MEET THE INSTITUTE OF TRANSLATIONAL HEALTH SCIENCES

ITHS | Institute of Translational Health Sciences

Accelerating Research. Improving Health.

Overview

Our Focus

- Speeding science to the clinic for the benefit of patients and communities throughout WWAMI
- We promote the translation of scientific discovery to practice by:
  - ❑ Fostering innovative research
  - ❑ Cultivating multi-disciplinary research partnerships
  - ❑ Ensuring a pipeline of next-generation researchers through robust education and career development programs

Laboratory | Clinic | Community

Who We Are

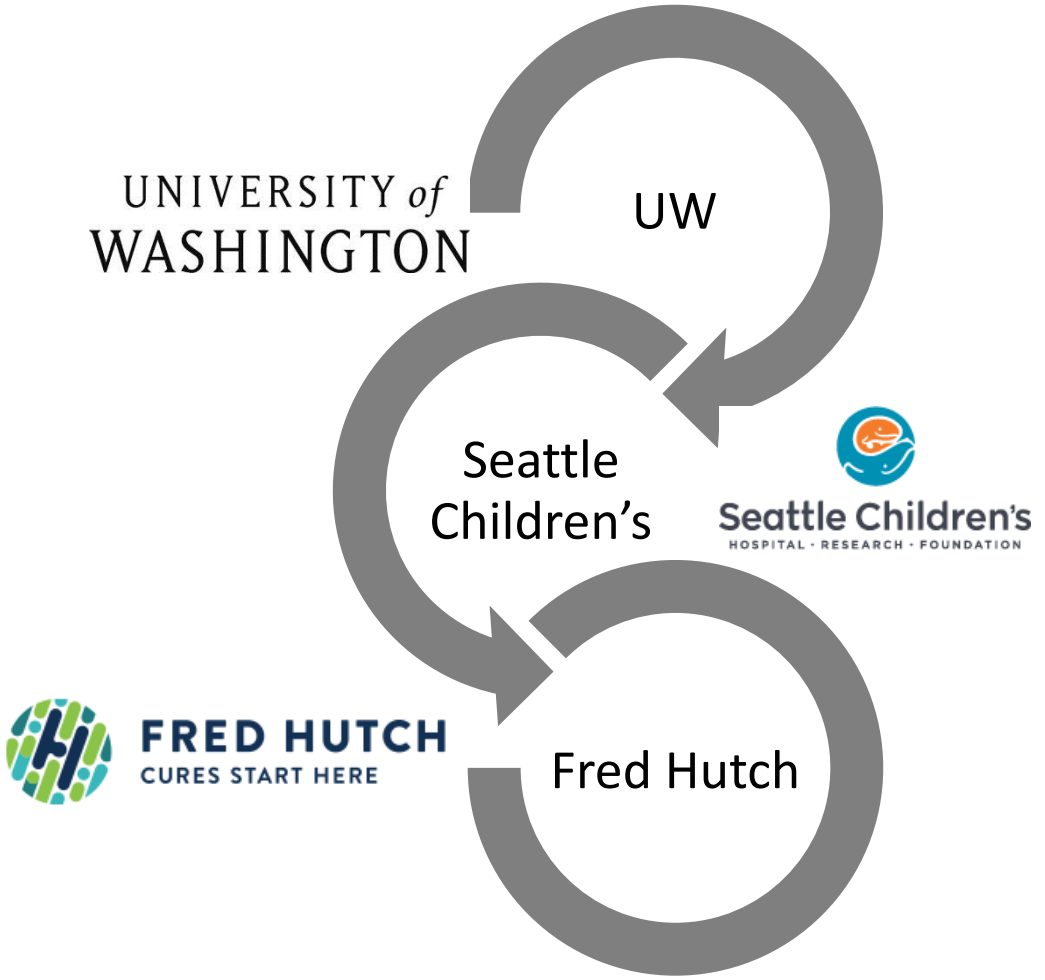
Key Statistics:

- One of 62 NIH-funded CTSA sites nationally
- Approximately 160 faculty and staff from across all health science disciplines

Funding:

- Approximately $17 million/year
- Primary source is NCATS
- Additional funding from institutional support and program income

Our Partners:



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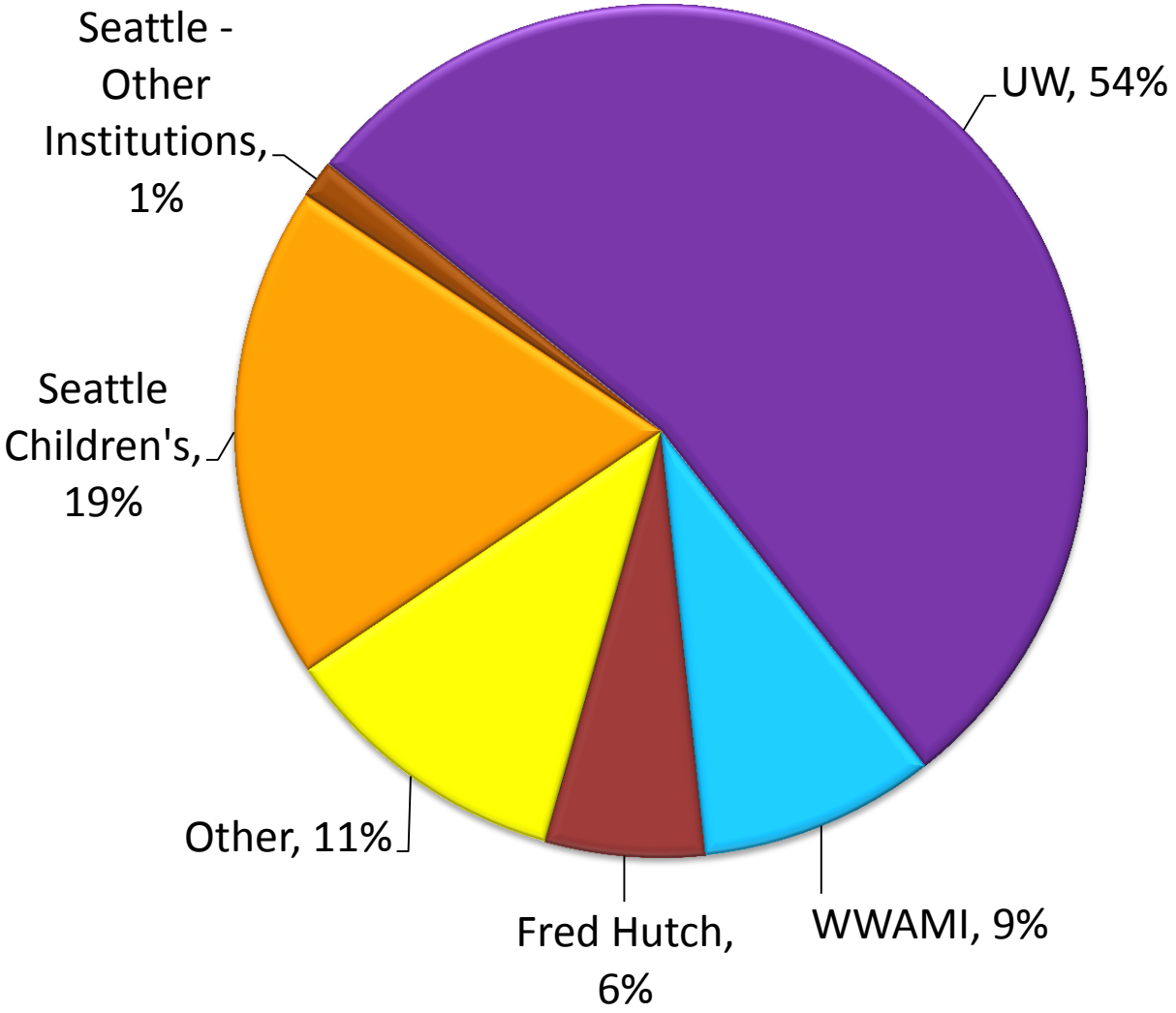
Who We Support



