Research Administration Updates
May 16, 2018
11:00 am
IOP Auditorium
Topics Covered

• Using ClinCard (Greenphire) for Federally Sponsored Clinical Research Studies – Ryan Mulligan, SCTRI Institute
• OCR & ORSP Workflow for Federal and Industry Sponsored Clinical Studies – Cullen McWhite, OCR
• Outgoing Sub-awards – Becky Timpner, ORSP
• Cayuse Expansion Update – Robbie Lee, ORSP
• Notices/Updates/Reminders – ORSP
ClinCard for Federal Studies

Ryan Mulligan, MRA, MS, CCRP, CRA
ClinCard Program Manager, Office of Clinical Research
What Is the ClinCard?

• The ClinCard system is a web based portal that automates participant compensation and mileage reimbursement, for clinical research studies, utilizing a reloadable debit card to provide real-time payments.

• The goal of the system is to reduce administration, increase patient retention, promote protocol compliance, and overall improve the site and patient experience while centralizing reporting and reducing costs.
ClinCard Package Example

1. Your ClinCard Prepaid MasterCard® is active once your first payment is loaded. Please sign the back of the card and then you can immediately begin using it by inserting the "chip" into a store or for online purchases.

2. Your ClinCard does not come with a personal PIN. In order to use your ClinCard at an ATM location or to make a purchase using the "debit" option in stores, please call 1-866-952-3795 to set your PIN.

3. This prepaid MasterCard card is reloadable, so please be sure to keep it so that additional funds may be credited to your ClinCard.

4. You may view your available balance, review transactions and manage your account at www.myclincard.com or by calling 1-866-952-3795.

Tips on using your ClinCard Prepaid MasterCard:

* If you "opt-in" to receive email and/or text messaging, you will be notified when funds are applied to the card. You may also receive messages to remind you about upcoming appointments and other study information.

* Standard text messaging rates may apply. See center for details.

* As a prepaid card, your ClinCard can only be used for purchases up to the amount of your available balance. If you wish to make a larger purchase, you must know your available balance and inform the cashier of the amount you wish to charge to your ClinCard. Merchants are unable to check your balance or transaction history.
ClinCard is now available for federally sponsored clinical research studies
Budgeting for ClinCard - Federal Studies

Federally funded clinical research

• No setup fee
• $0 ClinCard*
• $0 Transaction/Load Fee*

*The cost of the ClinCard and the transaction fees have been deemed an institutional F&A expense.
Budgeting for ClinCard - Industry Studies

Industry initiated/Industry funded:

• $350 New Study Setup Fee
• $5 ClinCard (each)
• $1.15 Transaction/Load Fee (each)
Budgeting for ClinCard - Other Studies

Foundation/Internal/Investigator initiated/etc.

- No Setup Fee
- $5 ClinCard (each)
- $1.15 Transaction/Load Fee (each)
Requesting to use ClinCard

- Office of Clinical Research, PRA Intake Form
- Submit a request for a ‘Study Setup (new)’ under Greenphire ClinCard
About SPARCRequest

Browse Service Catalog

- Medical University of South Carolina
- South Carolina Clinical and Translational Research Institute (SCCTR)
- Center for Genomics Medicine
- Media Training for Researchers
- CEDAR: Comparative Effectiveness and Data Analytics Research Network
- Office of Clinical Research (OCR)
- National Center for Nanotechnology for Rehabilitation (NC NMR)
- Core & Facilities
- Laboratory Services
- Office of Research Integrity
- GreenShingles ClinCard
- ClinCard by GreenShingles
- Study Team Assessments

Search by Service Name or CPT Code...

ClinCard by GreenShingles

ClinCard is a reloadable debit card to facilitate study participant compensation and mileage reimbursement.

