the use of iPS cells and some researchers have moved to countries where there is less stem cell restrictions.

Similarly, Participant 16 (FRP) related that there may be limits on what research can be carried out using ESCs with federal funds, but most research is concentrated on the use of adult stems in the United States. Other part participants described the effects of the federal policy on stem cell research as limited or negligible, such as Participant 10 (FIP) who noted that the current research that she is a part of is not affected by federal or state regulations because they are using iPS cells, which are generated from fibroblasts donated by patients. Similar to Participant 10, Participant 11(FSU) shared that government restrictions are less of a concern as researchers increasingly include adult-derived stem cells and iPSCs. Participant 11 further shared that few of her "colleagues are performing research with ESCs, though this may change concurrently with changes in policy." Participants 3, 18, and 19 also discussed the use of adult-derived stem cells as a viable alternative to ESCs. Participant 3 (MSU) related that the federal stem cell policy is not very restrictive since researchers can use ESC lines as well as adult-derived stem cells. In addition, Participant 3 noted that ESCs can be derived from nonhumans as well as from skin cells. Participant 18 (FRP) and participant 19 (FRP) related that the policy does not have an effect or is an issue as research is more inclusive of adult stem cells in contrast to ESCs.

While Participant 17 (FSU) also noted the limited effects that the stem cell policy has on research, Participant 15 pointed out a way in which federal restrictions might have a negative effect on research despite the variety of alternatives to hESCs. Participant 15 stated, "[Federal policy] does not allow us to compare data generated from adult versus ESC research, which [is] the only way to know if the use of iPS cells is comparable."

Participant 8 (FIP) related that that federal policy restrictions related only to federal funding of research in certain areas and that alternative funding sources were available to researchers who wanted to work in those areas:

> If you mean the ban on federal funding for embryonic research put in place during the Bush administration and lifted during the Obama administration, it only banned the use of taxpayer dollars to pay for embryonic research. Taxpayer dollars have always been a significant source of funding for adult stem cell research and now iPS cell research. The ban only meant that if you wanted to do ESC research, you'd have to get private grants or venture capital to cover the costs. ESC research continued in labs across the country, but was largely leapfrogged by the discovery of iPS cells in 2012.

Subtheme 2: Perceptions of the Obama administration's funding policy. On March 9, 2009, President Obama issued EO 13505, *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, with the goal of strengthening hESC research in the United States (Levine, 2011; Nature Cell Biology, 2010). The Secretary of Health and Human Services, through the Director of the NIH, may support and conduct responsible, scientifically worthy human stem cell research, including hESC research, to the extent permitted by law (Obama, 2009). However, President Obama's new stem cell policy did not approve the 21 hESC lines that were eligible under the Bush administration (Levine, 2011). Participants' perceptions of the Obama administration's policy fell into two broad categories, which are as follows: (a) Some participants believed that the policy's positive intentions had been realized while (b) others believed that the policy had

been rendered partially or completely ineffective due to contextual factors. Some participants perceived the policy as having positive effects and cited significant advancements in knowledge that were attributed to President Obama's executive order. Participant 13 (FRU) stated:

> Significant progress has been made in stem cell research over the last 7 plus years and we are at the cusp of realization of its clinical potential. In addition, there has been a great push for using stem cell as disease models and for in vitro toxicity testing. All these advancements can be largely contributed to President Obama's funding policies.

Participant 21 (MIP) related the relaxation of funding policies during the Obama administration has benefitted scientists due to "access to a greater array of hESC lines and through a greater normalization of the field, reducing some of the complications associated with working with these cells." Participant 4 (MRP) related that U.S. researchers have benefitted from relaxed policies that govern the use of NIH funds to work on established hESC lines. For example, Participant 4 reported that "there is ample data to show that different lines of stem cells have intrinsic differences in their ability to differentiate into different lineages" and when researchers have the ability to use multiple lines of ESCs in NIH-funded research, they are able "to characterize these differences and explore the causes to ultimately help understand fundamental properties of differentiation." Participant 4 further noted that researchers still have a lot to learn about stem cell function; thus, research is essential. Participant 12 (MSU) noted that relaxed federal funding policies led to more private donations, which has been beneficial to stem

cell researchers. Participants 4, 5, 10, 14, 16, 17, 19, and 20 described the Obama administration's funding policy as beneficial to stem cell researchers.

Some participants expressed approval of the current funding policy, such as Participant 2 (MIG) who believed that the policy was beneficial and made it easier for researchers to use federal funds to work with new ESC lines. Participant 2 also discussed President Bush's stem cell restrictions and noted that the restrictions for researchers in California were not a problem as the voters in California created the CIRM through Proposition 71 in 2004, giving the stem cell agency $3 billion to fund stem cell research in the state. Thus, Participant 2 emphasized that while researchers in other states faced barriers and strict limits on what they could use their stem cell research funding for, in California, researchers did not have such problems as they could bypass the federal government and fund their own research. On the other hand, Participant 3 (MSU) related that the effects of the more stringent Bush administration policies had a negative effect on current research in the United States. In addition, Participant 3 questioned whether researchers have benefitted from the more relaxed Obama administration policy as more researchers are doing research outside the United States, which he attributed to the Bush administration policies. Participant 3 stated, "Once you are banned from doing something and you move on to something else, you don't usually turn back." Participant 15 (FSU) related that scientific research has benefitted from the federal stem cell policy, but noted that the policy does not go far enough to have a real effect on medical applications. Participant 4 noted that the Obama administration's stem cell policy was issued through

an EO, which can be reversed by any subsequent president; thus, researchers cannot rely on the indefinite continuation of the current funding guidelines.

Participants 1, 6, 7, and 9 reported that while the federal stem cell policy was favorable to stem cell research, it had not been implemented. Participant 9 (FSU) stated that the relaxed funding policies have not really been implemented and compared stem cell research to travelling to Cuba, which she noted "is still incredibly difficult." Similarly, Participant 6 (FIP) related that while there are benefits to the federal stem cell policy, the full benefit has not been realized. Participants 1 (FRP) and 7 (MSU) related that while the Obama administration's stem cell policy is a positive step, stem cell research is still stagnant and benefits have not increased from 2009 due to a lack of bipartisan support.

Participant 5 (MIG) reported that researchers have benefitted from the relaxed restrictions because there are many more hESC lines currently eligible for research supported by NIH. However, Participant 5 noted that the use of iPS cells has lessened the need for new hESC lines. In addition, Participant 5 related that the stem cells lines that were approved for research under the Bush administration appears "to remain the most heavily used cell lines because researchers are comfortable with them and have been using them for years." Participant 8 (FIP) reported that President Obama's EO did not make any difference in stem cell research and stated the following:

> For most researchers, the problem with embryonic cells is less ethical than scientific. Embryonic cells multiply at an extremely rapid pace and have a propensity to form cancers. They can be used for disease modeling and drug

> screening in a lab, but will not be used in people, with the exception of a very small number of ophthalmology projects, until their cancer-forming properties can be controlled. In the meantime, iPS cells have leapfrogged the need to use them.

Subtheme 3: Perceptions of the NIH's ethical policy. hESC lines have to be in compliance with the NIH strict ethical policies (Nature Cell Biology, 2010). Applicant institutions proposing research using hESCs derived from embryos donated in the United States must use human embryos that were created through IVF for reproductive purposes and that were no longer needed for this purpose (NIH, 2015a). In addition, the hESCs must be donated by individuals who sought reproductive treatment and gave voluntary written consent for the human embryos to be used for research purposes (NIH, 2015a). Most participants agreed with the NIH's ethical policy. Participant 13 (FRU) reported that the NIH policy helped to ensure that researchers used stem cell lines responsibly:

> The NIH policy restricted the generation of new stem cell lines. However, there needs to be strict supervision on such ethical policies. ESCs have great power and ensuring that it is handled responsibly is possible only through strict supervision.

Similar to Participant 13, Participant 4 (MRP) related that all research, including embryonic and stem cell research, should be done ethically by following approved and vetted standards. Participant 13 further related that the International Society for Stem Cell Research (ISSCR) helped create the first set of standards on ethical embryonic and adult stem cell research and recently released an updated set of guidelines. Participant 13 stated that all scientific research benefits by following ethical scientific practices and that "there are many benefits of the new policies and procedures that NIH uses to vet the provenance

of the lines, including protecting patients and donors and helping to maintain the integrity of the process." Participant 21(MIP) described the current ethical policies as "particularly strict;" but noted that the NIH ethical guidelines represents "a reasonable compromise between the obligation to protect embryo and gamete donors and the desire to help advance the science." Participants 3, 12, and 19 also described the policy as strict while sharing that they agreed with it. Participant 3 (MSU) also stated:

> NIH strict policy . . . promoted the idea of nonembryonic use and moved research into a different path, which is more universally useful. It also brought up the ethical issue of how many embryos would be sacrificed to create one transplant, which then created the ethical issue of who could afford to use this process, in most cases, meaning only wealthy people could afford to have a chance at using the therapy from embryonic tissues. ESCs are not very scalable, so to have something of value, the product or service must be scalable.

Participants 6, 10, 11, 14, 16, 17, 18, and 20 agreed with the policy without any reservations. However, Participants 5, 7, 8, and 9 expressed concerns about the NIH policy. Participant 9 (FSU) related that while the NIH ethical policy is scientifically informed regarding safety and is dynamic as new therapies are always developing, "the ethical interpretations of ESC use are not scientifically informed and restrictions should be reevaluated without political or religious input." Participant 8 (FIP) related that ESCs used for research purposes have always been harvested from IVF clinics with the express permission of the individuals involved. Participant 8 stated that the NIH guidelines do not constitute ethical policy, but clarifies the source of cells. Participant 7 (MSU) described

the policy as a potential cause of misunderstanding, stating, "The NIH is legally bound to the policies, and as such, has a limiting impact and causes confusion in people's minds about the differences between human embryonic and adult stem cells and their uses for research." Participant 5 (MIG) agreed with the ethics of the policy, but believed that certain issues were not addressed. Participant 5 related that informed consent for the donors of embryos used to create hESC lines remains an important policy, but he noted two concerns. In regard to Participant 5 first concern, he related that "the NIH policy on using only embryos left over from IVF may skew the source of new lines to less than healthy embryos as these are more likely not to be implanted." In discussing his second concern, Participant 5 related that the Food and Drug Administration (FDA) has not kept up with stem cell science in regard to its guidance or requirements for preclinical studies needed to move stem cell-based therapies into clinical trials. Participant 5 emphasized that he is not arguing that researchers should follow the Japanese model and that he has great concerns about the Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act, instead, he noted that he would like to see the FDA "issue clear guidance and play a more active role in regulating the unregulated stem cell clinics currently marketing unapproved, untested therapies." Participant 5 also stated,

> Finally, U.S. policy with regard to preventing the FDA from even considering applications involving genetic engineering or modification of human embryos should not be enshrined perpetually in law as the Dickey-Wicker amendment has become . . . . The FDA's process is slow, laborious, and highly inconsistent. It

means that therapies can take up to 20 years and billions of dollars to get approval. Very few companies can afford that time or money.

Subtheme 4: Perceptions of the Dickey-Wicker Amendment. The Dickey-Wicker Amendment restricts the use of federal funds for creating, destroying, or knowingly injuring human embryos. Participants' perceptions of the amendment were divided, with Participants 2, 4, 5, 7, 9, 13, and 21 disagreeing with the amendment, while Participants 1, 6, 10, 11, 12, 14, 16, 18, and 20 expressed their agreement with the amendment. Participants 5, 7, and 9 noted that the amendment was irrational. Participant 9 (FSU) stated, "I strongly disagree [with the amendment]. This is a religious agenda. Females can discard embryos in late menstruation, yet this is not regulated. We don't scoop them up, protect them, [and] have funerals." Participant 7 (MSU) related that the amendment created a path that is based on people's feelings than on science. Participant 5 (MIG) related that the amendment is a clear case of the nonseparation of church and state, which puts the beliefs of one religion over that of others and instills those beliefs in federal legislation. Participant 5 (MIG) also noted that recent technology had limited the effects of the amendment due to the use of iPS cell technology and the continued addition to the NIH registry of new hESC lines created with other funds.

