Agenda

* Welcome and Introductions
  Marcia Smith, AVC - ORA

* Update on Effort Reporting Status
  Shannon McGarry, CAO - Institute for Research on Labor & Employment
  Greg Swindell, Assistant Director - EFM

* Preparing for NSF Audit
  Marcia Smith, AVC – ORA

* OHRPP Revised Consent Form Templates and Updated Guidance
  Sharon Friend, Director – OHRPP

* OCGA Processing of Fellowships
  Cindy Gilbert, eRA Coordinator - OCGA
  David Jaquez, Manager & DRA - Department of Pathology & Laboratory Medicine

* Questions and Discussion
Effort Reporting System

- Greg Swindell
  Assistant Director, Compliance and Cash Flow Extramural Fund Management

- Shannon McGarry
  Chief Administrative Officer
  Institute for Research on Labor and Employment
Historical Effort Reporting Metrics

As of 4/23/10

- Completion Rates at UCLA
  - ~80% overall completion rate
- Open Reports
  - 24,788 open reports

As of 4/13/11

- Completion Rates at UCLA
  - 72% certification rate for Summer 2010
  - 92% certification rate on Campus
- Open Reports
  - 9,321 open reports out of 120,313
As of 8/9/11

 Completion Rates at UCLA
  • 79.5% certification rate for Fall and Winter 2010-2011
  • 94.7% certification rate on Campus

 Open Reports
  • 6,996 open reports out of 131,045

 Reports Certified between 4/13 and 8/9/2011
  • 13,057 moved to fully certified status
ERS Initiatives Update

- Memo to Dean’s regarding ERS sent out last week
  - Highlighted Progress
  - Distributed links to new UCOP PI Briefing

- Link to the “Effort Reporting Briefing for Investigators”
  - You can find the training here: [http://www.research.ucla.edu/efm/EffortRpt.htm](http://www.research.ucla.edu/efm/EffortRpt.htm)

- Continuing to work through the backlog of reports requiring certification

- Installing and testing latest version (10.6) of ERS software

Questions in the meantime? Contact ershelp@research.ucla.edu
Individual Fellowship Applications/Awards
Transition from Graduate Division to ORA

Cindy Gilbert
eRA Coordinator
Office of Contract and Grant Administration

David Jaquez
Departmental Research Administrator
Department of Pathology and Laboratory Medicine

June 11, 2011
Prior to July 1, 2011

- Some individual fellowships, most notably PHS/NIH NRSA, managed by OPVSS in Graduate Division
- ORA only set-up fund and filed financial reports
- Day-to-day oversight and administration was responsibility of department in coordination with Grad Division
Effective July 1, 2011

- ORA is primarily responsible for management of extramurally funded fellowships.
- Grad Division involvement is limited to disbursement of stipends.
- Day-to-day oversight and administration is the responsibility of the department and units in ORA.
Proposals

- Should always be reviewed and approved by OCGA (or DRA) regardless of sponsor requirements for institutional signature

- **Goldenrod:**
  - List the mentor as the PI (box 1)
  - Identify the fellow in the *Fellow Name* field in box 5

- For PHS applications *only* [PHS PI Signature Form](#) must be signed by the Fellow

- Financial Interest Disclosure forms *not* required

- Submit to OCGA for review/approval *at least* five business days prior to the deadline
  - Check with DRAs for specific departmental requirements
Awards

- Only OCGA can accept awards – *not* fellows, mentors, or departmental administrators
- EFM should be notified of any checks that are deposited by departments
- Award synopsis and account set-up handled like any other award
Awards

Contact:

- Grad Division – processing of Fellowship Award Transmittal (Form 10)
- OCGA
  - non-financial reporting/close-out
  - administrative actions/questions
- EFM – financial reporting/close-out
Whew!!! We made it through the first F-type application deadline

30 proposals submitted

High level guidance available on OCGA website:

http://www.research.ucla.edu/ocga/NRSA.htm
# PHS/NIH NRSA

## Who Does What?

<table>
<thead>
<tr>
<th>Form</th>
<th>Institutional Signature Required?</th>
<th>Signing Official(s)</th>
<th>Paper or Electronic?</th>
<th>Applicable Project Type(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application/Proposal (SF424)</td>
<td>Yes</td>
<td>OCGA Grant Analyst or DRA</td>
<td>Electronic – UCLA S2S Grants</td>
<td>Individual Fellowships (F type)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Institutional Training (T type)</td>
</tr>
<tr>
<td>Statement of Appointment (PHS 2271)</td>
<td>No</td>
<td>n/a</td>
<td>Electronic – NIH xTrain</td>
<td>Institutional Training (T type)</td>
</tr>
<tr>
<td>Activation Notice (PHS 416-5)</td>
<td>Yes</td>
<td>OCGA Grant Analyst</td>
<td>Paper</td>
<td>Individual Fellowships (F type)</td>
</tr>
<tr>
<td>Payback Agreement (PHS 6031)</td>
<td>No</td>
<td>n/a</td>
<td>n/a</td>
<td>Individual Fellowships (F type)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Institutional Training (T type)</td>
</tr>
<tr>
<td>Progress Report for Continuation Support (PHS 416-9)</td>
<td>Yes</td>
<td>OCGA Grant Analyst or DRA</td>
<td>Paper</td>
<td>Individual Fellowships (F type)</td>
</tr>
<tr>
<td>NRSA Termination Notice (PHS 416-7)</td>
<td>Yes</td>
<td>EFM Team Supervisor</td>
<td>Electronic – NIH xTrain</td>
<td>Individual Fellowships (F type)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Institutional Training (T type)</td>
</tr>
</tbody>
</table>
PHS/NIH NRSA

Coming updates:
- Estimating total on F-type applications
- Details about Fellow biosketches
- Reporting of prior NRSA funding
- Other Suggestions? Send e-mail to: cgilbert@research.ucla.edu
Hints and Tips:

- Dual Doctoral Degree Fellowships (F30); be aware of differences in student fees between academic and professional programs (e.g.; PhD versus MD).

