

Independent Citizens' Oversight Committee



Interim Regulations Governing iPSC Banking Initiative

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San Francisco

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Background

- Concept approved by ICOC December 8, 2011
- 3 separate RFAs will be posted:
 - Disease Modeling /Tissue collection (up to\$4M)
 - Cell line derivation (up to\$16M)
 - Repository/Distribution (up to\$10M)
- IP and Industry Subcommittee met May 8, 2012 and by unanimous vote of those present passed a motion recommending approval of the Interim Regulations (substantially similar to those considered today)



Unique Aspects of Program Requires a Different Approach



- ❑ Current IP Regulations provide that Grantees own all IP generated; Here we want to maintain ultimate control through ownership
- ❑ Current IP Regulations permit Grantees to exclusively license the IP they develop; Here we want to encourage very broad access which could be limited by exclusive licensing
- ❑ Other examples where IP regulations are not applicable: (e.g. Invention & Licensing Reporting (100602), Publication Related Biomedical Material Requirements (100603), Licensing & Assignment of CIRM-Funded Inventions and Technology reporting provisions (100606), March in Rights (100610)



Key Provisions of Interim Regulations



- Ownership of cell lines: Lines which are developed through this funding will be owned by CIRM
 - Consistent with best practice: NIH's Center for Regenerative Medicine owns lines it is funding
- Publication: Will require acknowledgement of CIRM funding and identification of name of repository published where CIRM funded lines from the repository are used
- IP Regulations will Not apply
- The Grants Administration Policy applies in full
- The Scientific and Medical Accountability Standards applies in full



Other Controls

- Deposit Agreement (Between CIRM and Repository)
 - Fees charged to researchers; favorable pricing for Californian researchers
 - Prohibition on exclusively licensing of lines
 - Possible revenue sharing (ensuring repository is self sustaining)
 - Will require compliance with all laws including privacy laws



Recommendation



- Approval of the Interim Regulations

