

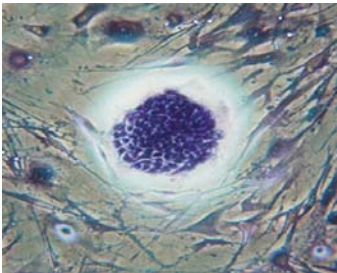
# Updates to Stem Cell Research Oversight

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IRB/SCRO Panel Meeting

August 10, 2010

Mario McKay Garcia



geron

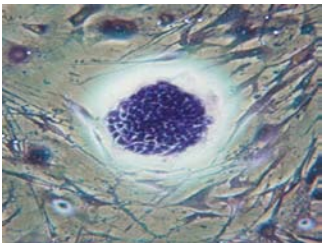


CIRM

# FDA lifts hold on Geron's hESC Clinical Trial

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- The Clinical Trial tests cells in patients with new spinal cord injuries
- FDA placed hold in August 2009 due to cysts forming on animals treated with the therapy
- Geron developed new markers and assays to ensure safety
- FDA lifted clinical hold July 30, 2010



geron

# CIRM Final Rule: SCRO Notification

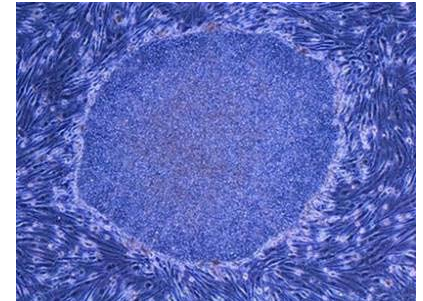
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**Effective Date is July 29, 2010**

Research involving

- purely in vitro research
- with the aim to create or use a covered stem cell line
- from non-identifiable cells
- and animal assays may be used to evaluate pluripotency

may not commence until IRB/SCRO receives  
**written notification** (rather than review)



iPS cells (AFP/Shinya Yamanaka-Kyoto University/File)

# CIRM Final Rule: SCRO Notification

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## Research involving

- CIRM-funded human subjects research
- with the aim to create or use a covered stem cell line from sources other than human gametes, blastocysts or embryos
- and animal assays may be used to evaluate pluripotency

may not commence until IRB/SCRO receives **written notification** (rather than review)

# CIRM Final Rule: Informed Consent

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- For embryos procured after November 22, 2006 consent is required from the oocyte **and** sperm donor
  - Prior to this date, consent from only the oocyte donor is sufficient if sperm donor is unknown
- For CIRM funded research with somatic cells collected after November 22, 2006
  - When CIRM-funded somatic cell research is for **transplantation into humans**, SCRO must confirm donors provided informed consent that fulfills section 100100.



# CIRM Section 100100

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- Derived cells or products may be kept for many years
- Plan to recontact donor if identity is retained
- Cell lines may be used in future studies not now foreseeable
- Cell lines may be used in research involving genetic manipulation
- Derived cells may be transplanted into humans or animals
- Donation is made without restriction on recipient
- Neither consent nor refusal to donate will affect medical care
- Donor will have no legal or financial interest from donation
- Donor may impose restrictions, but donated cells may not be used