Office of Sponsored Research Services (OSRS)

RA Forum
September 2012

OSRS Updates
**Before**

Faculty and Departments

- Proposal Submission
  - Federal & Found. Research Grants SoM
  - Federal & Found. Research Grants DC
  - Federal Contracts DC & SoM
  - Industry Lab Research Contracts
  - Industry Clinical Trials Contracts

**Process**

- OVCR RAS OSRS-SoM
- OVCR RAS OSRS-DC
- OVCR OTM
- SoM CCS (SoM CFO)

**Exceptions:** VCR

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**After**

Faculty and Departments

- Proposal Submission
  - Grants
  - Contracts

**Process**

- OVCR RAS-OSRS Grants
- OVCR RAS-OSRS Contracts
- SoM CCS Industry Clinical trials

**Exceptions:** VCR
OSRS Contracts Update

Process Improvement Initiative Updates

Industry-Sponsored (Non-Clinical) Research Agreements (SRAs) and Service Agreements (SAs)

- The processing of SRAs and SAs have moved from the Office of Technology Management (OTM) to the OSRS, effective July 1, 2012.
- Nathan Collins, Interim Senior Contracts Manager and Export Controls Officer, is overseeing the transition and management of SRAs and SAs.
- To support the initiative, Molly Gaschler and Kathy Leiva-Rosario, Contracts Coordinators, have moved to 276 N. Skinker, Suite 220, to consolidate the OSRS contracts team into one location.
Process Improvement Initiative Updates

OVCR/OSRS and SoM/CCS Contracts Partnership

- The contracts staff from the School of Medicine’s Center for Clinical Studies has completed its move to 276 N. Skinker, Suite 220.
- Cathy Berg, Terry Krupp, Melissa Schonlau and Dan Riordan, Contracts Specialists, and Cheryl LaRue, Contracts Secretary, are now co-located with the OSRS contracts team.
- A new consolidated contracts webpage will soon be available at http://research.wustl.edu/PGC/Pages/SubagreementsContracting.aspx. Look for upcoming announcements regarding its release.

Service Agreements

Distinguishing Service Agreements from Research Agreements

Service Agreements (SA):

Definition: Fee for Service agreement in which services are performed in accordance with specifications or protocols and without any scientific input into the service specifications or protocol by WU PI or other employee. No basic or applied research will be conducted during the provision of the service.

Criteria:
- No inventions or discoveries resulting from grant funding or industry sponsored research can be included in the deliverables of the service.
- WU or PI will not own data, results or intellectual property resulting from the service.
- PI and any WU employee may not publish on the service.
- PI and any WU employee may not use the results of the service for any other purpose.
- Only funding from the service recipient will be used in the service.
- Students will not receive any academic credit for their participation.
Service Agreements

Distinguishing Service Agreements from Research Agreements

**Sponsored Research Agreement (SRA):**

**Definition:** Document that describes the scope of work and budget to be undertaken by the PI during the term of the project.

**Criteria:**
- Systematic study intended to increase knowledge or understanding of the subject being studied.
- WU will own the data, results or intellectual property resulting from the project.
- Data may be used for other purposes as defined by the PI.
- PI retains the right to publish.
- Reports required.

<table>
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<tr>
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<th>Research</th>
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<tr>
<td>No Scholarship</td>
<td>Scholarship (conception, design, execution, interpretation of data) – “basic research”</td>
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<tr>
<td>Protocol implementation, raw data analysis for reporting &amp; QC</td>
<td>Hypothesis testing, methods design, experimental conduct, results analysis for hypothesis testing &amp; conclusions</td>
</tr>
<tr>
<td>Outcomes and deliverables are predefined or expected</td>
<td>Research question to be answered</td>
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<tr>
<td>WU cannot use deliverables or materials for any other purpose outside the service</td>
<td>Deliverables and data/results may be used for further WU research and educational purposes</td>
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<tr>
<td>Intellectual property is owned by the service recipient</td>
<td>Intellectual Property is owned by WU</td>
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<tr>
<td>No publication of results/deliverables</td>
<td>Publication of results permitted</td>
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<tr>
<td>No funding other than from the service recipient</td>
<td>Multiple funding sources may be used</td>
</tr>
<tr>
<td>Funding managed by the department</td>
<td>Funding managed by OSRS and SPA</td>
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</table>
Service Agreements

Process

• Service Agreements are processed in OSRS and are overseen by Nathan Collins.
• Contract managers work with the PI, department and/or Core Facility to put agreements in place and negotiate directly with the service recipient.
• Please submit the service agreement intake form to OSRS – include:
  ➢ Description of services and costs
  ➢ Approved overhead rate
  ➢ Company information
  ➢ PI acknowledgement
• Service Agreement is signed only by an authorized WU official.
• Income received from performance of the services is managed by the department business manager (not SPA).
• For questions, please contact Nathan Collins, collinsn@wustl.edu, 935-7551.

