

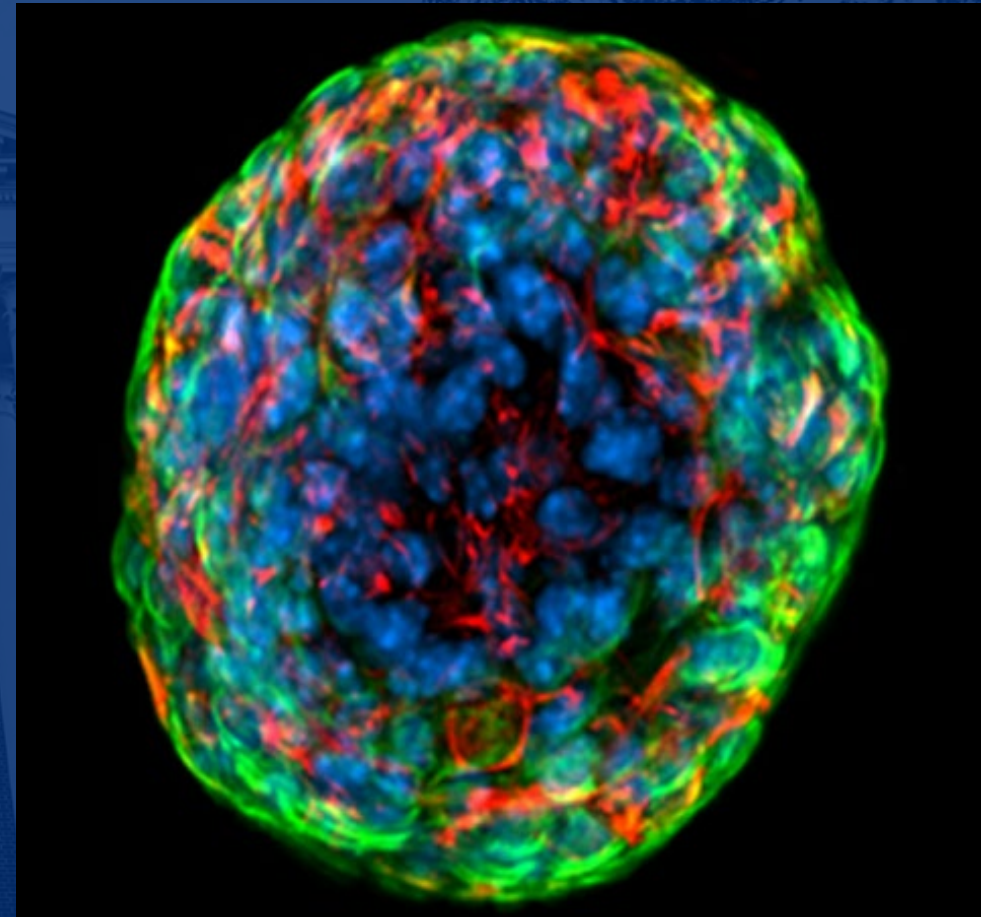


JOHNS HOPKINS

WHITING SCHOOL
of ENGINEERING

Cell and Tissue Engineering

Stem Cell History and Regulation, Part 2



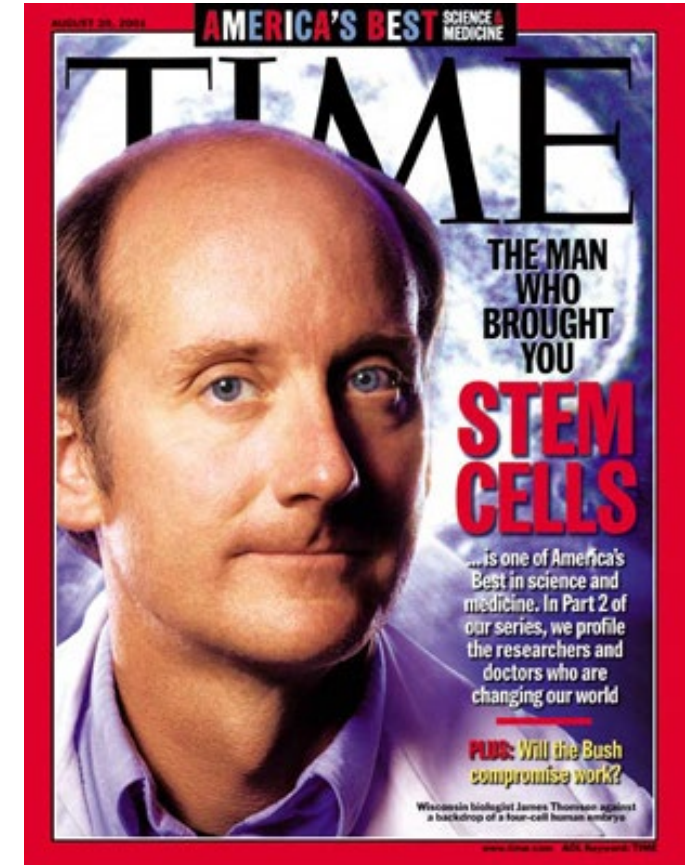
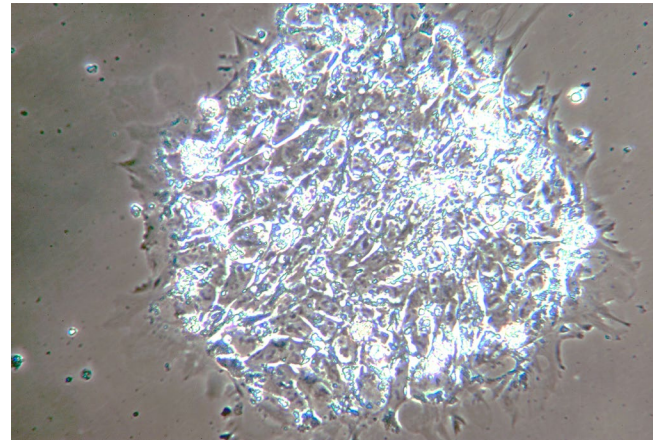
Timeline – embryonic stem cells

1998

James Thomson isolates human embryonic stem cells

Embryonic Stem Cell Lines Derived from Human Blastocysts

James A. Thomson,* Joseph Itskovitz-Eldor, Sander S. Shapiro,
Michelle A. Waknitz, Jennifer J. Swiergiel, Vivienne S. Marshall,
Jeffrey M. Jones



Timeline - US stem cell legislation

1999

NIH Guidelines for Research Using Human Pluripotent Stem Cells

- **only embryos “created for the purpose of fertility treatment”**
- **“in excess of the clinical need of individuals seeking such treatment”**
- **Informed consent**



Timeline – limited US hESC research

2001

President Bush permits federal funding for hESC research only on cells from embryos that have already been destroyed

21 → 16 approved hESC lines

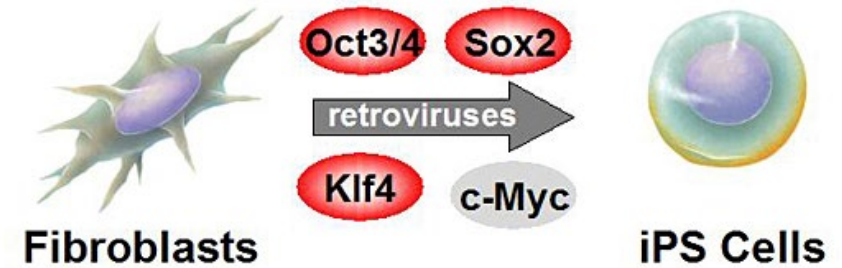
"the life and death decision has already been made"