Participant 21 (FSU) also described the amendment's restrictions as limited, but still significant. Participant 21 (FSU) related that state and private funding have helped researchers to work around the restrictions, but the restrictions are still a challenge for the field. Participant 13 (FRU) expressed a similar opinion about the limited scope of the amendment, but emphasized the legislation's negative effect on research:

> While it does not restrict the use of hESCs for research purposes, it still restricts the generation and establishment of new stem cell lines from embryos. While there needs to be strict supervision regarding use and destruction of embryos, with the current amendment, the field is restricted to the use of just handful of lines.

Participants 4 and 8 pointed out that IVF embryos that are not used in stem cell research are usually discarded. Participant 4 related that although the amendment was designed to protect embryos, it does not do so because although embryos cannot be used for federally funded research, they are likely discarded when they are no longer needed for fertility treatments. Similarly, Participant 8 related that individuals have three options for embryos that are theirs, which are being cryopreserved at an IVF clinic: throw them away, donate them to research, or continue to cover the costs of storing them indefinitely. Participant 8 reported that most embryos are discarded.

Participant 3 (MSU) discussed the difficulty of evaluating the amendment and noted that he did not have an answer about how the amendment restricts the use of federal funds for creating, destroying, or knowingly injuring human embryos. Participant 3 stated:

> This is a complex issue that deals with ethical issues like the use of eggs [in an] in vitro sterilization clinic . . . . Should they be implanted in another female or used to further research study? So, with something so complex, it may be best to not complicate the issue by using those embryos with federal funds, without a clear purpose in mind. The cells of embryos can become abused if people believe there is a financial gain from it, so it must be clear what the benefit will be or should be.

I do not have an answer for this question and believe it needs to be discussed more at a broader level.

Similarly, Participants 1 and 17 related that the amendment should remain in place until there is a clear understanding of how hESC can be beneficial and the amendment should be reviewed annually for changes to funding. Participant 6 (FIP) reported that the amendment is needed, but it is limiting in relation to federal funds. Participant 2 (MIG) shared that while the amendment prohibits the use of federal funds for research on human embryos, it does not limit the use of federal funds for research on embryonic cell lines; thus, it has a limited effect on stem cell research. However, Participant 2 noted that this could change with a different administration.

Subtheme 5: Perceptions of competition between the United States and other countries. Participants discussed their perceptions of the extent to which U.S. federal policy had slowed U.S. stem cell research relative to the research being conducted in other countries. Participants 2, 5, 6, 10, 11, 12, 14, 16, 18, 19, and 21 did not believe that the United States lagged behind other countries in relation to stem cell research. Participants 10 and 18 shared that the policy has neither diminished nor improved stem cell research competitiveness with other countries. Participant 21 (MIP) shared that scientists and institutions worked around the Bush administration's funding restrictions with state and private funding and that the United States is among the top tier of countries producing key stem cell research advances. Participant 5 (MIG) also described U.S. researchers as succeeding despite the federal policy:

> The United States remains in the forefront, but other countries, the UK in particular, have in some ways more opportunities to conduct research that it is not possible to conduct here. My impression is that at least parts of the European Union also allow more. Fortunately, the sheer size of the biomedical research enterprise and the amount of funds the United States contributes to research allow the United States to remain competitive in all but a few areas.

Participants 2 (MIG) and 21 discussed the restrictive funding policy of the Bush administration. Participant 2 shared that the restrictions during the Bush administration resulted in U.S. researchers being at a disadvantage compared to researchers in Europe and Asia. However, Participant 2 noted that the United States no longer lags behind other countries and in many ways is as or more advanced than most countries. Some participants shared that the Obama administration's relaxation of funding restrictions had improved United States' competitiveness. Participant 20 (MSU) related that under the Bush administration, the stem cell policy was too restrictive, but the "current policy is a good balance of ethics and ability to do research." Participant 12 (MSU) shared that United States' competitiveness has improved, the country does not lag behind in stem cell research, and an example of this is that his group has had a large growth. Similarly, Participant 19 (FRP) agreed that the situation for U.S. researchers had been improved due to the Obama administration's policies, which have helped the United States to become more competitive with other countries. Similar to Participants 12 and 19, Participant 7 shared that the Obama administration's more expansive policy has improved competitiveness, but researchers "are still restricted to the creation of new lines due to the

lack of using federal funds." Participant 12 also argued that if the stem cell policy is further relaxed, U.S. research could have a global effect.

Some participants noted that the federal policy has hindered U.S. stem cell research. Participant 1 (FRP) reported that stem cell research has not improved and more research should be done. Similarly, Participant 13 (FRU) related that U.S. stem cell policy has diminished United States' competitiveness with other countries; specifically, Japan and Europe. Participant 13 also noted that for the last 5 years there has been an increase in U.S. studies; however, while such studies are at the forefront, the volume of research and the number of stem cell researchers in the United States are still limited. Participant 15 (FSU) indicated that restrictions on stem cell research in the U.S. might give an advantage to other countries, such as China, since the chances for a breakthrough and discovery are greatly increased in places other than the United States. Participant 15 also recommended that researchers and the stem cell community advocate for more relaxed stem cell policies as some hESC lines are still needed for research since iPS cells may not behave exactly the same as embryonic cells. Therefore, Participant 15 noted that researchers need to continue their examination of all stem cell types since they do not know which one will be the best to use in therapy. Participant 6 (FIP) shared that due to limitations in the United States, companies who want to be more competitive do research in other countries and then bring the results of their research to the United States, which makes it very costly for everyone to reap the benefits. Participants 8 (FIP) and 9 (FSU) agreed that federal restrictions were causing the United States to lag in stem cell research. Participant 8 related that stem cell research in the United States is at a disadvantage due

to stringent FDA regulatory requirements, which are stricter than those of other countries. Participant 4 (MRP) related that the federal policy has slowed the creation of new lines of hESCs, since that research can only be done using nonfederal funds. Participant 4 also stated, "While funding science to the highest levels makes economic sense for our country, stem cell research is a global enterprise, and discoveries and stem cell-derived therapies in one country will benefit those in other countries."

Research Question 2

What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research? Based on Research Question 2 analyzed data, one overarching theme and five subthemes emerged to answer this research question. Participants expressed a variety of perceptions of the moral debate surrounding hESC research. Some participants believed that opposition to the research was invalidated either by its subjective or irrational impetus or by its failure to address all the facts. Participants also noted that the scope of the disagreement was limited to hESCs and that emerging iPS cell technology might render it moot. Regarding the possibility of compromise between proponents and opponents of hESC research, two participants were pessimistic, while other participants viewed iPS cell research as an existing compromise. Some participants believed that education about hESC research would lead to widespread acceptance of the technology.

In regard to the context of each research setting, the majority of the participants agreed that until religion has been removed from the stem cell debate, a compromise is not possible between opponents and proponents of stem cell research. To improve the

outcome of stem cell research, participants discussed the need for a bipartisan bill, greater education, and a stable policy that does not change every 4 to 8 years. Table 5 depicts the occurrences and percentages for perceptions of the moral disagreement subthemes.

Theme 2: Perceptions of the moral disagreement about stem cell research. This theme has five subthemes, which are as follows: (a) understanding opposition, (b) religious or moral objections, (c) stem cell source, (d) reasoning, and (e) the possibility of compromise. Participants' responses are categorized in the five subthemes below.

Table 5

Subtheme Occurrences and Percentages for Perceptions of Moral Disagreement

Theme	Subthemes	No. of occurrences	% of occurrences
Perceptions of the moral disagreement about stem cell research	Understanding opposition	5	11%
	Religious or moral objections	8	18%
	Stem cell source	10	23%
	Reasoning	4	9%
	Possibility of compromise	17	39%
	Total	44	100%

Subtheme 1: Understanding opposition. Participants 10, 11, 12, 16, and 18 noted that they understood, but did not agree with the ethical objections to hESC research. Participants 10 (FIP) and 12 (MSU) related that they understood the perceptions and concerns of the general public in regard to the use and potential misuse of human tissues

for research purposes. Participants 11 (FSU) and 16 (FRP) acknowledged the disagreement, but emphasized the necessity for an ongoing dialogue. Participant 11 shared that the disagreement is understandable, but the topic should be further discussed. Participant 16 stated, "I am sympathetic to it, but at the same time, the beneficial aspects of this research can be insurmountable, so there needs to be ongoing communication." On the other hand, Participant 18 (FRP) noted that everyone has a right to their own belief.

Subtheme 2: Religious or moral objections. Some participants were less sympathetic toward opponents of hESC research. Participant 1 (FRP) abstained from making a judgment and shared that "a lot of the moral disagreement is related to the Christian views related to how embryos are being used to accomplish scientist goals." Participant 15 FSU) believed that opposition to hESC research was due to combination of political calculation and misdirected sentiment:

> I do not believe there is a moral disagreement; rather a religious perception and power calculations to distract the electorate from important social and political issues. Morality is intimately linked to politics in the United States. We have the moral obligation to save lives. If the material we use was procured from spontaneous abortions or medically recommended abortions, we are not conducting an immoral activity.

Participant 2 (MIG) was sympathetic to stem cell opponents' belief about stem cell research and related that there are many people with strong religious faith who are opposed to the use of fetal tissue or ESCs in research because they consider these a violation of the sanctity of life. Participant 2 respected those views, but disagreed that the

use of fetal tissue or ESCs is ethically or morally wrong. Participant 2 noted an "obligation to pursue the use of these materials in scientific work because of their enormous potential to save the lives of millions of people around the world who are currently battling deadly diseases and disorders that have no cures." Participant 5 (MIG) reported that the moral disagreement with stem cell research is rooted primarily in Christianity and discussed the lack of separation of church and state. Participant 5 also noted that while the adult stem cells have many advantages, they also have limitations when compared to hESCs.

Participant 14 (FIG) also discussed the connection between religious opposition to hESC research as well as religious opposition to abortion. Participant 14 noted that many opponents of stem cell research, like religious leaders, compared stem cell research to abortion. Participant 14 noted that for the Catholic Church, life begins at conception, which makes stem cell research comparable to homicide because it results in the destruction of many embryos. Participant 14 noted that from a moral standpoint, stem cell research may be perceived as wrong, but researchers are right in doing stem cell research. Participant 4 (MRP) also discussed the connection between the opposition to abortion and hESC research. Participant 4 noted that the misperception that hESC research is connected to abortion will continuously entangle this research in political debates. Participant 4 argued that embryos no longer needed for fertility treatments will be discarded as medical waste if they are not donated to science or adopted by another couple, which rarely occurs. Thus, stopping ESC research does not save the embryos. Similar to Participants 4 and 14, Participant 3 (MSU) discussed the moral disagreement

with stem cell research in relation to abortion. Participant 20 (MSU) shared that the moral disagreement about hESC research was between an ethical consensus among medical professionals and the subjective reactions of some private individuals. Participant 20 shared that the moral issue is a personal issue because the U.S. policy is in line with most bioethics considerations.

Subtheme 3: Stem cell source. Three participants out of 21 (14%) noted that the moral disagreement surrounding stem cell research depended on the source of the cells in question. Participant 1 (FRP) stated, "In the United States, we get caught up with the logistics, such as whether the stem cells are being used from human embryos or from one's own stem cells, which is two different processes, but is still misunderstood to this day." Participant 4 (MRP) related that the disagreement with stem cell research is over the destruction of embryos to create hESC lines and not over stem cell research in general. Participant 21 (MIP) related that the debate over the moral status of the embryo will remain stagnant and will continue to shape public opinion toward the field. On the other hand, Participant 4 was more optimistic about the chances for a satisfactory resolution due to emerging technology. Participant 4 stated, "More companies are moving to fibroblast stem cell [iPSC] research, so the issue will become invalid soon, essentially making it a nonissue."

