Approved: March 15, 2006

Date

### MINUTES OF THE HOUSE FEDERAL AND STATE AFFAIRS COMMITTEE

The meeting was called to order by Chairman John Edmonds at 1:30 P.M. on February 21, 2006 in Room 313-S of the Capitol.

All members were present except:

Representative Broderick Henderson- excused

Committee staff present:

Dennis Hodgins, Kansas Legislative Research Department Mary Torrence, Revisor of Statutes Office Carol Doel, Committee Secretary

Conferees:

Dr. Barbara Atkinson, Executive Vice Chancellor Executive Dean, KUMC

Others attending:

See attached list

The Chairman opened the floor for bill introductions, and hearing none he introduced Dr. Barbara Atkinson, Executive Vice Chancellor, Executive Dean KUMC (Kansas University Medical Center) who presented a briefing on *Stem Cell Research 101*.

Dr. Atkinson explained the vocabulary used in stem cell research and the importance of it. She also instructed that stem cells are unspecialized cells that give rise to more than 250 specialized cells in the body which serve as the body's repair system. The two major types of stem cells, mature stem cells and early stem cells as well as the sources of these cells were explained. Dr. Atkinson also related the manner in which these cells are can be used for treatment of disease processes as well as the advantages and disadvantages of this process. The sources of the early stem cells and the place where they are found was covered in Dr. Atkinson's presentation. She further explained the possible economic impact of banning SCNT. Kansas University Medical Center (KUMC) has a \$1.5B economic impact on the state of Kansas. The National Health Institute helps finance stem cell research with the National Academies of Science overseeing the research ethics in the U.S. Information provided for committee review related the happenings in Kansas regarding the stem cell research. KUMC has a website for the gathering of further information. (Attachment 1)

Dr. Atkinson also provided booklets entitled *University Of Kansas School Of Medicine Annual Report* and *Research In Medicine University of Kansas School of Medicine*. (These booklets are available at the Office of the Executive Dean KUMC - Telephone - 913-588-5200 or online at www.kumc.edu/som.)

With no further business before the committee, Chairman Edmonds adjourned the meeting.

# FEDERAL AND STATE AFFAIRS GUEST LIST

Date 2-21-06

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# Stem Cell Research 101

Barbara Atkinson, MD
Executive Vice Chancellor, University of Kansas Medical Center
Executive Dean, KU School of Medicine

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# Stem Cell Research 101 Agenda

- Science and Stem Cell Research
- Mature Stem Cells
- Early Stem Cells IVF and SCNT
- Promise of Stem Cell Research
- Public Policy and Ethics
- What's Happening in Kansas

Stem Cell Research 101

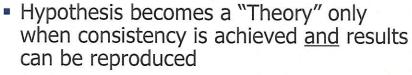
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# Science and Stem Cell Research

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## How Do Scientists Think?

- Scientific Method
  - ➤ Multi-step process
  - ➤ Never "prove" a hypothesis; only confirm or rule out a hypothesis



 Unprejudiced — minimizes scientist's bias on outcome

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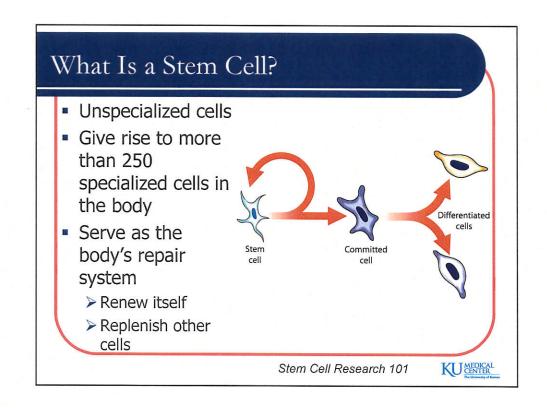
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# Why Is Vocabulary Important?

- Key Terms
  - >"Mature" versus "adult" stem cells
  - ➤"Early" versus "embryonic" stem cells
  - >"Therapeutic" versus "reproductive" cloning
  - >"Alive" versus "a life"

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# What Are the Two Major Types?