- ~1,800 unique investigators last year
- Junior and senior researchers
- Administrators and staff
- Community members
- Pre- and post-docs

What We've Helped Accomplish

Accomplishments supported since 2007

- Worked with more than 6,500 researchers from nearly 200 institutions across the five-state WWAMI region
- Helped realize more than $585 million in federal grant funding
- Helped realize publication of more than 1,800 articles

CLINICAL RESEARCH EDUCATION SERIES

March 24, 2016

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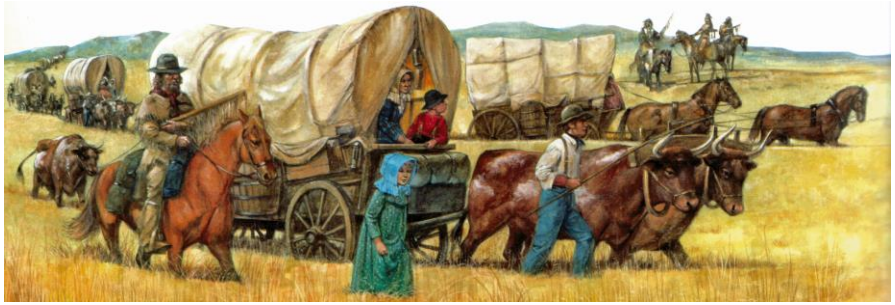
Accelerating Research. Improving Health.

The New Frontier: Informed Consent for Stem Cell Research



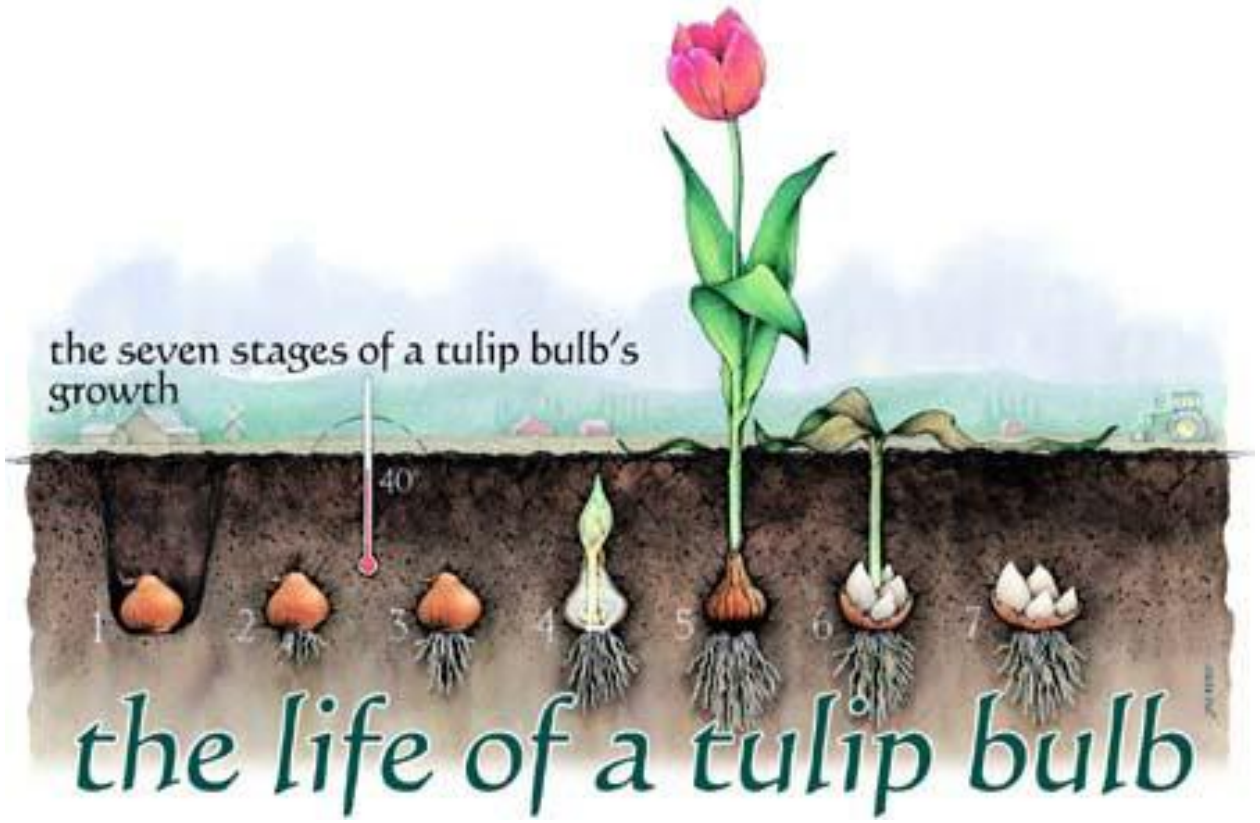
http://www.rootsweb.ancestry.com/~moicgs/Web-Images/Wagon_Train1.gif

Erica C. Jonlin, PhD
Regulatory Manager
UW Institute for Stem Cell and Regenerative Medicine
March 24, 2016

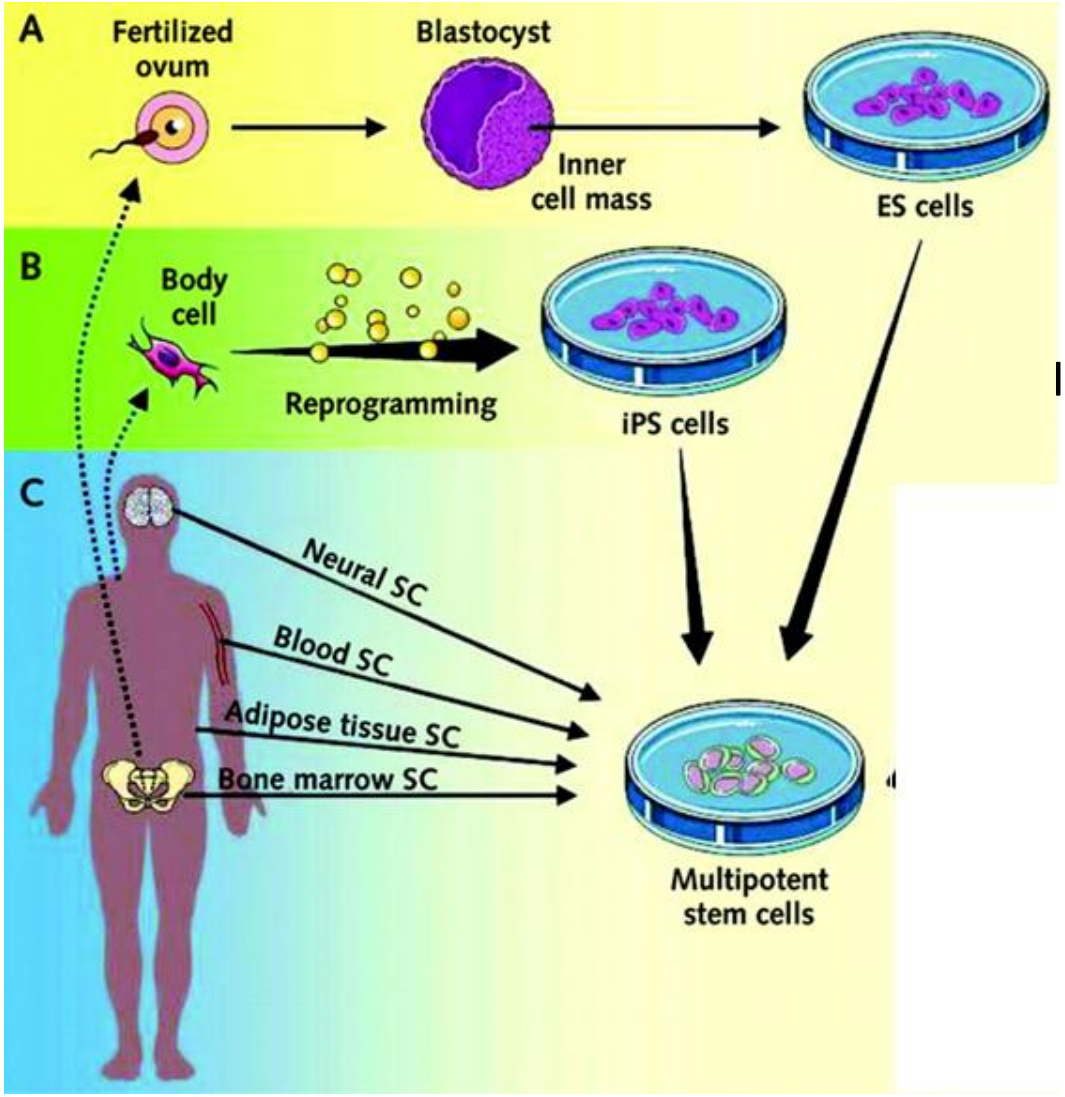
That is . . .