Subtheme 4: Reasoning. Some participants questioned the validity of the debate, not because the reason for disagreement was religious or moral, but because they perceived the reasoning of hESC research opponents as flawed. Participant 7 (MSU) related that the moral disagreement with stem cell research is a nonissue because if

people understood that most of the vaccines that "have been derived from these tissues being discussed and if they looked further into what the actual usage is and reasons are behind it, most people would understand the importance of the research." Similarly, Participant 17 (FRP) related that the moral disagreements with stem cell research are mainly due to lack of scientific knowledge and factual information because many times facts are misrepresented, which perpetuates a false perception. Participant 17 believed that hESC research might be promoted by an appeal to common sense and argued that instead of wasting stem cells, why not put them to good use that benefits all people. Participant 8 (FIP) believed that public's understanding of the controversy was impaired by equivocal terminology:

> There is no moral disagreement about stem cell research. You shed your skin regularly because skin stem cells are constantly renewing and replacing damaged, old skin. You can donate a lobe of your liver and it will grow back because liver stem cells will regenerate it. Every tissue in your body constantly renews itself through tissue-specific stem cells. To say you have a moral disagreement with stem cell research is like saying you object to your liver. There is controversy about the use of ESCs for research, but I see it as a far greater issue in the lay public than it is in the research community. Most scientists I know find it less an ethical problem than a scientific one. Because ESCs form cancers, their primary contribution will continue to be disease modeling and drug screening. And the ethical concerns about using embryonic cells have been completely leapfrogged

by the discovery of iPS cells. Even the Vatican supports and funds adult and iPS cell research.

Subtheme 5: The possibility of compromise. Participants 4 and 5 believed that compromise between proponents and opponents of stem cell research was unlikely. Participant 4 related that compromise is not possible, while Participant 21 (MIP) shared that compromise is not likely for those with strong views on the moral status of the human embryo. Participant 5 suggested that the benefits of hESC research might gradually persuade its opponents:

> Unfortunately, I do not think hESC opponents are willing to compromise, but when hESC-based treatments [and] therapies for diseases that afflict them or their family members become available, I hope they will take advantage of them and maybe reconsider their stance.

Participants 3, 10, 15, 16, and 21 believed that deriving the necessary research materials from uncontroversial sources would render the hESC debate moot. Participant 21 suggested that focus on less contentious technologies, such as iPS cells and use of existing rather than new hESC lines offer some hope. Similarly, Participants 10 (FIP) and 16 (FRP) noted that continued use of iPS cells can be considered as a compromising option. Participant 15 (FSU) noted that the use of iPS cells is a compromise with stem cell research opponents; however, researchers still do not know the real potential of this technology and its application to therapy. Participant 3 (MSU) suggested that contention could be alleviated by working to develop and improve lines in which ethical issues have been thoroughly discussed.

Some participants recommended more effective education of the public as a means of promoting compromise. Participant 7 (MSU) placed the burden of promoting education on opponents of stem cell research. Participant 7 shared that compromise can occur with the use of more meaningful questions about stem cell research outcomes, "such as what does the research mean to my family and to the country now and into the future." Participant 6 (FIP) placed the burden on proponents of stem cell research, suggesting that they should "provide a greater understanding." Participant 12 (MSU) referred to education and the concurrent use of uncontroversial materials as a means of achieving a compromise:

> I believe the best compromise is using other stem cell lines beyond embryonic and making the public aware of the differences. For example, hMSCs [human mesenchymal stem cells], which we use, are from a human, adult, healthy donor and these cells have shown to be great in curing very devastating conditions such as stroke or cardiac problems.

Research Question 3

What do U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States? Based on Research Question 3 analyzed data, one theme and four subthemes emerged to answer this research question. Participants suggested that U.S. federal stem cell policy could be improved by (a) excluding religious considerations from political discussions, (b) involving outsiders and nonprofessionals in the debate, (c) promoting outreach education about the advantages

and disadvantages of stem cell research for laypersons and legislators, and (d) increasing federal funding.

In regard to the context of each research setting, researchers, investors, and stakeholders recommended the need for increased federal funding to improve stem cell research in the United States as well as the need to educate the general public and lawmakers. Stakeholders recommended including people from the outside in stem cell discussions and removing religious agendas. Table 6 depicts the occurrences and percentages for policy recommendations subthemes.

Theme 3: Policy recommendations. This theme has four subthemes, which are as follows: (a) funding, (b) involving outsiders, (c) excluding religion, and (d) education. Participants' responses are categorized in the four subthemes below.

Table 6

Subtheme Occurrences and Percentages for Policy Recommendations

Theme	Subthemes	No. of occurrences	% of occurrences
Policy recommendations	Funding	9	26%
	Involving outsiders	7	21%
	Excluding religion	4	12%
	Education	14	41%
	Total	34	100%

Subtheme 1: Funding. Participants 1, 2, 8, 9, 20, and 21 made policy recommendations to increase federal funding. Participant 2 (MIG) shared that it is going to take a huge investment by the government to really push stem cell research forward.

Participant 8 (FIP) summarized her recommendations in the form of an equation, stating, "Streamlined process plus money equals competitive advantage, where streamlined process referred to an acceleration of the FDA approval process. Participant 2 also mentioned FDA requirements and noted that it is "going to take changes in the way the FDA regulates stem cell therapies to enable the science to move ahead as fast as it needs to." Participants 1, 9, 20, and 21 also recommended an increase in federal funding.

Subtheme 2: Involving outsiders. Participants 3 and 7 suggested involving outsiders and laypersons in the stem cell research discussion. Participant 3 (MSU) recommended bringing in people from the outside, not just professionals. Similarly, Participant 7 (MSU) also recommended the engagement of lay people who are recipients of the therapy along with professionals in the field. Participant 7 explained that involving the public might be an effective political agenda because "people are very similar when it comes to saving lives. People respect human life and are more practical in their understanding if they can relate outcomes to their own family and loved ones."

Subtheme 3: Religion. Participant 9 (FSU) recommended the removal of religious agendas from the dialogue, stating, "The ethical interpretations to ESC use are not scientifically informed and restrictions should be reevaluated without political or religious input." In addition, Participant 9 recommended that legislators vote to overturn religious agendas because stem cell research will not move forward until the policies change.

Subtheme 4: Education. Some participants recommended different forms of education to make federal policy more favorable to hESC research. Participant 9 (FSU)

recommended "improved science education, public announcements educating the public, [and] encouraging open discussion of policy, ethics, and science." Participant 14 (FIG) shared that the general public should be educated about the benefits of stem cell research because they do not know enough. Participant 14 recommended reaching out to community residents. Participant 17 (FRP) recommended educational outreach where both sides of stem cell research are discussed with stakeholders with the goal of reaching a common, middle ground. Participant 19 (FRP) agreed with Participant 17 and recommended that people need to be educated on the advantages and disadvantages of stem cell research. Participant 1 (FRP) suggested that educational efforts should not only focus on the general public, but that lawmakers should be educated as well.

Summary of Findings

The purpose of this qualitative phenomenological research study was to explore the perceptions of 21 stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. In-depth telephonic semistructured interviews with 21 stem cell researchers, stakeholders, and investors in the United States were used to address the three research questions. Using Attride-Stirling's (2001) six steps or stages on how to conduct a thematic analysis, three overarching themes (perceptions of the effects of the Obama administration's federal stem cell policy, perception of moral disagreement about stem cell research, and policy recommendations)

and 14 subthemes emerged in answering the research questions. The 14 subthemes are discussed below.

First, in regard to U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States, participants discussed their perceptions of the Obama administration's funding policy, the NIH's ethical policy, the Dickey-Wicker Amendment, and competition between the United States and other countries. Findings indicated those participants' perceptions of U.S. federal stem cell policy varied widely as some participants perceived the policy as beneficial, irrelevant, or a constraint on stem cell research. Only a few participants expressed approval of the current stem cell policy. Some participants who perceived the federal stem cell policy as beneficial to U.S. stem cell research expressed their approval, stating that the Obama administration's comparatively relaxed funding policy was more advantageous to stem cell researchers than the Bush administration's restrictions, although the Obama administration's policy was not necessarily optimal. Some participant noted that while the federal stem cell policy makes it easier to do more research, funding is still slow due to past policies and restrictions. Some participants described the policy as a significant constraint because despite all the testing that is taking place, the benefit from stem cell is still not fully realized. Other participants believed that funding restrictions, which only affected research conducted on hESCs, had lost much of their significance with the increasing prevalence of research involving iPS cells and adult stem cells. Six participants (29%) believed that current funding restrictions prescribed by the Dickey-Wicker Amendment

were invalidated by their reliance on justifications that were perceived as irrational, although 13 participants (62%) agreed with the amendment. Almost all participants, however, agreed with the NIH ethical policy, with 17 of 21 participants (81%) describing the policy as a valuable means of promoting ethical science. Some participants expressed concerns about the NIH policy, such as the ethical interpretations of ESC use are not scientifically informed and restrictions should be reevaluated without political or religious input. Some participants highlighted that restrictive stem cell policies could have a negative effect on the international standing of U.S. stem cell research because major research companies move their stem cell research division to other countries where scientists are permitted to conduct research without any restriction.

Second, in regard to U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research, participants discussed understanding of the opposition, religious or moral objections, stem cell source, reasoning, and the possibility of compromise. Findings indicated that participants had different perceptions of the moral debate surrounding hESC research. Some participants believed that opposition to the research was invalidated either by its subjective or irrational impetus or by its failure to address all the facts. Some participants shared that opposition to hESC research was due to combination of political calculation and misdirected sentiment. Some participants also discussed the connection between religious opposition to hESC research as well as religious opposition to abortion. Some participants noted that embryos no longer needed for fertility treatments were discarded as medical waste if they were not donated to science or adopted by another couple; thus,

stopping ESC research does not save the embryos. Participants also noted that the scope of the disagreement was limited to hESCs and that emerging iPS cell technology might render it moot. Hence, some participants pointed out that the disagreement with stem cell research is over the destruction of embryos to create hESC lines and not over stem cell research in general. Some participants questioned the validity of the stem cell debate because they perceived the reasoning of hESC research opponents as flawed. Regarding the possibility of compromise between proponents and opponents of hESC research, some participants were pessimistic, while other participants viewed iPS cell research as an existing compromise. Some participants believed that education about hESC research would lead to widespread acceptance of the technology.

Third, in regard to what U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States, participants discussed funding, involving outsiders, excluding religion, and the need for education. Findings indicated that participants believed that the U.S. federal stem cell policy could be improved by excluding religious considerations from political discussions, involving outsiders and nonprofessionals in the debate, promoting outreach education about the advantages and disadvantages of stem cell research for laypersons and legislators, and increasing federal funding. In Chapter 4, I included the introduction, setting, demographics, data collection, data analysis, evidence of trustworthiness, results, and a summary. In Chapter 5, I include the introduction, interpretation of findings, limitations of the study, recommendations, implications, and a conclusion.

Chapter 5: Discussion, Conclusions, and Recommendations

In this phenomenological study, I explored seven U.S. stem cell researchers', seven U.S. stakeholders', and seven U.S. investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States. I collected data through in-depth telephonic semistructured interviews. This study was designed to answer three research questions: (a) U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States, (b) U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research, and (c) U.S. stem cell researchers, stakeholders, and investors recommendations to improve stem cell research policy in the United States.

Using Attride-Stirling's (2001) six steps of thematic analysis, I found three overarching themes (perceptions of the effects of the Obama administration's federal stem cell policy, perception of moral disagreement about stem cell research, and policy recommendations) and 14 subthemes. Findings indicated that participants' perceptions of U.S. federal stem cell policy varied as some participants perceived the policy as beneficial while others perceived it as irrelevant or a constraint on stem cell research. Only a few participants expressed approval of the current stem cell policy. Some participants who perceived the federal stem cell policy as beneficial noted that the Obama administration's comparatively relaxed funding policy was more advantageous to stem

cell researchers than the Bush administration's restrictions, although the Obama administration's policy was not necessarily optimal.

In sharing their perceptions about the moral disagreement with stem cell research, participants discussed understanding of the opposition, religious or moral objections, stem cell source, reasoning, and the possibility of compromise. Findings indicated that participants had different perceptions of the moral debate surrounding hESC research where some participants believed that opposition to the research was invalidated either by its subjective or irrational impetus or by its failure to address all of the facts. Participants also noted that the scope of the disagreement was limited to hESCs and that emerging iPS cell technology might render it moot. Some participants pointed out that the disagreement with stem cell research is over the destruction of embryos to create hESC lines and not over stem cell research in general. Findings also indicated that participants believed that the U.S. federal stem cell policy could be improved by excluding religious considerations from political discussions, involving outsiders and nonprofessionals in the debate, promoting outreach education about the advantages and disadvantages of stem cell research for laypersons and legislators, and increasing federal funding. In Chapter 5, I present the interpretation of findings, limitations of the study, recommendations, implications, and a conclusion.