OSRS Grants Update
OSRS Grant Team Staffing Update

New Grant Analyst started 9/1/12, reporting to Dyanna Vitale

Brittany Douglas
Submission and Award Data

<table>
<thead>
<tr>
<th>Campus</th>
<th>Proposals Submitted</th>
<th>Awards Received</th>
<th>Award Dollars</th>
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<tbody>
<tr>
<td>Danforth Schools</td>
<td>704</td>
<td>372</td>
<td>$84M</td>
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<tr>
<td>School of Medicine</td>
<td>3,020</td>
<td>1,774</td>
<td>$536M</td>
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<tr>
<td>Total</td>
<td>3,724</td>
<td>2,146</td>
<td>$620M</td>
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Tips & Reminders

S2S Applications – Roles & Responsibilities

1. DA creates the PDS doc and routes PDS doc to GA for review.
2. GA reviews PDS doc for:
   - General information
   - Compliance
   - Key personnel detail
   - Budget
   - Correct data entry to ensure smooth S2S transmission for known Grants.gov issues, such as:
     - Checking direct costs-limited budgets (e.g., modulars) for rounding issues
     - OSRS email included
     - Federal identifier
     - PI credentials
Tips & Reminders

S2S Applications – Roles & Responsibilities

3. GA works with DA to correct errors.
4. GA approves PDS doc, which locks the budget. DA cannot modify budget after this point.
5. DA sends hard copy to GA for final approval (PC form, compliance approvals, budget justification, resources, etc.).
6. GA reviews hard copy; once approved, checks the “Central Area Approval Box” in the PDS doc.
   • This allows DA to submit electronically via S2S to Grants.gov to agency.

7. DA works with PI to complete and attach all required docs, including scientific narrative.
   • Note: this can also coincide with prior steps.
8. DA “builds and previews forms”.
   • Review to ensure the forms (cover page, budget pages, etc.) were electronically “translated” from PDS to the NIH application forms as expected.
9. DA submits application to agency.
Tips & Reminders

S2S Applications – Roles & Responsibilities

10. GA works with DA to check and repair any Grants.gov or eRA Commons system transmission errors.

11. DA or PI or other PI delegate logs into NIH eRA Commons, after it is received error-free, to verify application was transmitted correctly from Grants.gov, including all form pages, charts, figures, scientific narrative, etc.

Top 10 S2S Tips and Reminders

1. Start and finish the process early.
2. Congressional District format = MO-001.
3. Complete the PI Credentials field (=eRA Commons ID) for all PD/PIs.
4. Ggov roles are required for all Senior Key Personnel, including Other Significant Contributors.
5. Detailed Budgets – all individuals in the Personnel category must have effort greater than 0.
7. All attachments must be in PDF format and the file name cannot have special characters or spaces.
8. Before submitting, “build and preview” forms to ensure the forms (cover page, budget pages, etc.) were properly translated from PDS to the NIH application forms.
9. Applications must be error free at the agency (e.g. eRA Commons) by 5:00 pm on deadline day.
10. View in NIH ERA Commons to verify application was transmitted correctly from Grants.gov, including all form pages, charts, figures, scientific narrative, etc.
Addresses on Forms, Letters, Etc.

To be properly read and delivered by the United States Postal Service (USPS), correspondence must include:

• Second (2nd) from bottom line: **Street Address** ONLY
• Bottom line: **City, State, Zip Code** ONLY

Example:

Washington University
Sponsored Projects Accounting
Campus Box 1034
700 Rosedale Avenue
St. Louis, MO 63112-1408

Teri Medley’s Information

Please change all forms accordingly.