- ClinCard Setup (new)
- Visit Load Fee
- Request Additional ClinCards

My Services

- Open
- Completed

You do not have any active requested services

Continue

Help/FAQs

Feedback

Contact Us

News

- SPARCRequest Email Issue
  - April 13, 2018
- New Professional Services Imported into SPARC
  - April 3, 2018
- April 4, 2018
- New Release: SPARCRequest Version 3.2.0 & SPARC2UtilVersion 2.7.0
  - April 2, 2019

Calendar

No events scheduled within a month from today
For Questions or More Information:
Office of Clinical Research
(843) 792-7900
ClinCard@musc.edu
Billing Compliance Workflows

Leila Forney, DNP, CCRP
Associate Director, Prospective Reimbursement Analysis
Office of Clinical Research

Cullen McWhite, BS, CCRC
Prospective Reimbursement Analysis Manager
Office of Clinical Research
Corporate Studies

- **Study Team submits PRA**
- **Study Team submits ePDS**
- **PRA team receives notification of ePDS submission**
- **Study Team requests changes to budget**
- **PRA Team/ORSP requests changes to contract**
- **ORSP finalizes contract**
- **ORSP executes contract**
- **PRA Team/Study Team reviews final budget/contract**
- **ORSP finalizes budget**
- **Study Team finalizes budget**
- **PRA Team reviews final budget/contract**
- **ORSP negotiates contract language with Sponsor**

**Diagram Links:**
- ORSP negotiates contract language with Sponsor
- **Study Team submits PRA**
- Study Team submits ePDS
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Non-Corporate Studies

Coming June 1st 2018!

ORSP receives Just-In-Time request

ORSP notifies Study Team and PRA Team of Just-In-Time notice

Study Team submits PRA

PRA Team assesses billing risks

PRA Team notifies Study Team if billing risks are identified

PRA Team works with Study Team to resolve billing risks

PRA Team provides notification to Study Team and ORSP

Study Team notifies ORSP when all institutional approvals have been obtained

Study Team notifies ORSP when all institutional approvals have been obtained
Corporate Studies (IRB III)

- Federal regulations require the ICF to detail “any additional costs to the subject that may result from participation in the research”*
- All studies submitted to IRB III will require a PRA review before the study may proceed with IRB review
  - REGARDLESS of review type (exempt, expedited, full board)
- PRA Team will ensure the cost language in the ICF is consistent with the Study Billing Plan

*45 CFR 46.116(b)(3) and 21 CFR 50.25(b)(3)
Coming June 20th 2018!

PRA Team will issue OCR approval once IRB approves and releases the study.
PRA Summary Memo

• Includes:
  • Study Demographics
  • Sponsor
  • Regulatory Status of IP
    • IND, IDE, etc.
  • Qualifying Clinical Trial Status
    • Will have potential benefit
  • Payer
    • Research, Participant, Mixed
  • Approved ICF Cost Language

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Delegate, Office of Clinical Research: Kim Spencer

Digitally signed by Kim Spencer
Date: 2016.08.15 11:57:02 -04'00"
Corporate Studies (IRB III)

- Plan ahead and know your target IRB submission date
  - PRA team needs time to review, approve, or request changes to the cost language

IRB Exempt
- Submit to OCR 4 days prior to IRB submission

IRB Expedited or Full Board
- Submit to OCR 3 weeks prior to IRB submission

*This is the minimum time required for OCR review. Please submit as soon as possible.
THANK YOU

Office of Clinical Research (OCR)
Email Address: musc-ocr@musc.edu
Phone Number: (843) 792-7900
Address: Roper Medical Office Building, Suite 170

Web Address: http://horseshoe.musc.edu/research/ocr
Subawards: (MUSC as the PTE*)

*Pass-Through Entity
What is needed so ORSP can issue an outgoing Subaward?

Typical NIH requirements for PTE to collect from Subawardees at proposal stage:
- Letter/Statement of Intent – signed by subrecipient
- Statement of Work
- Detailed budget
- Budget Justification
- FCOI Certification / applicable forms
- Subrecipient’s federally negotiated F&A rate agreement (if applicable)
- Biosketches/CVs as required by the funding agency
- A completed PHS 398 Facepage is recommended, and contains most of the information necessary to prepare the subaward

NOTE: Please upload these as a separate attachment from the full proposal file
What considerations are required to establish a subaward/consortium once an award is made?