Interpretation of the Findings

I explored seven stem cell researchers', seven stakeholders', and seven investors' perceptions in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell

research, and recommendations to improve stem cell research policy in the United States. This qualitative phenomenological study was designed to answer three research questions. The findings are interpreted in the context of Rogers's (1962) DOI theory, Kingdon's (1995) agenda-setting theory, and the literature review. This section contains the following subsections: Research Question 1, Research Question 2, and Research Question 3.

Research Question 1

What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States? The results of Research Question 1 included participants' perceptions of the Obama administration's funding policy, the NIH's ethical policy, the Dickey-Wicker Amendment, and competition between the United States and other countries. Participants' perceptions of U.S. federal stem cell policy varied widely as some participants perceived the policy as beneficial while others perceived it as irrelevant or a constraint on stem cell research. Only a few participants expressed approval of the current stem cell policy. Some participants who perceived the federal stem cell policy as beneficial stated that the Obama administration's comparatively relaxed funding policy was more advantageous to stem cell researchers than the Bush administration's restrictions, although the Obama administration's policy was not necessarily optimal. Some participants noted that although the current stem cell policy makes it easier to do more research, funding is still slow due to previous policies and restrictions. Some participants described the policy as a significant constraint because despite all the testing

that is taking place, the benefits from stem cell research are not fully realized. Other participants reported that funding restrictions, which only affected research conducted on hESCs, had lost much of their significance with the increasing prevalence of research involving iPS cells and adult stem cells. Six participants (29%) commented that current funding restrictions prescribed by the Dickey-Wicker Amendment were invalidated by their reliance on justifications that were perceived as irrational, although 13 participants (62%) agreed with the amendment. Almost all participants agreed with the NIH ethical policy, with 17 participants (81%) describing the policy as a valuable means of promoting ethical science. Some participants expressed concerns that ethical interpretations of ESC use are not scientifically informed and restrictions should be reevaluated without political or religious input. Some participants highlighted that restrictive stem cell policies could have a negative effect on the international standing of U.S. stem cell research because major research companies move their stem cell research division to other countries where scientists are permitted to conduct research without any restriction.

Findings from Research Question 1 may be interpreted using Rogers's (1962) DOI theory. Restrictive stem cell policies could have a negative effect on the international standing of U.S. stem cell research as major research companies move their stem cell research division to other countries where scientists are permitted to conduct research without restriction. Amidon (2005) noted that limiting the spread of innovation slows growth. Rogers (1995) argued that diffusion, which is the means of how information is shared among a group of people in a network, may prevent the innovation

of a new product, idea, or practice from being accepted by others of a particular culture or network. The DOI theory can also be applied to the finding that although the current stem cell policy makes it easier to do research, funding is still slow due to previous policies and restrictions. This finding is consistent with what has been reported in the literature where differences in national regulatory approaches have generated competition to implement stem cell programs that will give countries an edge in the global knowledge economy (Gottweis et al., 2009). Countries such as China, India, South Korea, and Singapore have been identified as emerging biotech powers (Wahlberg, 2012).

Some participants described the U.S. stem cell policy as a significant constraint because despite all the testing that is taking place, the benefits from stem cell are not fully realized. This finding can be examined using Rogers's (1995) discussion of the diffusion and adoption step in the innovation-development process. Rogers noted that this is the most difficult step in the innovation-development process, which involves diffusing the product to potential adopters. As with all new products, there is pressure to move it to market due to the problem and need being high priority. Sometimes public funds are used until there is a positive outcome that will be beneficial to potential adopters. The move to market is where scientists seem to have the greatest concern around innovation, which includes unveiling the product and putting it into practice.

Participants' perceptions that the Dickey-Wicker Amendment was irrational and that restrictions from the amendment are a challenge for the stem cell field are consistent with the Kingdon's (1995) agenda-setting theory. In regard to Kingdon's three streams (problems, policies, and politics), Chayabunjonglerd (2012) reported that problems with

hESC began with the 1998 discovery that introduced new possibilities, and scientists sought to gain more funding through government sponsorship. According to Chayabunjonglerd, scientists argued that the Dickey-Wicker Amendment that banned the use of human embryos in federally funded projects hindered significant advances in health care. Chayabunjonglerd noted that the issue of federal funding of hESC research raised the important question of whether the government should fund hESC research. Chayabunjonglerd claimed that President Bush's inauguration represented significant change in the political stream, which opened a window for him to push forward his policy on hESC research. This resulted in the policy stream, where President Bush issued a Presidential Statement in 2001 that limited federal funding of research involving hESCs (Chayabunjonglerd, 2012; Obama, 2009).

Some participants commented that the federal stem cell policy was beneficial to U.S. stem cell research and expressed their approval, stating that the Obama administration's comparatively relaxed funding policy was more advantageous to stem cell researchers than the Bush administration's restrictions, although the Obama administration's policy was not necessarily optimal. This finding is consistent with what has been reported in the literature. Hyun (2010) related that although the controversy over embryo destruction continues, the Obama administration's friendlier stance toward hESC research has helped the proponents' public debate over hESC research. President Obama's EO removed limitations on scientific inquiry and expanded the NIH support for the exploration of stem cell research, with the purpose of enhancing the contributions of U.S. scientists to make important discoveries and create new therapies for the benefit of

humanity (Obama, 2009). However, despite President Obama's reversal of some of the barriers to hESC research, questions remain about the extent to which U.S. stem cell researchers have truly benefited from this more relaxed federal funding policy (Nature Cell Biology, 2010; Wolinsky, 2009).

Research Question 2

What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research? The results of Research Question 2 included participants' understanding of the opposition, religious or moral objections, stem cell source, reasoning, and the possibility of compromise. Participants had different perceptions of the moral debate surrounding hESC research. Some participants commented that opposition to the research was invalidated either by its subjective or irrational impetus or by its failure to address all of the facts. Some participants shared that opposition to hESC research was due to a combination of political calculation and misdirected sentiment. Some participants also discussed the connection between religious opposition to hESC research as well as religious opposition to abortion. Some participants noted that embryos no longer needed for fertility treatments are discarded as medical waste if they are not donated to science or adopted by another couple, and stopping ESC research does not save the embryos. Participants also noted that the scope of the disagreement was limited to hESCs and that emerging iPS cell technology might render it moot. Some participants pointed out that the disagreement with stem cell research is over the destruction of embryos to create hESC lines and not over stem cell research in general. Some participants questioned the validity of the stem cell debate

because they perceived the reasoning of hESC research opponents as flawed. Regarding the possibility of compromise between proponents and opponents of hESC research, some participants were pessimistic while others viewed iPS cell research as an existing compromise. Some participants believed that education about hESC research would lead to widespread acceptance of the technology.

Findings from Research Question 2 may be interpreted using Rogers's (1962) DOI theory. Some participants discussed the connection between religious opposition to hESC research and religious opposition to abortion. Rogers (2003) argued that there are five factors that influence the adoption of innovation probability rate: (a) relative advantage, (b) compatibility, (c) complexity, (d) trialability, and (e) observability. Compatibility is determined by the acceptability of social or religious norms in the country, which may forbid certain practices, attitudes, or behaviors. Findings from the current study indicated that some participants believed that education about hESC research would lead to widespread acceptance of the technology. Rogers also discussed the five innovation-decision processes: (a) knowledge, (b) persuasion, (c) decision, (d) implementation, and (e) confirmation. In the knowledge stage, individuals are exposed to an innovation, but they do not have information about the innovation. Perhaps additional knowledge about hESC research, such as the knowledge that embryos no longer needed for fertility treatments are discarded as medical waste if they are not donated to science or adopted by another couple, may lead to more widespread acceptance of hESC research.

The finding that opposition to hESC research was due to a combination of political calculation and misdirected sentiment can be interpreted using Kingdon's (1995)

agenda-setting theory. In the politics stream, Kingdon noted that politics are factors that influence agendas, such as political climate or mood and the voices of advocacy or opposition groups. Findings indicated that participants had different perceptions of the moral debate surrounding hESC research. This finding is consistent with the literature indicating that the ethical and moral disagreement about hESC research and the destruction of embryos continues between proponents of religion and science (Doerflinger, 2010). Stem cell research remains highly controversial because there are unresolved questions about human cloning, therapeutic abortions, and reproductive rights (Adelson & Weinberg, 2010). Lysaght and Campbell (2012) reported that there are concerns that have generated political and public bioethical debates. Fadel (2012) discussed the issue of ethics in stem cell research and noted that it remains a lengthy and heated debate in the scientific literature, religious circles, and the political arena. Fadel noted that the debate includes the need to protect human life from the time of inception versus curing many debilitating diseases.

Regarding the possibility of compromise between proponents and opponents of hESC research, some participants were pessimistic, while other participants viewed iPS cell research as an existing compromise. This finding is consistent with the literature as those in support of hESC research have argued that it is morally permissible to use surplus embryos for biomedical research that may save many lives (Mintrom, 2013). However, those who oppose hESC research do not agree with this argument and have argued that such research would still support the destruction of embryos. Levine (2011) related that due to the divisiveness of the hESC research debate and the history of

policymaking in other morally charged areas, policy certainty will continue to prove difficult. Hence, some degree of uncertainty may be unavoidable and as a result, hESC researchers should prepare for continued policy changes, legal challenges, and other challenges to their research. Although the controversy over embryo destruction continues, Hyun (2010) related that the creation of human iPS cells, which are genetically engineered to act like hESCs, have helped the proponents' public debate over hESC research. The researcher noted that the main bioethical considerations now focuses more on how stem cell research should be conducted instead of whether it should be conducted. Those who oppose hESC research applauded the iPS cell revolution, which they hoped would end ESC research. However, most stem cell researchers believe that iPS or other alternative source of stem cells do not take away the need for ongoing hESC research. Thus, some participants recommended that researchers and the stem cell community advocate for more relaxed stem cell policies as some hESC lines are still needed for research since iPS cells may not behave exactly the same as embryonic cells.

Research Question 3

What do U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States? The results of Research Question 3 indicated that participants discussed funding, involving outsiders, excluding religion, and the need for education. Participants believed that the U.S. federal stem cell policy could be improved by excluding religious considerations from political discussions, involving outsiders and nonprofessionals in the debate, promoting outreach education

about the advantages and disadvantages of stem cell research for laypersons and legislators, and increasing federal funding.

Findings from Research Question 3 may be interpreted using Rogers's (1962) DOI theory, such as some participants recommending the removal of religious agendas from the dialogue and that legislators vote to overturn religious agendas because stem cell research will not move forward until the policies change. Rogers (1995) noted that groupthink tends to limit the spread of innovation. Leaders of a group exert influence over the behaviors of individuals and adopters in their networks, such as influencing followers' beliefs (Anderson, 2006; Janis, 1989; Rogers, 1983). Limiting the spread of innovation also slows down growth (Amidon, 2005). According to Amidon (2005), individuals in political or social settings tend to accept groupthink as a form of solidarity and unanimity.

Rogers's (1962) DOI theory can also be attributed to participants' recommendation to involve outsiders or laypersons as well as well as using different forms of education to make federal policy more favorable to hESC research, such as improved science education, public announcements educating the public, and encouraging open discussion of policy, ethics, and science. Terin (2012) noted that diffusion of innovation is connected to an individual's perception of a new product or service, while invention is new. Therefore, Therin related that with the perception of newness, there must be knowledge about the service or product, otherwise that perception is not relevant. In addition, any new innovation must be known among the targeted population of potential adopters and a clear perception should be established. Once the

knowledge about the product and service has been conveyed, there should be a theoretical framework in place to rate the adoption of the new innovation.

Participants' recommendation to increase funding can be attributed to Kingdon's (1995) agenda-setting theory. Dresser (2010) reported that in the United States, the stem cell controversy opens a window to a larger moral problem (Dresser, 2010). According to Dresser (2010), the social justice inquiry about what justifies the United States substantial investment in biomedical innovation, when millions of people in the United States and abroad are denied access to proven medical interventions, raises questions about the priority that stem cell and other basic science studies should have in the competition for limited resources. Dresser argued that if government officials and health advocates want to help patients, meaningful help would also come from a system that supplied adequate health care to more people, both across the nation and worldwide.