The New Frontier: Informed Consent *to donate biospecimens* for Stem Cell Research

What is a stem cell?


the seven stages of a tulip bulb's growth
40°
1
2
3
4
5
6
7
the life of a tulip bulb

SOURCES OF HUMAN STEM CELLS



hESCs

Embryonic stem cells

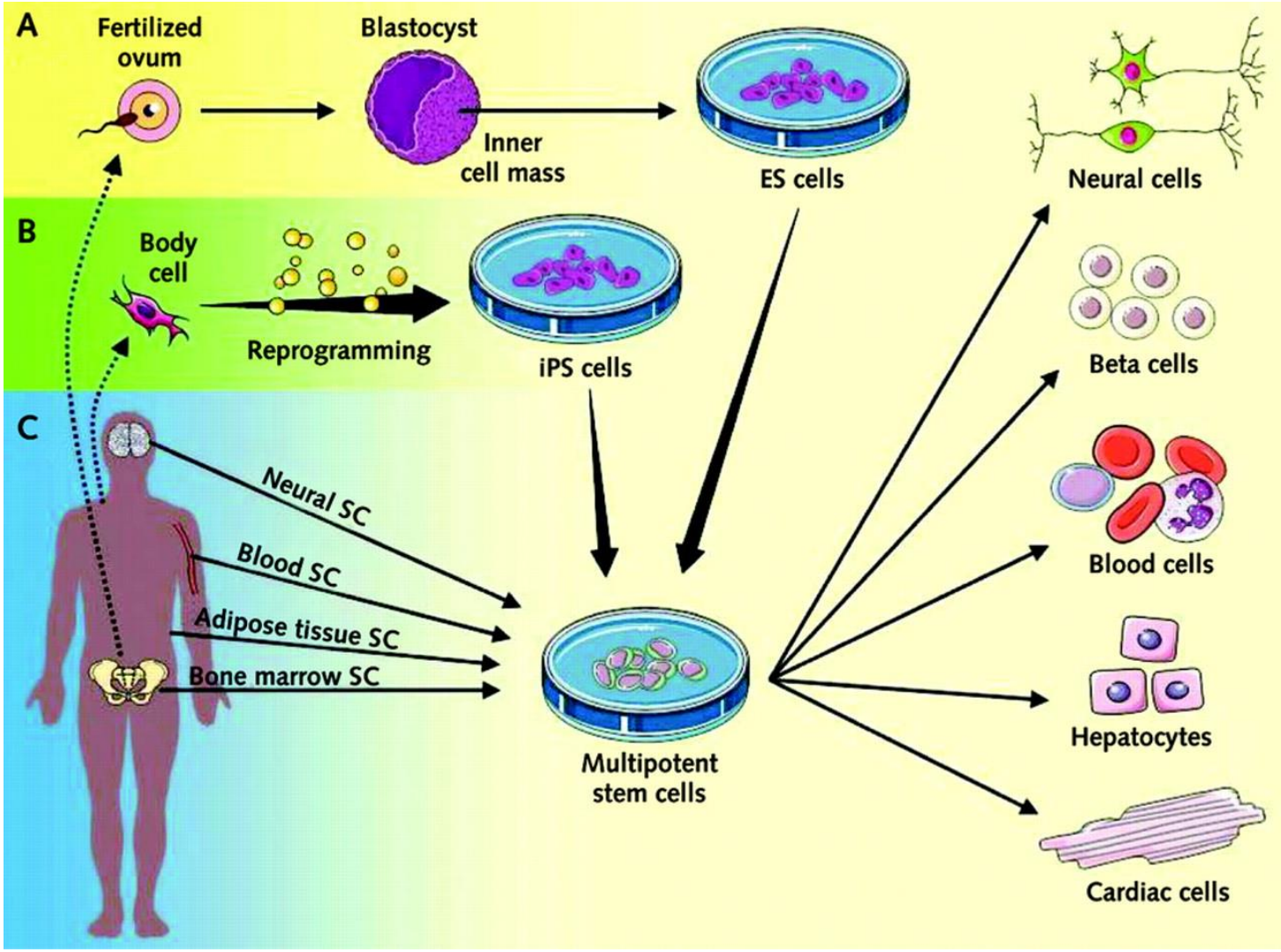
iPSCs

Induced pluripotent stem cells

pluripotent

Power, C. and Rasko, J. E. Ann Intern Med 2011; 155: 706-713

Derivation and differentiation of human stem cells for cell-based therapies.

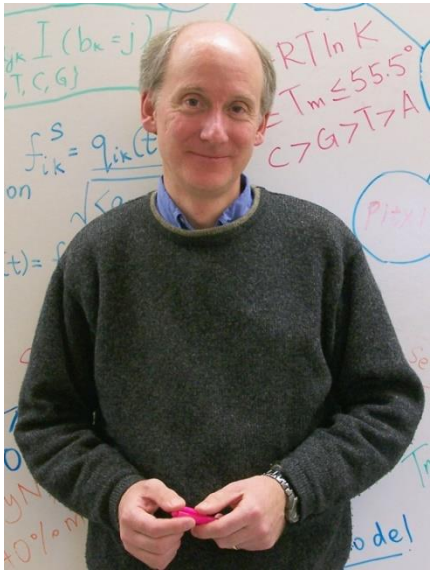


Power, C. and Rasko, J. E. Ann Intern Med 2011; 155: 706-713

Derivation of pluripotent stem cells

hESCs

- 1998
- James A. Thompson, et al
- University of Wisconsin



Discovery hailed by *Science* in 1999 as the "breakthrough of the year"

iPSCs

- 2006 (mouse); 2007 (human)
- Shinya Yamanaka
- Gladstone Institute & iPS Cell Research and Application, Kyoto University

Received the 2012 Nobel Prize in Physiology or Medicine

What's the difference?

hESC line

- Originates from an embryo
- Derivation results in destruction of the embryo
- Genome is a combination of genetic material from two individuals
- It would be very difficult to identify sperm and oocyte donors from DNA sequence data
- Epigenetically primitive; non-differentiated

iPSC line

- Originates from a differentiated cell
- Derived from easily accessed tissue: urine, blood, skin
- Genome sequence is identical to the genome sequence of one individual
- It would be theoretically possible to re-identify the donor from DNA sequence data
- May retain some epigenetic characteristics of originating tissue

Doing research in both areas is important.
Everything we know about stem cells we learn from the hESC lines.

