

Biobanking of Blastocysts for Research To Improve Human Health: The Need for Coherent National Policy

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I. INTRODUCTION

Almost every person in America knows someone with a health condition that is incurable. Many people have a desire to “do something” to help those with such conditions. An increasingly available option is to support medical research through the most personal of donations: providing a blood or other specimen for use in research.¹ Biobanking, or the collection of human specimens such as blood, tissue, or other bodily materials for research purposes, is a common and important way to advance our understanding of human health.

Banked specimens come from many sources, such as (1) patients’ families and altruistic individuals who volunteer to give blood or other specimens for research; (2) participants in clinical trials, who permit the use of their specimens for a given study and possible future

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¹ By analogy, organized bone marrow drives encourage friends, relatives, and community members to register and be tested to increase the chance that a patient will find a “match” for transplant treatment purposes. The National Marrow Donor Program (NMDP), which maintains an expansive registry for this purpose, also encourages individuals to provide an extra blood sample for research. National Marrow Donor Program, Opportunity to Participate in the NMDP Research Sample Repository (2005), http://www.marrow.org/DONOR/When_You_re_Asked_to_Donate_fo/PDF/research_sample.pdf; see also National Cancer Institute, Office of Biorepositories and Biospecimen Research, *Patient Corner: How Can Patients Help?*, available at <http://biospecimens.cancer.gov/patientcorner/how.asp> (last visited Mar. 31, 2009); Karen J. Maschke, *Biobanks: DNA and Research*, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS, 11 (Mary Crowley ed., 2008) (describing growth of public and private biobanking programs). See generally ELISA EISEMAN & SUSANNE B. HAGA, HANDBOOK OF HUMAN TISSUE SOURCES 133 (1999) (more than 300 million tissue specimens are in storage in the U.S., with the total growing by more than 20 million specimens per year).

research; and (3) patients who have surgery or other procedures for treatment purposes and agree that “excess” specimens can be used for research. One subgroup within this last category is patients who receive fertility treatment. Often patients who have undergone in vitro fertilization (IVF) treatment have blastocysts² that are in excess of their own need or unsuitable for reproductive use, and must decide what to do with them. According to a recent multi-state survey, a significant percentage of these patients want to help others by donating their excess blastocysts to medical research.³ With reports indicating that thousands of cryopreserved (frozen) blastocysts are in storage in the United States,⁴ biobanks that collect a portion of these could be an invaluable resource to biomedical research. Such research may help to improve fertility-care techniques for those desiring children, deepen scientific understanding of human development, and create stem cell lines that may reveal genetic answers to questions of how diseases develop.⁵

Unfortunately, the complex legal framework in the United States governing blastocyst research hinders development of such biobanks to their full potential as a biomedical research resource. This Article begins with an overview of the degree to which federal policy affects the creation and use of a research biobank of voluntarily donated blastocysts. The Article then explores the wide variation in state laws affecting medical research on blastocysts. This analysis leads to a discussion of the uncertainty surrounding interstate donation of blastocysts for research; that is, if one state bars blastocyst research, can patients there voluntarily donate their blastocysts to a biobank in a different state that permits the research? Further, when interstate donation occurs, which state’s laws govern oversight of the research and privacy of genetic or other medical information? The Article concludes with a discussion of opportunities for improved national policy that would clear a path for interstate donation of blastocysts to biobanks and related research, even if the federal government itself does not fund such research. Because the Obama Administration’s recent executive order facilitates the use of human embryonic stem cell lines⁶ but does not address blastocyst research itself, these policy issues continue to demand attention.

² A blastocyst is a very early-stage embryo of approximately 150 cells. This Article uses the term blastocyst to refer to the union of an egg and sperm by in vitro fertilization outside of the human body. See generally INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH, GLOSSARY OF THE INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH, available at <http://www.isscr.org/glossary/printversion.htm>; National Research Council and Institute of Medicine, 2008 Amendments to the National Academies’ Guidelines for Human Embryonic Stem Cell Research, available at http://www.nap.edu/catalog.php?record_id=12260.

³ A. Drapkin Lyerly et al, *Fertility Patients’ Views About Frozen Embryo Disposition: Results of a Multi-Institutional U.S. Survey*, FERTILITY & STERILITY (forthcoming 2008) (manuscript on file with author) (reporting that, of surveyed patients who had decided not to use remaining stored blastocysts to have another child, “41% considered research donation very likely,” compared to smaller percentages of patients opting for other disposition, and noting that these results are “[c]onsistent with single-site studies from Europe and Australia”).

⁴ David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1069 (2003).

