

DRAWING THE LINE

ETHICAL, POLICY, AND
SCIENTIFIC PERSPECTIVES ON
U.S. EMBRYO RESEARCH

POLITICS AND POLICIES GUIDING HUMAN EMBRYO RESEARCH IN THE UNITED STATES

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“A Survey of Policies Guiding Human Embryo Research in the United States”

Introduction

“It is not birth, marriage or death, but gastrulation, which is truly the most important time in your life.”

— Lewis Wolpert (2015)

The Nuremberg Code describes ethical principles that should govern human research (Nuremberg Code 1949). Developed in response to significant human rights violations related to Nazi research on concentration camp prisoners, the code’s basic elements shaped future human subject codes and regulations. However, it was not until 1972, when the public learned of the U.S. Public Health Service study at Tuskegee University of untreated syphilis—where subjects were not given access to drug treatments so researchers could observe the disease’s natural course of development—that the idea of federal oversight of human research gained widespread support in the United States.

The National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHSBBR), whose reports and recommendations would be highly influential in shaping the federal regulations governing much of the human research in the United States today (National Research Act of 1974; NCPHSBBR 1979). The U.S. Department of Health and Human Services (DHHS) would also eventually publish the Federal Policy for the Protection of Human Subjects in 1991 (45 C.F.R. §46.202(c)), with a new version in January 2017 (Federal Policy for the Protection of Human Subjects 2017). These regulations—also known as the “Common Rule”—are followed by 18 federal agencies; they include rules for approving and overseeing human research and limit what investigators may do to human research participants (U.S. DHHS 2016). Although some provisions are widely debated, there is widespread acceptance of the research permitted and restricted by the Common Rule. However, there is much less agreement on where to draw the line between permissible and impermissible research on human embryos, which are not fully encapsulated by the Common Rule.

The term “embryo” is widely accepted as the mass of cells in the earliest stages of development into a new organism. Scientists define the human embryo as the time from fertilization to the eighth week of gestation (56 days after conception), when it becomes known as a fetus and starts to develop more advanced physical and neurosensory features (Sadler 2015). U.S. federal law does not define the term “embryo”; instead, it defines a fetus as the entity from the implantation stage (which scientists define as 7–14 days after conception) to delivery. For this paper, we will use the term “embryo” to describe the time of development from conception to 56 days post-conception.

Human embryo research has been controversial, as it sets the pursuit of knowledge through biomedical research and the commitment to advance knowledge against the moral commitment to protect early human life. It forces us to consider who counts as a person, what it means to be a human being, what rights and interests are accorded to human beings

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at various stages of development, and what may be done to humans at various stages of life under different circumstances. The research has also been linked to public debates and disagreements, in the U.S. especially, related to abortion and right-to-life and pro-choice discussions. Finally, this area of research requires us to determine the limits we should place on scientific research and knowledge. Is any human embryo research that advances knowledge acceptable? If not, what limits should be imposed, and who should set them?

Early human embryo research led to *in vitro* fertilization (IVF), which revolutionized medical treatments for infertility (see Table 1). Scientists conducted research for decades to develop IVF techniques before it was first successfully performed in 1978 by British scientists Robert Edwards and Patrick Steptoe (Tauer et al. 2014). Human embryo research received substantial media attention when such research was linked to the emerging field of regenerative medicine. In 1998, scientists—many of whom were from the United States—reported culturing human embryonic stem cells (hESCs) for the first time (Thomson et al. 1998). hESCs, obtained from five- to six-day-old embryos, offered scientists the possibility of creating almost any cell or tissue in the human body, providing a new tool to study early human development and different disease states with the goal of eventually developing treatments to replace diseased or injured cells or tissues. However, this research and the isolation of hESCs required the destruction of embryos.

Table 1. Major Scientific and Political Events for Human Embryo Research Regulation

Human embryo research has been impacted by various ethical commissions (blue); regulations, legislation, and other policy developments (green); and scientific achievements (red).

Truman	1949	The Nuremberg Code is released.
Nixon	1974	The National Research Act establishes the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
Carter	1978	The first IVF baby is born in the United Kingdom (Louise Brown).
	1979	The U.S. DHEW report is released with the first mention of a 14-day limit.
Reagan	1981	The first IVF baby in the U.S. is born (Elizabeth Carr).
	1984	The U.K. Warnock Commission releases report upholding and supporting the 14-day limit for human embryo research.
	1986	The “Baby M” case results in new U.S. congressional hearings on IVF and human embryo research.
	1988	The ASRM releases “Fertility and Sterility” report supporting 14-day limit.
George H.W. Bush	1991	The OTA publishes report titled “Infertility: Medical and Social Choices” that includes suggestions for IVF and human embryo research oversight.
		The U.S. DHHS adopts the Federal Policy for the Protection of Human Subjects (Common Rule).

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Clinton	1993	The National Institutes of Health Revitalization Act revoking the requirement for an EAB to review human embryo research is passed.
	1994	The HERP report upholding 14-day limit, but suggesting later time points, is released.
	1996	The Dickey-Wicker Amendment is passed.
	1997	The paper describing Dolly, the first cloned mammal, is published.
	1998	The paper describing the first cultured hESC is published.
	1999	The NBAC report on hESCs recommending research on only IVF eggs that are leftover.
George W. Bush	2001	President George W. Bush creates hESC compromise: no federal funding of research on hESCs created after August 9, 2001.
	2004	The PCB report on assisted reproductive technologies (ART) that mentions an international consensus on a 14-day limit is released.
		Proposition 71 passes in California, creating the CIRM.
	2005	NASEM's first report on hESC guidelines that includes a 14-day limit is released.
	2006	The ISSCR releases hESC guidelines that include a 14-day limit to research.
Obama	2009	President Barack Obama removes August 2001 ban on federal funding of hESC research.
		<i>Sherley v. Sebelius</i> , a lawsuit to block federal funding of hESC research, is filed.
	2010	Final version of NASEM hESC guidelines is released.
	2013	The U.S. Supreme Court dismisses <i>Sherley v. Sebelius</i> .
	2016	Two groups report culturing human embryos <i>in vitro</i> for 14 days before halting their experiments.
The ISSCR releases updated stem cell guidelines that include a 14-day limit.		
Trump	2017	The U.S. DHHS releases a draft of a strategic plan that adds "beginning at conception" to mission statement discussing its role at various stages of life.

Source: Authors' analysis

Even before IVF was first successfully carried out in 1978, discussions were underway in the United States over whether research that uses embryos or results in their destruction is ever permissible and, if so, under what circumstances (Kass 1971). Over the past four decades, policies have been proposed by national bioethics commissions, but little has been achieved in terms of a legislative solution. Instead, most human embryo research is guided by an unofficial limit allowing research only until the 14th day of development, which dates back to a 1979 U.S. Department of Health, Education and Welfare (DHEW) report on IVF (U.S. DHEW 1979a). This end date is not specified in any law and is irrelevant to federally funded research, since no human embryo research is funded by the federal government (as will be outlined below). But the limit is accepted by nongovernmental organizations (NGOs), especially professional societies that oversee scientists and doctors who would participate in such research.

The 14-day guideline was chosen for several reasons. This time point corresponds to the beginning of embryo organization, as the cells begin to organize into a band referred to as the primitive streak, which should be easily visible under a microscope. Day 14 is also toward the end of the process of implantation, prior to which the embryo spontaneously dies in an estimated 50 percent of cases (U.S. DHEW 1979b). Furthermore, it is the last point at which twinning can occur and is thus seen by some people as the point of true individuation (U.S. DHEW 1979a; U.S. DHEW 1979b; Warnock 1984; Hyun 2016; Webster and McEwen 2016). Others note that the embryo has little to no potential to further develop at this time without implantation (Pera 2017). LeRoy Walters, professor emeritus at Georgetown University and noted bioethicist involved in the preparation of the 1979 DHEW report, believed that the 14-day date was also chosen because it was far beyond researchers' ability to grow human embryos *in vitro* in 1978, such that the limit did not restrict research in actuality (Webster and McEwen 2016). For these reasons, and perhaps others, the 14-day guideline has been accepted by governments and NGOs around the world (Hyun 2016).

Scientists' ability to study early human embryo development *in vitro* has, until recently, been limited to the time the implantation stage begins (between days 5 and 7), which is also when an IVF egg would be implanted. However, in May 2016, two research groups (one from the U.S. and the other from the U.K.) reported culturing human embryos *in vitro* up to the 14-day limit (Shahbazi 2016; Deglincerti 2016). After these groups had to halt their experiments because of the 14-day guideline, some scientists and ethicists called for a reevaluation of the decades-old rule (Hyun 2016; Harris 2016; Feltman 2016). Proponents of extending the guideline to later time points cite the therapeutic possibilities that could arise with more research on early development. But other scholars noted that the guideline was a hard-won compromise and urged that it not be lifted (Feltman 2016; Warnock 2017). Many have suggested that science alone ought not be the justification for a change, pushing for a careful evaluation of the moral status of the embryo, as well as of the ethical implications of allowing research beyond the 14th day, before any policy decision is made.

With such a wide range of perspectives to consider, it will be difficult to reach a consensus. But without a federal policy in place, the issue will continue to come up—as it often has—whenever a new party is elected to the presidency. Compromise will be needed, ideally based on considerations of different ethical perspectives, as well as the potential for advancing scientific knowledge in order to promote the public good. But it will be a challenge to satisfy all parties.

In this section, we review U.S. human embryo policy dating back to the 1970s. We describe current federal legislation that guides U.S. research and identify policy gaps. In addition, we describe governmental bioethics reviews and policy recommendations over the past six administrations, from President Jimmy Carter to President Barack Obama, and discuss current efforts by the Trump administration. We also survey state policies and guidelines from major NGOs that fund or oversee human embryo researchers. Finally, we highlight the further actions that would be needed at the federal level if the guidelines are changed.

U.S. Federal Policies and Guidelines

“Fetus means the product of conception from implantation until delivery.”

— U.S. 45 C.F.R. §46.202(c)

Unlike many other countries such as the United Kingdom, the United States does not have a federal policy on human embryo research that covers all federal and nonfederal research (Matthews and Rowland 2011). In addition, there are no references to the 14-day limit on research contained in federal statutes. Instead, the focus of existing legislation is predominantly on what research can and cannot be federally funded via the Dickey-Wicker Amendment (DWA). This lack of federal policy allows state- and locally funded research to be controlled at those levels, and for private research to be governed by whatever guidelines a sponsor or host institution chooses.