Induced pluripotent stem cells

- "iPSCs don't have the ethical issues."

But they last forever.

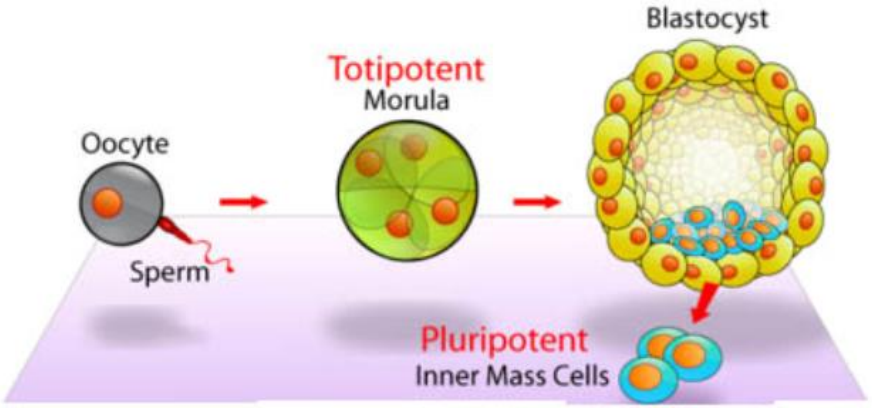
and

the DNA is identical

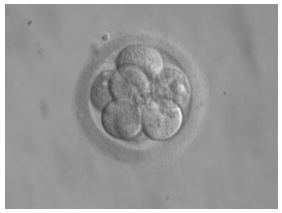
to that of the donor

(. . . More on this later . . .)

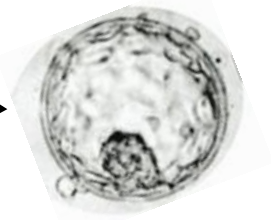
Generating a human embryonic stem cell line



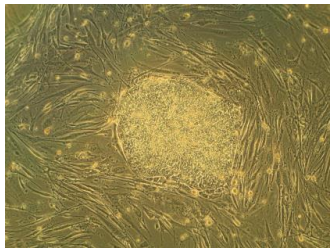
Real photos:



8-cell



Blastocyst:
5 day old embryo



Embryonic stem cells growing in culture

Is this legal?

- Human embryonic stem cell research is not and has never been illegal in the U.S.
- Human embryo **destruction**, for research purposes, is not and has never been illegal in the U.S.
- The government WILL NOT PAY for research involving human embryo destruction.

However,

- the government WILL PAY (that is, you could get an NIH grant) for research on human embryonic stem cell lines if:
  - you paid for the embryo destruction with private dollars!

AND

  - you have followed the NIH Guidelines on Human Stem Cell Research

NIH Guidelines on Human Stem Cell Research July 7, 2009: The Political Compromise that defines what hESC research is eligible for Federal Funding

What hESC research is eligible for NIH funding?

- hESCs should have been derived from human embryos:

1. That were created using in vitro fertilization (IVF) for reproductive purposes [*i.e., the intent was to create a pregnancy*] and that were no longer needed for this purpose
2. That were donated by individuals who sought reproductive treatment (hereafter referred to as "donor(s)") and who gave voluntary written consent for the embryos to be used for research purposes

Other requirements

a. At the fertility clinic, “all options available” for embryos no longer needed for reproductive purposes must be explained to the individual(s) who sought reproductive treatment.
b. No payments, cash or in kind, may be offered for the donated embryos
c. Policies and/or procedures must be in place at the fertility clinic that neither consenting nor refusing to donate will affect the quality of care provided to the potential donor(s)
d. There is a clear separation between the prospective donor(s)’s decision to create embryos for reproductive purposes and the prospective donor(s)’s decision to donate human embryos for research purposes.

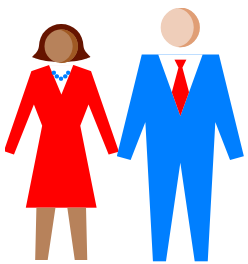
Special requirements regarding contents of the Consent Form

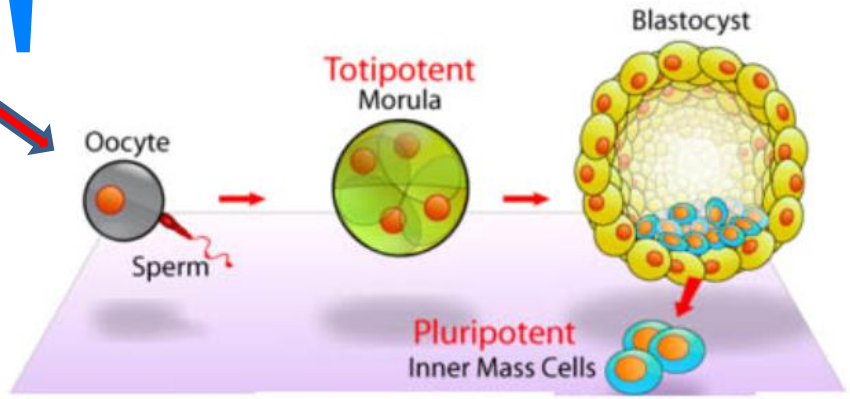
The donors must be informed:

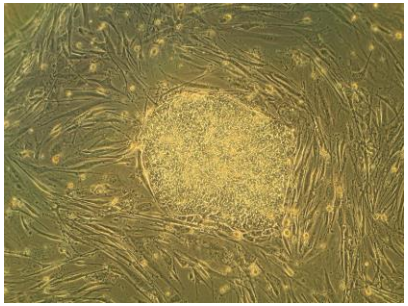
i. That the embryos would be used to derive hESCs for research
ii. What would happen to the embryos in the hESC derivation (e.g., they would be destroyed)
iii. That the hESCs may be kept for many years
iv. That the donation is made with no restriction or direction as to who may receive medical benefit from the hESCs, such as who may be the recipients of cell transplants
v. That the research was not intended to provide direct medical benefit to the donors
vi. That the results may have commercial potential, and that the donors will not receive financial or other benefits from any such commercial development
vii. Whether information that could identify the donors would be available to researchers

Donor(s) should also be informed that they retain the right to withdraw consent for the donation of the embryo until the embryos are actually used to derive embryonic stem cells or until information which could link the identity of the donor(s) with the embryo is no longer retained, if applicable.

If you want to do this, you have to talk to us!