Participants' recommendation for increase funding is also consistent with the literature. Adelson and Weinberg (2010) noted that the continuous changes in the policy by each President have been a source of great concern for representatives of states such as California, who support hESC research. Therefore, states such as California, have added additional revenue to the budget to further stem cell research programs. For example, in 2004, after President Bush's policy denied the use of federal funds to further research, California officials created the California Research Cures Initiatives to continue with their research after law was passed to stop federal funding to support stem cell research and to ban those who continued their study on stem cells from using laboratories and facilities that were supported by federal funds. California went on to create the CIRM

to provide oversight and created funding for all research in their state. The CIRM agreed to contribute $3 billion over a decade and create another $3 billion through the sale of public bonds and the state general fund to aid in the study of stem cells. Gottweis et al. (2009) emphasized that differences in national regulatory approaches have generated competition to implement stem cell programs that will give countries an edge in the global knowledge economy.

Limitations of the Study

There were several limitations of this study. First, findings were limited by the snowball sample of seven stem cell researchers, seven stem cell stakeholders, and seven stem cell investors; each category of participants contained a smaller number than the overall sample of 21. Due to the small sample size for each category of participant, caution has to be taken in transferring the findings to similar populations of U.S. stem cell researchers, stakeholders, and investors. In addition, the results of the study may not be transferrable to other populations or countries. As a result, in future research, the sample population for each type of participant could be increased to achieve a broader understanding of their stem cell research policy experiences. In future studies, a different sampling strategy could also be used, such as random sampling.

Second, social desirability bias was considered as stem cell researchers, stakeholders, and investors may have wanted to be perceived positively, so they may not have responded honestly to the interview questions. However, I assumed that participants would honestly and openly answer the interview questions by sharing their perceptions about the phenomenon. Third, there were limitations with self-reported data as

participants may not have accurately or fully evaluated themselves. However, I assumed that participants accurately and fully self-evaluated.

Recommendations

The six recommendations for future studies are grounded in the strengths and limitations of the study as well as the literature reviewed in Chapter 2: (a) Use random sampling for each group of participants, (b) focus on how subsequent U.S. administration stem cell policies affect stem cell research in the United States, (c) focus on the general public's knowledge of stem cell research as well as those of legislators, (d) focus on involving outsiders and laypersons in the stem cell research discussion, (e) investigate the divisiveness of the hESC research debate and what can be done to create a cohesive or bipartisan federal ESC public financing policy, and (f) focus on examining and comparing international communities' stem cell policies. These six recommendations are discussed in further detail below.

First, as noted in the limitations of the study section, it is recommended that in future research studies, the sample population for each type of participant (stem cell researchers, stakeholders, and investors) could be increased to achieve a broader understanding of their stem cell research policy experiences. In doing this, different sampling strategies could also be used, such as random sampling. Second, policy uncertainty affects researchers' plans more significantly than temporary funding bans (Levine, 2011). Adelson and Weinberg (2010) noted that continuous changes in the policy by each President have been a source of great concern for representatives of states. Participants also noted that stem cell policies could change with each subsequent

administration. Kingdon (1995) related that windows can predictably or unpredictably appear due to events such as election results or a sudden crisis, respectively (Kingdon, 1995). Therefore, future research could focus on how subsequent U.S. administration stem cell policies affect stem cell research in the United States, such as those of the new Trump administration.

Third, participants suggested that educational efforts should focus on the general public as well as lawmakers. Thus, future research studies could focus on the general public's knowledge of stem cell research as well as those of legislators. Fourth, participants suggested involving outsiders and laypersons in the stem cell research discussion; thus, future research studies could focus on this recommendation. Fifth, some participants noted that while the Obama administration's stem cell policy is a positive step, stem cell research is still stagnant and benefits have not increased from 2009 due to a lack of bipartisan support. Thus, future research could further investigate the divisiveness of the hESC research debate and what can be done to create a cohesive or bipartisan federal ESC public financing policy.

Sixth, participants shared that the Obama administration's more expansive policy has improved competitiveness, but researchers are still restricted to the creation of new lines due to the lack of using federal funds. In addition, participants argued that if the stem cell policy is further relaxed, U.S. research could have a global effect. Participants argued that U.S. stem cell policy has diminished United States' competitiveness with other countries; such as China, Japan, and Europe. Participant also shared that due to limitations in the United States, companies who want to be more competitive do research

in other countries and then bring the results of their research to the United States, which makes it very costly for everyone to reap the benefits. Thus, future research study could focus on examining and comparing international communities' stem cell policies, such as those in China, Japan, Europe, India, South Korea, and Singapore, who have been identified as emerging biotech powers (Wahlberg, 2012), with those of the United States so that lessons can be learned and to ensure that stem cell research continues to improve in the United States.

Implications

To improve stem cell research policy in the United States, U.S. stem cell researchers, stakeholders, and investors recommended the exclusion of religious considerations from political discussions, involving outsiders and nonprofessionals in the debate, promoting outreach education about the advantages and disadvantages of stem cell research for laypersons and legislators, and increasing federal funding. These recommendations have several implications for stem cell policymakers to focus attention and resources on creating a consistent federal hESC funding policy to ensure that stem cell research continues to improve in the United States. While some participants noted that funding restrictions, which only affected research conducted on hESCs, had lost much of their significance with the increasing prevalence of research involving iPS cells and adult stem cells, other participant recommended that researchers and the stem cell community should advocate for more relaxed stem cell policies as some hESC lines are still needed for research since iPS cells may not behave exactly the same as embryonic cells. Thus, a bipartisan hESC funding policy will lead to positive social change in the

health care field as hESCs can be used for cell-based therapies to replace ailing or destroyed tissues, such as macular degeneration, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis (NIH, 2015b). In addition, hESCs can be used to treat Alzheimer's and Parkinson's diseases; however, the need for transplantable tissues and organs far outweighs the available supply (CIRM, 2015b; NIH, 2015b).

Participants recommended the removal of religious agendas from the stem cell research policy dialogue. Policy entrepreneurs, who are political actors who seek policy changes to existing situations in areas of public policy, have faced significant opposition to government funding and favorable regulations to advance hESC research due to morality issues (Mintrom, 2013). The most restrictive stem cell laws are in countries where Roman Catholicism is a dominant religion or Christian democratic parties have been on the rise (Fink, 2008; Mintrom, 2013). Mintrom (2013) reported that the UK has a permissive approach to the hESC research regulation and that it is correlated with the low percentage of adults who identify with the Roman Catholic faith (9%) in the UK. Mintrom noted that in the UK, moral issues have been widely investigated and extensively debated; however, they have not inhibited scientific research.

Unlike the UK and other permissive countries, hESC research in the United States is divisive and controversial, which has resulted in continuous stem cell policy uncertainty (Levine, 2011; Levine et al., 2013; Mintrom, 2013). Participants related that stem cell policies could change with a different administration. Thus, there is no cohesive or bipartisan federal hESC funding policy, which stifles the United States' standing to be

a leading country for the advancement of hESC research (Mintrom, 2013; Sano, 2013). As a result, U.S. hESC researchers continue to face policy fluctuations, legal challenges, and other hurdles to their future research (Levine, 2011; Levine et al., 2013; Mintrom, 2013; Sano, 2013).

Participants recommended that outsiders and nonprofessionals should be involved in the stem cell research policy debate and outreach education on the advantages and disadvantages of stem cell research should be given to the general public and legislators. Participants also related that the moral disagreements with stem cell research are mainly due to lack of scientific knowledge and factual information because many times facts are misrepresented, which perpetuates a false perception. Thus, with educational outreach, where both sides of stem cell research are discussed with stakeholders, a common, middle ground may be reached.

Participants made policy recommendations to increase federal funding as it would increase U.S. stem cell research competitive advantage. Gottweis et al. (2009) reported that differences in national regulatory approaches have generated competition to implement stem cell programs that will give countries an edge in the global knowledge economy. Hence, to compete with countries such as China, India, South Korea, and Singapore, who have been identified as emerging biotech powers (Wahlberg, 2012), and to ensure that everyone can reap the benefits of stem cell research, a cohesive and more permissive federal hESC funding policy in the United States is needed. In this study, I addressed a gap in research by making an original contribution to the public policy and administration literature on U. S. stem cell research policy. In addition, along with the

fields of public policy and administration, a wide array of other fields, agencies, and organizations might be interested in the research findings as well, to include the fields of biology and regenerative medicine, and agencies such as the CIRM and the NIH.

Conclusion

To further understand and address the problem of federal support and funding for hESC research in the United States being behind stem cell programs in many countries and the continually evolving federal policies that have further hindered research efforts, it was important to obtain the perceptions of stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and recommendations to improve stem cell research policy in the United States because they have expertise in the field of stem cell research.. Researchers noted that unlike the UK and other permissive countries, hESC research in the United States are divisive and controversial, which has resulted in continuous stem cell policy uncertainty (Levine, 2011; Levine et al., 2013; Mintrom, 2013). There is no consistent federal hESC funding policy, which stifles the United States' standing to be a leading country for the advancement of hESC research (Mintrom, 2013; Sano, 2013). Levine (2011) related that policy uncertainty affects researchers' plans more significantly than temporary funding bans (Levine 2011). As a result, Levine recommended that lawmakers who are supportive of hESC research should work to create policies that reduce the uncertainty facing stem cell scientists. Nature Cell Biology (2010) related that while each state government will create restrictive policies for stem cell research within their borders, where several states

have already done so, a liberal policy at the federal level also softens the tone of hESC debate and promote greater acceptance of such research within the United States. As a result, from a policy perspective, more remains to be done to ensure that stem cell research improves in the United States.

Findings are directed at stem cell policymakers to focus attention and resources on creating a hESC federal funding policy that is cohesive to ensure that stem cell research continues to improve the United States. A bipartisan federal hESC funding policy will lead to positive social change in the health care field as hESCs can be used for cell-based therapies to replace ailing or destroyed tissues, such as macular degeneration, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis (NIH, 2015b). In addition, hESCs can be used to treat Alzheimer's and Parkinson's diseases; however, the need for transplantable tissues and organs far outweighs the available supply (CIRM, 2015b; NIH, 2015b). Therefore, by stem cell researchers, stakeholders, and investors educating the general public and lawmakers about hESC research, as well as involving the public in stem cell research discussions, maybe a common, middle ground can be reached.

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Appendix A: Invitation to Participate and Recommendation Request

Dear **Name Will Be Inserted Here**,

My name is Dorothy Moore and I am currently a doctoral student at Walden University. I am exploring the perceptions of stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and their recommendations to improve stem cell research policy in the United States.

I would greatly appreciate your participation.

Your participation would involve participating in a telephone interview which would take about 45 minutes. Interviews will be conducted at a time that is convenient for you.

The information from the interviews will be kept strictly confidential and no one who participates will be identified in any way.

If you have any questions about the study, please feel free to e-mail me at [E-mail address redacted] or give me a call at [Phone number redacted].

If you are interested in participating in the study and/or would like to recommend another stem cell researcher who works at a government organization, private company, or university; a stem cell stakeholder who is a faculty member at a univeristy where stem cell research is being conducted; or an investor who works for a government organization or private company that invests in stem cell research in the United States, please complete the questions below in a reply e-mail to me.

Thank you in advance for your consideration and assistance with my research project.