- Termination Notices
  - routed to Belinda Tucker prior to June 30;
  - still in status of “Pending BO”
  - PI needs to “Recall” these notices in xTRAIN;
  - and
  - Re-route to the EFM Supervisor
QUESTIONS???
OHRPP Update

Sharon Friend, Director
August 2011
Using the UCLA Biomedical Consent Form Template
Consent, Assent and Screening Templates

Rather than dividing the templates into biomedical and behavioral templates, they are divided into the templates used for minimal risk studies, greater than minimal risk studies or for both. In addition, please see guidance and references at the bottom of this page. If you're unsure which template to use, please contact the OHRPP office.

Minimal Risk Research Informed consent Templates (expedited or exempt)
- Consent Template for Subjects Recruited from Student Subject Pools
- Consent Template (includes signature) - for minimal risk studies
- Parent Permission Template (parents provide permission for child to participate) - for minimal risk studies
- Parent Consent Template (parents complete research procedures themselves) - for minimal risk studies
- Oral Consent Script Outline
- Study Information Sheet (no signature)

Greater than Minimal Risk Research Informed Consent Templates (full committee review)
- Consent Template (with section-by-section hyperlinks to guidance) - for greater than minimal risks studies (biomedical focus) New!
- Consent Template (with one hyperlink to guidance) - for greater than minimal risk studies (biomedical focus) New!
- NCI-UCLA Biomedical Consent Template - for greater than minimal risk studies (can be used for all oncology)
- Humanitarian Use Device (HUD) Consent Template New!

Templates for Minimal Risk and More Than Minimal Risk Research
- Addendum Consent Template for Non-Treatment Studies (for new procedures, risks)
- Addendum Consent Template for Treatment Studies (for new procedures, risks)
- Adolescent Assent Template for Non-Treatment Studies (Age 13-17)
- Child Assent Template (Age 6-12)
- Screening Script for non-Treatment Studies
- Screening Script for Treatment Studies

Standards, Sample Language & Comprehension Tools
- Behavioral Consent Form Standards and Sample Language
- Medical Consent Form Standards and Sample Language New!
- PRISM Readability Tool Kit New!
- Self-Certification of Surrogate Decision Makers for Potential Research Subject’s Participation in UC Research (Only to be used when approved by IRB)
- Subject Comprehension Assessment Tool

Other References
- Research Participant’s Bill of Rights - available in 34 languages
- Conducting Risk-Benefit Assessments New!

Feedback
We appreciate your suggestions for improving templates and/or adding sample language to the standards documents. Please email sfriend@research.ucla.edu to provide your feedback.

© Copyright UC Regents 2011. All Rights Reserved.
Improved Readability, Better Comprehension

- **Question and answer format**
  - Assists in reading comprehension
  - Function like FAQs

- **Use of active voice**
  - Headings in 1st person
  - Responses in 2nd person

- **Plain language, conversational style**
  - 6-8th grade reading level (USA Today newspaper)
  - When read aloud, it sounds like a conversation
New Consent Standards Document

- General consent preparation instructions
- **Section-by-section** instructions and guidance (e.g., what to include in the risks section)
- Sample consent language
Required sections are the basic elements of informed consent (per regulation) and must be in every consent document*

Optional sections are the additional elements of informed consent and should be included if they apply to the study

*unless an alteration is approved by IRB; minimal risk research only
Very little of the template and standards language is required to be used; however, the suggested language is:

- Crafted with readability & comprehension in mind
- Endorsed by IRB members
  - IRBs might request language from these documents when alternate language is not in lay language.
  - Example: costs language for insurance billing
Required Language is Required

Do not alter it!

- UC(LA) treatment and compensation for injury
- Collection and use of specimens
- April 2012: Clinicaltrials.gov statement
Updated and New Guidance
Researcher Focused

- Updated Formats
- Improved Readability
- Table of Contents for Each Guidance
- Linked References
- Examples Provided
- One-Page Tip Sheets or Quick Guides when Possible
New Guidance

- Determining When Use of Data and Specimens Requires IRB Review
- Conducting Risk-Benefit Assessments and Determining Level of IRB Review
- ClinicalTrials.gov Registry
- Use of Drugs and Biologics in Clinical Research and Treatment
- Media Interviews
Updated Guidance

- Obtaining and Documenting Informed Consent
- Research Involving Multiple Performance Sites or Collaborations
- Post-Approval Reporting Requirements—Summary Sheet
- Reporting Suspected Abuse of Children, Elderly and Others