Timeline – induced pluripotent stem cells

2007

**Yamanaka and Thomson
independently derive iPS
cells**



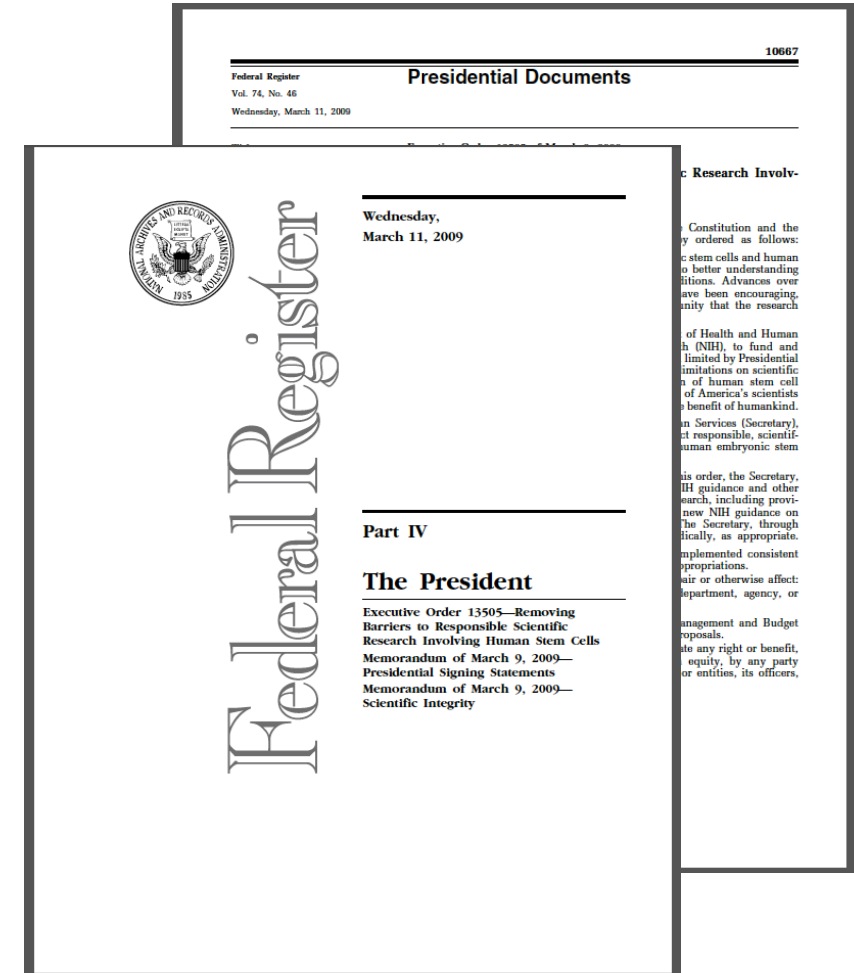
James Thomson and Shinya Yamanaka

Removing barriers to responsible scientific research involving human stem cells

2009 – Obama issued an executive order nullifying Bush's policy

"[NIH] may support and conduct responsible, scientifically worthy stem cell research including human embryonic stem cell research, to the extent permitted by law."

"That the potential [hESC research] offers is great, and with proper guidelines and strict oversight, the perils can be avoided." Obama, Signing the Executive Order, 3/09/2009



Current NIH guidelines



- No funding for the derivation of hESCs
- Funding of research using hESCs
 - Derived from embryos **created using IVF for reproductive purposes** (not research purposes or SCNT)
 - **No longer needed** for IVF purposes
 - Obtained from donors with **informed consent**
 - Donors are not paid and would not receive financial or any other benefit from commercial development generated from the donation if the research has scientific merit
- hESCs must be listed in the NIH Registry
- Does not require that the IVF physician be different from the hESC researcher