Mature Stem Cells	Early Stem Cells			
a.k.a. Adult	a.k.a. Embryonic; blastocystic			
Cells obtained from specific mature body tissues, umbilical cord, placenta	Cells obtained from inner cell mass of a blastocyst			
Multipotent — Give rise to limited cell types	Pluripotent — Flexible, give rise to all cell types in the body			

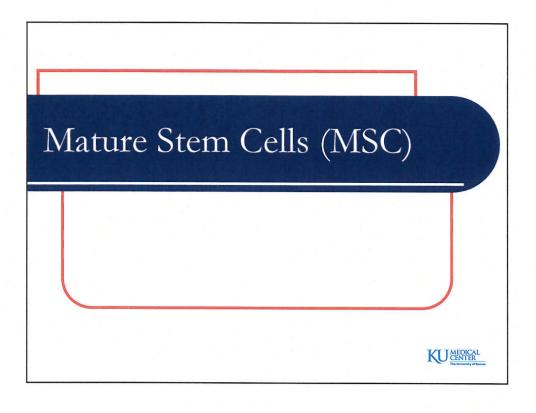
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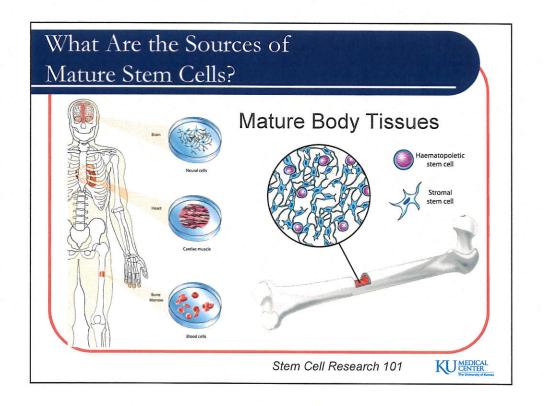


# What Is the History of SCR?

Mature Stem Cells	Early Stem Cells		
First isolated in 1960s	First isolated in 1998		
50+ years of research	7 years of research		
Federal Funding = >\$2.7 Billion (FY 99-04)	Federal Funding = \$57 Million (FY 02-04)		
Results: 50+ human therapies	Results: Only in animal trials; No human trials		

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# What Are the Sources of Mature Stem Cells?

### **Umbilical Cord & Placenta**

- Isolated immediately following birth
- Wharton's Jelly showing promise as a source
- Some pluripotent characteristics
- Research is limited but growing

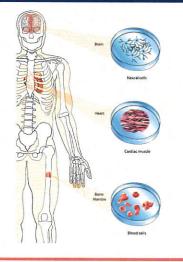


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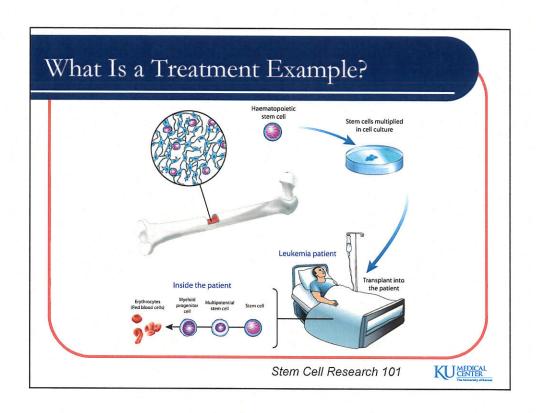
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# What Are the Characteristics?

- Mature Stem Cells typically develop into the cell types of the tissue or organ from which they originate
- Specific sources within each tissue type are not well understood yet



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# What Are the Advantages?

### Mature Stem Cells

- Organ/tissue rejection unlikely if patient receives own stem cells
- Some are easy to find (e.g., blood stem cells)
- Partly specialized
- Less coaxing in culture required to stimulate growth of specific cell types

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# What Are the Disadvantages?