⁵ For discussion of the goals of such research, see, e.g., Gina Kolata, *Picture Emerging on Genetic Risks of IVF*, N.Y. TIMES, Feb. 16, 2009, at D1 (describing ongoing molecular and genetic research to identify risk factors affecting blastocyst development); George Daley, *Your Inbox, Mr. President*, 457 NATURE, 4, 258, 259 (2009) (explaining that cell lines derived from blastocysts that have undergone pre-implantation genetic diagnosis “can be used to model human diseases” in diverse areas).

⁶ Exec. Order No. 13,505 (Mar. 9, 2009), *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, 74 Fed. Reg. 10,667 (Mar. 11, 2009).

II. FEDERAL POLICY AND UNIQUE ISSUES FOR THE BIOBANKING OF BLASTOCYSTS

Unlike some countries, the United States government has few regulatory standards governing research on human blastocysts.⁷ The United States lacks a comprehensive regulatory system for blastocysts because much federal regulation of biomedical research is tied to federal support of the research,⁸ and the federal government does not support research on human blastocysts.⁹ Biomedical research also triggers federal rules when studies fall within the Food and Drug Administration's (FDA) jurisdiction over drugs, devices, biologics, and other products, but much blastocyst research is currently outside of that scope. Accordingly, as explained below, federal policy on blastocyst research consists primarily of federal-funding restrictions; the ethical standards that are actually used reflect either state regulation or research entities' voluntary consideration of regulatory and ethical standards, such as the federal Common Rule and guidelines published by the National Academies of Science (NAS) and International Society for Stem Cell Research (ISSCR). The aggregate effect is that diverse and conflicting standards govern blastocyst research within the United States. This patchwork hinders development of robust biobanking resources.

A. Federal Standards Commonly Applicable to Biobanks

To appreciate the effective absence of federal direction for blastocyst biobanks, a brief overview of federal requirements for more common types of biobanks is useful. Generally, research entities that create or maintain biobanks need to consider the federal Common Rule's protections for human subjects research, FDA regulations, and the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules.¹⁰

To understand how these requirements apply, consider the common scenario of an academic medical center that maintains a biobank of cancer specimens for research. The biobank receives federal support from the National Institutes of Health (NIH). Researchers obtain samples for the biobank by asking cancer patients if they are willing to allow research use of specimens that were removed for clinical care reasons and are no longer needed for diagnostic purposes, and by asking clinical trial participants to provide extra specimens for biobank

⁷ NATIONAL BIOETHICS ADVISORY COMMITTEE, 1 ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH 33 (2001) (noting that apart from select state laws, "no viable regulatory system exists to guide or control the practice of human embryo research in the United States"). For comparisons to other countries, see generally Baroness Ruth Deech, *Playing God: Who Should Regulate Embryo Research?*, 32 BROOKLYN J. INT'L L. 321 (2007); Alicia Ouellette et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J. L. & MED. 419 (2005).

⁸ See, e.g., 45 C.F.R. § 46.101(a) (West 2009).

⁹ The author acknowledges the highly sensitive, controversial nature of blastocyst research and does not undertake to describe the arguments for and against such research in this Article. Rather, a premise of this Article is that blastocyst research is permissible in the U.S., with federal policy primarily barring the use of federal funds for such research. This Article does not challenge the existing federal funding restrictions on blastocyst research, but rather calls for clarification at the national level of how permissible blastocyst research can go forward despite a patchwork of state laws and related implications.

¹⁰ For a more comprehensive description and analysis of these requirements, see REPORT OF THE PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH (PRIM&R) HUMAN SPECIMEN/BANKING WORKING GROUP 11-26 Part I and 1-20 Part II Tool A (2007), available at http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/Tissue%20Banking%20White%20Paper%203-7-07%20final%20combined.pdf [hereinafter, PRIM&R White Paper].

research. Researchers store these specimens in the biobank, and often maintain a link to identifiable health information in order to enhance the value to future research.

Several federal requirements potentially apply:

- The Common Rule is a federal regulation adopted by seventeen federal departments and agencies to protect human subjects in federally-supported research.¹¹ The creation of the cancer biobank in this example would trigger the Common Rule, because the project has federal support and core regulatory criteria are met – the biobanking project involves an interaction or intervention with living individuals, and a link to identifiable health information for research.¹² The Common Rule, as interpreted by the Office for Human Research Protections (OHRP), requires an institutional review board (IRB) to review and approve the creation of the biobank, conduct ongoing oversight, and ensure informed consent is obtained from individuals who provide specimens.¹³
- FDA regulations may, but do not necessarily, apply to the hypothetical cancer biobank. FDA regulations apply to clinical investigations when the research relates to the safety and efficacy of regulated products and thus falls within the FDA’s jurisdiction.¹⁴ To determine whether these regulations apply – particularly FDA informed consent rules – a biobank needs to consider before collecting specimens whether the anticipated research may fall under the agency’s jurisdiction.¹⁵
- The HIPAA Privacy and Security Rules typically apply to medical centers’ research.¹⁶ To create a research biobank of cancer specimens linked to individually identifiable health information, researchers generally need written permission from the individuals. To obtain this authorization, researchers must describe with specificity what identifiable health information will be used and shared, with or by whom, and for what purposes.¹⁷
- The National Cancer Institute developed “Best Practices for Biospecimen Resources” with input from the regulated community.¹⁸ While currently voluntary, this federal

¹¹ 45 C.F.R. Pt. 46, Subpart A.