The lack of a federal policy on human embryo research appears to be the result of disagreements among lawmakers about the ethics of this research, as well as its link to abortion debates. These political divisions have hampered the development of many policies related to reproductive technologies and rights (Parens and Knowles 2003). This lack of consensus has left research on IVF and human embryos, and its oversight, up to fertility clinics and biomedical laboratories that use private funds. With the results of some of this work never disseminated through scientific, peer-reviewed publications, it is unclear whether the research conforms to standard informed consent policies that are otherwise applicable in federally funded research settings. Nor is it clear if the research goes through an hESC research oversight committee, the traditional oversight board for such research in academia (Parens and Knowles 2003). These clinics are only required to report research to the Centers for Disease Control and Prevention (CDC) if an embryo is intended to be transferred to a uterus to initiate a pregnancy (CDC 2017).

Defining a Human Embryo as a Fetus

Scientists define the embryo stage as the human organism from conception until eight weeks of gestational age and the fetus stage from this point until birth. On the contrary, the federal government codified the definition of a fetus to include the embryonic stage (45 C.F.R. §46.202(c)). Specifically, U.S. federal regulations governing human research define a fetus as “the product of conception from implantation until delivery.” Other federal laws ban research or funding of research on a fetus unless the research will “enhance the well-being or meet the health needs of the fetus” or “will pose no added risk of suffering, injury or death to the fetus” (Fetal Research 42 U.S.C. §289g).

These laws therefore impact all embryonic research post-implantation (which occurs between six and 12 days post fertilization, dpf). While institutions and individuals are governed by these human subject regulations, federal regulations do not consider *ex vivo* embryos “human subjects” for these purposes (PCB 2004). Because of their wording, the

regulations impact *in utero* embryos, but allow *in vitro* embryo research for any length of time (Tauer et al 2014).

Dickey-Wicker Amendment

While federal human subjects research regulations do not prohibit research on *ex vivo* embryos, legislation for federal funding appropriation does so through the DWA. Named after the authors of the bill, Rep. Jay Dickey (R-AK) and Rep. Roger Wicker (R-MS), the DWA bans federal funding for “the creation of human embryo or embryos for research purposes” or research on human embryos (Matthews and Rowland 2011) (see Box 1). The DWA also defines the human embryo to include products of “fertilization, parthenogenesis, cloning or other means from one or more human gametes or human diploid cells.” Between this definition and the language of the ban, the DWA effectively prohibits human embryo research projects from obtaining federal funds.

The DWA is attached annually to the funding bill associated with the DHHS and, more recently, to larger omnibus appropriation bills for the federal government. It has been replicated verbatim every year since its first appearance in the 1996 fiscal budget bill. The amendment impacts all agencies within the DHHS, including the National Institutes of Health (NIH), the CDC, and the Food and Drug Administration (FDA). With its approximately \$37 billion annual budget, the NIH is responsible for the vast majority of biomedical research in the United States, which causes the ban to have significant impact on research.

In addition, the NIH traditionally plays a strong role in promoting policy for biomedical research apart from providing funding. For example, when the NIH published hESC guidelines in 2009 (more than 10 years after such cells were first isolated *in vitro*), most research organizations matched these guidelines. Previously, they had used the series of National Academy of Science, Medicine and Engineering (NASME) guidelines developed from 2001–2008, which were slightly different. Despite the influence it can exert in some areas, because it does not provide funding to support human embryo research the NIH does not

Box 1. The Dickey-Wicker Amendment

SEC. 508. (a) None of the funds made available in this Act may be used for—

- (1) the creation of a human embryo or embryos for research purposes; or
- (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. §289g(b)).

(b) For purposes of this section, the term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Source: H.R. 244: Consolidated Appropriations Act, 2017

participate in discussions on the ethical oversight of such studies, although several bioethics commissions (presidential and federal) have addressed it in the past. Thus, the oversight of human embryo research receives no active scrutiny from the agency. The NIH does not review protocols or set guidelines for embryo research as they do with other controversial topics such as recombinant DNA and hESCs. This leaves a noticeable void in embryo research oversight.

Furthermore, scientists involved in human embryo research are not only banned from receiving federal grants for any such project, but they are also prohibited from using materials such as equipment previously purchased for other federally funded projects. And since federal grants pay for overhead, such as building maintenance and purchasing expensive shared research equipment, the use of these buildings or equipment in a human embryo research project is also prohibited under the DWA. Therefore, when conducting human embryo research, scientists must use dedicated, nonfederally funded facilities and equipment, in addition to purchasing the necessary reagents and materials, in order to do so lawfully.

While it imposes significant limitations on funding human embryo research, the DWA only applies to federal funding and does not impact research funded on the state, local, or private levels. For instance, human embryo research is being conducted using funds from state agencies, such as the California Institute for Regenerative Medicine (CIRM), or private foundations like the Juvenile Diabetes Research Foundation (JDRF). Private research is only constrained by laws of the state in which it is being conducted, if any exist (Fletcher 2001). This lack of regulation is arguably a compromise that has continued through both Republican and Democratic presidential administrations.

Historical Federal Policies and Bioethics Reviews

“The [HERP] report would have been immeasurably strengthened, in this author’s opinion, if it had squarely acknowledged that it is impossible for a governmental body to determine the moral status of the embryo.”

—R. Alta Charo (1995)

Discussions regarding human embryo research date back to before IVF was even successful. When the Common Rule was first passed, it originally stated that the DHEW (now the DHHS) could fund human embryo research if the grant applications were reviewed by an ethical oversight board (45 C.F.R. §46.204(d)(1)), which would determine whether the projects were acceptable from an ethical standpoint (Bonnicksen 2002). Thus, this law led to the creation of the Ethics Advisory Board (EAB) to determine the acceptability of human embryo research.

From the Carter administration through the George W. Bush administration, different federal ethics commissions made recommendations regarding the regulation of human embryo and IVF research. Overall, these bioethics committees’ effectiveness in helping

pass the human embryo research policies they recommended was limited, especially if the policies required a significant change made or action to be taken by Congress. In fact, some have argued that the DWA was a negative response to one such committee's recommendations on human embryo research (Annas 1996; Hurlbut 2017). Reviewing past ethics committee recommendations and legacies in order to learn from their successes and shortcomings is important for future planning.

The Carter Administration: The Ethics Advisory Board and the First U.S. Human Embryo Report

As discussed previously, human embryo research was not banned outright when human subject regulations were being developed. Instead, federal regulations required the DHEW to create the EAB to approve or reject each research proposal. In 1977, Pierre Soupart, a researcher from Vanderbilt University, submitted the first proposal to conduct federally funded research using human embryos in order to develop IVF (Hurlbut 2017; Bonnicksen 2002). The proposal was accepted for funding by peer review within the NIH. But the proposal also triggered the formation of the EAB, since federal regulations required an ethics board to review and determine if the research was “ethically acceptable from an ethical standpoint” (U.S. DHEW 1979a).

The EAB was first chaired by James C. Gaither, a lawyer, with David A. Hamburg, the president of the Institute of Medicine (now the National Academy of Medicine), as vice chair. The all-male board included 13 members and two consultants (Bonnicksen 2002) who were all doctors, legal experts, or ethicists (U.S. DHEW 1979a). In 1978, the newly formed board agreed to review Soupart's proposal and set overall guidelines for human embryo research. During this process, they asked for written and oral comments from scholars in the fields of reproductive medicine, ethics, theology, law, and social sciences. They also held 11 total hearings in nine cities across the country (Atlanta, Bethesda, Boston, Dallas, Denver, Detroit, Kansas City, Philadelphia, and Seattle). In the end, the board reportedly received more than 2,000 documents from the public.

In May 1979, the EAB released its report with recommendations for limited human embryo research. The board unanimously found that human embryo and IVF research were “acceptable from an ethical standpoint,” although they acknowledged that it was “ethically defensible but still legitimately controverted” (U.S. DHEW 1979a). Gaither said that “an ethical finding by narrow majority was not an ethical finding at all.” He believed that it was important for the report to be unanimous because “what is ‘ethical’ is by necessity acceptable to a ‘broad range of thinking’” (Hurlbut 2017). Ultimately, the EAB concluded that “the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons” (U.S. DHEW 1979a).

However, the EAB did not leave human embryo research open or unregulated (see Box 2). It required that the research comply with human subjects regulations and also suggested that it focus on improving the safety and efficacy of IVF (U.S. DHEW 1979a). Furthermore, it prescribed that any embryos transferred to a woman's uterus be from a married couple,

that any risks discovered be shared with the public, and that the gametes donated be obtained with informed consent. Finally, the board mandated that human embryos not be sustained past “the completion of implantation,” or 14 dpf.

Box 2. The Ethics Advisory Board Guidelines for Human Embryo Research

The Ethics Advisory Board finds that it is acceptable from an ethical standpoint to undertake research involving human in vitro fertilization and embryo transfer provided that:

- A. If the research involves human in vitro fertilization without embryo transfer, the following rules are satisfied:
 1. The research complies with all appropriate provision of regulations governing research with human subjects (45 CFR 46);
 2. The research is designed primarily:
 - a) to establish safety and efficacy of embryo transfer and
 - b) to obtain important scientific information toward that end not reasonably attainable by other means;
 3. Human gametes used in such research will be obtained exclusively from persons who have been informed of the nature and purpose of the research in which such materials will be used and have specifically consented to such use;
 4. No embryos will be sustained in vitro beyond the stage normally associated with the completion of implantation (14 days after fertilization); and
 5. All interested parties and the general public will be advised if evidence begins to show that the procedure entails risks of abnormal offspring higher than those associated with natural human reproduction.
- B. In addition, if the research involves embryo transfer following human in vitro fertilization, embryo transfer will be attempted only with gametes obtained from lawfully married couples.

Source: U.S. DHEW 1979a

The EAB report was the first to mention the 14-day time limit for human embryo research. The board recognized the importance of setting limits for research, including how long an embryo can be cultured *in vitro*, for political and pragmatic reasons (Hurlbut 2017). The restrictions the EAB placed on human embryo research were a compromise in order to gain unanimous approval within the committee as well as, the members believed, to respect differing views. As Hamburg stated during the meeting, “I think we are restricting the grounds for ethical acceptability; and in so doing, are trying to some extent to accommodate the different values that enter into this picture” (Hurlbut 2017).

However, some scholars have expressed concerns about the lack of a strong argument for the specific boundary the EAB set (Hurlbut 2017). This concern is significant because the 14-day limit has become a policy norm, widely replicated in human embryo research policies both nationally and internationally. For example, in 1984 a U.K. report for human embryo research and IVF regulation adopted the limit, although with more detailed justifications (Warnock 1984). The 14-day limit has become the equivalent of a “standard of care” that is replicated without thought or discussion as to whether it is efficient, or, in this case, ethically appropriate and justifiable. This 14-day limit was arguably the most lasting impact of the DHEW report.