Timeline - clinical trials in stem cell research

2010

Geron initiates first clinical trial of hESC-based therapy



*Frozen GRNOPC1
Manufactured Product*



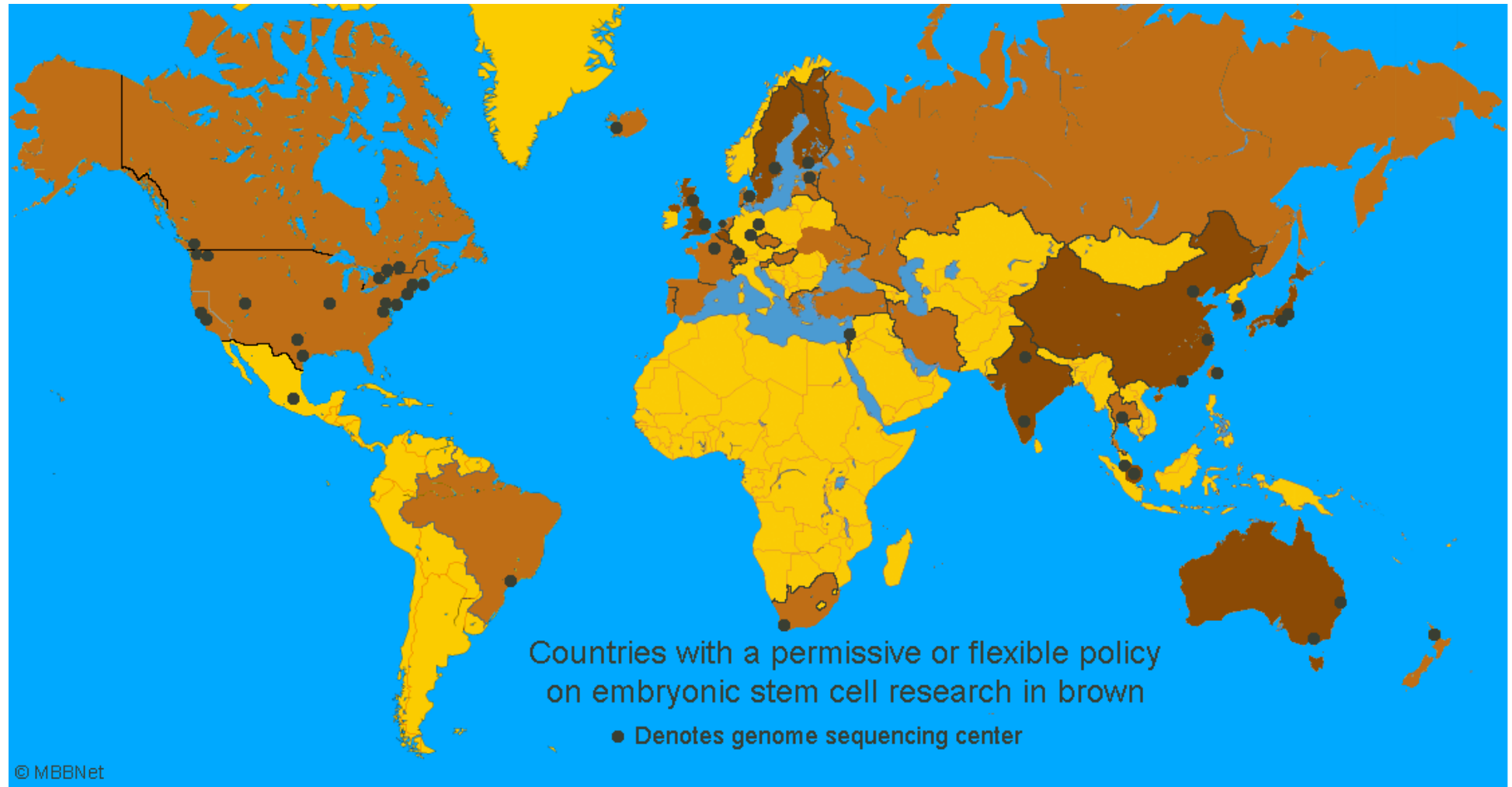
Advanced Stem Cell Therapy (ASCT)
is FDA approved for hESC therapy
for degenerative eye disease