¹² *Id.* § 46.102(f) (noting that intervention/interaction and use of identifiable information are alternative criteria). Certain research is exempt from the Common Rule if it involves use of existing specimens without identifiable information, *id.* § 45.101(b)(4).

¹³ *See, e.g., id.* §§ 46.109, 46.111, 46.116. *See also* United States Dept. of Health and Human Services Office for Protection from Research Risks, Issues to Consider in the Research Use of Stored Data or Tissues, 1-2 (1997), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm> [hereinafter “OPRR Tissue Banking Guidance”]; U.S. Dept. of Health and Human Services Office for Human Research Protections, Guidance on Engagement of Institutions in Human Subjects Research, 5-6 (2008), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.pdf>.

¹⁴ 21 C.F.R. §§ 56.101, 56.102(c), (e), and (l).

¹⁵ *See* PRIM&R White Paper, *supra* note 10, at 20-21; *see also* Food and Drug Administration, Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable 4-7 (2006), available at <http://www.fda.gov/cdrh/oivd/guidance/1588.pdf>.

¹⁶ 45 C.F.R. §§ 164.500, 164.104(a)(3). *See generally* Research Repositories, Databases, and the HIPAA Privacy Rule, NIH Pub. No. 04-5489 (2004), available at http://privacyruleandresearch.nih.gov/pdf/research_repositories_final.pdf.

¹⁷ 45 C.F.R. § 164.508(c).

¹⁸ NATIONAL CANCER INST., NATIONAL CANCER INSTITUTE BEST PRACTICES FOR BIOSPECIMEN RESOURCES 3-25 (2007), available at http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf [hereinafter NCI BEST PRACTICES]; *see also* Karyn Hede, *New Biorepository Guidelines Raise Concerns*, 98 J. NAT’L CANCER INST. 952 (2006).

publication comprises over twenty pages of detailed recommendations for biobanks with the goal of “optimizing biospecimens for cancer research.”¹⁹

These federal standards provide considerable unifying direction for research entities that maintain common types of biobanks. The framework facilitates numerous collaborative scientific studies and the efficient sharing of materials from valuable resources. The federal regulatory system governing biobanks is not perfect or comprehensive; given variation in the size, nature, and funding of biobanks and real operational complexities, those who analyze and implement the standards have criticized aspects of the existing system.²⁰ However, the ongoing national dialogue on common types of biobanks starts at a sophisticated level and aims for further improvements,²¹ in stark contrast to the absence of federal policy direction on blastocyst biobanks.

B. *The Application of Federal Policies to a Biobank of Blastocysts*

In contrast to the above analysis, this section explores what federal requirements currently apply if a medical center wants to create a biobank of voluntarily donated blastocysts for research to improve human health. The Dickey-Wicker Amendment, passed by Congress in 1996, prohibits the use of federal funds for research that destroys or substantially harms an embryo.²² Accordingly, research in which donated blastocysts will be destroyed, including fertility care research or human embryonic stem cell research, can be conducted only with non-federal funds.

Since this research is ineligible for federal funding, the creation of a blastocyst biobank does not directly trigger the Common Rule’s requirements for IRB oversight, informed consent, and other protections.²³ HHS has special rules governing research involving pregnant women, fetuses, and neonates, but these rules do not apply to IVF blastocysts pre-implantation.²⁴ Accordingly, a biobank of blastocysts need not comply with federal human subjects research protection rules. However, many academic medical centers and universities voluntarily apply the Common Rule to all human subjects research, regardless of the funding source. These centers are most likely academic entities that receive federal support for other research and already have an IRB and regulatory compliance infrastructure in place. In contrast, some companies focusing on pre-clinical research, and many private fertility clinics, do not conduct federally-supported research and thus may not have an IRB structure in place. These fertility clinics may have a high volume of cryopreserved blastocysts in storage, and if patients permit the clinics or companies to store the excess blastocysts for research, the Common Rule would not

¹⁹ NCI BEST PRACTICES, *supra* note 18, at 1.