The report was neutral on the subject of federal funding. The EAB “decided not to address the question of the level of funding, if any, which such research might be given” (U.S. DHEW 1979a). The board avoided discussing whether human embryos should be used for more general research (Box 3), and the report did not distinguish between creating embryos for research and using embryos left over from IVF (Tauer et al. 2014). In addition, the EAB recommendations were broadly worded to help guide the DHEW in making future decisions on human embryo research. The recommendations were also intended to be a tool to help institutional review boards (IRB), which would have oversight of this research within academia even if that research did not use DHEW funding.

After the report was released, however, the recommendations, including the 14-day limit on human embryo research, were never implemented (Bonnicksen 2002). Secretary of Health, Education, and Welfare Joseph Califano was fired in 1979 and replaced by Patricia Harris. With the election of Ronald Reagan to the presidency in 1980, getting the Belmont principles (i.e., the Common Rule) for human subjects research codified as federal regulations before Reagan took office was a higher priority than implementing EAB recommendations for the Carter administration (Hurlbut 2017). Furthermore, funds for the EAB were transferred to the newly created President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (PCEMBBR), since Congress and DHEW staff did not know the difference between the two boards in terms of their roles and responsibilities (Hurlbut 2017). The EAB was disbanded and its office closed in May 1980 (Bonnicksen 2002; Hurlbut 2017).

After 1980, no subsequent boards were appointed under the DHEW stipulation; therefore, there was no one to review human embryo research applications (Tauer et al., 2014). No further research or broader ethical topics related to human embryos—including whether research not involving embryo transfer, but for general knowledge, should be supported ethically—were reviewed by the EAB, since it no longer existed. While not directly banning human embryo research, the absence of the EAB amounted to, and was seen as, a moratorium on federal funding for such research (Bonnicksen 2002).

Box 3. The Ethics Advisory Board: Should Fundamental Research on Human Embryos be Conducted?

Potentially valuable information about reproductive biology, the etiology of birth defects, and other subjects may be revealed through research involving human in vitro fertilization, without embryo transfer, and unrelated to the safety and efficacy of procedures for overcoming infertility. The Board makes no judgment at this time regarding the ethical acceptability of such research nor does it speculate about what research might be sufficiently compelling to justify the use of human embryos. Instead it notes that applications for support of such research should be submitted to the Board for ethical review in accordance with 45 CFR 46.204(d).

Source: U.S. DHEW 1979a

In the end, the legacy of the EAB included the 14-day limit on human embryo research and the notion that the human embryo was due profound respect and had a special status that was different from other cells in the human body (Hurlbut 2017). Many argue that this special status granted to the human embryo was in fact a public policy tool, and that it was promoted to allow research while accommodating the feelings of those who object. Others have argued that since we allow research to be conducted on the human embryo, it has, in fact, no status at all (Jones 2011).

The Reagan and George H.W. Bush Administrations: 12 Years of Pro-life Republican Presidencies

While the first birth resulting from IVF occurred in 1978 in the United Kingdom, Elizabeth Carr was the first American IVF birth in 1981 (Hurlbut 2017), the result of work by Howard and Georgeanna Jones of the Jones Institute for Reproductive Medicine at Eastern Virginia Medical School. But during the 12 years that presidents Reagan and George H.W. Bush were in office, there was no movement regarding human embryo research. Both presidents ran on pro-life campaigns; in addition, Reagan proclaimed “the inalienable personhood of every American, from the moment of conception until natural death” (Reagan 1988). While in office, both presidents also worked to limit federal funding of research using human fetuses.

In 1985, the Health Research Extension Act—which prohibited federal funding for fetal research, including the *ex utero* fetus (a fetus that is not in the uterus)—was passed (Parens and Knowles 2003; Health Research Extension Act of 1985). But it did not impact human embryo research conducted *in vitro*. The Research Freedom Act, introduced in 1990 by Rep. Henry Waxman (D-CA), was passed by Congress in 1992 but was vetoed by Bush (Hurlbut 2017). It would have overridden a moratorium on the use of fetal tissue from elective abortions. It also included a provision that the secretary of DHHS could not withhold funding from research that was approved by “entities presently responsible for

reviewing such research or research proposals” (Research Freedom Act of 1990). The bill only allowed for research funds to be withheld for ethical reasons if it was the consensus of the EAB, which they hoped to reconstitute.

IVF became a topic of public and policy discussion again following the infamous 1986 “Baby M” case involving surrogacy rights, and Congress began holding hearings to discuss IVF and human embryo research. The case involved a dispute after Mary Beth Whitehead, a surrogate hired to be artificially inseminated with the sperm of William Stern, refused to give up the child after birth, despite signing a legal document and being paid for her services. The case highlighted the complicated nature of surrogacy, as well as the lack of federal oversight of IVF and human embryo research.

In May 1988, the Congressional Office of Technology Assessment (OTA) published “Infertility: Medical and Social Choices.” The report described several options for human embryo research including taking no action, conducting another review of human embryo research and funding it, appointing members to the EAB to potentially approve funding, or implementing the 1979 DHEW recommendations (OTA 1988). Soon after the release of the report, OTA staffer and project director Gary Ellis declared to Congress that “the nine-year absence of the Ethics Advisory Board has...robbed infertile couples seeking IVF of the ultimate consumer protection” (Hurlbut 2017). As a result of increased pressure from the public and from Congress, the DHHS created a new charter for the EAB and posted it on the Federal Register on September 12, 1988, but no further action was taken. President George H.W. Bush took office soon afterward, and all actions to reconstitute the board were halted.

Although the president’s ethics committee (PCEMBBR) that was created at the end of the Carter administration continued to exist during the Reagan administration, only once did they focus on an area broadly linked to human embryo research. In 1982, the commission addressed genetic engineering in the report “Splicing Life,” but noted that “the term genetic engineering has sometimes been used to refer to several other new technologies such as *in vitro* fertilization and cloning of an organism...They are regarded here as examples of reproductive (rather than genetic) technologies and thus are outside the scope of this Report” (PCEMBBR 1982). After the Reagan administration ended, the PCEMBBR was no longer active. Unlike Reagan, Bush did not have a bioethics committee during his term to address broader discussions on these and other bioethics topics.

The Clinton Administration: Human Embryo and Embryonic Stem Cell Research Debates

While there was essentially no change in human embryo research policy over the 12 years of the Reagan and Bush administrations, this changed soon after President Bill Clinton took office. On his third day as president, Clinton issued a series of orders dealing with abortion and reproductive rights, including one that lifted the restriction on federal funding of fetal tissue research (Clinton 1993). After this announcement, several further changes occurred, including new legislation and the creation of two commissions

(the Human Embryo Research Panel [HERP] and the National Bioethics Advisory Commission) to review the guidelines contained in the DWA for the first time.

The first change was legislative. In June 1993, Congress passed the National Institutes of Health Revitalization Act of 1993, which revoked the requirement for an ethics advisory board to review and approve funding for research proposals involving human embryos (Tauer et al. 2014; Fletcher 2001; National Institutes of Health Revitalization Act of 1993). Specifically, this legislation removed the ethics board oversight provision so that the NIH had the ability to fund human embryo research (Hurlbut 2017; Tauer et al. 2014).

As a result of this act, the NIH—under the direction of Harold Varmus—created the HERP to review human embryo research guidelines (NIH 1994; Tauer et al. 2014; Hurlbut 2017; Parens and Knowles 2003). This 19-member panel brought together male and female experts from the fields of embryology, reproductive medicine, law, bioethics, sociology, and patient advocacy (Hurlbut 2017). The panel was formed to make recommendations and “to consider various areas of research involving the *ex utero* preimplantation human embryo and to advise as to those areas that (1) are acceptable for Federal funding, (2) warrant additional review, and (3) are unacceptable for Federal support” (NIH 1994).

The goal of many on the HERP, it was believed, was to bring human embryo research under the purview of the NIH, which would allow for stricter guidelines and oversight (Hurlbut 2017). As part of the efforts to achieve this goal, the panel discussed the 14-day limit extensively and tried to reinforce the rationale behind it (Hurlbut 2017). Furthermore, some panel members saw the HERP as an opportunity to move the discussion from ethics and policy back to a purely scientific discussion. One member, Patricia Donahoe, believed that they should broaden the scope of human embryo research, saying, “it would be a shame for those therapeutic potentials if we limited ourselves to 14 days, because there’s going to be a revolution of understanding that will come out of this” (Hurlbut 2017).

The panel convened from February through October 1994, releasing a final report in December of that year (NIH 1994). Over the course of its deliberations, the panel held six public meetings, heard 46 oral presentations, and received over 30,000 pieces of correspondence. While the document narrative was unanimously approved, the resulting recommendations represented the views of the majority, with dissenting opinions noted.

The HERP recommendations supported embryo research, stating that “although the preimplantation embryo warrants serious moral consideration as a developing form of human life, it does not have the same moral status as an infant or child.”

The HERP recommendations supported embryo research, stating that “although the preimplantation embryo warrants serious moral consideration as a developing form of human life, it does not have the same moral status as an infant or child” (NIH 1994). They also proposed that “research involving preimplantation embryos should be limited to the shortest time period consistent with the goals of each research proposal” (NIH 1994). The reasons for this recommendation included “the absence of developmental individuation in the preimplantation embryo, the lack of even the possibility of sentience and most other qualities considered relevant to the moral status of person, and the very high rate of natural mortality at this stage” (NIH 1994). The report also called for federal funding for embryonic research, including research that could necessitate destroying embryos—one such example being the creation of hESCs, which successfully occurred in 1998. But it still required that human embryos be treated as a special class different from other human cells and from nonhuman embryos (Tauer et al. 2014).

The HERP report also upheld the 14-day rule, saying that “research involving human embryos should not be permitted beyond the time of the usual appearance of the primitive streak *in vivo* (14 days)” (NIH 1994). While this was not unexpected or even controversial since other similar bodies came to the same conclusion, the panel left the option open for extending research beyond day 14, which was unusual. The report permitted this exception “for research between the appearance of the primitive streak and the beginning of closure of the neural tube,” which occurs approximately 18 to 22 dpf (NIH 1994). The panel believed this extended period would help answer crucial questions in reproductive medicine.

The report’s most controversial recommendation, though, was allowing human embryos to be created for research purposes. The 1979 DHEW report only allowed for human embryo research to be conducted to further develop IVF; in contrast, the HERP report stated that “studies that require the fertilization of [the human egg] are needed to answer crucial questions in reproductive medicine... It would therefore not be wise to prohibit altogether the fertilization and study of oocytes for research purposes” (NIH 1994).