<table>
<thead>
<tr>
<th><strong>School of Medicine:</strong></th>
<th><strong>Danforth:</strong></th>
</tr>
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<tbody>
<tr>
<td>Teri Medley, Director of Grants, OSRS</td>
<td>Teri Medley, Director of Grants, OSRS</td>
</tr>
<tr>
<td>Washington University</td>
<td>Washington University</td>
</tr>
<tr>
<td>Campus Box 8018</td>
<td>Campus Box 1054</td>
</tr>
<tr>
<td>660 South Euclid</td>
<td>One Brookings Drive</td>
</tr>
<tr>
<td>St. Louis, MO 63110</td>
<td>St. Louis, MO 63130-4899</td>
</tr>
<tr>
<td>Phone: 314-747-4134</td>
<td>Phone: 314-935-5889</td>
</tr>
<tr>
<td>Fax: 314-362-0315</td>
<td>Fax: 314-935-5862</td>
</tr>
<tr>
<td>Email: <a href="mailto:msosrs@wustl.edu">msosrs@wustl.edu</a></td>
<td>Email: <a href="mailto:dcosrs@wustl.edu">dcosrs@wustl.edu</a></td>
</tr>
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</table>
Clarification: Time Limit on NIH Resubmission Applications
NOT-OD-12-128

After thirty-seven months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the thirty-seven month time period.
NIH Updates

Changes Involving Human Subjects in Active Awards That Require Prior NIH Approval
NOT-OD-12-129

- From non-human subjects research to human subjects research (exempt or non-exempt)
- From exempt to non-exempt human subjects research
- From “No Clinical Trial” to “Includes a Clinical Trial”
- The new inclusion of subject populations that are covered by additional regulatory protections (e.g. pregnant women, human fetuses, and neonates; prisoners; or children)
- Any change to the study protocol that would result in an overall increase in risk level for subjects, including physical, psychological, financial, legal or other risks.
- New information that comes to light after a study is underway which indicates a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.

NIH Updates

Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards)
NOT-OD-12-130

Delayed Onset awards generally fall into one of three broad categories:

- Single project awards in which results from initial pre-clinical research are needed before the human subjects research can be fully planned.
- Clinical research networks or consortia often funded as cooperative agreements or multi-project awards, that plan to add new protocols over the course of the award.
- Award mechanisms that include funds for small projects that will be selected and funded by the awardee (e.g. pilot projects for junior faculty).
NIH Updates

Pilot Processes for Submitting Post Award Relinquishing Statements to NIH NOT-OD-12-132

- Original institution will be able to submit a post-award relinquishing statement through the eRA Change of Institution module.
- New institution will be able to view a relinquishing statement through the eRA Change of Institution module in eRA Commons.
- The relinquishing statement may be submitted electronically even if the corresponding application is submitted on paper.

NIH Updates

Pilot Processes for Post-Award Change of Grantee Organization Applications to NIH NOT-OD-12-134

- NIH will publish a single parent Funding Opportunity Announcement (FOA) for all post-award Change of Institution (Type 7) requests.
- Pilot is only available for post-award Change in Grantee Organizational Status applications for activity codes currently submitted electronically through Grants.gov (e.g. R01, R21, K08).
**NIH Updates**

**NIH Special Council Review of Applications from PDs/PIs with More Than $1.0 Million Direct Costs in Annual NIH Support**

**NOT-OD-12-140**

- Advisory Council members will provide additional consideration of new and renewal applications from well-supported investigators who currently receive $1 million or more in direct costs of NIH funding to support Research Project Grants (e.g. R00, R01, R03, R21, R37, U01)
- This policy does not represent a cap on NIH funding.
- Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the SCR threshold along with a justification of the IC’s recommendation to consider for funding or not consider for funding.
- Effective September 2012.

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**NIH Updates**

**Research Performance Progress Report (RPPR) Module and Training Webinar Available to NIH Grantees**

**NOT-OD-12-142**

- RPPR is an initiative to establish a uniform format for interim performance reporting on Federally-funded research and research-related activities.
- On October 19, 2012, all grantee institutions will have access to the NIH RPPR for most Streamlined Non-competing Award Process (SNAP) and Fellowship awards.
- Be aware: decide which progress report format to use (RPPR or eSNAP) before starting the process in the eRA Commons. Once a progress report has been initiated as either an RPPR or an eSNAP, the only way to change the progress report format is with the assistance of the eRA Help Desk at Commons Support. It may take eRA up to 2 business days to reset the progress report so the user can initiate a progress report in a different format.
- Cont’d.
NIH Updates

Research Performance Progress Report (RPPR) Module and Training Webinar Available to NIH Grantees (cont’d.)