²⁰ See, e.g., PRIM&R White Paper, *supra* note 10, at 7-26; Leonard Glantz, Patricia Roche, & George J. Annas, *Rules for Donations to Tissue Banks – What Next?*, 358 NEW ENG. J. MED. 298, 301-03 (2008); Hede, *supra* note 18, at 952-53; Sharyl J. Nass, Laura A. Levit, & Lawrence O. Gostin, *Summary of BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH* 1, 10-11 (Sharyl J. Nass, Laura A. Levit, & Lawrence O. Gostin, eds., 2009).

²¹ See, e.g., Secretary’s Advisory Committee on Human Research Protections (SACHRP), Charge to Tissue Repositories Panel (2008), available at <http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-08/present/Charge-Tissue.html>.

²² Pub. L. No. 104-99, tit. 1, §128, 110 Stat. 26, 34 (1996). The Dickey-Wicker Amendment has been regularly included in subsequent appropriations bills for HHS since 1996.

²³ See, e.g., OFFICE FOR HUMAN RESEARCH PROTECTIONS, OHRP GUIDANCE ON STEM CELLS 1-4 (2002), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/stemcell.pdf>.

²⁴ 45 C.F.R. Pt. 46 Subpart B.

apply. Moreover, unless the resulting research involved testing or developing a product subject to FDA's jurisdiction, FDA research regulations would not apply to the creation of a biobank of blastocysts.

The HIPAA Privacy Rule may apply to the research biobank of donated blastocysts in particular circumstances. If the researchers belong to a covered entity and retain identifiable health information with the stored blastocysts, then the Privacy Rule applies. However, the Privacy Rule does not apply to a research biobank that does not store identifiable health information. The Privacy Rule also does not apply to a blastocyst biobank maintained by a life sciences company, because such companies are ordinarily not subject to the Privacy Rule.²⁵

In summary, the above discussion illustrates that while federal policy provides considerable direction to common types of biobanks, there is minimal unifying direction for blastocyst biobanks. Absent federal oversight of blastocyst research, direction has emerged from two sources: (1) state law; and (2) national and international ethical guidelines developed for stem cell research. Since research entities and researchers are legally bound by state law, those requirements are discussed next.

III. A MEDLEY AND MINEFIELD OF STATE LAWS

The fifty states have widely varying laws and policies relating to research on blastocysts. State approaches fall roughly into three categories: (1) explicit support of ethically conducted research on blastocysts; (2) explicit restriction or banning of the research; and (3) silence on the issue of such research. Researchers can develop and use a biobank of blastocysts only in a state that supports the research or does not prohibit it.

Complicated legal questions arise when a research biobank considers accepting blastocysts provided by out-of-state IVF patients. Interstate donations may be critical to the collection of a sufficient number of specimens for the study of specific genetic conditions and illnesses. These donations are also scientifically valuable for entities that develop a centralized resource to oversee procurement, storage, and allocation of specimens. Is blastocyst donation from out-of-state patients always permissible if the biobank is in a state that supports the research? Or is analysis of each patient's home-state law needed to ensure that donating or using blastocysts for research is permissible there? The state overview below aims to show why coherent national policy is needed to: (1) minimize uncertainty and risk within the broad research community; (2) equalize the information given to patients about disposition of excess blastocysts; and (3) maximize the ability of biobanking resources to lead to better understanding of health conditions and new treatments.

A. *Supportive States*

On August 9, 2001, former President George W. Bush announced that federal funds could not be used for research on human embryonic stem cell lines derived from human blastocysts, unless the lines were created prior to his announcement. This federal funding policy constrained researchers even more than had the Dickey-Wicker Amendment, because the 2001 announcement extended to studies of cell lines even when researchers had no role in the use of donated blastocysts. Not long after the Bush Administration's announcement, states began to take the lead in stem cell research by authorizing this research and, in many cases, providing funding support. From 2002 through 2008, at least twelve states enacted measures permitting or

²⁵ 45 C.F.R. § 164.502 (definition of covered entity).

supporting stem cell research on blastocysts with the ultimate goal of advancing scientific understanding and prompting new medical discoveries. The legal measures include state ballot initiatives, legislation, regulations, and executive orders, as well as state contractual requirements for research grant recipients. The permissive states include California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Michigan, Missouri, New Jersey, New York, Rhode Island, and Wisconsin, as well as New Hampshire based on earlier law.²⁶ Most of these states explicitly permit stem cell research using donated blastocysts, subject to ethical and legal standards, while the last three states noted above support the research in other ways.²⁷ The state legal landscape continues to evolve; Michigan's state constitutional amendment enabling the use of excess, donated blastocysts for research that was previously barred by statute took effect in mid-December 2008.²⁸

Many permissive state initiatives share fairly common requirements to protect donors and to ensure ethical oversight of stem cell research. Typical requirements include

- institutional oversight of the research;
- voluntary, informed consent from individuals who donate blastocysts for research;
- prohibitions on paying donors of blastocysts, to minimize coercion; and
- institutional reporting duties to the state.