In an article published after the report was released, committee member R. Alto Charo argued that the problem with the recommendations was that the panel tried to determine the moral status of the human embryo (Charo 1995). She believed that the report’s recommendations would have been strengthened “if it had squarely acknowledged that it is impossible for a governmental body to determine the moral status of the embryo” (Charo 1995). Furthermore, additional scholars have argued that while the panel said the human embryo was a research tool entitled to respect, they allowed it to be destroyed for research, so it was not really protected (Hurlbut 2017).

Following the report’s release, Clinton announced his opposition to the most controversial recommendation—creating embryos for research purposes (Tauer et al. 2014; Hurlbut 2017). He issued a presidential order and proclamation prohibiting federal funding for such research, stating, “I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that

NIH not allocate any resources for such research” (Charo 1995). NIH director Harold Varmus accepted the other recommendations in the HERP report and started to move toward funding human embryo research. But before funding could be allocated for such research, the DWA was passed for the first time in 1996.

The political climate in Washington, D.C., changed after the midterm elections in 1994, with both chambers of Congress going from having Democrat majorities to being controlled by Republicans. This change was very significant, considering the Democrats had controlled the House of Representatives for approximately 40 years. That winter, the president and Congress—under the leadership of Speaker of the House Newt Gingrich (R-GA)—fought over the federal budget. This disagreement eventually led to the government shutdown the winter of 1995–1996 when a federal budget bill could not be passed. The resulting omnibus funding bill, H.R. 2880—Balanced Budget Downpayment Act I—passed in early 1996 and included a small amendment to DHHS funding: the DWA.

As discussed previously, the DWA banned federal funding of human embryo research (Matthews and Rowland 2011). Because the amendment was added to a larger budget bill required to fund the federal government after the shutdown, it was passed with little discussion. This amendment is believed to be a response in part to the HERP report and its recommendation for the expansion of human embryo research, including the use of human embryos created for research purposes (Annas 1996; Annas, Caplan, and Elias 1996; Hurlbut 2017). It is unclear why the amendment has had such staying power; it has stood for more than 20 years, even when Democrats controlled both chambers of Congress. It seems to represent a compromise both Democrats and Republicans are comfortable with, since it blocks federal funding but does not impact private or state funding for human embryo research.

Clinton faced several other bioethical challenges linked to human embryo research during his tenure, including fears related to the possibility of human cloning and questions about the acceptability of hESC research. To address these and other issues, in 1995 he created the National Bioethics Advisory Commission (NBAC), which first addressed human cloning. In 1997, the commission released a report in response to scientific developments related to the first cloned mammal, a sheep named Dolly, that said little about human embryo research (Matthews and Rowland 2011). The NBAC, similar to the Reagan bioethics commission, simply said they would “not revisit either the question of the cloning of humans by embryo-splitting or the issues surrounding embryo research. The latter issue has, of course, recently received careful attention by a National Institutes of Health panel, the Administration, and Congress” (NBAC 1997).

In their 1999 report “Ethical Issues in Human Stem Cell Research,” the NBAC responded to concerns after researchers at the University of Wisconsin cultured hESCs (Matthews and Rowland 2011; NBAC 1999). At this point, the commission addressed human embryo research as it was directly linked to hESC research, because the hESCs come from five- to six-day-old fertilized eggs (at the blastocyst stage). The commission recommended federal funding of hESCs isolated from embryos left over from IVF treatment. But unlike

the HERP, the NBAC report stated that “federal agencies should not fund research involving the derivation or use of [hESCs] from embryos made solely for research purposes” (NBAC 1999). This report disagreed with the HERP assessment, saying that “either from a scientific or a clinical perspective, there is no compelling reason to provide federal funds for the creation of embryos for research at this time” (NBAC 1999). But due to the DWA, no human embryo research, regardless of the source of the embryo, was ultimately funded during the Clinton administration.

The George W. Bush Administration: The Compromise Policy

George W. Bush ran for office in 2000 on a platform opposing both human embryo and hESC research (Tauer et al. 2014; Matthews and Rowland 2011). When he took office in January 2001, he halted all federal funding for hESC research at the NIH and kept the funding ban in place for human embryo research. Interestingly, instead of banning all funding for hESC research, he instead developed a compromise in the form of an executive order. It allowed for the federal funding of hESC research using hESCs already developed or in development, but no funds would be available for cells created after the date of the announcement—August 9, 2001 (Tauer et al. 2014; Matthews and Rowland 2011). Bush also allowed private or nonfederal funding to continue without oversight or regulation, essentially maintaining the status quo from previous administrations. While in office, Bush encouraged the use of stem cells from nonembryo sources, as well as the creation of hESCs through means that would not require the destruction of an embryo (Bush 2007). For example, one method frequently discussed was removing one cell at the eight-cell stage, allowing the rest of the cells to continue to divide and grow (this is the same stage at which IVF doctors take a cell for preimplantation genetic diagnosis).

In 2001, Bush also created a bioethics committee, the President’s Council on Bioethics (PCB). The committee reviewed research creating or using hESCs, human cloning, and other controversial issues in medicine and biomedical research. With regard to human embryo research, the PCB released a report in 2004 focused on assisted reproductive technologies (ART) titled “Reproduction and Responsibility: The Regulation of New Biotechnologies,” which recommended additional federal oversight of IVF and human embryo research. Furthermore, it mentioned the international consensus on the 14-day rule, stating that “there seems to be some agreement among scientific professional societies that embryos should not be cultivated beyond fourteen days’ development—a limit that has been proposed by a number of bodies, both governmental and nongovernmental” (PCB 2004).

The Obama Administration

Soon after taking office, President Barack Obama made changes to several of the science policies of his predecessor, including signing Executive Order 13505 titled “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells” (Obama 2009). This executive order removed Bush’s restriction on funding for research on hESC lines created after August 9, 2001, and allowed hESC research to qualify for federal funding if it passed rigorous ethical guidelines that the NIH was to develop (Tauer et al. 2014; Matthews

and Rowland 2011). By July 2009, the NIH had created guidelines for hESC research. Over the eight years Obama was in office, the NIH approved more than 300 different hESC lines (cells grown in culture from one original cell), a significant increase from the 21 lines available during the George H.W. Bush administration.

Soon after the NIH guidelines were released, the new hESC policy and the DHHS's interpretation of the DWA were questioned in court. In the case "Sherley v. Sebelius," the plaintiffs—two stem cell researchers named James Sherley and Theresa Deisher, along with several anti-hESC groups—challenged the NIH's hESC guidelines, saying any hESC research contradicted the DWA (Cuchiara, Lawford Davies, and Matthews 2013). The plaintiffs won the first round when a U.S. district court issued an injunction halting all research utilizing hESCs (which had been occurring both under George W. Bush's compromise and Obama's expansion). Ultimately, the federal appeals court ruled in favor of the DHHS, pointing to eight years of precedence under the policy of the George W. Bush administration, which allowed limited hESC research while the DWA was in place (Cuchiara, Lawford Davies, and Matthews 2013).

During his administration, Obama created his own bioethics committee, the Presidential Commission for the Study of Bioethical Issues (PCSB). The commission developed 10 reports on topics including Ebola, brain science, and whole genome sequencing privacy issues, but none of them addressed human embryo research. Furthermore, aside from changing federal funding guidelines to allow more hESC research, there were no real changes to federal rules governing human embryo research. The DWA was still passed annually as part of the NIH appropriations bill, and nothing was done to oversee nonfederally funded research.

The Trump Administration

As of January 2019, there have been no changes to the federal policy during the first two years of the Trump administration, although Vice President Mike Pence is known to be against hESC research. President Donald Trump has not mentioned creating a bioethics committee, and policy scholars and analysts believe it is unlikely one will be formed, since the president has publicly maligned federal advisory committees in general. He also has taken almost two years to appoint the bulk, although not all, of science-related appointments after more than one year in office (Union of Concerned Scientists 2018).

President Donald Trump has not mentioned creating a bioethics committee, and policy scholars and analysts believe it is unlikely one will be formed.

In addition, in October 2017 the DHHS released the draft of its strategic plan with new language, stating that "HHS accomplishes its mission through program and initiatives that cover a wide spectrum of activities, serving and protecting Americans at every stage of life, beginning at conception" (Hellmann 2017). The statement is almost identical to

that during the Obama administration—except for the inclusion of the phrase “beginning at conception,” which is in line with the pro-life stance of the Trump administration (Hellmann 2017).

State Policies: A Patchwork of Policies

“The resulting multifaceted and, at times, overlapping and discordant regimes present both within and between different jurisdictions constitute what we term a ‘patchwork of patchworks.’”

—Timothy Caulfield et al. (2009)

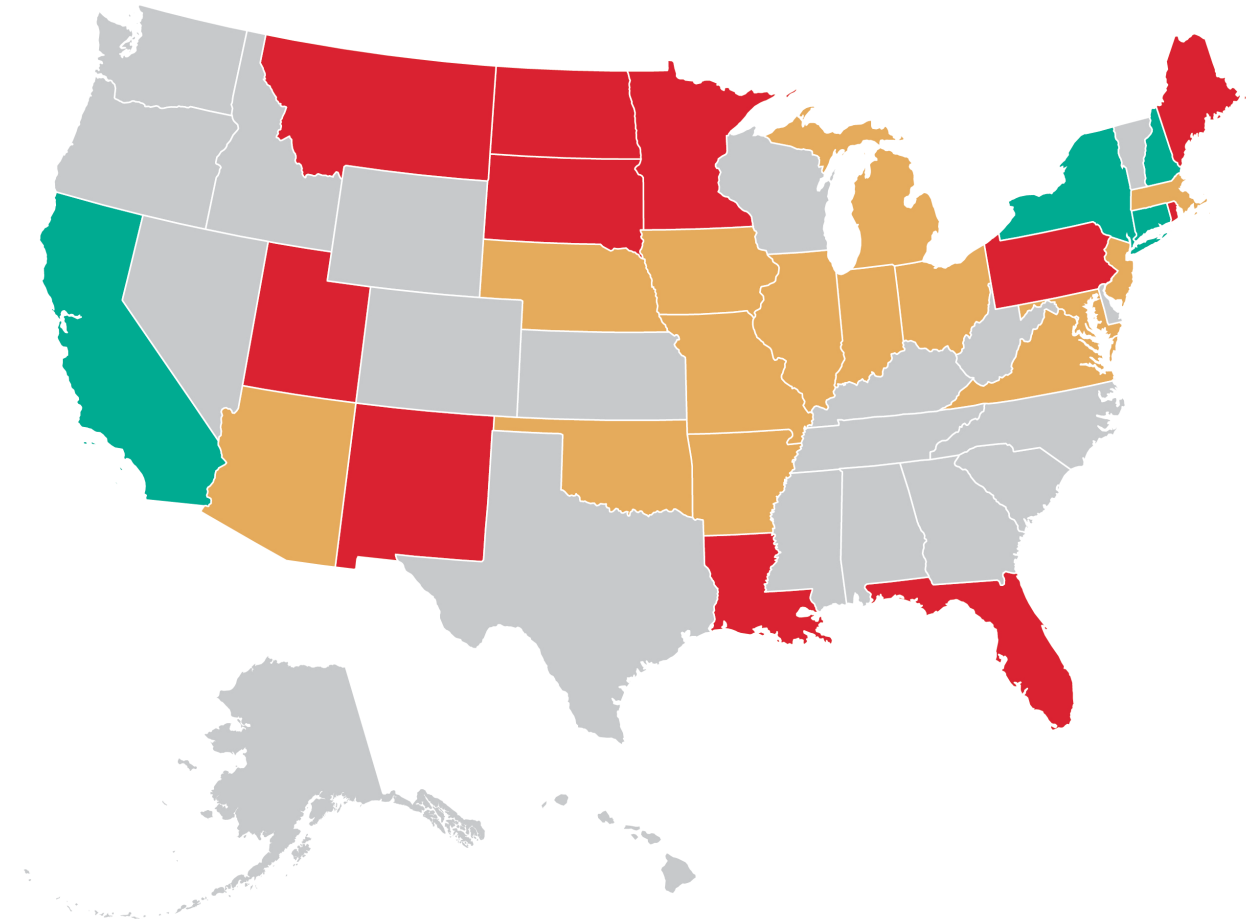
In addition to the federal government, state legislatures also play an important role in regulating human embryo research. Because the DWA only addresses what can and cannot be federally funded, some individual states have determined policies within their own borders, many of which have been passed within the last two decades.