Sincerely,

Dorothy Moore

Dorothy Moore
[Phone number redacted]
[E-mail address redacted]

If you are interested in participating in the study and/or would like to recommend another stem cell researcher, stakeholder, or investor to be a participant in the study, please complete the questions below in a reply e-mail to me at [E-mail address redacted] **:**

1. Are you a stem cell researcher who works at a government organization, private company, or university? (please select by bolding your answer)
    a. Yes
    b. No
2. Are you a stem cell stakeholder who is a faculty member at a univeristy where stem cell research is being conducted? (Please select by **bolding** your answer)
    a. Yes
    b. No
3. Are you a stem cell investor who works for a government organization or private company that invests in stem cell research in the United States, stakeholder, or investor? (Please select by **bolding** your answer)
    a. Yes
    b. No
4. What is your gender? (Please select by **bolding** your answer)
    a. Male
    b. Female
5. What is your telephone number and preferred e-mail address?
6. Would you be willing to share your perceptions about about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and your recommendations to improve stem cell research policy in the United States, which will take approximately 45 minutes in a telephone interview?
7. If you participate in the study, would you be willing to verify the accuracy on your interview transcript that would be e-mailed to you at a later date after the interview has been completed and the interview has been transcribed?
8. Is there another stem cell researcher who works at a government organization, private company, or university; a stem cell stakeholder who is a faculty member at a univeristy where stem cell research is being conducted; or an investor who works for a government organization or private company that invests in stem cell research in the United States that you would like to recommend to be a participant in this study? If so, please provide their personal contact information or public work contact information that is available online, but please do not provide their nonpublic work contact information as it is considered private information.

Appendix B: Interview Guide

Interview Guide

Introduction

- Welcome participant and introduce myself.
- Explain the general purpose of the interview and why the participant was chosen.
- Discuss the purpose and process of interview.
- Explain the presence and purpose of the recording equipment.
- Outline general ground rules and interview guidelines such as being prepared for the interviewer to interrupt to assure that all the topics can be covered.
- Address the assurance of confidentiality.
- Inform the participant that information discussed is going to be analyzed in aggregate form and participant's name will not be used in any analysis of the interview.

Discussion Purpose

The purpose of study is to explore the perceptions of stem cell researchers, stakeholders, and investors in the United States about the effects of the current federal stem cell policy on stem cell research in the United States, the moral disagreement with stem cell research, and their recommendations to improve stem cell research policy in the United States.

Discussion Guidelines

Interviewer will explain:

Please respond directly to the questions and if you don't understand the question, please let me know. I am here to ask questions, listen, and answer any questions you might have. If we seem to get stuck on a topic, I may interrupt you. I will keep your identity, participation, and remarks private. Please speak openly and honestly. This session will be tape recorded because I do not want to miss any comments.

General Instructions

When responding to questions that will be asked of you in the interview, please exclude all identifying information, such as your name and names of other parties. Your identity will be kept confidential and any information that will permit identification will be removed from the analysis.

Possible Probes

- Could you elaborate more on that?
- That was helpful, but could you provide more detail?
- Your example was helpful, but can you give me another example to help me understand further?

Interview Questions

1. What do you perceive to be the effects of the current federal stem cell policy on stem cell research in the United States? **If clarity about the federal stem cell policy is needed:** President Obama issued an executive order, titled, *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, with the goal of strengthening human embryonic stem cell research in the United States (Levine, 2011; Nature Cell Biology, 2010). The Secretary of Health and Human

Services, through the Director of the NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law (Obama, 2009). However, President Obama's new stem cell policy did not approve the 21 hESC lines that were eligible under the Bush administration (Levine, 2011).

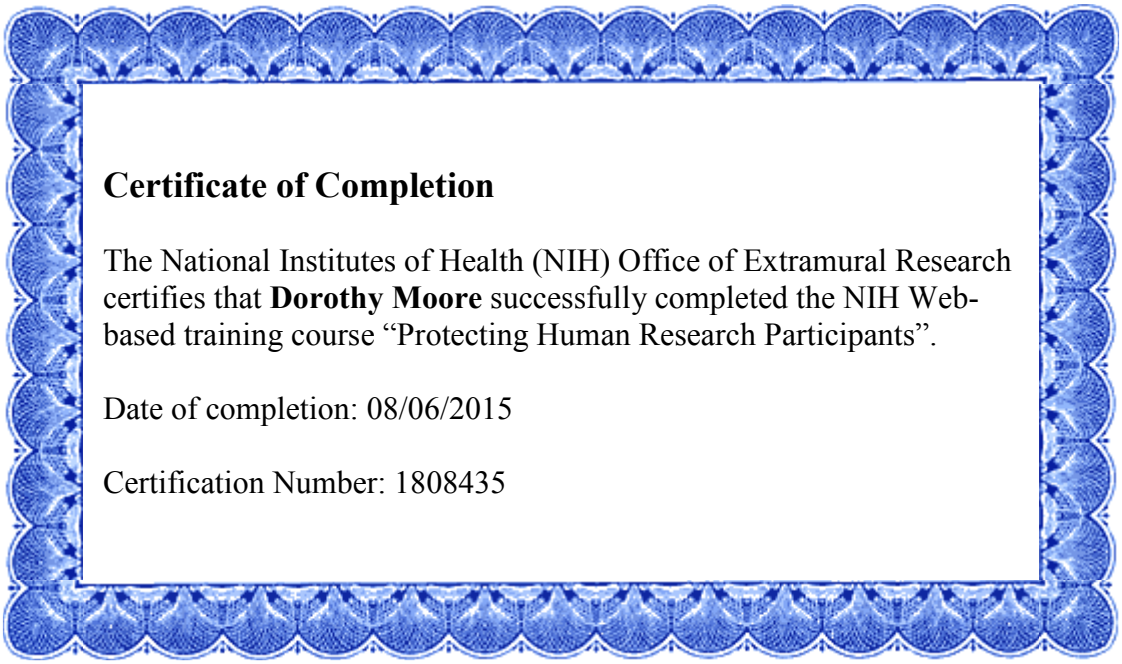
2. What are your thoughts about the National Institutes of Health strict ethical policies regarding human embryonic stem cell research and its effect on stem cell research in the United States? **If clarity about the NIH policy is needed:** Human embryonic stem cell lines have to meet the National Institutes of Health strict ethical policies (Nature Cell Biology, 2010). Applicant institutions proposing research using human embryonic stem cells derived from embryos donated in the United States should be derived from human embryos that were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose (NIH, 2015a). In addition, the human embryonic stem cells were donated by individuals who sought reproductive treatment and gave voluntary written consent for the human embryos to be used for research purposes (NIH, 2015a).
3. What are your perceptions about whether U.S. stem cell researchers have really benefited from President Obama's more relaxed funding policies?
4. What are your thoughts about how the Dickey-Wicker Amendment restricts the use of federal funds for creating, destroying, or knowingly injuring human embryos? **Possible Probe:** What steps can be taken to eliminate the Dickey-Wicker Amendment?

5. What are your perceptions on how the U.S. stem cell policy has diminished or improved U.S. stem cell research competitiveness with other countries?
6. What are your thoughts on how the U.S. can become more competitive with other countries that they lag behind in relation to stem cell research?
7. What are your perceptions about the moral disagreement with stem cell research?
8. What are your thoughts on how stem cell proponents and opponents can compromise on stem cell research?
9. What do you recommend to improve stem cell research policy in the United States?

Conclusion

- Discuss the transcription review process with participant, ask and answer any questions, and thank the participant for his or her time.

Appendix C: NIH Certificate



Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Dorothy Moore** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 08/06/2015

Certification Number: 1808435

Appendix D: Thematic Analysis Step 1 or Categorization of Text

Research Question 1

Research Question 1: What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States?

Thematic Label 1: What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the effects of the current federal stem cell policy on stem cell research in the United States.

Theme 1: Perceptions of the effects of the current federal stem cell policy.

Subtheme 1: Overall perceptions:

Participant 12 stated:
I do believe the current federal policy is for the betterment of science research and will have positive long-term effects on disease and disease treatment.

Participant 13 related:
Current federal stem cell policy has certainly boosted stem cell research considerably over the last 7 years. [The Obama administration's policy] has allowed stem cell researchers more flexibility in choosing cell lines of interest. In addition, there has been more investment in stem cell research, which has resulted in significant milestones being achieved in stem cell research in the United States. Importantly, multiple clinical trials have been initiated for stem cell therapy of degenerative diseases.

Participant 21 reported:
The current policy is fairly permissive and does not limit scientists' abilities to address most interesting and important questions.

Participant 7 noted:
The policy is restrictive. Although I appreciate the thoughtfulness behind the policy, it is still restrictive in terms of access to the research taking place.

Participant 6 stated:
The current federal stem cell policy makes it easier to do more research, but funding is still slow to roll out, due to past policies and restrictions.

Participant 1 explained:

The current policy does not give access to the research as it should. With all the testing that is taking place, the benefit from stem cell is still not fully realized by many because of access.

Participant 14 reported:
Stem cell policy has an impact. Major research companies move their stem cell research division to other countries where scientists are permitted to conduct research without any restriction.

Participant 15 stated:
These policies limit stem embryonic cell research and more importantly rapid advancement in therapeutic approaches and applications. The current stem cell policy does not affect my research. To my knowledge, as a scientist, progress has been made despite strict current policies.

Participant 20 related:
This policy does limit ongoing research in this important area. However, I understand that there is limited impact on research.

Participant 16 reported:
There may be limits on what research could be carried out using ESCs with federal funds, but most research is concentrated with the use of adult stems in the United States.

Participant 10 stated:
The current research that I am a part of is not affected by federal or state regulations. We are using iPS cells, induced pluripotent stem cells, which are generated from fibroblasts donated by patients.

Participant 11 noted:
I feel that governmental restrictions are less and less of a concern as research increasingly includes adult-derived stem cells and iPS cells. Few of my colleagues are performing research with ESCs, though this may change concurrently with changes in policy.

Participant 18 stated:
The policy does not have an impact, as research is more and more inclusive of adult stem cells versus ESCs.

Participant 19 stated:
Current policy is not an issue as ESC research is being done less and more adult stem research is being completed.

Participant 3 related:

The current policy as it stands is not very restrictive since people are able to use ESC lines as well as adult derived stem cells. In addition, ESCs can be derived from nonhumans as well as produced from skin cells.

Participant 17 noted:
Stem cell policy has a limited impact, if any, at this time.

Participant 15 stated:
[Federal policy] does not allow us to compare data generated from adult versus ESC research, which [is] the only way to know if the use of iPS cells is comparable.

Participant 8 stated:
If you mean the ban on federal funding for embryonic research put in place during the Bush administration and lifted during the Obama administration, it only banned the use of taxpayer dollars to pay for embryonic research. Taxpayer dollars have always been a significant source of funding for adult stem cell research and now iPS cell research. The ban only meant that if you wanted to do ESC research, you'd have to get private grants or venture capital to cover the costs. ESC research continued in labs across the country, but was largely leapfrogged by the discovery of iPS cells in 2012.

Subtheme 2: Perceptions of the Obama administration's funding policy:

Participant 13 stated:
Significant progress has been made in stem cell research over the last 7-plus years and we are at the cusp of realization of its clinical potential. In addition, there has been a great push for using stem cell as disease models and for in vitro toxicity testing. All these advancements can be largely contributed to President Obama's funding policies.

Participant 21 stated:
The relaxation of funding policies during the Obama administration has almost certainly benefitted scientists. This has come, in part, through access to a greater array of hESC lines and through a greater normalization of the field, reducing some of the complications associated with working with these cells.

Participant 4 elaborated further on the benefits of the relaxed funding policy:
U.S. researchers have absolutely benefitted from the relaxed policies governing the use of NIH funds to work on already established lines of hESCs. For example, there is ample data to show that different lines of stem cells have intrinsic differences in their ability to differentiate into different lineages. Having the ability to use multiple lines of ESCs in NIH-funded research allows scientists to characterize these differences and explore the causes to ultimately help understand fundamental properties of differentiation. We are a long way from understanding stem cell function, so research like this is essential.

Participant 12 noted that relaxed federal funding policies stimulated private funding sources:
Relaxed funding policies lead to more pharma and private donations, which is a good thing, and stem cell researchers have been the beneficiary.

Participants 4, 5, 10, 14, 16, 17, 19, and 20 gave responses that agreed in substance with those quoted above, describing the Obama administration's funding policy as beneficial to stem cell researchers.

Participant 2 believed that the current funding policy was beneficial and added:
It's easier for researchers to now use federal funds to work with new ESC lines. That wasn't true for most of the United States before President Obama lifted the federal restrictions.