As states enacted permissive measures, national and international bodies of experts published guidelines for human embryonic stem cell research, including research using donated blastocysts.²⁹ These voluntary guidelines, first issued by the National Academies of Science (NAS) in 2005, appear to have influenced later state legal measures as well as interpretation and implementation of earlier state measures.³⁰ Given separate state political dynamics and processes, however, variation remains among these states. Some of the permissive states' requirements apply only to state-funded studies, while some measures govern stem cell research but not other blastocyst research. States' implementation of the common principles described above also differs at the ground level.

To understand how state regulation may apply to a research biobank of blastocysts, consider California, which has perhaps the most expansive and detailed set of rules in the country for

²⁶ A full discussion of these states' specific measures is beyond the scope of this Article. For more information, see Susan Stayn, *A Guide to State Laws on hESC Research and a Call for Interstate Dialogue*, BNA MED. RES. L. & POL'Y REP., NOV. 1, 2006, at 718-25. See also Interstate Alliance on Stem Cell Research, www.iascr.org (last visited Mar. 29, 2009).

²⁷ Wisconsin does not expressly permit research on blastocysts, but it has provided funding support for the stem cell research field, and Jamie Thomson of the University of Wisconsin used donated blastocysts to derive the first reported human embryonic stem cell lines in 1998. Rhode Island permits somatic cell nuclear transfer, though has an older legal restriction on research involving a fetus or embryo. New Hampshire does not address stem cell research specifically, but permits certain blastocyst research. For differences in the scope of research authorized by supportive jurisdictions, see generally Geoff Lomax & Susan Stayn, *Similarities and Differences Among Stem Cell Research Policies: Opportunities for Policymakers, Patients, and Researchers*, BNA MED. RES. L. & POL'Y REP., NOV. 5, 2008, at 695.

²⁸ MICH. CONST. art. I, § 27 (West 2009).

²⁹ NATIONAL RESEARCH COUNCIL & INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH (adopted in 2005, amended in 2007 and 2008); INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH GUIDELINES FOR THE CONDUCT OF HUMAN EMBRYONIC STEM CELL RESEARCH (2006), available at <http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf>.

³⁰ See Richard O. Hynes, *US Policies on Human Embryonic Stem Cells*, 9 NATURE REV.: MOLECULAR CELL BIOLOGY 993, 995 (2008).

research involving blastocysts.³¹ Suppose researchers create a biobank of donated blastocysts for a range of human health research with funding support from the California Institute of Regenerative Medicine (CIRM).³² The researchers must follow CIRM regulations and the federal Common Rule, which CIRM incorporates by reference. Several legal requirements apply, based partly on the shared principles above but with greater specificity. These requirements include

- institutional approval and ongoing oversight of the biobank by both an IRB and a stem cell research oversight (SCRO) committee;
- detailed informed consent criteria, so that individuals are aware of the breadth of possible future research and unique ethical issues arising in stem cell research, and have an opportunity to impose restrictions;
- no payment to donors of blastocysts, although shipping and related costs may be covered for clinics or other entities that transfer the specimens;
- privacy protections, including the requirement that researchers obtain permission from donors in advance if they may want to recontact the donors in the future for additional health information or to convey research findings;
- recordkeeping and accountability standards; and
- state agency compliance audits.

In addition to these rules for CIRM-funded research, California law requires providers of fertility care to inform patients of all of their dispositional options for blastocysts remaining after treatment. Choices include (1) storage for possible future reproductive use; (2) donation to another couple for reproductive use; (3) donation to research; or (4) discarding the blastocysts.³³ Under state law, patients must be informed of all options before making a decision. A handful of other states have similar laws that require providers of infertility care to inform patients in this manner.³⁴ However, most states do not require this, and many IVF patients must seek information independently.³⁵

B. Restrictive States

Several states restrict or bar research on blastocysts. For example, Louisiana law defines a blastocyst as a “juridical person” with independent rights and prohibits research on a blastocyst.³⁶ South Dakota’s similarly restrictive law bars non-therapeutic research on a

³¹ Again, differences among these states’ regulatory systems preclude generalizations about whether or how each permissive state would regulate a research biobank of blastocysts.

³² CIRM is the California state agency that funds stem cell research, in accordance with Proposition 71, CAL CONST. art. XXXV (West 2009). Even absent state funding, this analysis would be substantially the same (at least with regard to use of banked IVF blastocysts for stem cell research), due to California legislation and guidelines. See Cal. S.B. 1260 (2006); California Advisory Committee Guidelines for Human Embryonic Stem Cell Research, available at <http://www.cdph.ca.gov/services/boards/HSCR/Documents/MO-HSCRGuidelines-10-2008.pdf>.