Map of national policy on public funding for research

Map reflects

- Permissive
- Flexible
- Restrictive OR no established policy



NIH funding of stem cell research

Research/Disease Areas (Dollars in millions and rounded)	Stem Cell Research	Stem Cell Research - Embryonic - Human	Stem Cell Research - Embryonic - Non-Human	Stem Cell Research - Induced Pluripotent Stem Cell	Stem Cell Research - Induced Pluripotent Stem Cell - Human	Stem Cell Research - Induced Pluripotent Stem Cell - Non-Human	Stem Cell Research - Nonembryonic - Human	Stem Cell Research - Nonembryonic - Non-Human	Stem Cell Research - Umbilical Cord Blood/Placenta	Stem Cell Research - Umbilical Cord Blood/Placenta - Human	Stem Cell Research - Umbilical Cord Blood/Placenta - Non-Human
2008	\$938	\$88	\$150	+	+	+	\$297	\$497	\$46	\$38	\$9
2009	\$1,044	\$120	\$148	+	+	+	\$339	\$550	\$49	\$42	\$10
2009 ARRA	\$187	\$23	\$29	+	+	+	\$58	\$88	\$10	\$9	\$1
2010	\$1,099	\$126	\$175	+	+	+	\$341	\$570	\$42	\$40	\$5
2010 ARRA	\$187	\$40	\$20	+	+	+	\$74	\$74	\$8	\$7	\$1
2011	\$1,179	\$123	\$165	+	+	+	\$395	\$620	\$41	\$36	\$10
2012	\$1,374	\$146	\$164	\$206	\$175	\$48	\$504	\$653	\$47	\$43	\$8
2013	\$1,273	\$146	\$154	\$228	\$199	\$43	\$431	\$613	\$40	\$35	\$7
2014	\$1,391	\$166	\$150	\$313	\$280	\$49	\$443	\$627	\$34	\$28	\$7
2015	\$1,429	\$180	\$159	\$324	\$282	\$61	\$445	\$632	\$35	\$32	\$6
2016	\$1,516	\$206	\$146	\$374	\$335	\$56	\$457	\$652	\$42	\$33	\$10
2017	\$1,646	\$252	\$129	\$421	\$382	\$59	\$484	\$704	\$40	\$35	\$6
2018	\$1,824	\$278	\$130	\$507	\$468	\$68	\$518	\$758	\$39	\$36	\$4
2019	\$2,014	\$306	\$140	\$607	\$563	\$74	\$569	\$781	\$38	\$36	\$2
2020	\$2,105	\$309	\$141	\$657	\$613	\$73	\$608	\$830	\$35	\$31	\$5
2021 Estimated	\$2,150	\$317	\$144	\$672	\$627	\$75	\$620	\$846	\$36	\$31	\$5
2022 Estimated	\$2,229	\$329	\$149	\$697	\$651	\$77	\$642	\$880	\$37	\$32	\$6

State stem cell funding

State	Initial Funding	
California	622M	2004
Connecticut	10M	
Illinois	15M	
Indiana		
Maryland	15M	2006
Massachusetts	1M	
New Jersey	23M	2004 – First to appropriate state funds for embryonic stem cell research
New York	100M	
Ohio		First to appropriate funds for adult stem cell research
Washington	28M	
Wisconsin	1M	
Virginia		

Private stem cell funding

Private philanthropists

- 25M to USC
- 16M to UC-San Fran
- 75M to UC-Davis
- 100M to JHU (Bloomberg)



THE MICHAEL J. FOX FOUNDATION FOR
PARKINSON'S
RESEARCH



THE STARR FOUNDATION

Review of stem cell regulation

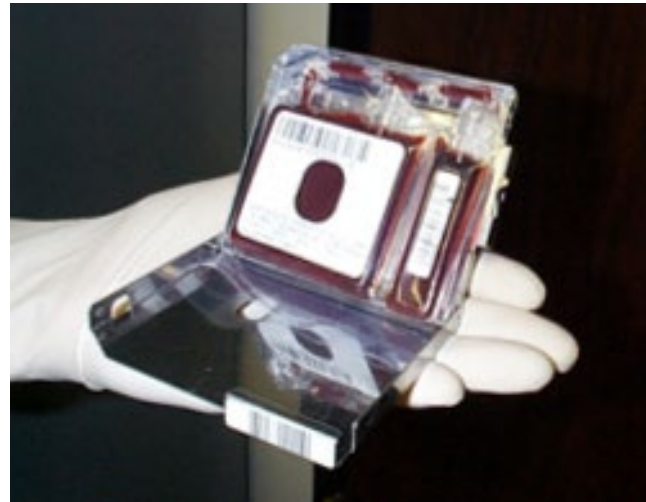
**The discovery of
stem cells**



**The Dicky-Wicker
Amendment**



**The discovery of cord
blood stem cells**



**Bush's Executive Order
The discovery of iPS cells
Obama's removal of the order**





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