Updates to the RSRB Amendment Process

Over the past four months, the Research Subjects Review Board (RSRB) implemented several changes to the amendment process in the RSRB Online Submission System (ROSS). These changes include revisions to the amendment form and implementation of an ‘amendment light’ process for study staff changes.

The amendment process revisions are summarized below, but it is essential for study staff submitting amendments to carefully read all questions and corresponding gray box instructions within the revised amendment form. The amendment process within ROSS differs significantly and making assumptions without reading instructions will result in amendments being return to the study team for revisions.

Amendment Types & Branching

Previously, when an amendment was created in ROSS, the form opened to a brief instructional page where no data pertaining to the amendment was collected. With the recent amendment changes, this page now asks whether the amendment includes changes to University of Rochester (UR) affiliated study personnel only (not including Principal Investigator). See Image 1. Answering ‘yes’ to this question will direct the study team to the ‘amendment light’ form. Answering ‘no’ to this question directs the study team to the traditional ‘full’ amendment form.

Once this initial question (‘Is this a request to change only UR-affiliated study personnel?’) has been answered and submitted (meaning the continue button has been selected to move to the next page), the study team will not be able to modify the response to the question. The study team will either need to continue with the study personnel changes and then submit a second ‘full’ amendment to address any other changes, or withdraw the study personnel only amendment and start over with a ‘full’ amendment that includes all changes.

‘Amendment Light’ Requests

The new ‘amendment light’ allows a shorter process for changes to UR-affiliated study personnel. This process does not permit changes to the Principal Investigator, non-UR study personnel, or study documents.

Once the amendment form has branched to the ‘amendment light’ process, study teams will be directed to a copy of Sections 1.5 (Co-Principal Investigator), 1.6 (Sub-Investigators), 1.7 (Study Coordinator), 1.7.1 (Additional Study Coordinators), and 1.7.2 (Other Study Personnel). Changes (adding or deleting study personnel) can be made to the applicable sections and then saved and submitted. Once submitted, the designated RSRB (continued on page 2)
Specialist will review the form, request any necessary revisions, and then confirm the study personnel changes. Board chairs will not be required to review and approve the ‘amendment light’ changes.

The study team will receive e-mail confirmation that the reviewed changes were accepted, but a formal approval letter will not be issued. To demonstrate compliance with federal regulations and institutional policy, study teams must maintain a copy of this confirmation in their study file (along with all other RSRB approvals). Furthermore, study teams are encouraged to print a copy of the amendment’s ‘Change Log’ found on the ‘History’ tab of the amendment form in ROSS (See Image 2). This log documents all study personnel that were added or removed with each modification. In some instances, based on how modifications were completed within the form, the study team may need to print more than one ‘Change Log’ to demonstrate all revisions included within the amendment.

Want to see the process in action? Tiffany Gommel, Director of the RSRB, presented the amendment updates summarized above, including the submission of a sample ‘Amendment Light’ amendment, during the December 20, 2016 ‘Achieving High Quality in Clinical Research’ Seminar Series. A video recording of the seminar and a copy of the slides presented are available on the Office for Human Subject Protection’s (OHSP) website.

‘Full’ Amendment Form Revisions

Revisions to the ‘full’ amendment form primarily affect page 1 (‘Request for Amendment’). This page collects information pertaining to the requested changes, amendment rationale, and re-consent of subjects. In addition to requiring a response to every question on
Updates to the RSRB Amendment Process

(continued from page 2) page 1, the following modifications were implemented:

• Section 1.0 (Request for Changes): This is a checklist that identifies the category(ies) of revisions in the amendment. It was expanded to include additional items.

• Section 3.2 (Amendment Version Date): This question was added as a new field and allows the study team to identify an amendment version date, which will subsequently appear on the approval letter. Amendment version dates are typically provided by the study sponsor and/or coordinating center on multi-site research and may appear on the notification about the amendment or on the title page of a revised protocol. Amendment version dates may not necessarily apply to all research and should not be erroneously selected by individual sites. If an amendment version date has not been identified, the study team should respond ‘no’ to this question.