³³ CAL. HEALTH & SAFETY CODE § 125315 (West 2009).

³⁴ See, e.g., NATIONAL CONFERENCE OF STATE LEGISLATURES, STATE LAWS ON FROZEN EMBRYOS (2007), <http://www.ncsl.org/programs/health/embryodisposition.htm> (including, e.g., California, Connecticut, Maryland, Massachusetts, and New Jersey).

³⁵ Lyerly, *supra* note 3 (reporting survey results that show that “good alternatives for embryo disposition are lacking: patients either prefer options not generally available to them, such as research donation, or reject available options”); Shari Roan, *Donating Embryos for Research May Be Easier Said Than Done*, L.A. TIMES, Oct. 6, 2008, at F-6 (citing R. Alta Charo on lack of a “clear pathway” for research donation among IVF patients who are outside of the select states that fund stem cell research).

³⁶ LA. REV. STAT. ANN. §§ 9:121–122; :129 (West 2009).

blastocyst, as well as the use of cells that one knows were derived from a blastocyst.³⁷ Pennsylvania criminalizes non-therapeutic research on an “unborn child,” defined to begin at fertilization.³⁸ State legislative activity in this field continues to develop: Oklahoma’s “Advancement in Stem Cell Cures and Therapies Act,” which bars research on blastocysts while permitting adult stem cell research, took effect in November 2008.³⁹ Other restrictive states restrict therapeutic cloning (creation and use of an embryo-like product) or bar the use of state funds for such research.⁴⁰ Additional states have laws that pre-date IVF care and stem cell research and restrict research on a fetus; some of these laws define a fetus to include a blastocyst, while other statutes are vague.⁴¹

Certain states extend their bans by prohibiting not only the actual research but also the transfer of blastocysts for the prohibited purpose. This means that IVF patients possibly could be at risk for donating excess IVF blastocysts to research. For example, the South Dakota statute criminalizes the “transfer” of a blastocyst for non-therapeutic research that would harm or destroy the blastocyst.⁴² Maine prohibits the “transfer” or “giv[ing] away” of a “live human fetus, whether intrauterine or extrauterine... for scientific experimentation,” without defining whether a fetus includes an IVF blastocyst with reproductive potential. A West Virginia bill introduced in 2008 proposed specifically to ban the transfer of a blastocyst out-of-state for any purpose that would result in its destruction.⁴³ Some state statutes do not explicitly ban transfer but rather use broad prohibitive language that yields a similar result; for example, the Louisiana law prohibits intentional destruction of a blastocyst by a person or “through the actions of any other such person.”⁴⁴ Moreover, it is unclear whether a legal theory of “aiding and abetting” a violation of state law could be asserted against those who transfer blastocysts elsewhere, in good faith, for research that is illegal in their home state.

State laws that affect medical research typically apply to research in the state. In collaborative studies, however, where researchers may conduct activities in and outside of the state, the general understanding is that applicable jurisdictions’ laws must be met.⁴⁵ If IVF patients live in a state that prohibits research on blastocysts or the giving away of blastocysts for research, to what extent are patients at risk by authorizing transfer of their blastocysts to a

³⁷ S.D. CODIFIED LAWS §§ 34-14-16 to -20 (West 2009).

³⁸ PA. CONS. STAT. ANN. §§ 3203, 3216(a) (West 2009).

³⁹ OKLA. STAT. § 63-1-270.2.

⁴⁰ Many states in both the permissive and restrictive categories prohibit reproductive cloning. See, e.g., National Conference on State Legislatures, State Human Cloning Laws (2008), <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm>.

⁴¹ See Lori B. Andrews, *Appendix E, Legislators as Lobbyists: Proposed State Reg. of Embryonic Stem Cell Research, Therapeutic Cloning and Reproductive Cloning*, in THE PRES.’S COUNCIL ON BIOETHICS REP. (2004), available at http://www.bioethics.gov/reports/stemcell/appendix_e.html.

⁴² S.D. CODIFIED LAWS §§ 34-14-17 (“No person may knowingly conduct nontherapeutic research that subjects a human embryo to substantial risk of injury or death. No person may sell or transfer a human embryo with the knowledge that the embryo will be subjected to nontherapeutic research.”).

⁴³ West Va. H.B. 4463 (2008) (“A frozen human embryo located within the State of West Virginia may not be intentionally destroyed, nor may any frozen embryo be transported to another state or any other location for the purpose of its destruction.”).

⁴⁴ LA. REV. STAT. ANN. § 9:129 (West 2009).