Participant 2 also noted that the relaxation of funding restrictions was not equally urgent for all researchers and stated:
President Obama's decision to lift the restrictions imposed by President Bush has certainly made it a lot easier for researchers around the United States to do work involving ESCs. Those restrictions were not really a problem as the voters of this state created CIRM through Proposition 71 in 2004, giving the stem cell agency $3 billion to fund this kind of work California. While researchers in other states faced huge barriers and strict limits on what they could use their stem cell research funding for, in California, we had no such problems as we could bypass the Feds and fund it ourselves.

Participant 3 described the lingering effects of the more stringent policies of the Bush administration as having a negative effect on current research in the United States. This participant stated:
Not sure if anyone has benefitted from the more relaxed policy as more people are doing more research outside the United States, which is a push from the Bush legacy. Once you are banned from doing something and you move on to something else, you don't usually turn back.

Participant 15 stated:
Yes, scientific research has benefitted from these policies, but they did not go far enough to have a real impact on medical applications.

Participant 4 noted that the Obama administration's policy, which rests on an executive order, can be reversed by any subsequent president, such that researchers cannot rely on the indefinite continuation of the current funding guidelines:
I would characterize the environment as unstable, especially around presidential elections, where the new president with a different ideology can rescind the order with the stroke of a pen.

Other participants expressed the perception that while the current policy was favorable to research, it had not been put into effect. Participant 9 stated:
The relaxed funding policies have not really been implemented, kind of like travel to Cuba, it really is still incredibly difficult.

Similarly, Participant 6 stated:
The full benefit has not been realized, but clearly there are benefits.

Participant 7 suggested a reason why the policy might have failed to have its intended effect:
[The policy] is definitely a good thing, but we still are stagnant in the research and its use. The benefit has not increased much from 2009 as the bipartisan support needed is not available.

This response was echoed by Participant 1:
In 2009, when President Obama did the EO that removed the barriers to responsible research, it should have been a good thing, but we still are stagnant in the research and its use; therefore, the benefit has not increased much from 2009 as the bipartisan support needed is not available.

The alternatives to hESC were also described as depriving President Obama's EO of some of its effect. Participant 5 stated:
Researchers have definitely benefitted from the relaxed restrictions, as there are many more hESC lines currently eligible for research supported by NIH. That said, the advent of iPS cell has to some extent lessened the need for new hESC lines. Additionally, the preponderance of the Bush lines, those approved for research under President Bush, appear to remain the most heavily used cell lines because researchers are comfortable with them and have been using them for years.

Participant 8 indicated that President Obama's executive order had been deprived of much of its intended force by the nature of hESCs:
I don't think [the EO] makes any difference. For most researchers, the problem with embryonic cells is less ethical than scientific. Embryonic cells multiply at an extremely rapid pace and have a propensity to form cancers. They can be used for disease modeling and drug screening in a lab, but will not be used in people, with the exception of a very small number of ophthalmology projects, until their cancer-forming properties can be controlled. In the meantime, iPS cells have leapfrogged the need to use them.

Subtheme 3: Perceptions of the NIH's ethical policy:

Most participants expressed agreement with the NIH ethical policy. Participant 13 expressed that the NIH policy helped to ensure that scientists used the technology responsibly:

The NIH policy restricted the generation of new stem cell lines. However, there needs to be strict supervision on such ethical policies. ESCs have great power and ensuring that it is handled responsibly is possible only through strict supervision.

Participant 4 expressed a similar perception, citing the importance of ethical science and the value of the NIH policy in promoting it:
I think all research should be done ethically by following approved and vetted standards. Embryonic and adult stem cell research is no different. The ISSCR helped create the first set of standards on ethical embryonic and adult stem cell research and recently released an updated set of guidelines. There are many benefits of the new policies and procedures that NIH uses to vet the provenance of the lines, including protecting patients and donors and helping to maintain the integrity of the process. All scientific research benefits by following ethical scientific practices.

Participant 1 stated:
I would describe the current ethical policies as particularly strict.

Participant 21 stated:
The NIH ethical guidelines represent, in my view, a reasonable compromise between the obligation to protect embryo and gamete donors and the desire to help advance the science.

Participants 3, 12, and 19 also described the policy as "strict" while expressing agreement with it.

Participant 3 related:
NIH strict policy . . . promoted the idea of nonembryonic use and moved research into a different path, which is more universally useful. It also brought up the ethical issue of how many embryos would be sacrificed to create one transplant, which then created the ethical issue of who could afford to use this process, in most cases, meaning only wealthy people could afford to have a chance at using the therapy from embryonic tissues. ESCs are not very scalable, so to have something of value, the product or service must be scalable.

Participants 6, 10, 11, 14, 16, 17, 18, and 20 agreed with the policy without reservation.

Other participants expressed misgivings about the policy. Participant 9 stated:
[The NIH ethical policy] is scientifically informed regarding safety. It is dynamic as new therapies are always developing. The ethical interpretations of ESC use are not scientifically informed and restrictions should be reevaluated without political or religious input.

Participant 8 expressed the belief that the ostensibly ethical policy was actually unrelated to ethics:
ESCs used for research purposes have always been harvested from IVF clinics with the express permission of the individuals involved. The NIH guidelines do not constitute ethical policy, they just clarify the source of cells.

Participant 7 described the policy as a potential cause of misunderstanding:
The NIH is legally bound to the policies, and as such, has a limiting impact and causes confusion in people's minds about the differences between human embryonic and adult stem cells and their uses for research.

Participant 5 agreed with the ethics of the policy and believed that certain additional issues remained unaddressed, stating:
Informed consent for the donors of embryos used to create hESC lines remains an important policy.

Participant 5 added two objections. The first of these objections was expressed in these terms:
The NIH policy on using only embryos left over from IVF may skew the source of new lines to less than healthy embryos, as these are more likely not to be implanted.
The second objection was stated as follows:
The FDA has not kept up with the science in regard to its guidance or requirements for preclinical studies needed to move stem cell-based therapies into clinical trials. I am not arguing for following the Japanese model and I also have grave misgivings about the REGROW Act, rather I would like to see the FDA issue clear guidance and play a more active role in regulating the unregulated stem cell clinics currently marketing unapproved, untested therapies. Finally, U.S. policy with regard to preventing the FDA from even considering applications involving genetic engineering [or] modification of human embryos should not be enshrined perpetually in law as the Dickey-Wicker Amendment has become . . . . The FDA's process is slow, laborious, and highly inconsistent. It means that therapies can take up to 20 years and billions of dollars to get approval. Very few companies can afford that time or money.

Subtheme 4: Perceptions of the Dickey-Wicker Amendment:

Participants' opinions of the amendment were divided, with some interviewees expressing strong disagreement for various reasons, but with a number expressing assent (i.e., Participants 1, 10, 11, 12, 14, 16, 18, and 20). Of those participants who disagreed, three related that the amendment's impetus was irrational. Participant 9 stated:
I strongly disagree [with the amendment]. This is a religious agenda. Females can discard embryos in late menstruation, yet this is not regulated. We don't scoop them up, protect them, have funerals, etc.

Participant 7 stated:
The amendment is unfortunate. It created a path that is based more on people's feelings than on science.

Participant 5 had a legal objection:
I think Dickey-Wicker is a clear case of the nonseparation of church and state. The amendment puts the beliefs of primarily one religion over that of others and instills those beliefs in federal legislation.

Participant 5 also noted that recent technology had limited the amendment's effect:
Fortunately, with the advent of iPS cell technology and the continued addition to the NIH registry of new hESC lines created with other funds, the amendment is not the barrier it once was.

Participant 21 also described the amendment's restrictions as limited but still significant:
State and private funding have helped work around this restriction, but this is clearly a key challenge for the field.

Participant 13 expressed a similar opinion about the limited scope of the amendment, but emphasized the legislation's negative effect on the research that fell within its purview:
While it does not restrict the use of hESCs for research purposes, it still restricts the generation and establishment of new stem cell lines from embryos. While there needs to be strict supervision regarding use and destruction of embryos, with the current amendment, the field is restricted to the use of just handful of lines.

Two participants pointed out that IVF embryos, which are not used in stem cell research, will usually be discarded. Participant 4 stated:
In theory, the amendment was designed to protect embryos, but in fact it does not do so. Although the embryos cannot be used for federally funded research, they will likely be discarded when they are no longer needed for fertility treatments.

Similarly, Participant 8 stated:
You have three options for embryos that are yours and being cryopreserved at [an] IVF clinic: throw them away, donate them to research, or continue to cover the costs of storing them indefinitely. Most of them are discarded.

Participant 3 discussed the difficulty of evaluating the amendment:
This is a complex issue that deals with ethical issues like the use of eggs [in an] in-vitro sterilization clinic . . . . Should they be implanted in another female or used to further research study? So, with something so complex, it may be best to not complicate the issue by using those embryos with federal funds, without a clear purpose in mind. The

cells of embryos can become abused if people believe there is a financial gain from it, so it must be clear what the benefit will be or should be. I do not have an answer for this question and believe it needs to be discussed more at a broader level.

Participant 17 also believed that more information was needed before the amendment could be properly evaluated and that enforcing it was a more prudent course of action than overturning it:
The Dickey-Wicker Amendment should remain as is until there is a clear understanding of what and how hESC can be a benefit.

Participant 1 also viewed the amendment as a prudent precaution:
I believe that the Dickey-Wicker Amendment should stay in place. As with any exploratory science, one can go overboard, so the amendment should stay in place and continue to be reviewed annually for changes to funding, if necessary.

Participant 6 agreed with the amendment, but emphasized its negative effect on the funding of research:
The Dickey-Wicker Amendment is needed, but it is limiting, where federal funds are concerned.

Participant 2 pointed that the effect on funding was limited:
While the Dickey-Wicker Amendment prohibits the use of federal funds for research on human embryos, it does not, at least under the current interpretation, limit the use of federal funds for research on embryonic cell lines. So in that sense, it really has a limited impact on stem cell research. Of course, that could change with a different administration.

Theme 5: Perceptions of competition between the United States and other countries:

A number of respondents did not believe that the United States lagged behind other countries (i.e., Participants 2, 5, 6, 10, 11, 12, 14, 16, 18, 19, and 21).

Participant 10 believed that federal policy had no effect on U.S. competitiveness:
I do not think the policy has either diminished or improved competitiveness with other countries.

Participant 18 expressed the same perception:
Policies have no effect on improving or diminishing competitiveness with other countries.

Participant 21 suggested that U.S. researchers were succeeding despite the federal policy:

Scientists and institutions worked around [the Bush administration's funding restrictions], with state and private funding and the United States is clearly among the top tier of countries producing key stem cell research advances.

Participant 5 also described U.S. researchers as succeeding despite the federal policy:
The United States remains in the forefront, but other countries, the UK in particular, have in some ways more opportunities to conduct research that it is not possible to conduct here. My impression is that at least parts of the EU also allow more. Fortunately, the sheer size of the biomedical research enterprise and the amount of funds the United States contributes to research allow the United States to remain competitive in all but a few areas.

Participant 2 echoed Participant 21's reference to the restrictive funding policy of the Bush administration:
The restrictions [during the Bush administration] clearly put U.S. researchers at a disadvantage compared to scientists in Europe and Asia . . . [but] I don't think the United States lags behind other countries any more. In many ways, we are as advanced if not more so than most countries.

Participant 20 shared that the Obama administration's relaxation of funding restrictions had improved U.S. competitiveness. Participant 20 stated:
Under Bush, it was too restrictive. The current policy is [a] good balance of ethics and ability to do research.

Participant 12 stated:
I think U.S. competitiveness has improved, as seen with the large growth within my group alone. From attending world and international stem cell conferences, I do not believe we lag in comparison with other countries.

Participant 19 agreed that the situation for U.S. researchers had been improved:
I think the policies [of the Obama administration] have helped the U.S. become more competitive with other countries.

Similarly, Participant 7 stated:
Obama's more expansive policy has improved competitiveness. We are still restricted to the creation of new lines due to the lack of using federal funds. More people are not aware that this is an ongoing issue. With wider bandwidth, U.S. research could be felt on a global basis.

Other participants agreed that federal policy had an inhibitory effect on U.S. stem cell research. Participant 1 stated:

We have not improved [and] as a country, we could be doing far more than what we are doing.

