

The Need for Coherent National Policy: Biobanking for Stem Cell & Human Health Research

Presented to the
Interstate Alliance on Stem Cell Research

Susan Stayn, Esq.
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Stanford University



Introduction

➤ Sept. 08:

(1) RESOLVE presentation to IASCR: Difficulty of IVF patients' decisions about disposition of excess embryos

- Insufficient & unequal information about patients' options
- Lack of direct route to research opportunities

(2) Biobanking Symposium at Stanford: Legal, ethical, and policy issues and scientific value of biobanking

➤ Scientific need for donated materials

- Researchers need donated materials to carry out state-funded stem cell research projects and other protocols
- Researchers need specialized materials (e.g., with certain genetic traits) to advance disease-specific research



U.S. Legal & Policy Framework

- Federal policy: Minimal direction on human embryo research (Dickey-Wicker)
- State laws: Diverse and conflicting laws
- Privacy laws: Federal floor of privacy protection, but there are gaps as applied to research; states also have varying patient privacy laws
- Patchwork legal framework: Hinders development of valuable biobanking resources to support stem cell research and human health research



Questions in Current Framework

- Say IVF patients in a restrictive-research state want to donate excess IVF embryos to researchers in a supportive state.
 - Which state's laws govern the transfer and donation of IVF embryos to research?
 - Which laws govern consent and privacy of patient/donor information?
 - What are the risks to patients, IVF clinics, and other participating entities?



Questions in Current Framework

➤ Examples of Questions and Uncertainties:

(1) Some states ban embryo research

- *Ex.:* Louisiana, Oklahoma, Pennsylvania, South Dakota

(2) Some state restrictions cover "transfer" of embryos for the prohibited purpose

- *Ex.:* South Dakota, Maine, W.Va. proposed legislation (2008)

(3) Some states are “gray” (interpretive issues)

(4) State legal landscape continues to evolve: some proposed measures affect the legality of the research

- *Ex.:* Colorado (2008), Georgia, Montana, Texas



Need for Coherent National Policy

- National direction is needed, even if the federal government does not fund embryo research
- Opportunities, if objective is to advance research:
 - (1) Inform all IVF patients about all dispositional options
 - (2) Protect patients and clinics who donate materials to researchers in a permissive state
 - (3) Protect patient privacy at a uniform, high federal level (Certificates of Confidentiality)