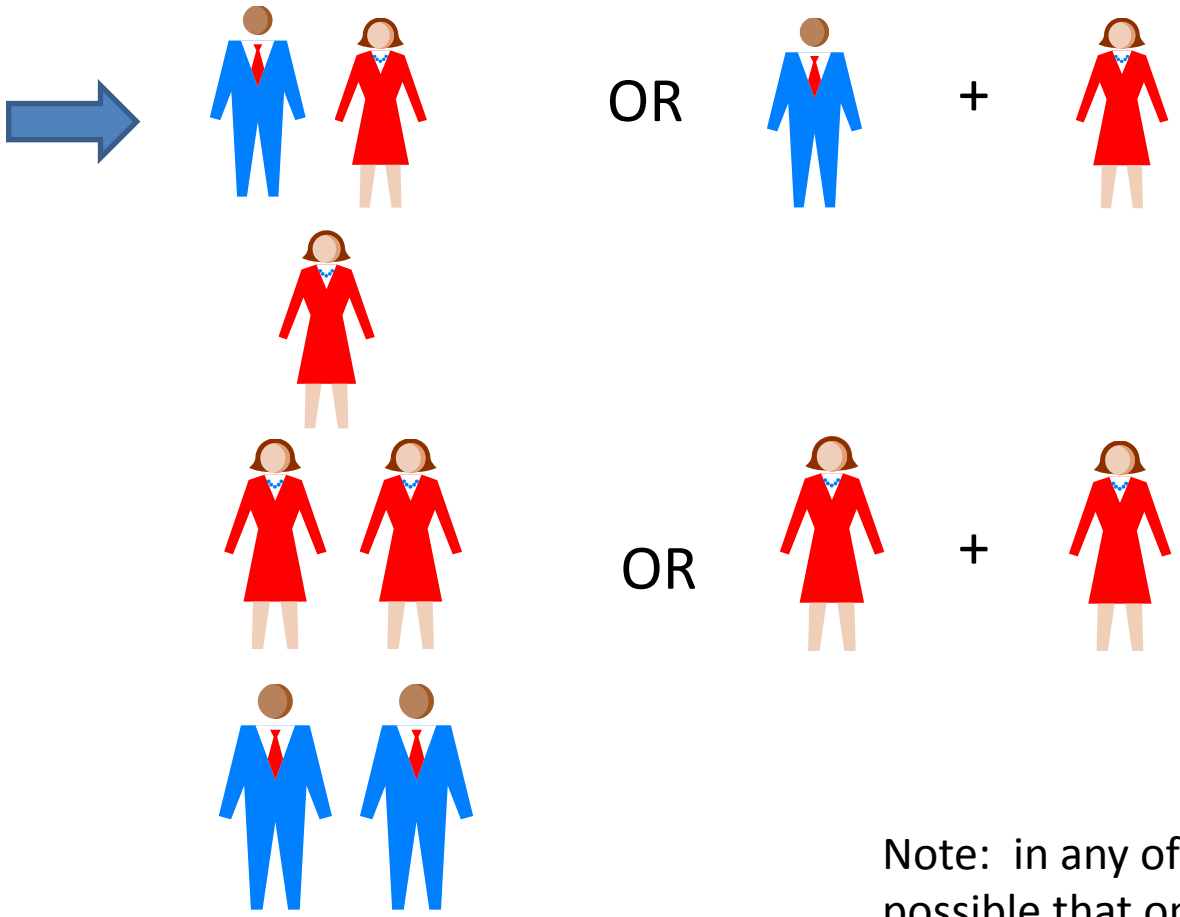
ISCRM's Embryo Donation Program

- Donation of Excess Human Embryos for Establishment of Human Embryonic Stem Cell Lines and for Human Embryonic Stem Cell Research
- IRB application no. 32659
- Principal Investigator: Carol B. Ware, PhD
- Original IRB application approved 2008
- I do all of the consenting

The study

- One procedure: administer informed consent to fertility clinic patients for donation of their excess frozen embryos
- No advertising; all word of mouth
- Clinics give patients my phone number/email address and they contact me
- I call or email back and set up a time for consenting
- I mail (USPS) or email the consent form
- Consent is over the phone or in person – usually in the evening or on a weekend
- Discussion is ~15 minutes to one hour
- If the potential donor(s) are comfortable making the donation, they sign the consent form and mail it back to me
  - I need the original, signed consent form
- We pick up the embryos from the clinic, or send a shipper

The Embryo Donors: the people who have legal decision-making authority for leftover embryos



Note: in any of these cases, it is possible that one or both legal parents are not the biological parents

What do we know about embryo donors and their experience?

In Vitro Fertilization

There are five basic steps in the IVF and embryo transfer process which include the following:

1. Monitor and stimulate the development of healthy egg(s) in the ovaries.
2. Collect the eggs.
3. Secure the sperm.
4. Combine the eggs and sperm together in the laboratory and provide the appropriate environment for fertilization and early embryo growth.
5. Transfer embryos into the uterus.

Step 1: Fertility medications are prescribed to control the timing of the egg ripening and to increase the chance of collecting multiple eggs during one of the woman's cycles. This is often referred to as *ovulation induction*. Multiple eggs are desired because some eggs will not develop or fertilize after retrieval. Egg development is monitored using ultrasound to examine the ovaries, and urine or blood test samples are taken to check hormone levels.

Step 2: Eggs are retrieved through a minor surgical procedure that uses ultrasound imaging to guide a hollow needle through the pelvic cavity. Sedation and local anesthesia are provided to reduce and remove potential discomfort. The eggs are removed from the ovaries using a hollow needle, a procedure called *follicular aspiration*. Some women may experience cramping on the day of retrieval, which usually subsides the following day; however, a feeling of fullness or pressure may continue for several weeks following the procedure.

Step 3: Sperm, usually obtained by ejaculation is prepared for combining with the eggs.

Step 4: In a process called *insemination*, the sperm and eggs are placed in incubators located in the laboratory. The incubators enable fertilization to occur. In some cases where there is a lower probability of fertilization, intracytoplasmic sperm injection (ICSI) may be used. Through this procedure, a single sperm is injected directly into the egg in an attempt to achieve fertilization. The eggs are monitored to confirm that fertilization and cell division are taking place. Once this occurs, the fertilized eggs are considered embryos.

Step 5: The embryos are usually transferred into the woman's uterus from one to six days later, but in most cases the transfer occurs between two to three days following egg retrieval. At this stage, the fertilized egg has developed into a two-to-four cell embryo. The transfer process involves a speculum which is inserted into the vagina to expose the cervix. A predetermined number of embryos are suspended in fluid and gently placed through a catheter into the womb. This process is often guided by ultrasound. The procedure is usually painless, but some women experience mild cramping.

These steps are followed by rest and watching for early pregnancy symptoms. A blood test and potentially an ultrasound will be used to determine if successful implantation and pregnancy have occurred.

http://americanpregnancy.org/infertility/ivf.html

Risks of IVF

Ovary stimulation carries the risk of hyperstimulation, where the ovaries become swollen and painful. This condition, “Ovarian Hyper stimulation Syndrome”, is usually rare, mild, and involves the following potential side affects: nausea, vomiting, lack of appetite, or a feeling of being bloated. More severe symptoms that occur in 1% of cases, include the following:

- Severe abdominal pain
- Severe nausea or vomiting
- Decreased urinary frequency
- Dark-colored urine
- Shortness of breath
- Ten pound weight gain within three to five days

Egg retrieval and the use of laparoscopy carry the typical risks associated with receiving anesthesia. Additionally, there is a slight risk of bleeding, infection, and damage to the bowel, bladder, or blood vessel. Less than one patient in 1,000 will require surgery to repair damage caused during the egg retrieval process.

The chance of a multiples pregnancy is increased in all assisted reproductive procedures. There are additional risks and concerns related to multiples during pregnancy including the increased risk of premature delivery.

Assisted reproductive technology (ART) involves a significant physical, financial, and emotional commitment on the part of a couple. Psychological stress and emotional problems are common, especially if IVF is unsuccessful.

http://americanpregnancy.org/infertility/ivf.html

Success Rate of IVF

- Depends on a number of factors, including patient characteristics and treatment approaches
- Note: Pregnancy rates are not the same as live birth rates
- In the United States, the live birth rate for each IVF cycle started is approximately:
  - 30 to 35% for women under age 35
  - 25% for women ages 35 to 37
  - 15 to 20% for women ages 38 to 40
  - 6 to 10% for women ages over 40

http://americanpregnancy.org/infertility/ivf.html
(visited October 2013)

Costs of IVF

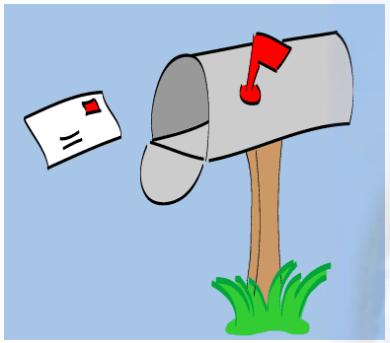
- Average cost = $12,000 for one cycle
  - Includes fertility drugs, ultrasound, monitoring, blood work
- If single sperm injection (ICSI) is needed, add $1000-$1500
- PGD – add ~$3000
- Embryo freezing and storage – can be hundreds of dollars/year
- Use of donor egg: $25,000-$30,000 per cycle
- Use of donor sperm: $13,000-$17,000 per cycle

According to
http://infertility.about.com/od/ivf/f/ivf_cost.htm
(visited October 2013)

People have gone through a lot to make these embryos.