**NOT-OD-12-142**

- Training on the use of the new NIH RPPR will be provided via webinar on October 17, 2012.
- NIH expects to require use of the RPPR for most SNAP awards and Fellowships in the spring of 2013.

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**RECO / OSRS**

Conflict of Interest (COI)

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Washington University in St. Louis
Conflict of Interest

Per Federal Regulations, Revised WUSTL Research Conflicts of Interest Policy is in Effect as of August 24, 2012

In PDS, when generating PC Form, new tab labeled “COI Disclosure List”

- Lists individuals responsible for the design, conduct, or reporting of the research on the project (i.e. covered individuals) and must include the following types of individuals (with or without a WU appointment).
  - The following individuals will populate from the PDS doc:
    - The PI/PD
    - Any individual identified as a key person (which includes mentors and fellows on individual fellowship grants)
    - Any individual identified as a co-investigator/co-PI
  - The following individuals must be manually added in the COI Disclosure List tab:
    - Any other individuals the PI designates as independently involved in the design, conduct, or reporting of the research

This list must match the list on the PC Form that is submitted to OSRS.

Conflict of Interest

Revised PC Form with New Conflicts of Interest Language

Revised language is incorporated into the last page of the PC Form as part of the “Principal Investigator Certifications and Signatures” and reads as follows:

I certify, as Principal Investigator/Project Director, all persons responsible for the design, conduct, or reporting of the research on this project, as indicated below, have an up-to-date financial disclosure statement, as required by the sponsoring agency; and I understand failure of any individual, involved in the design, conduct, or reporting of the research, from maintaining the necessary disclosures during the period of award and/or complying with the Research Conflicts of Interest Policy and corresponding procedures will result in a review for non-compliance and, when applicable, sanctions for non-compliance.
Conflict of Interest

Revised PC Form with New Conflicts of Interest Language

• By signing the PC Form the PI is attesting that the above statement is true.
• These changes will help minimize delays in your grant submission once it arrives in OSRS.
• The revised PC Form is required for all proposals submitted to OSRS beginning August 24, 2012 regardless of the due date of the application.

Conflict of Interest

Outgoing Subcontracts (when WUSTL is prime) Changes

Revised Letter of Intent (when WUSTL is prime) now includes FCOI verbiage.

XYZ Institution:

☐ has a financial conflicts of interest policy that complies with 42 CFR Part 50.
☐ will adhere to the financial conflicts of interest policy of Washington University which does comply with 42 CFR Part 50.
Conflict of Interest

Outgoing Subcontracts (when WUSTL is prime) Changes (cont’d.)

OSRS will accept, when required by an agency*, one of the following to satisfy the COI assurances and certifications required at the time of submission, prior to application being signed, of the grant/contract:

1. Letter of Intent from the subrecipient providing the appropriate assurances and certifications regarding COI;
2. Confirmation that the subrecipient has certified compliance via the Federal Demonstration Partnership’s FCOI Clearinghouse (http://sites.nationalacademies.org/PGA/fdp/PGA_070596); or
3. The covered individuals, under the subagreement, will be required to comply with WU’s Research COI Policy by completing a FDS prior to submission.

This process is effective immediately.

* Compliance with these COI regulations is applicable to all applications and awards from, including but not limited to, the National Institutes of Health, National Science Foundation, American Heart Association, American Cancer Society, Arthritis Foundation, Susan G. Komen Foundation and the Alliance for Lupus Research.

Conflict of Interest

Award Process Changes

All persons responsible for the design, conduct, or reporting of the research (covered individuals) on a project must complete the Financial Conflicts of Interest web-based education (FCOI Education) module prior to OSRS setting up any accounts for new, competing or non-competing awards, or within the next 12 months, whichever occurs first.

For example, if you have any research funding due to start on December 1, 2012, the education module must be completed prior to December 1st in order to prevent delays in your award set-up.
# Conflict of Interest

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<th>Functional Activity Descr</th>
<th>Frequency Description</th>
<th>Compliance Type Descr</th>
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<td>Disclosure Review Committee: 314-747-2904</td>
<td>One Time Only</td>
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