Research Administrators Forum

Sponsored by
Office of Research Administration

Marcia Smith
Associate Vice Chancellor
Research Administration

January 14, 2010
Meeting Agenda

- Welcome and Announcements
  - Marcia Smith, ORA

- ARRA Reporting Update – Changes in FTE Calculation for Jobs Created and Retained
  - Marcia Smith, ORA
  - Terry Novorr, NPI
  - Neda Navab, SOM

- Update on Stem Cells
  - Steve Peckman, Broad Stem Cell Research Center

- NIH RCR Requirements
  - Ann Pollack, RPC

- ORA Portal Enhancements – Demonstration
  - Gloria Su, ORIS

- OCGA Update and S2S Grants Subaward Demonstration
  - Cindy Gilbert, OCGA
ARRA Reporting Update

Changes in FTE Calculation for Jobs Created and Retained

- Marcia Smith, ORA
- Terry Novorr, NPI
- Neda Navab, SOM
Arra Reporting Update

- New Guidance Issued
  December 18, 2009
- New FTE Calculation
- Retroactive Transfers
- Stipends
- Subawards In
- Process for Corrections after February 2, 2010
- Changes in ARRA Tools
ARRA Reporting Update

- New FTE calculation to be used beginning with the reports for the quarter ending December 31, 2009.
- Job estimates will be reported on a quarterly, rather than a cumulative, basis. Calculation no longer requires averaging FTEs across multiple quarters:

\[
\text{total effort paid with ARRA funds in the quarter} \div \text{full-time effort in a quarter} = \text{quarterly FTE}
\]
ARRA Reporting Update

Examples:
100% effort in one month of the quarter = .33 FTE

100% effort in one quarter and 50% effort in the next quarter =
  1 FTE in first quarter
  .5 FTE in next quarter

(Retroactive transfers will not be accounted for with elimination of cumulative averaging.)
ARRA Reporting Update

- Stipends must be counted as FTE on training grants and fellowships.
- Reports for ARRA awards that are subawards to UCLA must be reported through and submitted by EFM, even if the Prime contacts PI directly.
- Reports for subawards issued by UCLA are collected by OCGA and provided to PI for incorporation in PI’s report.
ARRA Reporting Update

Process for updating December 31st reports to incorporate new FTE calculation:

• All ARRA reports will be reopened on the ORA Portal
• Departments must review all reports, update them to apply the new FTE calculation, and resubmit to EFM
• Reports must be resubmitted even if there are no changes
• EFM will upload changes to the Federal reporting site
ARRA Reporting Update

- Demonstration of changes to ARRA Reporting Tools
Update on Stem Cells

Steve Peckman, BSCRC
Human Pluripotent Stem Cells: A patchwork of rules. What’s New???

January 14, 2010

Steven Peckman
University of California, Los Angeles
Eli & Edythe Broad Center of Regenerative Medicine and Stem Cell Research
A Patchwork of rules?
I thought President Obama changed everything…

Human embryonic stem cell research (hESC)

- Where we were?
- Where we are?
- How do we get there from here?
Pres. GW Bush Policy: Federally funded research permitted on ~22 useable hESC lines derived prior to Aug. 9, 2001.
What did President Obama say?

Overturned Pres. GW Bush’s Executive Order:

“The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research….”

- Pres. B. Obama: Executive Order March 9, 2009
Translating Executive Orders into Policy

We’re here to help you with your stem cell research. I’m from NIH and he’s a politician.....
This page will list human embryonic stem cell lines that may be used in NIH-supported research. Please check back later.

Scientists may also wish to know which lines have been submitted to NIH for consideration: Go to list of lines pending NIH review.

Go to NIH Stem Cell Information Page
Federal Registry of Approved Stem Cell Lines

Submit documentation of ethical acquisition to the Working Group of the Advisory Committee to the Director (ACD)

The Working Group makes recommendations to the ACD

The ACD will make recommendations to the NIH Director who will make final decisions about eligibility
### NIH Human Embryonic Stem Cell Registry

**Research Using These Lines is Eligible for NIH Funding**

The lines listed below are eligible for use in NIH funded research.


- **Eligible Lines:** 40 (in 3 Submissions)
- **Sorted by:** NIH Approval Number
- **Date/Time:** 01/13/2010 at 01:02 PM

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**December 2009 – January 2010**
## RESTRICTIONS ON USE OF THE LINES WITH FEDERAL FUNDING!

### NIH Human Embryonic Stem Cell Registry

**Research Using This Line is Eligible for NIH Funding**

<table>
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<th>Detailed information for selected cell line:</th>
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<td><strong>Line Name:</strong></td>
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### Provider Restrictions:

HUES line recipients must provide documentation of ESCRO (or equivalent ethical) review for the research planned with the requested lines to Harvard University.

### NIH Restrictions:

NIH-funded research with this line is limited to research consistent with the following language from the informed consent document: "These cells will be used to study the embryonic development of endoderm with a focus on pancreatic formation. The long-term goal is to create human pancreatic islets that contain β cells, the cells that produce insulin, for transplantation into diabetics."  

**Approval Date:** 12/14/2009
What happened at Harvard & NIH?

Harvard justified broad use of the hESC lines based on their IRB waiver that the PI obtain additional informed consent from donors:

1. Rapid advances in hESC research made it impossible to foresee the full range of the use of the lines at the time of the pancreatic project

2. Granting the waiver of additional informed consent under Federal human subjects regs [45 CFR 46.116(d)] assured that the additional uses will not compromise donor welfare or privacy.

3. The additional uses of the cell lines posed minimal risk to the donors, as the donors were self-defined, very much endorsed stem cell research as illustrated by their embryo donations, and agreed to both pancreatic research and research in general.