“Giving them away” is a very big deal.

Consenting for donation of excess embryos



What I do & do not know about donors

- I know (if they tell me):
  - Some have used donated eggs
  - Some have used donated sperm
  - Many have twins; some may have triplets
  - Some have had no children through IVF
- What I learn, if they make the donation
  - Address
  - Birthdate(s) of donors
  - Whether donated eggs and/or sperm were used
  - Infectious disease test results for tests required by fertility clinic
- I don't know and I do not collect information about:
  - Race/ethnicity
  - Socioeconomic status
  - Detailed medical history
- If donated sperm or oocytes were used to create the embryos, neither we nor the embryo donors have access to the identities of the egg or sperm donors - these are anonymous by law.

Elements of consent

- Purpose of the Study
- Study Procedures
- Risks, Stress, or Discomfort
- Alternatives to Taking Part in This Study
- Benefits of the Study
- Other Information

PURPOSE

"Regenerative medicine involves the study of how tissues are made from stem cells. There is a need for human embryos to study the earliest developmental time points. Human embryos are also needed to create new human embryonic stem cell lines, which are derived from selected cells from human embryos. The purpose of this consent form is to ask if you would be willing to donate your excess frozen embryos for human embryonic cell research."

Purpose: I explain the science

- What is a stem cell?
- What is a cell line?
- What does pluripotent mean?
- How does it become an advanced cell line?
- How do you make a tissue?

STUDY PROCEDURES

- We will pick up your excess frozen embryos
- Embryos will be labeled with code numbers, not your name
- Studies:
  - Cellular changes during thaw
    - Embryos may be allowed to develop up to 4 days
  - Removal of cells (inner cell mass) and attempt to develop new human embryonic stem cell lines
- Cell lines
  - May continue to divide indefinitely
  - We will study self-renewal, early embryonic development, development of specific tissues
  - We may change some genes, and then observe the results
  - We may put some of the cells into lab animals to learn whether/how the cells may develop into a specific cell type
  - We may use cells from a cell line derived from your embryo to develop a cell therapy to treat other people
    - E.g., develop stem cell-derived tissues for transplant into patients with serious diseases

STUDY PROCEDURES

- There are many future possible research uses that are unknown at this time
  - "A committee at UW will review the research studies to ensure they are scientifically sound and meet ethical standards"
- We may provide cell lines to researchers outside of UW (they must have approval from their institutions for embryonic stem cell research)
- "The embryos will not be used in any way to create a pregnancy"
- We may perform a whole genome wide analysis of the DNA from the embryos or embryonic stem cell lines
  - "It is critical to know the genetic make-up of any cell-derived treatment"
- Whole genome sequence info will be provided to a databank at the NIH. No personally identifying info will be provided.

Procedures: I clarify that a cell therapy could result from their embryo

- If we derive a cell line from your embryo, that cell line may become the source material for a cell therapy
- A cell therapy will be put into other people
- The cell therapy will have the DNA of the originating embryo
- Because the cell therapy may be put into other people its DNA will likely be fully sequenced.
- If it is therapeutic, it may have commercial value

RISKS, STRESS, OR DISCOMFORT

"In the process of developing human embryonic stem cell lines, the embryos you donate will no longer be capable of development into human beings. The process of removing selected cells from the embryo to make embryonic cell lines destroys the ability of the embryo to develop further. Some people find this type of research objectionable. If you do not want us to try to make a line from your embryos, you should not donate them to our research."

RISKS, STRESS, OR DISCOMFORT

- The list linking your names to the code numbers will be kept indefinitely. Dr. Ware and Dr. Jonlin will have access to this list.
- Employees of the FDA may see this list if they audit our records.
- “There is a small possibility of breach of confidentiality. However, we have systems to keep your identity private. The consent forms and the list of names are kept in a locked file in a locked room in a secure building. We will not release your name or any information about you to other researchers or to members of the public.”
- “We do not think that there will be risks to your privacy and confidentiality by sharing the whole genome analysis of an embryonic stem cell line developed from your embryo. It is important to remember that the genes in an embryonic stem cell line are a complex mixture of genes from the man who provided the sperm and genes from the woman who provided the egg that led to creation of the embryo. As a result, it would be very difficult to identify biological embryo donors using genetic information from an individual embryo or embryonic stem cell line.”

ALTERNATIVES TO TAKING PART IN THIS STUDY

- Participation is voluntary
- You may refuse to donate
- Refusal to donate will not affect the treatment you receive a the fertility clinic or at the UW
- If you think you may want or need the embryos, you should not donate them.
- If you do not donate the excess frozen embryos to our research, the clinic will tell you your other options. This may include discarding the embryos.

BENEFITS OF THE STUDY

- You will not personally benefit from this research. However, society may benefit. Human embryonic stem cell research may provide significant new knowledge that could benefit human health. In addition, because human embryonic stem cells have the ability to develop into any cell type, they may someday be used to develop therapies for serious diseases such as Alzheimer's Disease, Parkinson's Disease, and diabetes, among many others. In these diseases the patient's cells are not working properly and it is thought that human embryonic stem cells or products derived from human embryonic stem cells, such as new cells and even tissues, could possibly cure the illness.

OTHER INFORMATION

- We will receive some medical information:
  - Your ages, no. of embryos, results of infectious disease tests that you when undergoing fertility treatments, whether the embryos were created with donor eggs and/or donor sperm
  - If you had pre-implantation diagnosis, you may provide us with the results
  - You may change your mind about donating up until the time we obtain the embryos.
  - Stem cell lines cannot be withdrawn
  - Embryos are labelled with a code number.
  - Names, addresses, consent forms are stored in a locked cabinet, in a locked room, in a secure building.

OTHER INFORMATION

- Officials from local and government agencies, like the FDA, may review the research records, including consent forms.
- Reports, publications will not reveal your name or any identifying information
- You will not receive any money for your donation. You will also not be charged any fees. We are not paying the storage facility for the embryos.
- Research using your donated embryos may lead to the development of commercial products, including therapies. There are no plans to provide compensation to you should this occur.
- If you believe you have been harmed by your participation in this research, please contact Dr. Erica Jonlin right away at 206-221-0339. She will work with you to address your concerns.

My signature box

Printed name of researcher obtaining consent Signature

Date of consent discussion

Date consent was received in the mail if consent was conducted over the telephone

Donors' signature box

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can call Dr. Carol Ware at (206) 616-5143 or Erica Jonlin at (206) 221-0339. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to receive my infectious disease testing results and limited medical information, as described above, from the fertility clinic. I will receive a copy of this consent form.

Printed name of donor	Signature	Date

Printed name of donor	Signature	Date

Copies to: Dr. Jonlin, Donors

What do embryo donors want to know?