It is important to note here that the legal research conducted for the purposes of this report was limited to statutes that explicitly include the following terms: “human embryo,” “fetus,” and “*in vitro* fertilization.” Therefore, there may be other state or federal laws that impact the interpretation of these statutes that were not captured in this legal review. In addition, the statutory interpretations were limited to the plain language of said statutes and excluded legislative history and case law.

Human embryo research policies vary significantly from state to state, making a complicated patchwork of policies that scientists must navigate in order to conduct research (Figure 1). Not all states have policies; of those that do, some states are more permissive than the federal government, and a few even fund human embryo research (which is often linked to hESC research). Others are more restrictive, banning all human embryo research.

Figure 1. U.S. Map of State Human Embryo Research Policies

While some states have no legislation (gray), others range from prohibitive (red) to permissive (green). A few state policies lack an explicit prohibition of in vitro research (tan). For more details, see the Appendix.



	No legislation	Alabama, Alaska, Colorado, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Kansas, Kentucky, Mississippi, Nevada, North Carolina, Oregon, South Carolina, Tennessee, Texas, Vermont, Washington,* West Virginia, Wisconsin, Wyoming
	Legislation, but no explicit research prohibition	Arizona, Arkansas, Illinois, Indiana, Iowa, Maryland, Massachusetts, Michigan, Missouri, Nebraska, New Jersey, Ohio, Oklahoma, Virginia
	Permissive	California, Connecticut, New Hampshire, New York
	Prohibitive	Florida, Louisiana, Maine, Minnesota, Montana, New Mexico, North Dakota, Pennsylvania, Rhode Island, South Dakota, Utah

* Washington does not have legislation, but the University of Washington does enforce a 12-day limit.

Source: Authors' analysis

Twenty-one states and the District of Columbia lack any specific policies on human embryo research, relying instead on federal policies and guidelines. This means that there are neither state funds to support such research, nor any regulations or institutions to oversee it. However, human embryo research can still be conducted with nonfederal funds, since there are also no bans or limitations. Politically, these states range from conservative (e.g., Texas) to more liberal (e.g., Oregon) (Voting America 2018). The states opting out of creating a policy do not necessarily have much in common politically; they have chosen not to pass legislation for various reasons, such as the topic not being a priority within the state, or not having the majority needed to push legislation through.

Of the states with policies, 11 of them have laws that are restrictive, banning human embryo research regardless of the time point of embryo growth or the source of funding. Among these states, Florida, Minnesota, Montana, New Mexico, and Pennsylvania frame their regulations to reflect a “do no harm” approach. For example, Florida’s policy declares that any manipulation is prohibited “except as necessary to protect or preserve the life and health of such fetus or premature infant” (Florida Chapter 390.0111-(6)). Considering the risks to the human embryo associated with this research, these laws effectively ban any form of experimentation on them. South Dakota’s policy states that “research that destroys human embryo [is] prohibited,” which effectively bans any experimentation on human embryos (South Dakota Stat § 34-14-16). North Dakota’s legislation is also not thorough, declaring that “a person may not use any live human fetus, whether before or after expulsion from its mother’s womb, for scientific, laboratory, research, or other kind of experimentation” (North Dakota Cent. Code § 14-02.2-01(1)). This portrayal of the live human fetus *in vivo* or *in utero* does not specifically address the culturing of embryos *in vitro*, but hints enough at a ban on human embryo research—especially in combination with an additional law specifically banning all human cloning—to classify North Dakota as being “restrictive.”

Of the remaining state human embryo policies, five are permissive: California, Connecticut, New Hampshire, New Jersey, and New York. These states expanded human embryo research opportunities (associated with permissive hESC research policies), often with additional funding—the most well-known case being California. It was the first state to pass a law (Proposition 71) that specifically allowed and funded stem cell research, including human embryo and hESC research (Proposition 71, 2003). Passed in 2004, Proposition 71 allocated \$3 billion to fund stem cell research over 10 years and established the California Institute for Regenerative Medicine (CIRM), a new state agency that would oversee the research. These measures gained momentum because of many citizens’ belief in the potential of hESC research to create therapeutic interventions. Public discussions shifted away from the moral status of the embryo to the idea that religion was impacting the secular democratic forces of science (Hurlbut 2017). In 2007, the CIRM’s “Guidelines for Human Stem Cell Research” mandated that projects utilizing human embryos were eligible for funding as long as they were only cultured up to 12 dpf or the appearance of the primitive streak, whichever came first (California Health and Safety Code §125118).

Politics and Policies Guiding Human Embryo Research in the United States

After California's stem cell legislation, several other states followed suit by passing laws that supported but regulated human embryo and hESC research. In 2005, Connecticut announced \$100 million in public funding for stem cell research and experimentation on human embryos, specifically for hESC research. This law required that all human embryo research be conducted before gastrulation occurs, which is typically around 17 dpf (Connecticut Public Act No. 05-149).

New Hampshire allows the culturing of human embryos up until 14 dpf. New Mexico likewise permits experimentation on embryos derived from any source until the formation of the primitive streak. While New York does not have an explicitly permissive legal statute, the New York State Stem Cell Science program within the state's Department of Health has a 14-day limit spelled out in the consent form for donating embryos for research that states, "Embryos will not be used to create a pregnancy, and will not be allowed to develop beyond 14 days" (NYSTEM).

Fourteen additional states, by virtue of lacking specific or thorough legislation, seem to allow human embryo research on embryos left over from IVF procedures. The IVF process often produces an excess of embryos that are frozen for later use. These embryos can be donated for research purposes, given to another couple, or destroyed. The use of embryos left over from IVF in research is often seen as less morally controversial, because they might otherwise be discarded. Massachusetts, Indiana, and Missouri prohibit the creation of embryos solely for the purpose of research; however, they seem to allow experimentation on leftover embryos. Massachusetts law bans embryo creation for research purposes, stating that "no person shall knowingly create an embryo by the method of fertilization with the sole intent of donating the embryo for research" (Massachusetts General Law Part I Title XVI Chapter 111L Section 8). Indiana and Missouri ban the creation of embryos solely to produce hESCs, stating that "no human blastocyst may be produced by fertilization solely for the purpose for stem cell research" (Missouri Constitutional Article III Section 38(d)). In Arizona, "a person shall not intentionally or knowingly engage in destructive human embryonic stem cell research" (AZ Rev Stat §36-2302, 11-13).

In Nebraska and Illinois, there is a ban on state funding for human reproductive cloning research (cloning a human being), as well as on creating human embryos solely for research purposes, but human embryo research is not prohibited outright. Interestingly, Illinois bans creating human embryos for research but also funds hESC creation and research. The Illinois governor signed Executive Order 6 (2005) and Executive Order 3 (2006), which established the Illinois Regenerative Institute for Stem Cell Research and allocated \$10 million in research funding. The orders also prohibited the use of these funds for research that creates embryos for research purposes, but allowed research on embryos left over from IVF procedures. In addition, the Illinois state legislature passed a law prohibiting human reproductive cloning but explicitly permitting therapeutic cloning (cloning to develop cells but not using them to create a human) and hESC and human embryo research (Illinois Compiled Statutes 2008).

Politics and Policies Guiding Human Embryo Research in the United States

Five states specifically ban research on aborted fetuses, whether or not state funds are used. In Nebraska, “no person shall knowingly, intentionally, or willfully use any premature infant aborted alive for any type of scientific, research, laboratory, or other kind of experimentation except as necessary to protect or preserve the life or health of such premature infant aborted alive” (Nebraska Stat §28-346). The federal definition of a fetus (there is none in the Nebraska statute) includes the embryo during the implantation stage, but these laws may not always impact human embryo research performed with embryos developed *in vitro*.

Nine states prohibit all reproductive cloning (cloning a human being), although this does not impact general human embryo research. Maryland, while banning reproductive cloning, still allows hESCs to be used in research. The Maryland Stem Cell Research Fund Act of 2006 declares that “nothing in this part may be construed to prohibit the creation of stem cell lines to be used for therapeutic research purposes” (Maryland Stem Cell Research Act §10-430 2006).

Sometimes, research institutions themselves have regulations, though the state government does not. For example, the state of Washington itself does not have a human embryo research policy; however, the University of Washington prohibits “*in vitro* culture of an intact human embryo for more than 12 days of development or until formation of the primitive streak, whichever occurs first” (GIM 36 2008).

Overall, the inconsistency among states’ laws make it complicated to determine what research can and cannot be conducted. The majority of the laws were developed specifically to address other issues, such as preventing research on aborted fetuses, or either prohibiting or promoting hESC research. Because they were created to address other issues, some overlap with and impact human embryo research, while others leave *in vitro* human embryo research unaddressed.

The Role of NGOs in Creating and Disseminating Policy

“Research under this category should not be pursued at this time because of broad international consensus that such experiments lack a compelling scientific rationale, raise substantial ethical concerns, and/or are illegal in many jurisdictions.”

— International Society for Stem Cell Research (2016)

Federal policies related to human embryo research lag behind the current state of the research due to the ban on federal funding. This opens the door for NGOs, especially foundations and professional societies that guide human embryo research, to play a vital role in civil society. In this section, we will review several major NGOs that helped develop the U.S. and international consensus regarding the 14-day guideline.