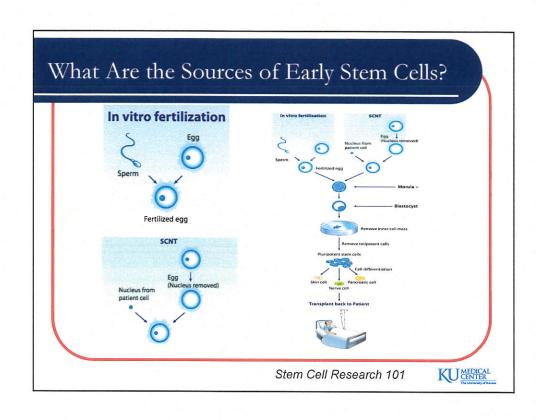
### Mature Stem Cells

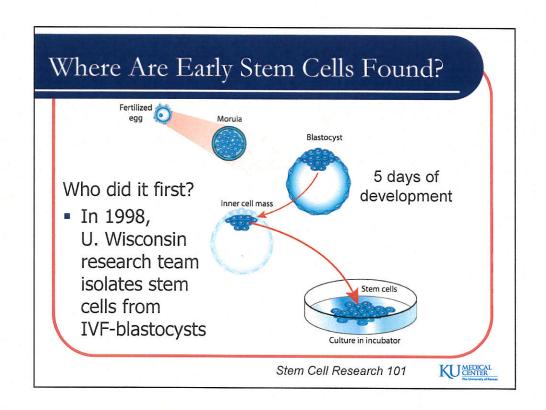
- Limited longevity in cell culture
- Difficult to isolate and extract
- Limited flexibility or types of cells that can be made
- Uncommon cells; more scarce with age
- Questionable quality due to age, toxins, and disease

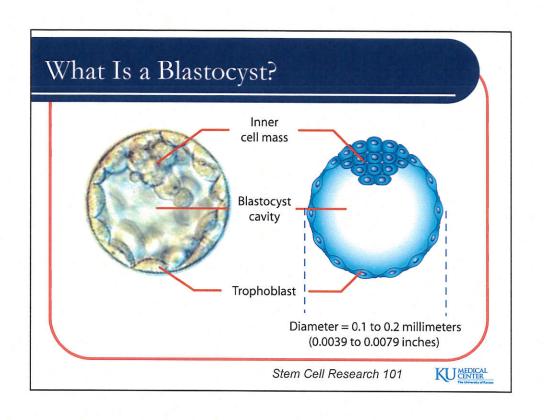
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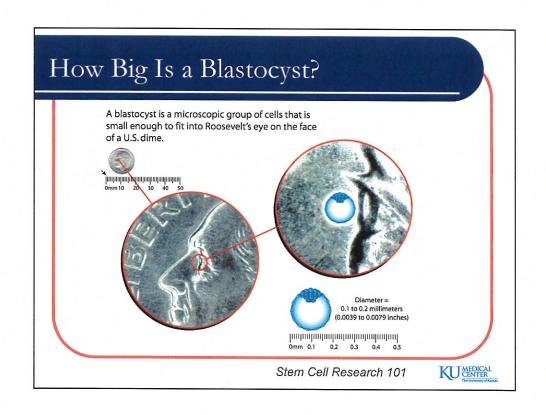
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# Early Stem Cells (ESC)



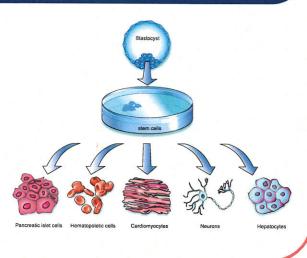








- Early stem cells are pluripotent
- Retain the special ability to develop into nearly any cell type



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# What Are the Advantages?

### Early Stem Cells

- Easy to grow in cell culture
- Very flexible can make all body cell types
- If SCNT, immune rejection unlikely
- Can be maintained for long periods of time in cell culture
- Potential unlimited source of all types of clinically relevant cells
- If IVF, available
  - More than 400,000 unwanted pre-embryos in U.S. today

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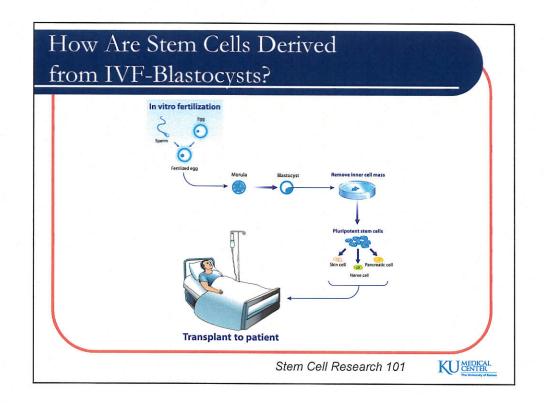
# ESC: What Are the Disadvantages?

