ITHS | Institute of Translational Health Sciences
Accelerating Research. Improving Health.

Clinical Research Education Series

The New Frontier: Informed Consent to Donate Biospecimens for Stem Cell Research

Bioethical Case Scenarios in Stem Cell Research

March 24, 2016

Case Scenario One:
Embryo donors and results

Questions

Should embryo donors be informed about what happened to their embryos?

- Do they have a right to know, if they want to know?
- How much detail do you relay?
    - How much information do the donors have the right to know?

Options

1. We may not thaw your embryos for a while. Call us in a year and we'll let you know if we made a line.
2. We will contact you to let you know whether or not we made a line. This may not be for about a year.
3. We will not be able to let you know the results of our research with you embryos. (Why?)

If you (and he IRB!) decide it is appropriate to give embryo donors the results of your experiments:

- How do you tell them that you thawed the embryos and extracted cells (which they know destroys the embryos) but that the cells did not grow into a line?
- If you made a line, what else do you tell them, if anything?
    - Do you tell them the name of the line?
    - Do you send them a publication? Note: it will have the name of the line and possibly genetic information about the line.
    - Can you now partner with them? Ask them for medical records?

Considerations

What issues have you identified in this Case Scenario?

ITHS | Institute of Translational Health Sciences
Accelerating Research. Improving Health.

Clinical Research Education Series
The New Frontier: Informed Consent to Donate Biospecimens for Stem Cell Research
Bioethical Case Scenarios in Stem Cell Research
March 24, 2016

Case Scenario Two: Partnership Model

Details

You have set up a registry for your regenerative medicine research project. You will partner with stem cell donors, including embryo donors, and donors of other types of specimens from which you will derive induced pluripotent cells. The specimen donors for iPSC derivation will include normal individuals and patients with genetic diseases (including children).

The partnership will consist of the following:

- What you will do:
  - Obtain specimens from the donors
  - Get consent for full, ongoing access to their medical records
  - Derive stem cell lines from the specimens
  - Fully characterize the lines, including next generation sequencing such as sequencing all the genes, studying protein expression, metabolism
  - Utilize the cells to make more mature cell types (differentiated cells) and tissues
  - Use the differentiated cells/tissues for many different kinds of experiments, to include:
    - Drug screening
    - Implantation in animals
    - Cell therapy development
  - For iPSC-derived tissues:
    - Do genotype/phenotype correlations by comparing the genetic results to the donors' medical records over time
- What the donors get:
  - Newsletter of latest findings of the research study
    - For example, advances in technology development, advances in regenerative medicine
  - Personal genetic test results that might be of importance to them

Considerations

What issues of concern have you identified in this Case Scenario?

What questions might the donors have?

- Unique concerns of the normal subjects
- Unique interests of patients with genetic diseases

What are the pros and cons of the Partnership Model?

ITHS | Institute of Translational Health Sciences
Accelerating Research. Improving Health.

Clinical Research Education Series
The New Frontier: Informed Consent to Donate Biospecimens for Stem Cell Research
Bioethical Case Scenarios in Stem Cell Research
March 24, 2016

Case Scenario Three:
Re-contacting embryo donors for medical information

Details

You have developed an embryonic stem cell line from an embryo donation. The cell line is extraordinarily useful to science. It may even form the basis of a new cell therapy.

Because you had informed the embryo donors that you would not be able to tell them the results of your experiments with their embryos, they do not know you made this line.

Now you wish you had more information about the medical history and current health status of the donors.

Questions

- Would it be okay to re-contact the donors and tell them you made a line?*
- Would it be okay to ask for consent to access to their medical records? *
- The FDA regards tissues developed from stem cell lines as "tissue donations." Tissue donors are required to undergo extensive infectious disease testing, including testing for prion disease. Would it be okay to ask the embryo donors for consent to undergo the FDA-required Tissue Donor tests?*

NOTE: if you did re-contact the couple, you could offer to provide the results of the genetic tests you have already performed on the line (e.g., disease resistance or risk), as well as the results of any testing you'd ask them to undergo.

Considerations

- How do you approach the couple?
- What if it has been several years since the embryo donation?
- What are the issues, pro and con of re-contacting the donors?

*Of course, you must have IRB approval to do this.