Several private foundations fund human embryo research, particularly that related to hESCs, filling a gap since no human embryo research is funded at the federal level.

However, their stated policies vary. Some foundations such as the JDRF explicitly state that “embryos used for research should not be maintained intact in culture beyond 14 days post-fertilization, the internationally accepted time limit” (JDRF). Another more common practice is for a foundation to state their adherence to the NASEM hESC guidelines, which also follow the 14-day limit. One such example is the Christopher & Dana Reeve Foundation, which states: “The Reeve Foundation recognizes that responsible stem cell research involves the careful orchestration of scientific and ethical issues and it believes that the National Academies of Science 2008 Amendment to 2005 Guidelines for Human Embryonic Stem Cell Research strike a proper balance” (Christopher & Dana Reeve Foundation). Many other foundations that fund human embryo or hESC research, such as the New York Stem Cell Foundation, do not publicly outline a policy. These organizations may not have an official one, or they may have policies that can only be found internally in private documents like grant applications or informed consent documents.

In addition to funding research, NGOs also advise scientists and those who practice medicine. Most often, this guidance is informally applied through their professional societies, especially the previously mentioned NASEM. Such societies offer scientists and doctors professional ethics standards and research guidelines and ask that their members abide by these informal rules—and the overwhelming majority do so.

NASEM is arguably the most significant scientific NGO in the United States. It was founded in 1863 to advise the government and advance discussion on scientific topics. Originally just the National Academy of Sciences, it was later expanded to also include the National Academy of Engineering and the National Academy of Medicine (formerly the Institute of Medicine). NASEM conducts policy research and makes recommendations by bringing together highly respected scientists and experts to convene discussions and build consensus on topics. The results of their deliberations are publically available and are used to help shape science and health policy.

But NASEM has not thus far explicitly deliberated on the 14-day rule or human embryo research. In 1979, David Hamburg, the president of the then Institute of Medicine, was a co-chair of the EAB, which first developed the guideline in the United States. In a 1989 report on ART titled “Medically Assisted Conception: An Agenda for Research,” a NASEM committee made recommendations about the direction of ART research and referenced two other organizations that affirmed the 14-day limit, the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (now the American Society for Reproductive Medicine [ASRM]). But the NASEM committee never explicitly stated that the 14-day rule should be followed. Again, a more recent NASEM report titled “Human Genome Editing” mentioned the 14-day rule but did not discuss it in depth (NASEM 2017).

The only NASEM recommendation regarding the 14-day rule was found in a subsection of a recommendation for hESC research. In 2005, NASEM published “Guidelines for Human Embryonic Stem Cell Research,” a report that was created to help fill the policy and regulation void, since the NIH was not funding research that involved the creation of

hESCs and therefore did not give researchers guidelines for the ethical creation of hESCs. The NASEM report was updated in 2007 and 2008, and a final version was released in 2010. It does not discuss the 14-day rule, but it does include a note that “research involving *in vitro* culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever occurs first,” is not permitted (NASEM 2010). Furthermore, it states that “neither blastocysts or morulae...nor parthenogenic or androgenic embryos may be transferred to a human or nonhuman uterus or cultured as intact embryos *in vitro* for longer than 14 days or until formation of the primitive streak, whichever occurs first” (NASEM 2010).

Another organization that shaped the field of stem cell biology is the International Society for Stem Cell Research (ISSCR). Founded in 2002 to promote stem cell research and international collaboration, the ISSCR currently has more than 4,000 members. In 2006, the organization developed its own member guidelines for hESC research that were updated in 2016 (ISSCR 2006). These guidelines state that prohibited research activities include “*in vitro* culture of any intact human preimplantation embryo or organized embryo-like cellular structure with human organismal potential, regardless of derivation method, beyond 14 days or formation of the primitive streak, whichever occurs first,” justifying this prohibition based on a “broad international consensus that such experiments lack a compelling scientific rationale, raise substantial ethical concerns, and/or are illegal in many jurisdictions” (ISSCR 2016). In addition, the organization suggested that a stem cell research oversight (SCRO) committee be involved in reviewing and approving human embryo research as well as its other mandated areas, including hESCs and induced pluripotent stem cells research.

The ASRM was an active player in developing human embryo research guidelines in the 1980s. Howard Jones, the doctor who conducted the first successful IVF procedure in the U.S. in 1981, is believed to have persuaded the ASRM to establish an ethics committee to review ART (Hurlbut 2017). The committee included four IVF practitioners, one endocrinologist, two developmental biologists, one lawyer, and two ethicists, one of whom was LeRoy Walters, a staffer who worked on the 1979 DHEW EAB report (Hurlbut 2017). In September 1986, this committee released a report titled “Ethical Considerations of the New Reproductive Technologies,” which incorporated the 14-day rule found in the reports from the DHEW and the U.K.’s Warnock Committee, convened in 1982 to establish guidelines for IVF in the U.K.

Other major NGOs have impacted or discussed human embryo research policies. The ACOG instituted a policy in 1986 prohibiting such research beyond the 14th day (NASEM 1989). But it was withdrawn in 1996 and not replaced (ACOG, pers. comm. August 24, 2017). The American Association for the Advancement of Science (AAAS) does not have a guideline, but it did issue statements during the Reagan administration in an effort to push the secretary of DHHS to reestablish the EAB so ART and human embryo research could be reviewed again (Hurlbut 2017).

In addition, after the NIH HERP report was published in 1994, two medical societies publicly supported the 14-day guideline, albeit somewhat tentatively. The American Academy of Pediatrics (AAP) stated that “a limit on the stage of development after which the use of human embryos is not allowed, such as that suggested by the NIH [HERP] panel, is necessary. However, given the complexity of this issue, additional consideration of this limit is necessary” (AAP 2001). The American Medical Association (AMA) also reportedly supported the panel’s recommendations (PCB 2004).

Furthermore, in May 2018 the journal *Nature* released a new policy that applies to human embryo and hESC research publications (*Nature* 2018). The policy requires papers on these subjects to be accompanied by an ethics statement to highlight ethical oversight of the work and the consent process. For more potentially controversial papers, the journal will have the paper reviewed by an independent ethicist in addition to implementing the traditional peer-review process.

In sum, the guidelines developed and supported by NGOs have helped set standards for researchers in the United States, providing scientists with the assurance that their work is ethically justifiable within certain limits.

Next Steps: Policy Changes for Beyond Day 14

“One lesson is that ignoring a public policy problem does not make it disappear.”

—LeRoy Walters (2001)

Policy options affecting the future of human embryo research include maintaining the status quo 14-day guideline set by some states and the private sector; restricting human embryo research further, which could be achieved through a new federal law; or increasing the scope of permitted research beyond 14 dpf. Human embryo research beyond 14 dpf is scientifically possible, but to conduct any substantial amount of embryo research in the United States, policy changes would be necessary. These changes would need to be implemented at the state and federal levels, and also in the private sector—including foundations that would fund such research and scientific and medical societies that oversee the professionals who would perform this work. In this section, we describe the changes that would be needed at each of these levels if the 14-day guideline is to be altered.

Federal Policy Changes

At the federal level, there is no policy that would impede human embryo research beyond 14 dpf. The only limitations at the federal level for *in vitro* embryos are associated with funding through the DWA. If the *in vitro* embryo subject to research is intended to be transferred to a womb, the FDA could have approval authority, as it controls clinical trials and can assert its authority to review work performed on human embryos intended for pregnancy. Furthermore, the procedure would be registered with the CDC, as it monitors and records all U.S. IVF procedures and protocols.

A common recommendation made by many scholars to increase human embryo and hESC research is to replace or alter the DWA. Such an alteration would allow the NIH to participate in research and set guidelines, either a 14-day limit or perhaps another time point. While the DWA was originally a Republican maneuver to block human embryo research funding, it is seen as a compromise between the two parties. Despite power changes in Congress and in the presidency over the past two decades, the amendment has continued to be passed annually. This is not likely to change in the future. With the Trump administration, scientists and research advocates are more concerned about the ban being expanded and all hESC and/or human embryo research being limited or prohibited.

Furthermore, several U.S. legislators are uncomfortable with experts making policy and moral decisions for the public on this issue (Hurlbut 2017). Therefore, it is unlikely that they would be moved if a new bioethics committee recommended federal funding of human embryo research, or expanding that research beyond 14 dpf.

State Policy Changes

As described previously, state government policies are diverse and complicated. However, changes in individual state policies may prompt the expansion of human embryo policy on a national level. On the other hand, states can choose to do the opposite by restricting the research within their borders even more than the federal government does. After California passed Proposition 71, several other states adopted human embryo and hESC research policies, fearing they might fall behind in scientific advancement and medical innovation. But a few states adopted more restrictive policies, passing legislation specifically banning some or all hESC research.

If the federal policy for embryo research were to be expanded, many states would have to change their policies to allow research to be expanded within their borders as well. Some states would need minor adjustments or clarifications to their policies; Indiana and Missouri, for instance, would perhaps need to expand on their policies to address human embryo research more broadly rather than hESC research specifically. In other states such as Louisiana and Rhode Island, extending human embryo research beyond 14 dpf would require a complete reversal of their laws, since they do not allow any human embryo research.

Overall, legislative changes in most states are unlikely from a political standpoint, especially where prohibitive language already exists in their laws. Many of these states do not have any vested research or infrastructure interests, such as universities or institutes conducting related work, that would apply pressure to the state legislature to make changes in this area.

Human embryo research beyond 14 dpf is scientifically possible, but to conduct any substantial amount of embryo research in the United States, policy changes would be necessary at the state and federal levels, and also in the private sector.

NGO Policy Changes

Altering NGO policies (specifically, professional societies and foundations funding hESC or human embryo research) would be more straightforward than revising state and federal policies, as it would only require a decision by the organizations' governing bodies. Changes to guidelines for private foundations would be more likely if science and medical societies first adopt a policy allowing human embryo research beyond 14 dpf. This would be especially true for reputable organizations such as the NASEM, which is looked to for guidance on ethical and policy concerns.

To alter existing guidelines, these scientific and medical societies will need encouragement from scientists to pursue discussions and create new ethics committees with various stakeholders including doctors, biologists, ethicists, social scientists, policy scholars, patient advocates, and other interested members of the public. Then if they do recommend increasing the limit to another time point or utilizing another mechanism to review research (such as an institutional human embryo ethics board), this decision will need to be disseminated and accepted by other stakeholders, especially private foundations and their donors, who would be funding this work. But private foundations might still be hesitant to make changes, especially if they rely on donations from the public.