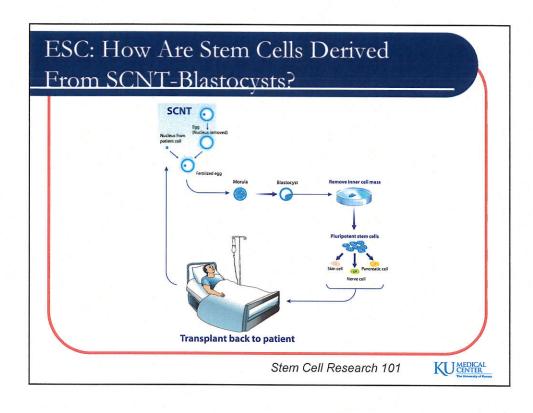
### Early Stem Cells

- If IVF, rejection is possible, but we don't know yet
- Difficult to control differentiation
- Requires many intermediate steps to coax into desired cell type

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### What Should You Know About SCNT?

- Purpose:
  - > Find cures and therapies for diseases
  - ➤ Awaken the natural capacity for self-repair that resides in our genes
- Potential Results:
  - ➤ Patients will receive own stem cells to treat disease
  - ➤ No need for donor match
    - Like transplantation, but without rejection

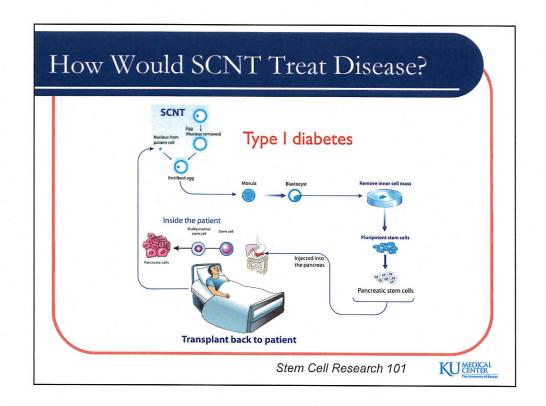
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### What Should You Know About SCNT?

- No sperm involved in SCNT
  - > Works with the cells of an already-living person
- SCNT stem cells are <u>alive</u> in a Petri dish
  - ➤ No different than any other cell in a Petri dish
- New evidence suggests that SCNT stem cells may never develop into a human
- Blastocysts produced by an egg and sperm and SCNT are fundamentally different
- Scientists are ethical
  - No reputable scientist wants to clone babies

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# What Could Be the Impact of Banning SCNT?

- Anti-science climate
  - Scientists of all types will avoid Kansas and go to states with more supportive research climates
- Direct economic impact and an indirect loss of additional business growth
  - ➤ KUMC has a \$1.5B economic impact on Kansas

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# Public Policy and Ethics

How Is Stem Cell Research Funded and Regulated?

### Who Funds Stem Cell Research?

- NIH All Stem Cell Research
   FY 1999 to FY 2004 = \$2.243 Billion
- NIH Early Stem Cell Research FY2002 to FY 2004 = \$57 Million

National Institutes of Health Funding (\$ millions)

	FY99 Actual	FY00 Actual	FY01 Actual	FY02 Actual	FY03 Actual	FY04 Actual	FY05 Estimate	FY06 Estimate
Total Stem Cell Research	\$225.4	\$256.3	\$305.9	\$386.6	\$516.6	\$552.5	\$566.1	\$567.6
Human embryonic stem cell research*				\$10.1	\$20.3	\$24.3	N/A	N/A

\*subset of all stem cell research N/A= Data not available

Source: NIH Budget Office, August 30, 2005

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# Why Is Federal Funding Important?

- Most basic research supported by NIH funds
- Basic research requires millions of dollars over many years
- Difficult to find private funding for research that is far from commercialization
- It will be difficult for ESC research to advance without federal funding

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# Who Is Overseeing Research Ethics in the U.S.?

- National Academies of Science
  - ➤ Issued recommended guidelines in April 2005
  - ➤ Scientific community developed guidelines
    - No government involvement
  - ➤ Purpose: enhance the integrity of privately funded early stem cell research by encouraging responsible practices
  - Urged all institutions to establish oversight committees; compliance is voluntary

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### What Are the Current Federal Restrictions?