• Has the subaward been approved as part of the awarded budget and project?
  • Is separate sponsor approval required by the award terms?
• Has the subaward budget and/or scope of work changed from the proposal?
  • Likely, if the overall budget or work scope has changed.
• Does the subaward scope of work include human and/or animal subjects?
  • If so, additional information may be needed to complete the subaward and complete our risk assessment.

Once these details have been determined, ORSP will begin the subaward issuance process and fulfil all requirements of the Uniform Guidance (2 CFR 200.331).
ORSP Subaward/Amendment Issuance Process

- Verify Subrecipient SAM registration is active (must be renewed each year).
  - Requires Subrecipient’s DUNS Number
- Verify Subrecipient’s FCOI policy is PHS compliant
  - Request additional documentation if needed
  - Participation in the FDP FCOI Clearinghouse
- Review A-133 audit or Mini-audit form as applicable.
  - Subrecipient’s Tax ID (EIN) number may be necessary
  - Participation in FDP Expanded Clearinghouse
- Check to make sure Subrecipient and Subrecipient PI are not debarred or suspended
- Assess risk of flowing funds to each potential Subrecipient
  - Risk Assessment Questionnaire (new subaward)
  - Continuing Assessment Tool (modification/amendment)
- Federal Funding Accountability and Transparency Act (FFATA)
  - Monthly FFATA Reporting
  - NIH FFATA resources: [https://grants.nih.gov/grants/public_accountability/ffata.htm](https://grants.nih.gov/grants/public_accountability/ffata.htm)

Subaward Amendment Requirements

Amendment (modification)

The following should be uploaded to the ePDS (with RPPR)
- Updated Statement of Work (if applicable)
- Detailed budget
- Budget Justification
- FCOI Certification / applicable forms

NOTE: Please upload these as a separate attachment from the RPPR file
Outgoing Subaward References and Resources

- ORSP “How Do I” web page: http://academicdepartments.musc.edu/research/orsp/policies_procedures/how_do_i
- Determine subawardee or contractor relationship?
- Prepare for an outgoing subaward as part of an MUSC proposal?
- FDP FCOI Clearinghouse
- FDP Expanded Clearinghouse

Still have questions? Please contact ORSP’s Becky Timpner

Email: timpner@musc.edu    Phone: 792-8702
Revised Process

Lead Time: 6 weeks (or more) prior to desired effective date

Single Point of Contact: Becky Timpner, timpner@musc.edu

The NEW process:

The requesting department will route an ePDS which will include the following:
- Completed Statement of Work Template
- Budget for the work (with salary and fringe separated)
- Indicate that this is a VA Personnel Services Agreement (PSA) and include the funded person’s name in the title of the project within the ePDS preceding the actual title of the VA Merit Award. Example: “VA PSA Jane Doe: Actual Title of the Merit Award here”.

After the ePDS has been approved by all at the department level, it will route to ORSP for review.

When ORSP reviews/approves the SOW, ORSP will send the SOW via email to the VA for approval. Upon VA approval, ORSP will approve the ePDS proposal.

When the Task Order is issued by the Pittsburgh VA contracting office, ORSP will award the ePDS associated with the SOW and Grants and Contracts Accounting (GCA) will assign a UDAK.
ORSP is hopeful that a single point of contact for both MUSC and the VA will alleviate some confusion, streamline/simplify the overall process, and allow for more accurate tracking.
Takeaways & Tools

SOW Template

VAMC Worksheet

When Filling out the ePDS for a SOW (one SOW per ePDS) be sure to:

- Include VA PSA (Insert Name of Person Here): (Title of merit award) in the title field
- The Current Budget Dates: The proposed funding dates for the SOW
- Total Project Dates: Merit Award Beginning and End dates
- The IDC rate on these is 0 at this time
- Make sure the Primary Unit is correct
- Questions 1-18 should be marked as “No”
Cayuse Sponsored Projects