⁴⁵ See R. Hakimian et al., *50-State Survey of Laws Regulating the Collection, Storage, and Use of Human Tissue Specimens and Associated Data for Research*, NATIONAL CANCER INSTITUTE CANCER DIAGNOSIS PROGRAM, NIH Pub. No. 05-5628, at 1-3 (2004) [hereinafter “50-State Survey”].

research biobank in a supportive state? A motivated local official could target such activity,⁴⁶ and there is sufficient legal uncertainty about the outcome that such risks could impede research donations.

C. Other States

Between the clearly permissive and clearly restrictive states are the many states whose laws are silent or gray with respect to blastocyst research. These states' silence often makes it unclear whether patients there may donate blastocysts to a research biobank in a permissive jurisdiction. How does one assess this, and does it require legal analysis of each state's statutes, case law, and proposed legislation or state constitutional amendments seeking to criminalize the activity?

Consider the state of Colorado. Colorado does not have a statute that either permits or prohibits stem cell research, including the use of blastocysts to derive human embryonic stem cell lines. Does statutory silence mean that blastocyst research in Colorado is permissible, or at least that IVF patients in Colorado can donate their excess blastocysts to research elsewhere? This conclusion cannot necessarily be drawn since a state constitutional amendment on the ballot in November 2008 proposed to define a "person" to include a fertilized egg. If Colorado patients approached researchers in a supportive state in the fall of 2008 about donating blastocysts to research, should the researchers accept the donation as long as the ballot initiative is not yet passed? Or should the existence of a ballot initiative affecting the legality of research on blastocysts effectively signal Colorado's political climate, such that out-of-state researchers should resolve risk and uncertainty by refusing the patients' request to donate until the state votes? For fertility clinics that would need to assist patients in carrying out their choice by shipping the specimens, how willing are they to accept risk when state law is uncertain and evolving? For each research entity in permissive jurisdictions that wishes to accept out-of-state patients' donated materials for human health research, it is extremely time-consuming and inefficient to research each silent state's existing and evolving legal environment prior to accepting donated blastocysts. The potential ongoing need for this is evident, as several states in early 2009 are pursuing measures that would affect the legality of blastocyst research.⁴⁷

D. State Privacy Issues

The HIPAA Privacy Rule provides a national floor of privacy protections for patients and applies to medical research in some contexts. Many states also have their own detailed privacy laws targeting sensitive areas, such as privacy of genetic information. These laws potentially apply when patients in one state donate specimens to a biobank elsewhere for research purposes.⁴⁸ If the patient resides in a state with protective genetic privacy laws requiring specific

⁴⁶ Cf. *Ferguson v. City of Charleston*, 532 U.S. 67 (2001) (describing city solicitor's prosecution of women who used cocaine during pregnancy, based on novel legal theories such as distributing drugs to a minor under 18 (the fetus *in utero*); ruling that drug testing for this purpose without consent or a warrant was unconstitutional).

⁴⁷ See, e.g., Shannon McCaffrey, *Some States Push Back Against Stem Cell Research*, AP/Newsweek (Mar. 11, 2009) (noting restrictive Montana and North Dakota measures that have passed in one legislative chamber each, as of March 11, 2009); James Osborne, *States Consider Harder Line on Stem Cell Research*, FOXNews.com (Mar. 24, 2009) (describing new restrictive measures that are advancing in certain state legislatures), available at <http://www.foxnews.com/politics/first100days/2009/03/24/states-consider-harder-line-stem-cell-research/> (last visited April 2, 2009).

⁴⁸ For further consideration of this issue, see 50-State Survey, *supra* note 45, at 1-8.

consent for disclosure of genetic information, must the biobank honor those protections if it anticipates genetic research will be conducted on identifiable specimens?

This question is relevant beyond biobanks of blastocysts, however, some unique privacy concerns arise in the area of blastocyst research. IVF patients who want to donate blastocysts to research may want assurance that their infertility conditions, as well as their participation in blastocyst research, will not be disclosed to others. This may be a particularly compelling concern given the controversial nature of research on blastocysts for moral, religious, political, and other reasons. In addition, to the extent that it is unclear whether a donation to blastocyst research is permissible in the patients' home state, the patients may want the utmost assurance that their identity will not be disclosed to governmental officials.

At the federal level, the NIH has authority to grant requests for Certificates of Confidentiality, which provide a very high level of privacy protection for individuals participating in research. Specifically, the Certificate protects researchers and their institutions from being compelled to release identifiable information about research participants for any federal, state, or local administrative, legislative, or judicial proceeding.⁴⁹ For example, if a state legislative committee or attorney general subpoenaed identifiable information relating to donors in a particular study, a Certificate of Confidentiality generally would protect against the forced release of that information.