- Diseases under study
- Can they find out what happened to their embryo
- How good are we at this
- Privacy issues
- Fundamental scientific questions
- Legal questions
- Ethical questions

Main Issue: Diseases Under Study

- "What diseases are you studying?"
  - UW: heart disease, diabetes, degenerative diseases of the eye
  - Note: we will share any lines we make and others may study many other additional diseases
- Particular interest: Diabetes, ALS, autism, Parkinson's, cancer, leukemia, spinal cord injury
  - Many donors tell me stories about a disease that they have in their family
- "Can we donate it for a particular type of research?"
  - No. Cannot direct the research.
  - Note also: even though the lines are "pluripotent," some lines are better at becoming a particular type of tissue.

Main Issue: Getting Results

- "Will you tell us if you made a line from our embryo?"
  - No.
- Why?
  - It is typical of research not to give results.
  - Issue: Most embryos do not become a line
    - But we learn something from all of them
  - Issue: sense of "ownership;" donor(s) cannot direct the research
- "I'm relieved we won't get the results because we'd wonder about it." vs. "I wish we could get the results."
  - Would like to hear about any breakthroughs
  - Request for a newsletter

Evaluating us

- What is your success rate at making lines?
  - Every lab is <10%
  - Depends on embryo quality, quality of freezing, age of embryos, embryo stage when frozen
  - Affected by laboratory conditions
  - “We learn something from every embryo.”
- How long have you been doing this?
- How many embryos do you get per year?

Privacy concerns

- Biggest concern: disclosure of their identity to the public
- “I don’t want my name in the paper”
- Are you keeping a database of names?

- And on the other hand one person asked: “Why does confidentiality matter?”

Scientific questions

- Can one embryo be used for more than one project?
- Do you put the line into people?
- Does the developmental stage of the embryo matter?
- Should we save the embryo for our own use – for example, if we or our children get a disease years from now – could it provide a treatment for us?
- If you get a product from these cells, can I get it if I get sick?
- What is the other kind of research that doesn't use embryos?
- Will the cell lines be immortal like the HeLa cell line?
  - Quite a few people have read The Immortal Life of Henrietta Lacks
- Why do you need to make more lines?

Legal questions

- Is this research legal?
- Questions about the changing political situation and how it affects the research
- Question about personal liability
- Question about tax benefits of making the donation

Ethical concerns

- Will it feel pain?
- Confirm that our embryo will not be used to create a pregnancy
- Confirm that you won't let it grow into a fetus.
- How long do you let it grow in the lab before destroying it?
- Could this technology be used to keep people alive longer than they should be?
- Are you doing human cloning?
- "I don't want research on my embryo lining the pockets of big pharma."

What no one seems to care about

- Not being able to get any money from the embryos if they lead to development of a product with commercial value

Ultimate reasons for donating

- They have benefited from science and now they want to give back
- They cannot handle raising more children
- They had a child by IVF who has “condition xyz” and they are afraid of having another child with that
- They do not want another one of their children “out there” (i.e., if they were to donate their excess embryos anonymously to others)
- They cannot pay for storage anymore
- They support science
- This could potentially save lives
- They do not want their embryos to go to waste
- They are relieved there is a use for the embryos
- They have had family members with a debilitating disease and they hope this will help

Reasons for not donating

- “We decided to try for another child.”
- “It’s not the right thing for us.”
- Disagreement between the donors within the couple
- No reason provided; no response at all
  - If I don’t receive a signed consent form back, we consider them “dropped”

Unresolved issues in embryo donation for research and ultimate therapeutics development

- For those embryos that were created using donated sperm or donated oocytes, it is not known whether the sperm or egg donor (who by law are anonymous) would have given consent for research use of the embryo
- The medical history of the biological donors is largely unknown
- Infectious disease testing of fertility clinic clients (at the time the embryos were created) is incomplete as compared to what the FDA expects of tissue donors

So why not just avoid the trauma of embryo donation and just work with iPCS?

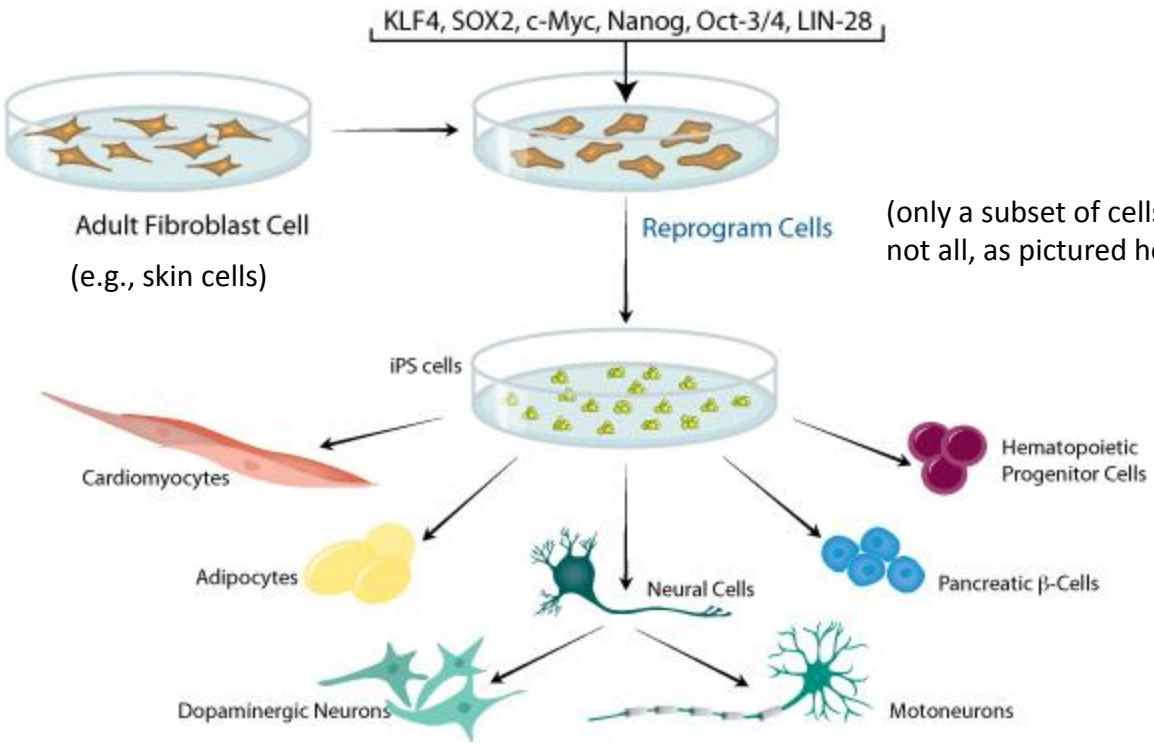
Shinya Yamanaka, MD, PhD
2012 Nobel Prize in Physiology or Medicine

Dr. Yamanaka, senior investigator at the Gladstone Institutes, Director of the Center for iPS Cell Research and Application (CiRA) at Kyoto University

Dr. Yamanaka receiving the Nobel prize from Sweden's King Carl Gustaf

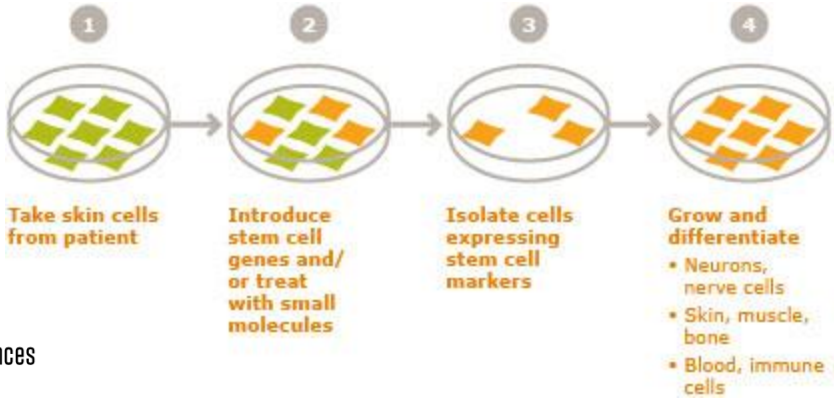
2012 Nobel for his discovery of how to transform ordinary adult skin cells into pluripotent stem cells like embryonic stem cells