Participant 13 related:
U.S. stem cell policy has certainly diminished U.S. competitiveness with other countries, in particular Japan and Europe. Over the last 5 years, we are experiencing some boost in U.S.-based studies. While such studies are at the forefront, the volume of research and number of stem cell researchers in the United States is still limited.

Participant 15 indicated that restrictions on stem cell research in the United States might give an advantage to other countries:
U.S. stem cell policies might have actually boosted stem cell research in countries like China, since the chances for a breakthrough and the first to discovery are greatly increased in places other than the United States.

Participant 15 also explained why U.S. researchers could not simply evade legislative constraints by focusing their efforts on fields of inquiry that were subject to fewer restrictions:
In the current environment, scientists and the community need to fight for more relaxed policies on stem cell research. For now, some hESC lines are still needed for research, since iPS cells may not behave exactly the same as embryonic cells. Therefore, we need to continue to examine all stem cell types since we do not know yet which one will be the best to use in therapy.

Participant 6 viewed the effect of federal restrictions as primarily economic:
There are limitations in America, but companies who want to be more competitive, do research outside the country, and transfer it back in, so it becomes very costly for everyone to reap the benefits.

Participants 8 and 9 agreed that federal restrictions were causing the United States to lag in stem cell research, with Participant 8 adding:
Stem cell research, all research in the United States is disadvantaged by stringent FDA regulatory requirements, far stricter than those of other countries.

Participant 4, however, while acknowledging the disadvantageous effect of federal policy, viewed international research as a cooperative endeavor from which the United States would ultimately benefit:
[Federal policy] has certainly slowed the creation of new lines of hESCs, since that research can only be done using nonfederal funds. While funding science to the highest levels makes economic sense for our country, stem cell research is a global enterprise, and discoveries and stem cell-derived therapies in one country will benefit those in other countries.

Research Question 2

Research Question 2: What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research?

Thematic Label 2: What are U.S. stem cell researchers', stakeholders', and investors' perceptions about the moral disagreement with stem cell research.

Theme 2: Perceptions of the moral disagreement about stem cell research.

Subtheme 1: Understanding opposition:

Participants 10, 11, 12, 16, and 18 described themselves as understanding, but not as agreeing with the ethical objections to hESC research. Participant 12 stated:
I understand the perceptions and concerns of the lay public in regards to the use of human tissues for research.

Similarly, Participant 10 related:
I understand the concerns of the general public with regards to the use and potential misuse of human tissues for research purposes.

Two participants acknowledged the validity of disagreement but emphasized the necessity for an ongoing dialogue. Participant 11 stated:
The disagreement is understandable and it is a topic worthy of ongoing discussion.

Participant 16 stated:
I am sympathetic to it, but at the same time the beneficial aspects of this research can be insurmountable, so there needs to be ongoing communication.

Participant 18 spoke in more general terms:
I believe everyone has their right to their own belief.

Subtheme 2: Religious or moral objections:

Participant 1 perceived the source of the opposition as a reason to abstain from giving a judgment:
I don't have an opinion, as a lot of the moral disagreement is related to the Christian views related to how embryos are being used to accomplish scientist goals.

Participant 15 believed that opposition to hESC research issued from a combination of political calculation and misdirected sentiment:
I do not believe there is a moral disagreement, rather a religious perception and power calculations to distract the electorate from important social and political issues. Morality

is intimately linked to politics in the United States. We have the moral obligation to save lives. If the material we use was procured from spontaneous abortions or medically recommended abortions, we are not conducting an immoral activity.

Participant 2 expressed sympathy with the beliefs of opponents of stem cell research, but expressed a belief similar to that of Participant 15, to the effect that moral concern was more properly directed toward the promotion of a life-saving technology:
There are many people of strong religious faith who are opposed to the use of fetal tissue or ESCs in research, considering these a violation of the sanctity of life. We respect those views completely. However, we don't agree that either of these approaches is ethically or morally wrong, a view Congress has supported since the 1950s. In fact, we feel we have an obligation to pursue the use of these materials in scientific work because of their enormous potential to save the lives of millions of people around the world who are currently battling deadly diseases and disorders that have no cures.

Participant 5 reiterated his earlier statement to the effect that moral opposition to stem cell research, when it took the form of legislation, was unconstitutional:
The moral disagreement with stem cell research is rooted primarily in Christianity and . . . raises the beliefs of one religion, or some branches thereof, above those of others and is a clear instance of lack of separation of church and state. Adult stem cells are great, but they have limitations that cannot, yet, possibly never be overcome that hESCs do not have, and to hold them up as a reason not to conduct hESC research is a specious argument.

Participant 14 noted the connection between religious opposition to hESC research and religious opposition to abortion:
Many opponents of stem cell research, like religious leaders, compared stem cell research to abortion. For the Catholic Church, for example, life begins at conception, making the stem cell research comparable to homicide because it results in the destruction of many embryos. Although scientists are right, but from a moral standpoint, it could be conceived as wrong.

Participant 4 made the connection between opposition to abortion and opposition to hESC research:
The misperception that this issue, hESC research, is tied to abortion will forever entangle it in a political quagmire. The fact remains that those embryos no longer needed for fertility treatments will be discarded as medical waste if not donated to science or adopted by another couple, which is exceptionally rare. Stopping ESC research is not saving embryos.

Participant 3 made a similar point:
[The moral disagreement] is a complex issue because of the abortion issue.

Participant 20 indicated a context for the debate by sharing the perception that the moral disagreement about hESC research was between an ethical consensus among medical professionals and the subjective reactions of some private individuals:
This moral issue is a personal issue. The U.S. policy is in line with most bioethics considerations.

Subtheme 3: Stem cell source:

Several participants noted that the moral disagreement surrounding stem cell research depended to a great extent on the source of the cells in question. Participant 1 stated:
In the United States, we get caught up with the logistics, such as whether the stem cells are being used from human embryos or from one's own stem cells, which is two different processes, but is still misunderstood to this day.

Participant 4 stated:
The disagreement is fundamentally over the destruction of embryos for the purpose of creating lines of hESCs and not [over] stem cell research in general.

For Participant 21, identifying moral concern over the embryo as the point of contention was a reason for pessimism about the prospects of compromise:
The debate over the moral status of the embryo isn't going anywhere and will continue to shape public opinion toward the field.

Participant 4 was optimistic about the chances for a satisfactory resolution by a consideration of emerging technology:
More companies are moving to fibroblast stem cell [iPS cell] research, so the issue will become invalid soon, essentially making it a nonissue.

Subtheme 4: Reasoning:

A few participants questioned the validity of the debate, not because the reason for disagreement was religious or moral, but because they perceived the reasoning of hESC research opponents as flawed. Participant 7 stated:
It is simple, the moral disagreement is a nonissue, because if people only understood that the majority of the vaccines have been derived from these tissues being discussed and if they looked further into what the actual usage is and reasons are behind it, most people would understand the importance of the research.

The idea that disagreement was a result of ignorance was echoed by Participant 13:
Moral disagreements are largely from lack of scientific knowledge and factual information. Often facts are misrepresented, which perpetuates a falsified perception.

Participant 17 believed that hESC research might be promoted by an appeal to common sense:
I think it's a gray area, but rather than waste stem cells, why not put them to a good use that benefits all humanity?

Participant 8 believed that public's understanding of the controversy was impaired by equivocal terminology:
There is no moral disagreement about stem cell research. You shed your skin regularly because skin stem cells are constantly renewing and replacing damaged, old skin. You can donate a lobe of your liver and it will grow back because liver stem cells will regenerate it. Every tissue in your body constantly renews itself through tissue-specific stem cells. To say you have a moral disagreement with stem cell research is like saying you object to your liver. There is controversy about the use of ESCs for research, but I see it as a far greater issue in the lay public than it is in the research community. Most scientists I know find it less an ethical problem than a scientific one. Because ESCs form cancers, their primary contribution will continue to be disease modeling and drug screening. And the ethical concerns about using embryonic cells have been completely leapfrogged by the discovery of iPS cells. Even the Vatican supports and funds adult and iPS cell research.

Subtheme 5: The Possibility of Compromise:

Two participants believed that compromise between proponents and opponents of stem cell research was unlikely. Participant 4 stated:
I don't see how a compromise is possible.

While Participant 21 left only slightly more room for optimism:
Compromise is not likely for those with strong views on [the] moral status of the human embryo.

Participant 5 suggested that the benefits of hESC research might gradually persuade its opponents:
Unfortunately, I do not think hESC opponents are willing to compromise, but when hESC-based treatments [and] therapies for diseases that afflict them or their family members become available, I hope they will take advantage of them and maybe reconsider their stance.

Five participants believed that deriving the necessary research materials from uncontroversial sources would render the debate moot. Participant 21 stated:
Focus on less contentious technologies [such as] IPS cells and use of existing rather than new hESC lines offer some hope.

Similarly, Participant 3 suggested that contention could be alleviated:

By working to develop [and] improve lines in which ethical issues have been thoroughly discussed.

Participant 16 stated:
I believe that continued use of iPS cells can be considered as a compromising option.

Participant 10 stated:
I believe iPS cells are a compromise on stem cell research.

However, Participant 15 pointed out that iPS cells might fail as a means of circumventing moral contention:
The use of iPS cells is a compromise with stem cell research opponents; however, we do not yet know the real potential of this technology and its application to therapy.

Other participants recommended more effective education of the public as a means of promoting compromise. Participant 7 placed the burden of promoting education on opponents of stem cell research:
They can find compromise by asking the more meaningful questions about stem cell research outcomes, such as what does the research mean to my family and to the country now and into the future.

Participant 6 placed the burden on proponents of the research, suggesting that they should "provide a greater understanding."

Participant 12 referred to education and the concurrent use of uncontroversial materials as a means of achieving a compromise:
I believe the best compromise is using other stem cell lines beyond embryonic and making the public aware of the differences. For example, hMSCs, which we use, are from a human, adult, healthy donor and these cells have shown to be great in curing very devastating conditions such as stroke or cardiac problems.

Research Question 3: What do U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States?

Thematic Label 3: What do U.S. stem cell researchers, stakeholders, and investors recommend to improve stem cell research policy in the United States.

Theme 3: Policy recommendations.

Subtheme 1: Funding:

All six participants who made policy recommendations related to federal funding believed that it should be increased. Participant 2 stated:

It's going to take a huge investment by the government to really push this research along.

Participant 8 summarized her recommendations in the form of an equation:
Streamlined process plus money equals competitive advantage, where streamlined process referred to an acceleration of the FDA approval process.

Participant 2 also mentioned FDA requirements:
It's going to take changes in the way the FDA regulates stem cell therapies to enable the science to move ahead as fast as it needs to.

Participants 1, 9, 20, and 21 also recommended an increase in federal funding.

Subtheme 2: Involving outsiders:

Two participants suggested involving laypersons in the discussion. Participant 3 recommended:
Bringing in people from the outside and not just the professionals.

Similarly, Participant 7 stated:
Engage lay people, who are recipients of the therapy, and not just those who are professionals in the field.

Participant 7 also elaborated on the reasons why involving the public might be an effective political agenda:
People are very similar when it comes to saving lives. People respect human life and are more practical in their understanding if they can relate outcomes to their own family and loved ones.

Subtheme 3: Religion:

Participant 9 proposed the removal of religious agendas from the dialogue, stating:
The ethical interpretations [to] ESC use are not scientifically informed and restrictions should be reevaluated without political or religious input.

Participant 9 added that legislators should:
Vote to overturn religious agendas [and] until the policies change, the science can't move forward.

Subtheme 4: Education:

Other participants recommended various forms of education as a means of making federal policy more favorable to hESC research. Participant 9 recommended:

Improved science education, public announcements educating the public, [and] encouraging open discussion of policy, ethics, and science.

Participant 14 stated:
The general public do not know enough about the benefits of stem cell research. Education is needed.

Participant 14 recommended:
Reaching out to our community.

Similarly, Participant 17 suggested:
Educational outreach so that both sides of the good and bad are discussed with stakeholders and a common, middle ground is reached. Hard to do but attemptable.

Participant 19 agreed with Participant 17 in recommending even handed education:
People need to be educated on the advantages and disadvantages.

Participant 1 suggested that educational efforts should not be focused solely on the general public, stating:
Educate the population and the lawmakers.