Research using "sensitive information" is eligible for a Certificate. NIH guidance cites some examples, including studies that collect "genetic information or tissue samples" or "information that, if released, might be damaging to an individual's... reputation within the community or might lead to social stigmatization."⁵⁰ NIH guidance further specifies that Certificates are *not* limited to federally-funded studies; rather, Certificates are available regardless of the study's funding source. The predecessor agency to OHRP also published guidance encouraging researchers to obtain a Certificate for biobanking research.⁵¹ NIH has discretion to determine when it grants a Certificate.

If NIH used its existing authority to grant a Certificate upon request to a biobank of blastocysts, then the result would be a uniform, high federal standard of privacy protection for individuals. This high standard could help to reduce the need to address differing state privacy laws in the context of interstate donation to a biobank of blastocysts. In at least one case occurring during former President George W. Bush's administration, however, the NIH declined to grant a Certificate to a biobank of blastocysts on the basis that the research was not subject to the Common Rule. However, the researchers planned to collect directly or indirectly identifiable information for research purposes,⁵² and although the research was not federally-supported (because it could not be), Certificates are available for non-federally funded research. Another reason for the denial was that the researchers' proposed confidentiality measures would suffice. However, in many studies covered by Certificates, researchers establish privacy safeguards but also request a Certificate to provide heightened protection against compelled legal disclosures. NIH has existing authority and discretion to issue Certificates, and given that infertility care and stem cell research are sensitive areas, the Obama Administration has an opportunity to exercise this authority in a supportive way.

⁴⁹ 42 U.S.C. § 241(d) (West 2009).

⁵⁰ See National Institutes of Health, Frequently Asked Questions on Certificates of Confidentiality (#6) (2002), available at <http://grants.nih.gov/grants/policy/coc/faqs.htm>.

⁵¹ OPRR Tissue Banking Guidance, *supra* note 13.

⁵² 45 C.F.R. § 40.102(f).

IV. OPPORTUNITIES TO FACILITATE BIOBANK RESEARCH TO IMPROVE HUMAN HEALTH

This analysis has shown that, given the current lack of federal direction on blastocyst research⁵³ and the evolving patchwork of state laws, it is challenging for researchers in supportive states to develop biobanks of blastocysts to their full potential. If the objective is to advance research in the United States to improve fertility care, understand disease development, and ultimately create new therapies, then the federal government could take at least three steps, without funding blastocyst research, to reduce or eliminate the uncertainty and risk that clouds interstate donation of blastocysts to research.

First, all individuals and couples undergoing IVF in the United States—not just patients in select states—should have the right to information about options for disposition of excess blastocysts. This information should follow the model of California, Massachusetts, and other jurisdictions by explaining the patients' options, including continued storage for their own reproductive purposes, donation to another couple for reproductive purposes, donation to research, or discarding the blastocysts. It is reasonable that patients choosing to donate their blastocysts to research might need to send their blastocysts to a different state; in fact, when patients opt to donate blastocysts to another couple for reproductive purposes, some fertility clinics refer them to out-of-state entities that specialize in donation services.

Second, if the objective is to advance scientifically valid research, then the federal government should clarify that patients and fertility clinics cannot be put at legal risk by transferring blastocysts to a permissive state for research. Rather, state laws should govern research conducted in the state. Provided there is oversight of the recipient biobank's activities, patients and their providers should not be at risk from possible expansive interpretation of their home states' laws to cover interstate activity. This recommendation can only be addressed successfully at the federal level; states cannot fix this given their disparate starting points, and ethical guidelines for blastocyst research do not have the force or protection of law.

Third, the NIH should use its existing authority to grant requests for a Certificate of Confidentiality to biobanks with blastocysts.

The Obama Administration and Congress have an opportunity to implement a vision of future medical research that will help to build families through improved fertility care, to reveal causes of serious health conditions, and to develop new treatments for these conditions. Experience in the cancer field shows that biobanks can be truly valuable resources and can advance collaborative research efforts toward better care. National policy direction is needed so that medical centers, universities, and other research entities can focus on the scientific research, rather than on strategies to overcome complicated legal obstacles and uncertainties.

⁵³ Congressional bills introduced in February 2009 would permit federal support of the *use* of cell lines derived from excess IVF blastocysts. While these bills concern the use of stem cell lines and not blastocysts, the bills would authorize federal support only if the blastocysts used to derive the cell lines were obtained with informed consent from donors and without financial inducement. Stem Cell Research Improvement Act of 2009, H.R. 872, 111th Cong. (2009); Stem Cell Research Enhancement Act of 2009, H.R. 873 and S. 487, 111th Cong. (2009). The bills authorize NIH to develop guidelines in this area. A separate, recently introduced bill would prohibit blastocyst research, while supporting adult stem cell research. Patients First Act of 2009, H.R. 877, 111th Cong. (2009).