- MUSC has purchased the Cayuse Sponsored Projects Module
  - Integrates with Cayuse 424 proposal preparation
  - Consolidates Documents, Data and Communications
  - Provides role-based dashboards for all users
- Grants on ERMA (ePDS) and Coeus will be retired
- Project Kick-Off is next Monday, May 21st
  - Expected implementation – 6 to 8 months
- Relevant Focus and Work Groups will be formed as needed during the implementation process
  - Send me an email if you are interested in participating
    - Robbie Lee - leer@musc.edu
## FY2019 Fringe Benefit Rates - REMINDER

<table>
<thead>
<tr>
<th>Employee Benefits Category</th>
<th>Fringe Benefits Rate</th>
<th>Applicable Employment Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
<td>38.4%</td>
<td>Faculty</td>
</tr>
<tr>
<td></td>
<td></td>
<td>9-Month Faculty</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unclassified Non-Faculty</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Classified, Research</td>
</tr>
<tr>
<td>Post-Doctoral Fellows</td>
<td>29.8%</td>
<td>Post-Docs</td>
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<tr>
<td></td>
<td></td>
<td>Residents</td>
</tr>
<tr>
<td>Temp Faculty/Temp non-Faculty</td>
<td>31.7%</td>
<td>Temporary Faculty</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Temporary Non-Faculty</td>
</tr>
<tr>
<td>Students/Other</td>
<td>6.9%</td>
<td>Student</td>
</tr>
<tr>
<td></td>
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<td>Ph.D. Students</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Research Grant Employees- No Benefits</td>
</tr>
</tbody>
</table>
NOT-OD-18-156

Career Award (K) Policy Update: Temporary Adjustments to Percent Effort or Part-Time Institutional Appointment

• K awardees may request to reduce their professional effort to less than 75% (equivalent to 9 person-months) for up to 12 continuous months.
  • See: NOT-OD-09-036 and NIH Grants Policy Statement (12.3.6.4)

• Clarification:
  • During the period of reduced effort, NIH will adjust the total salary amount committed to the K award consistent with the adjusted level of effort.
  • NIH will continue to provide full research costs in other budget categories.
  • The K awardee may request to extend the duration of the award to account for the reduced effort.
NOT-OD-18-157

Career Award (K) Policy Update: Concurrent Support from a Mentored K Award and a Research Grant

Updates NIH policy NOT-OD-08-065 concerning concurrent support from mentored career development (K) award and a research grant, specifically to:

• expand the categories of concurrent support for which mentored K awardees may request reduction of effort to include
  • PI/PD of peer-reviewed research grants of at least $100,000 in direct costs, obtained from non-Federal sources; e.g., foundations and professional societies
• clarify that during the period of reduced effort NIH will continue to provide full research development support costs
  • i.e., Other Personnel, Equipment, Travel, Participant/Trainee Support, and Other Direct Costs budget categories
NOT-OD-18-160
Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests
• Reminder of the requirements of 42 CFR Part 50, Subpart F, Objectivity of Research
  • Also known as the Financial Conflict of Interest (FCOI) regulation
• Clarifies Investigator disclosures with respect to foreign financial interests
  • Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).
Recent Notices

NOT-OD-18-175
Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2018

• Budget levels in this Notice apply only to Kirschstein-NRSA awards made with FY 2018 funds
• All FY 2018 awards previously issued using NOT-OD-17-084 and NOT-OD-17-003 will be revised to adjust funding to the FY 2018 levels.
• Appointments to institutional training grants that have already been awarded in FY 2018 must be amended to reflect the FY 2018 stipend levels once the training grant award has been adjusted by the NIH.
• Amended appointments must be submitted through xTrain in the eRA Commons.
• Retroactive adjustments or supplementation of stipends or other budgetary categories with Kirschstein-NRSA funds for an award made prior to October 1, 2017 are not permitted
NOT-OD-18-179

Transition from Inclusion Management System to New Human Subjects System (HSS) as of June 9, 2018