- Bush August 2001 decision
- Limits federal funding to 78 stem cell lines eligible [global]
  - > 22 stem cell lines available [global]
  - Concerns about contamination, ability to use in actual treatments, and long-term viability of stem cells

Table: National Institutes of Health List of Human Embryonic Stem Cell Lines

	Number of Stem Cell Lines			
Name	Eligible	Available		
Bresagen Inc., Athens, GA *The cells in line BG04/hESBGN-04 failed to expand into undifferentiated cell cultures.	4	3*		
Cell & Gene Therapy Institute (Pochon CHA University), Seoul, Korea	2			
Cellaritis AB, Goteborg, Sweden *Cell line SA03/Sahlgrenska 3 withdrawn by donor.	3	2*		
CyThera, Inc., San Diego, CA *The cells failed to expand into undifferentiated cell cultures.	9	0*		
ES Cell International, Melbourne, Australia	6	6		
Geron Corporation, Menlo Park, CA	7			
Goteborg University, Goteborg, Sweden	16			
Karolinska Institute, Stockholm, Sweden *The cells failed to expand into undifferentiated cell cultures.	6	0*		
Maria Biotech Co. Ltd. – Maria Infertility Hospital Medical Institute, Seoul, Korea	3			
MizMedi Hospital - Seoul National University, Seoul, Korea	1	1		
National Center for Biological Sciences/Tata Institute of Fundamental Research, Bangalore, India	3			
Reliance Life Sciences, Mumbal, India	7			
Technion University, Haifa, Israel	4	3		
University of California, San Franscisco, CA	2	2		
Wisconsin Alumni Research Foundation, Madison, WI	5	5		
Total	78	22		

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# What's Happening in Kansas?

# Does KUMC Do Stem Cell Research?

- Mature Stem Cell Research
  - ► All research funded by NIH
  - > Focus areas:
    - Cancer research (via umbilical cord stem cells)
    - Treatment for stroke and other oxygendeprivation injuries to different organs
    - Strong program focused on bone marrow and haematopoietic stem cell transplants

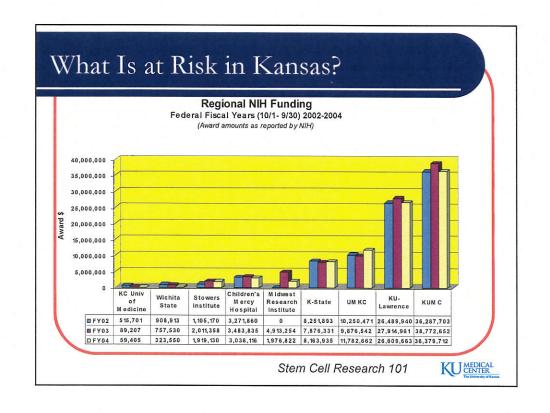
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## Does KUMC Do Stem Cell Research?

- Early Stem Cell Research
  - ➤ Three researchers studying 15 of the National Institutes of Health's approved early stem cell lines
  - ► All research funded by NIH
  - > Focus areas:
    - Placenta
    - Diseases associated with pregnancy
    - Diseases such as sickle cell anemia

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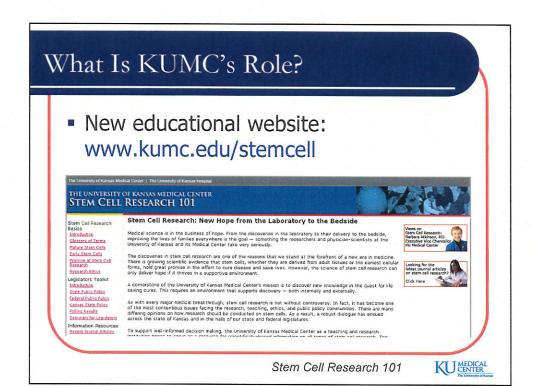


## What Is the Bottom Line?

- Respect people who have ethical objections to this work
- Stem cell research is causing a revolution in our understanding of human health
- Scientists want to compare ALL types of stem cells to each other
- We don't yet know what this will mean for treatment of human diseases; signs that it will have real impact
- Public wants this research to proceed

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# PRESERVE THIS Non-reproductive (therapeutic) Cloning

# **BAN THIS**Reproductive Cloning