Moving Forward

While science and research continue to progress, it is the role of policy to guide this research. As the Nuremberg Code and the Common Rule did for broader human subjects research, so the 14-day rule does for human embryo research. In this paper, we reviewed the history of federal, state, and private policies impacting human embryo research. We examined how changes might be applied, and the potential impacts such changes might have.

Beyond the policies that *can* be implemented, we should also address what *should* be done from a moral standpoint. These questions are addressed in the companion reports that will follow, which assess the scientific merit of expanded human embryo research—i.e., what can be done—and ethical questions associated with altering the 14-day guideline for human embryo research in the United States—i.e., what ought to be done.

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Appendix — Human Embryo Policies by State

Arizona

IVF is permitted, but the buying or selling of *in vitro* human embryos, research using aborted materials, and the destruction of a human embryo for the purpose of creating hESCs are prohibited.

- Ariz. Rev. Stat. § 36-2302 (2016)
 - Prohibits research on an aborted embryo
 - <https://www.azleg.gov/viewDocument/?docName=http://www.azleg.gov/ars/36/02302.htm>
- Ariz. Rev. Stat. § 36-2311 (2015) Definitions
 - “Destructive human embryonic stem cell research’ means any research that involves the disaggregation of any human embryo for the purpose of creating human pluripotent stem cells or human pluripotent stem cell lines.”
 - “Human embryo’ means a living organism of the species homo sapiens through the first fifty-six days of its development, excluding any time during which its development has been suspended.”
 - <https://www.azleg.gov/viewDocument/?docName=http://www.azleg.gov/ars/36/02311.htm>
- Ariz. Rev. Stat. § 36-2312 (2016)
 - Prohibits the creation of an embryo *in vitro* by means other than fertilization and the selling or buying of *in vitro* human embryos
 - <https://www.azleg.gov/viewdocument/?docName=http%3A%2F%2Fwww.azleg.gov%2Fars%2F36%2F02312.htm>
- Ariz. Rev. Stat. § 36-2313 (2015)
 - Prohibits destruction of embryos for hESC research
 - “A person shall not intentionally or knowingly engage in destructive human embryonic stem cell research.”
 - <https://www.azleg.gov/viewdocument/?docName=http%3A%2F%2Fwww.azleg.gov%2Fars%2F36%2F02313.htm>

Arkansas

Laws prohibit research on aborted embryos or fetuses born alive or dead, and the use of embryos produced by or for the purpose of cloning, but they do not necessarily limit the culturing of embryos *in vitro*.

- Ark. Senate Bill 185 20-16-1002 (2003)
 - Prohibits the use of embryos produced by cloning or for the purpose of cloning
 - <http://www.arkleg.state.ar.us/assembly/2003/R/Acts/Act607.pdf>
- Ark. Senate Bill 417 (2013)
 - Defines a person as “an unborn child *in utero* at any stage of development,” leaving the option open for research on *in vitro* embryos
 - <http://www.arkleg.state.ar.us/assembly/2013/2013R/Acts/Act1032.pdf>

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- Ark. House Bill 1407 (2015)
 - Prohibits research on aborted fetuses born dead
 - <http://www.arkleg.state.ar.us/assembly/2015/2015R/Acts/Act535.pdf>

California

In vitro culture of human embryos is allowed until the appearance of the primitive streak or 12 dpf, whichever is earlier.

- California Institute for Regenerative Medicine (CIRM)
 - Created after Proposition 71 “California Stem Cell Research and Cures Initiatives” passed in 2004
 - https://www.cirm.ca.gov/sites/default/files/files/about_cirm/prop71.pdf
 - Funds research on human embryos including the creation of new hESC lines
 - Specifies 12-dpf limit on research (slightly shorter than Warnock and DHEW date) or development of a primitive streak
- Guidelines for Human Stem Cell Research Pursuant to Health and Safety Code § 125118 (2012)
 - “100030. Activities Not Eligible for CIRM Funding. The following activities are not eligible for CIRM funding:...(b) The culture in vitro of (i) any intact human embryo or (ii) any product of SCNT, parthenogenesis or androgenesis, after the appearance of the primitive streak or after 12 days whichever is earlier. The 12 day prohibition does not count any time during which the embryos and/or cells have been stored frozen.”
 - <https://www.cdph.ca.gov/Programs/CFH/DMCAH/HSCR/CDPH%20Document%20Library/HSCR-StemCellResearchGuidelines.pdf>

Connecticut

Reproductive cloning is prohibited, but the laws seem to allow research on human embryos as long as it is conducted before gastrulation occurs (typically around 17 dpf).

- Connecticut Stem Cell Research Grants-in-Aid Program (June 2005)
 - Provided \$100 million in public support for stem cell research over 10 years
 - <http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389700>
- Public Act No. 05-149 (2005)
 - Prohibits reproductive cloning specifically “inducing or permitting a replicate of a living human being’s complete set of genetic material to develop after gastrulation commences”
 - Allows human embryo research “provided the research is conducted before gastrulation occurs” (typically around 17 dpf)
 - <https://www.cga.ct.gov/2005/act/Pa/2005PA-00149-r00sb-00934-pa.htm>
- Conn. Gen. Stat. § 47-4-28e
 - The state funds hESC research.
 - “For each of the fiscal years ending June 30, 2008, to June 30, 2012, inclusive, the sum of ten million dollars shall be disbursed... to the Regenerative

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Medicine Research Fund... for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research.”

- https://www.cga.ct.gov/current/pub/chap_047.htm#sec_4-28e

Florida

Experimentation on fetuses is prohibited unless it preserves or prolongs the life and health of the fetus.

- 2017 Fla. Stat. § 390.0111-6
 - “Experimentation on fetus prohibited; exception.— No person shall use any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to or subsequent to any termination of pregnancy procedure except as necessary to protect or preserve the life and health of such fetus or premature infant.”
 - http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0390/Sections/0390.0111.html

Illinois

Laws prohibit the use of state funds for reproductive cloning, induced abortions, or the creation of embryos solely for the purpose of research. It seems to allow research on embryos left over from IVF. The law restricts the time period that stem cells can be taken from an embryo to a maximum of 8-12 dpf, but does not mention the maximum time that the embryo can be kept in culture.

- Executive Order 6 (2005) and its update, Executive Order 3 (2006), created the Illinois Institute for Stem Cell Research.
 - Allocate \$10 million in funding for research, including hESC research
 - Prohibit the use of funds for reproductive cloning, creating embryos for research purposes, or the purchasing/selling of embryonic tissue
 - “Time limits for obtaining cells. Standards shall set a limit on the time during which cells may be extracted from blastocysts, which shall initially be 8 to 12 days after cell division begins, not counting any time during which the blastocysts or cells have been stored frozen.”
 - https://www2.illinois.gov/Pages/government/execorders/2005_6.aspx
 - https://www2.illinois.gov/Pages/government/execorders/2006_3.aspx
- 410 ILCS 110—Stem Cell Research and Human Cloning Prohibition Act (2008)
 - Allows the use of public funds for the derivation and use of hESCs from any source
 - Prohibits the purchase and sale of embryonic tissue for research purposes
 - <http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2938&ChapAct=410%26nbsp%3BILCS%26nbsp%3B110%2F&ChapterID=35&ChapterName=PUBLIC+HEALTH&ActName=Stem+Cell+Research+and+Human+Cloning+Prohibition+Act%2E>

Indiana

Laws prohibit any participation in cloning, implanting a cloned embryo into a uterine environment, or the use of a human embryo for hESC research, but they do not address experimentation on the embryo.

- I.C. § 35-46-5-3(d)
 - “Any person who recklessly, knowingly, or intentionally uses a human embryo created with an ovum provided to a qualified third party under this section for purposes of embryonic stem cell research commits unlawful use of an embryo, a Level 5 felony.”
 - <https://iga.in.gov/legislative/laws/2015/ic/titles/035/articles/046/>

Iowa

Laws prohibit all human cloning (reproductive and therapeutic).

- Iowa Code § 707B.2 (2003)—Purpose
 - “It is the purpose of this chapter to prohibit human cloning for any purpose, whether for reproductive cloning or therapeutic cloning.”
 - <https://www.legis.iowa.gov/DOCS/IACODE/2003/707B/2.html>
- Iowa Code § 707C.4 (2003)
 - 1. “A person shall not intentionally or knowingly do any of the following:
 - a. Perform or attempt to perform human reproductive cloning.
 - b. Participate in performing or in an attempt to perform human reproductive cloning.”

Louisiana

Laws prohibit all human embryo research unless it is related to IVF, with the intent of implantation into a uterine environment and pregnancy.

- LSA-R.S. 9 § 121 (1986) Louisiana Health Law, Chapter 3—Human Embryos
 - “The use of a human ovum fertilized *in vitro* is solely for the support and contribution of the complete development of human *in utero* implantation. No *in vitro* fertilized human ovum will be farmed or cultured solely for research purposes or any other purposes.”
 - https://biotech.law.lsu.edu/cases/la/health/embryo_rs.htm

Maine

Human embryos cannot be used, sold, or transferred for any type of experimentation.

- Me. Rev. Stat. tit. 22, 263-B § 1593—Sale and use of fetuses
 - Restricts the distribution of “any product of conception considered live born for scientific experimentation”
 - <http://legislature.maine.gov/statutes/22/title22sec1593.html>

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Maryland

Laws prohibit reproductive cloning but allow creation of hESCs and therapeutic cloning research.

- Maryland Stem Cell Research Act (2006)
 - § 10-430. “Creation of Stem Cell Lines Not Prohibited. Nothing in this part may be construed to prohibit the creation of stem cell lines to be used for therapeutic research purposes.”
 - § 10-440. “Prohibition on Human Cloning. (a) A person may not conduct or attempt to conduct human cloning.”
 - <http://www.msccrf.org/content/aboutus/actof2006.php>

Massachusetts

State law bans reproductive cloning and prohibits the creation of embryos solely for the purpose of research, but allows research on embryos left over from IVF procedures.

- Mass. Gen. Laws Part I, Title XVI, Chapter 111L, §8 (2005)
 - “No person shall knowingly attempt, engage in, or assist in human reproductive cloning.”
 - Prohibits creation of embryos solely for research purposes
 - “No person shall knowingly create an embryo by the method of fertilization with the sole intent of donating the embryo for research.”
 - <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111L/Section8>

Michigan

Laws prohibit reproductive cloning.

- Mich. Comp. Laws § 333.16275 (1998)
 - (1) “A licensee or registrant shall not engage in or attempt to engage in human cloning.”
 - [http://www.legislature.mi.gov/\(S\(budljxqna2scv3rflolpzjur\)\)/mileg.aspx?page=getobject&objectname=mcl-333-16275](http://www.legislature.mi.gov/(S(budljxqna2scv3rflolpzjur))/mileg.aspx?page=getobject&objectname=mcl-333-16275)

Minnesota

Laws only allow research that “does no harm” to the conceptus (the embryo in the uterus).