- NIH has developed a new Human Subjects System (HSS), which consolidates human subjects and clinical trial information in one place
  - Replaces the Inclusion Management System
    - The Inclusion link will no longer appear on the Commons Status page as of June 9, 2018
  - Information captured in HSS is generally submitted on the PHS Human Subjects and Clinical Trials Information form
  - Post-submission updates to human subjects and clinical trial-related information (including human subjects protections, participant and enrollment information, and Clinicaltrials.gov registration and reporting information) must be made in HSS via the eRA Commons Status page after June 9, 2018
NOT-OD-18-179 (continued)

Key Changes

• NIH will migrate enrollment records currently in IMS to HSS.
  • Updates to enrollment records must be submitted to NIH no later than June 8, 2018 or entered in HSS.
  • Updates not submitted by June 8, 2018 will not be available in HSS and must be re-entered.

• NIH recipients completing an RPPR (Research Progress Performance Report) will be prompted to access HSS to update inclusion enrollment reports.
  • Recipients may access the system through the Human Subjects link in the RPPR or the eRA Commons Status page.
Recent Notices

NOT-OD-18-179 (continued)

Key Changes

• Section 6: Clinical Trial Milestone Plan is intended for use in progress reports for competing applications submitted on or after January 25, 2018 and is not currently required unless otherwise noted in the Funding Opportunity Announcement or terms and conditions of award. Recipients should refer to the RPPR Instruction Guide for guidance.

• The HSS system includes a new interface and workflow. When submitting studies to NIH, Signing Officials will submit all study records associated with an application at one time rather than separately.

• Participant-level sex/gender, race, ethnicity and age data may be submitted in a CSV file to populate the Inclusion Enrollment Report. Participant level data will be required for applications submitted January 25, 2019 or later. See NOT-OD-116 for additional information.
Recent Notices

NOT-OD-18-179 (continued)

Key Changes

• Investigators and signing officials may make study updates or corrections (including just-in-time or off-cycle updates) by accessing HSS through the Human Subjects link in the eRA Commons Status page.
  • Some changes, including those involving increased risk to human participants, may require prior approval by NIH.

• Users are currently unable to delegate authority for HSS updates and/or submissions to another user.
  • Delegation authority is expected to be available in a future enhancement of HSS.
REMINDERS

• 3 Business Day Deadline

• What Exactly is REQUIRED in ORSP by the 3 Business Day Deadline?

Answer: “the complete proposal package” which includes: budget, budget justification, project narrative (science), all subaward documentation, FCOI forms, VA MOUs, Grant Certification forms, and any other items required by the sponsor in the proposal package

http://academicdepartments.musc.edu/research/orsp/faq_internal_deadline
REMINDERS

• Confirm (PI or PI support staff) Correct Funding Opportunity Announcement (FOA) is Used & the Intended Institute is Participating in the FOA

Note: Verify the NIH institute (e.g. NIMH, NIDA, NHLBI, etc.) is participating!

• New Human Subjects Section Requirements (longer to complete, so plan accordingly allowing adequate preparation time, let’s not be surprised)

Note: Forms E etc. are still relatively new, so if a PI has not experienced them yet, please alert them to allow enough time to address the new requirements. We understand the information requested is very time consuming to compile.
REMINDERS

• Utilize the Cayuse Validation Feature BEFORE ORSP Review
  1.) Select (click-on) lightning bolt in top bar above proposal
  2.) Which opens a window called “Electronic Submission”
  3.) Then select (click-on) “Validate Proposal” to see validations
  4.) System generated errors and warnings will listed for action to be taken
  5.) Proposal will NOT get submitted by using the validation feature
REMINDERS

ACH Payments

• Claim forms for ACH payments need to be done immediately upon notice of payment by completing a Remittance Advice.
• If the payment has already hit the unclaimed cash report the “Unidentified Receipts Claim” will need to be used.
• These forms can be found at: http://academicdepartments.musc.edu/vpfa/forms/formlib.htm
• Unclaimed Cash report should be checked by the department/fiscal unit at least monthly.
Final Thoughts

- Any Announcements?
- Questions or Comments?
- PLEASE complete a survey & THANK YOU
- Next ORSP Information Session:
  June 20, 2018 @ 11:00 IOP Auditorium