Induced Pluripotent Stem cells

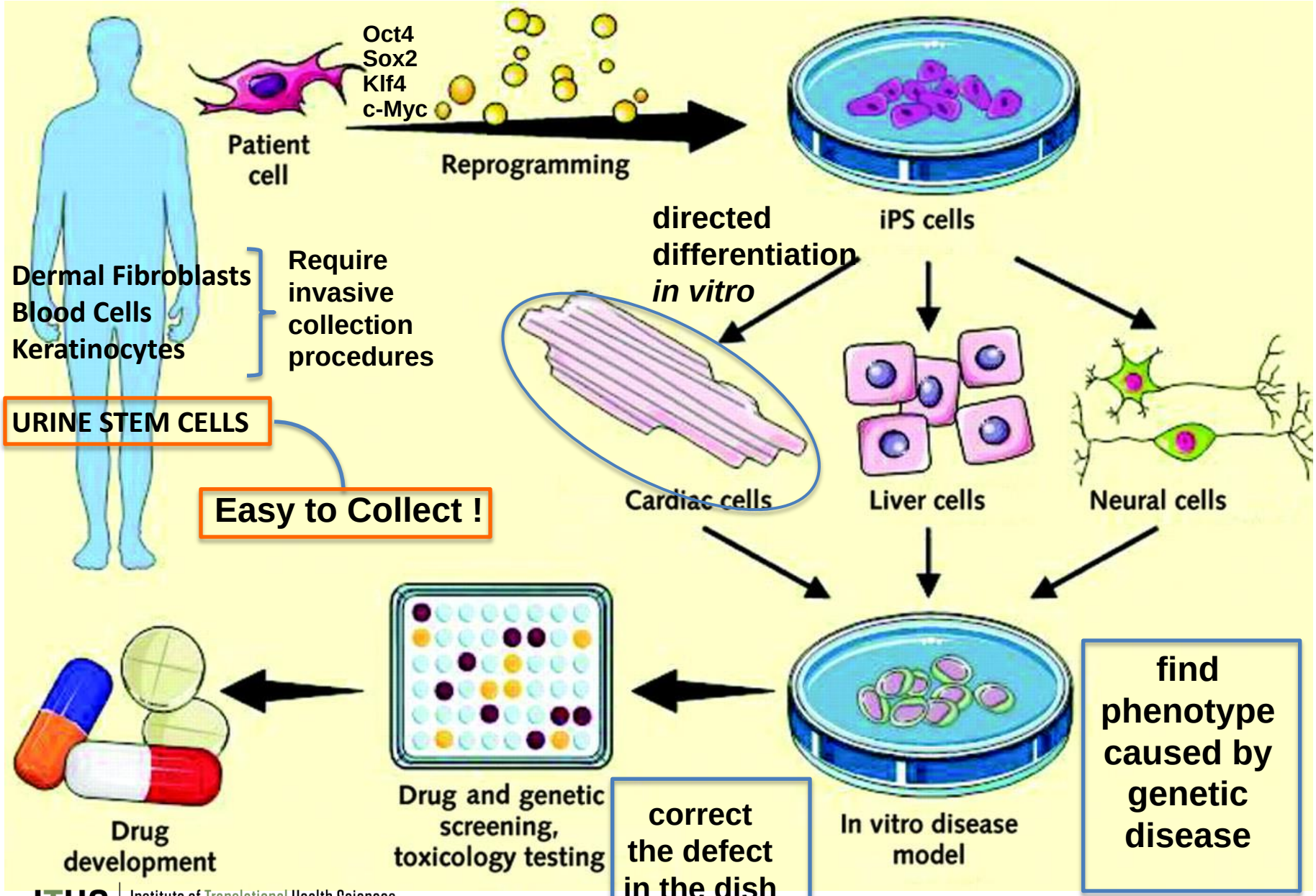


(only a subset of cells will reprogram, not all, as pictured here)

This is not easy to do, and has not been perfected for any organ system! Issues: efficiency, purity, "terminal differentiation"



Disease-in-a-Dish



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iPSCs are not without issues

- Permanent cell lines
- Widely distributed
- Fully sequenced
  - Only in this case, the sequence is of a living human being
- Give results? What are the obligations?
- If therapeutics development is contemplated, the donor needs to be tested for a fully array of “Tissue Donor” required tests

Partnership models?

COMMENT

NATIONAL PSORIASIS FOUNDATION

A participant's involvement in research doesn't have to end the day a sample is collected.

Treat donors as partners in biobank research

Proposed rules to protect research subjects will impede progress, say **Krishanu Saha** and **J. Benjamin Hurlbut**. Instead, give donors more say in how samples are used.

26 October. This is an opportune moment to reconsider the role and rights of participants in biomedical research.

Current practices in managing biobanks tend to see the public as little more than a resource for mining data and materials, and as a potential source of resistance. Participants provide information or tissues with little or no knowledge of the researchers' priorities, goals or expected outcomes. Barriers are erected. Materials and information are 'de-identified' to protect people's identities. Participants neither see how their donations are used, nor what the research produces.

As they stand, the proposed changes to the Common Rule[5] risk further widening the divide between researchers and donors. The changes encourage blanket consent — asking donors to authorize virtually everything, with opt-out checkboxes for predefined categories of research that might pose "unique concerns", such as creating a cell line[5]. Scientists could use the samples for additional projects without seeking re-consent. The changes are intended to ensure that the scope of authorized research is clear to all parties, thereby circumventing the ambiguities that were at the heart of the Havasupai case. But this is achieved by telling donors next to nothing about how and for what purpose their donation will be used. Although this may reduce administrative complexity, we believe that it will decrease, not increase, public involvement in biobanks and fail to deliver on its ethical aim of better protecting participants' rights.

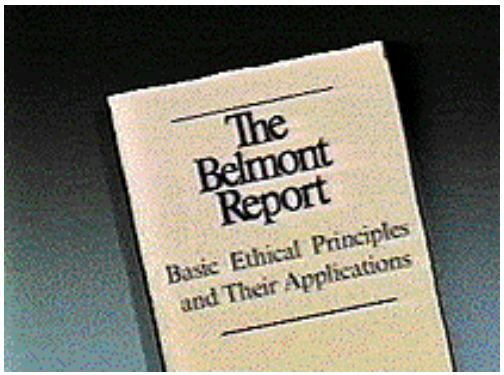
Most people prefer to have a say in how their donations are used. In a study in which donors were asked whether they would make their de-identified data available for

Partnership models?

- Stem cell donors would allow investigators continued access to their medical records
  - Would enable scientists to look for correlations between patient disease phenotype and cellular and tissue abnormalities observed in the lab.
  - In those rare cases when a pluripotent stem cell line is used to derive tissues for transplantation, medical records access and partnering with donors could prove especially advantageous
- Involve the use of interactive computerized tools to build long-term partnerships between research participants and researchers
- In exchange for allowing researchers extensive access to their records, donors would be kept apprised of progress in the research.
- Could help build trust between research subjects and researchers.
- Patient advocacy groups could provide an entrée for researchers seeking partnerships.

Belmont Report (1979)

(remember this?)



- Respect for persons
  - Informed consent
- Beneficence
  - Maximize benefits; minimize harms, risks
- Justice

➢ A partnership model might perhaps better address the spirit of the Belmont Report

Thank you

To YOU

And especially -

To the generous couples and individuals who make this extraordinary donation to science

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Additional references and more information

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