4. Re-contacting the donors posed greater than minimal psychological and privacy risks to the subjects

The NIH Director rejected the Harvard IRB waiver....
What if the hESC are not on the Registry?

• Approved under GW Bush (the gold standard lines)
  – WiCell (UofW)
  – UCSF
  – Bresagen (Australia)

• On-going NIH supported hESC research approved before 4/17/09:
  – May continue through the remainder of the currently approved competitive segment of the award
  – May not initiate new uses of hESC in funded project unless cells are on new NIH Registry & grantee notifies NIH
  – Competitive renewal must use only lines in new NIH registry

Non-Federally Approved Cells:

Who decides the adequacy of the provenance of hESC lines?

• California Law

  – Non-human subjects stem cell research: Stem Cell Research Oversight (SCRO) committee decides whether the proposed use of the cells is consistent with the promises made in the consent form.

  – Some agencies may not include the same restrictions on the use of hESC lines as the Federal Gov’t

  – Think about the scientific purpose of the experiment and whether segregation of funds is required.
How do I get a human pluripotent stem cell line?

• Identify the line you want from the NIH Registry or other source (some lines are available from the UCLA Broad Stem Cell Research Center Core Bank).

• Submit a UCLA Embryonic Stem Cell Research Oversight (ESCRO) committee application for review

• Complete the appropriate Material Transfer Agreement (MTA) and submit it to the Office of Intellectual Property Administration (OIPA)
“Our progress as a nation and our values as a nation are rooted in free and open inquiry. To undermine scientific integrity is to undermine our democracy.”

- B. Obama: 4/27/09
Research Policy & Compliance

Ann Pollack
Assistant Vice Chancellor – Research
January 14, 2010
NIH Update on Requirements for Instruction in the Responsible Conduct of Research

(Notice NOT-OD-10-019)
Responsible Conduct of Research

- Defined as the practice of scientific investigation with integrity
- Involves awareness and application of established ethical principles and established professional norms in activities related to scientific research
NIH Update on Instruction in RCR

- NIH Notice issued November 24, 2009
- UCLA Deans, Directors memo issued January 8, 2010
- *UCLA Principal Investigators are responsible for design of plans on a grant-by-grant basis*
NIH Update on Instruction in RCR

- New proposals submitted on or after January 25, 2010, must include plans for providing RCR instruction
- Non-competing continuation applications (progress reports) submitted for the January 1, 2011 deadline must report on instruction provided
- Applies to all training grants (institutional and individual), to career awards, and to other grants with training components
NIH Update on Instruction in RCR

- No prescribed curriculum
- Principles, key concepts, best practices outlined
- Online education alone is not sufficient (except for short term training programs or in unusual circumstances)
NIH Update on Instruction in RCR

- Peer review of proposal will include evaluation of RCR plans
- Individualized plans will be evaluated and rated as acceptable or unacceptable
- Fundable applications with unacceptable RCR plans will not be funded until acceptable plans are provided
Topics included in most acceptable plans

- Conflict of interest
- Protection of human and animal subjects
- Laboratory safety
- Ethical issues such as
  - The scientist as a responsible member of society
  - The impact of research on society and the environment
- Peer review
- Data acquisition, management, sharing, and ownership
- Research misconduct and responding to allegations of research misconduct
- Collaborative research
- Authorship and publication practices
NIH Expectations

- Faculty are encouraged to contribute to formal and informal instruction.
- RCR plans should include substantive contact hours between participants and faculty.
- Instruction is expected to occur during each career stage.
- Senior fellows and career award recipients may participate as lecturers or discussion leaders.
Where to find the notice:

Notice NOT-OD-10-019 is accessible at:

ORA Portal Enhancements

Gloria Su, ORIS
ORA Portal Enhancements

 Proposal Detail Drill-Down

- Re-enabled on Proposal and Award Statistics Reports (General Statistics tab)
- New security measures in place
- Default access is for home department only
- Additional access requires approval from CAO of department to which you are requesting access
- Email portal@research.ucla.edu and indicate request for Proposal Detail access
Search by Doc Upload Date

- New “Doc. Upload Date Between” field added to Award Status & Synopsis Report (Post-Award tab)
- Allows departmental users to search for awards within a specified date range
- Assists departments with the distribution of new award synopses
ORA Portal Enhancements

❖ Subscribe to ORA News
  • New link added to Portal homepage (top right hand corner) with instructions for subscribing to ORA News
  • Easier to locate
  • Encourage your staff and colleagues to sign-up if they haven’t already
  • Vehicle for communicating important news and updates
ORA Portal Enhancements

- Questions, comments and feedback are welcome at
- portal@research.ucla.edu
S2S Grants
Subaward Demonstration

Cindy Gilbert
Electronic Research Administration Coordinator
Office of Contract and Grant Administration

January 14, 2010
Announcements

- NIH Salary Cap $199,700
  - NOT-OD-10-041

- NIH Inflation Allowance of 2% for FY 2010
  - NOT-OD-10-039

- NIH Error Correction Window
  - NOT-OD-10-042

- Grants.gov Outage February 6 – 9
Announcements

❖ System Upgrade
  • Adobe Forms-B
  • NIH Training Applications
  • NSF Accepting Grants.gov Apps
  • Adobe Subaward Import

❖ S2S Grants Resources
  • http://www.research.ucla.edu/ocga/S2SGrantsInfo/index.htm
S2S Grants Subawards

Adding subawards to UCLA proposals in S2S Grants

Three Methods
  • Create New
  • Import from Cayuse
  • Import from Adobe Forms

Questions, Comments, Feeback
s2sgrantshelp@research.ucla.edu