- Minn. Stat. § 145.422 (2017)
 - Bans research involving the human conceptus unless it preserves the life of the organism
 - Permits hESC research “for research or experimentation which verifiable scientific evidence has shown to be harmless to the conceptus”
 - <https://www.revisor.mn.gov/statutes/?id=145.422>

Missouri

Laws prohibit the creation of embryos solely for the purpose of research and restrict the use of hESCs taken from the human embryo after 14 dpf, but do not address whether the embryo itself can be cultured beyond 14 dpf.

- Mo. Const. art. III, § 38(d)—Missouri Stem Cell Research and Cures Initiative (2006)
 - (2) “No human blastocyst may be produced by fertilization solely for the purpose of stem cell research.”
 - (3) “No stem cells may be taken from a human blastocyst more than fourteen days after cell division begins; provided, however, that time during which a blastocyst is frozen does not count against the fourteen-day limit.”
 - <http://www.sos.mo.gov/elections/2006petitions/ppStemCell>

Montana

Laws prohibit scientific experimentation on embryos unless it protects or preserves the life/health of the infant born alive.

- Mont. Code Ann. § 50-20-108(3) (2017)
- “A person may not use any premature infant born alive for any type of scientific research or other kind of experimentation except as necessary to protect or preserve the life and health of the premature infant born alive.”
- http://leg.mt.gov/bills/mca/title_0500/chapter_0200/part_0010/section_0080/0500-0200-0010-0080.html

Nebraska

Laws seem to allow human embryo and hESC research as long as it is not performed on aborted fetuses, but do not allow the use of state facilities or funds for hESC or human embryo research.

- Neb. Rev. Stat. § 71-7606 (2002)
 - Prohibits use of state funds appropriated under the Nebraska Health Care Funding Act for research involving the use of hESCs
 - (3) “No funds appropriated or distributed under the act shall be used for abortion, abortion counseling, referral for abortion, or research or activity of any kind involving the use of human fetal tissue obtained in connection with the performance of an induced abortion or involving the use of human embryonic stem cells or for the purpose of obtaining other funding for such use.”
 - <http://nebraskalegislature.gov/laws/statutes.php?statute=71-7606>
- NE Code § 71-8806 (2015)
 - Prohibits state facilities and funds being used for embryo research
 - “No state facilities, no state funds, fees or charges and no investment income on state funds shall be used to destroy human embryos for the purpose of research.”
 - <http://law.justia.com/codes/nebraska/2015/chapter-71/statute-71-8806>

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- Neb. Rev. Stat. § 28-342
 - Prohibits research on aborted fetuses
 - “The knowing, willful, or intentional sale, transfer, distribution, or giving away of any live or viable aborted child for any form of experimentation is a Class III felony.”
 - <http://nebraskalegislature.gov/laws/statutes.php?statute=28-342>
- Neb. Rev. Stat. § 28-346
 - “No person shall knowingly, intentionally, or willfully use any premature infant aborted alive for any type of scientific, research, laboratory, or other kind of experimentation except as necessary to protect or preserve the life or health of such premature infant aborted alive.”
 - <https://nebraskalegislature.gov/laws/statutes.php?statute=28-346>

New Hampshire

Laws restrict the culturing of an embryo after 14 dpf, but seem to allow research on human embryos *in vitro* up to that point.

- N.H. Rev. Stat. § 168-B:15 (2013)
 - “No preembryo shall be maintained *ex utero* in the noncryo-preserved state beyond 14 days post-fertilization development.”
 - <http://law.justia.com/codes/new-hampshire/2013/title-xii/chapter-168-b/section-168-b-15/>

New Jersey

Laws ban reproductive cloning but permit the use of cloned embryos (derived from any source).

- N.J. Rev. Stat. § 26:2Z-2 (2013)
 - Bans reproductive cloning but permits use of cloned embryos and hESCs for research
 - <https://law.justia.com/codes/new-jersey/2013/title-26/section-26-2z-2/>

New Mexico

Laws define a fetus as a product of conception and explicitly prohibit research on fetuses for nonmedical reasons.

- N.M. Stat. §24-9A-1 (2016)
 - Defines fetus as “the product of conception from the time of conception until the expulsion or extraction of the fetus or the opening of the uterine cavity, but shall not include the placenta, extraembryonic membranes, umbilical cord, extraembryonic fluids and their resident cell types and cultured cells”
 - <https://law.justia.com/codes/new-mexico/2016/chapter-24/article-9a/section-24-9a-1/>

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- N.M. Stat. §24-9A-3 (2016)
 - “No fetus shall be involved as a subject in any clinical research activity unless the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs or no significant risk to the fetus is imposed by the research activity.”
 - <https://law.justia.com/codes/new-mexico/2016/chapter-24/article-9a/section-24-9a-3/>

New York

Laws ban human reproductive cloning. Human embryos cannot be cultured beyond 14 dpf, as delimited on consent forms related to donating embryos for research to the state-funded New York State Stem Cell Science program. But there is no apparent restriction on research using nonstate funds.

- N.Y. Consolidated Laws, Public Health Law — PBH §265-a
 - Funds human embryonic stem cell research but bans funding of reproductive cloning
 - “No grants made available in the fund from any source shall be directly or indirectly utilized for research involving human reproductive cloning.”
 - <http://codes.findlaw.com/ny/public-health-law/pbh-sect-265-a.html>
- New York State Stem Cell Science Form for Embryo Donation for Human Embryonic Stem Cell Research
 - “Embryos will not be used to create a pregnancy, and will not be allowed to develop beyond 14 days” (page 2).
 - <https://stemcell.ny.gov/node/58>

North Dakota

Laws prohibit human cloning and experimentation on live fetuses in the context of leftover *in vivo* fetuses, but do not address *in vitro* embryo culturing.

- N.D. Cent. Code § 12.1-39
 - Defines a fetus as “a living organism of the species homo sapiens from eight weeks’ development until complete expulsion or extraction from a woman’s body”
 - Defines a human embryo as “a living organism of the species homo sapiens from the single-celled state to eight weeks’ development”
 - Prohibits human cloning, which is classified as a class C felony
 - <http://www.legis.nd.gov/cencode/t12-1c39.pdf>
- N.D. Cent. Code § 14-02.2-01(1)
 - “A person may not use any live human fetus, whether before or after expulsion from its mother’s womb, for scientific, laboratory, research, or other kind of experimentation.”
 - <http://www.legis.nd.gov/cencode/t14c02-2.pdf#nameddest=14-02p2-01>

Ohio

Laws restrict research on embryos derived from abortion, but seem to allow research on embryos left over from IVF as long as informed consent is obtained from the donor.

- Ohio Rev. Code § 2919.14—Abortion trafficking
 - (A) “No person shall experiment upon or sell the product of human conception which is aborted.”
 - <http://codes.ohio.gov/orc/2919.14>

Oklahoma

Laws explicitly restrict research on aborted embryos, leaving the option open for the culturing of and experimentation on embryos *in vitro*.

- Okla. Stat. tit. 63, § 1-270.2
 - Does not allow state funding for research using “a human embryo, including a human embryo produced using cloning technology” or hESC lines created after August 1, 2001
 - <http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=452736>
- Okla. Stat. tit. 63, § 1-735
 - B. “No person shall experiment upon the remains of a child or an unborn child resulting from an abortion.”
 - <http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=98162>

Pennsylvania

Laws are limited to banning nontherapeutic medical procedures on fetuses.

- 18 Pa. Cons. Stat. Ch. 32, § 3216—Fetal experimentation
 - (a) “Unborn or live child.--Any person who knowingly performs any type of nontherapeutic experimentation or nontherapeutic medical procedure (except an abortion as defined in this chapter) upon any unborn child, or upon any child born alive during the course of an abortion, commits a felony of the third degree. ‘Nontherapeutic’ means that which is not intended to preserve the life or health of the child upon whom it is performed.”
 - <http://www.legis.state.pa.us/cfdocs/legis/LI/consCheck.cfm?txtType=HTM&tl=18&div=0&chpt=32>

Rhode Island

Research on live human fetuses in any form is prohibited.

- 11 R.I. Gen. Laws § 11-54-1—Experimentation on human fetuses
 - (a) “No person shall use any live human fetus, whether before or after expulsion from its mother’s womb, for scientific, laboratory research, or other kind of experimentation.”
 - (c) “A fetus is a live fetus for purposes of this section when, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a

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spontaneously aborted fetus at approximately the same stage of gestational development.”

- <http://webserver.rilin.state.ri.us/Statutes/title11/11-54/11-54-1.HTM>

South Dakota

Research that destroys a human embryo is prohibited.

- S.D. Codified Laws § 34-14-16
 - “Research that destroys human embryo prohibited--Violation as misdemeanor. No person may knowingly conduct nontherapeutic research that destroys a human embryo. A violation of this section is a Class 1 misdemeanor.”
 - <http://sdlegislature.gov/statutes/DisplayStatute.aspx?Type=Statute&Statute=34-14-16>

Utah

Law prohibits research on “live unborn children,” which seems to include human embryos *in vitro*.

- Utah Code § 76-7-310
 - “Live unborn children may not be used for experimentation” (does not clarify whether embryos fall within the category “live unborn children”).
 - <https://le.utah.gov/xcode/Title76/Chapter7/76-7-S310.html>

Virginia

Laws ban human reproductive cloning. They seem to allow research on cloned embryos, but do not state a limit for culturing embryos *in vitro*.

- Va. Code Ann. § 32.1-162.22. Human cloning prohibited; civil penalty.
 - A. “No person shall (i) perform human cloning or (ii) implant or attempt to implant the product of somatic cell nuclear transfer into a uterine environment so as to initiate a pregnancy or (iii) possess the product of human cloning or (iv) ship or receive the product of a somatic cell nuclear transfer in commerce for the purpose of implanting the product of somatic cell nuclear transfer into a uterine environment so as to initiate a pregnancy.”
 - <https://law.lis.virginia.gov/vacode/title32.1/chapter5.2/section32.1-162.22/>

Washington

There are no state laws dealing with human embryo research, but the University of Washington (the most prominent research university in the state) has its own guidelines for embryo research.

- University of Washington GIM 36 – Human Embryonic Stem Cell Research Policy and Guidelines
 - Human reproductive cloning is prohibited.

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- Prohibited hESC activities include “*In vitro* culture of an intact human embryo for more than 12 days of development or until formation of the primitive streak, whichever occurs first.”
- <https://www.washington.edu/research/policies/gim-36-human-embryonic-stem-cell-research-policy-and-guidelines/>