• Section 7.2 – 7.2.1 (Re-Consent of Subjects; See Image 3): Section 7.2 requires the study team to identify how subjects will be notified of revisions. For example, re-consent with a revised consent document, re-consent with a new consent document [e.g., a consent addendum created specifically for the amendment’s revisions], information letter or verbal notification. Multiple options may be selected as different methods of notification may apply to different groups of subjects. If there is no local subject enrollment or notification is not necessary, the ‘not applicable’ checkbox should be selected.

Section 7.2.1 requires the study team to identify which groups of subjects will be notified of the revisions and to justify the response. Based on the revisions included in the amendment, notification could be provided to some or all of the following groups: all active subjects; active subjects on treatment; active subjects off treatment; subjects assigned to a specific treatment arm; or subjects who completed the study. Similar to Section 7.2, multiple options may be selected. Alternately, notification of the revision may not be necessary or may not be applicable (if no local subjects have been enrolled).

Finally, an additional revision was made to page 4 of the amendment form, on the ‘Protocol Updates’ page. This page now includes a new Section 1.1, which allows the study team to upload tracked versions of revised study protocols in a distinct section of the form (whereas these were previously uploaded with ‘clean’ versions of the document).

Questions pertaining to amendment process revisions described above, can be directed to your designated RSRB Specialist.
Implementing a Site-Specific Quality Management Plan

A Quality Management Plan (QMP) guidance tool will be available to assist study teams/research divisions in creating a system to identify research process improvements. The guide will assist in building and implementing a QMP.

Traditionally, assessing quality is reactive; errors are identified and addressed after a problem occurs. The ideal method of quality management is proactive, which involves the study team initiating and maintaining a process which continuously assesses the quality of the research process. Building quality measures into a study during the development stage is a great place to start!

In summary, this includes approaches to:

- **PLAN**: determining what to review, when, how, and who
- **DO**: execute the plan
- **CHECK**: in what manner to address the findings
- **ACT**: implementing corrective and preventative action plans

Implementing a QMP may help a study team to successfully achieve study objectives while:

- Protecting the health, safety, and welfare of subjects
- Conducting research compliant with federal and state regulations and institutional policy
- Ensuring data accuracy and validity
- Improving site performance
- Mitigating risk to the Investigator, study team, and institution
- Preparing for external quality-related reviews (e.g., FDA inspections or sponsor audits)

The UR-QMP guide was written in collaboration with UR Study Coordinators from the research community and will be available on the Office for Human Subject Protection web site. It focuses on and is intended to aid Investigators and research staff in QMP set-up, implementation, evaluation, and to prioritize areas of potential risk to target.

OHSP Quality Improvement is available to help your site evaluate needs and structure a 'personalized' QMP. Click here to email Kathleen Wessman and Jennifer Dolan.

Join OHSP staff and your study coordinator colleagues as they present the QMP at the January 26th seminar (see additional details on page 8).

### Research QI ‘Gold Star’ Award

The QI division is recognizing Laboratory of Interpersonal Violence and Victimization for their quality work on the ‘Assessing the Intersection of Suicide and Intimate Partner Violence in Community Mental Health Centers: Can We Improve Patient Engagement?’ study. This vibrant study team is a part of the Department of Psychiatry.

They received the OHSP-QI ‘Gold Star’ award for their commendable work in serving a challenging subject base, demonstrating attention to regulatory compliance/protocol adherence, exceptional subject safety practices, and conducting an excellent research process with high quality, organized study-related documentation.

Congratulations!
Communicating via E-mail with Study Subjects

Just as e-mail communication has become a routine part of everyday life, communicating with study subjects via e-mail has become increasingly popular. It is a quick and convenient way to convey information, provide reminders or distribute study measures and materials. But communicating with study subjects via e-mail is not necessarily as simple as sending off an e-mail to a friend or work colleague. As with research in general, study team members must be cognizant of weighing the potential risks related to this communication method and taking appropriate measures to minimize this risk.

Risks related to communicating via e-mail include:

- E-mail can be intercepted, altered, forwarded or used without authorization or detection;
- E-mail can be circulated, forwarded, stored and broadcasted to unintended recipients;
- E-mail senders can easily use an incorrect e-mail;
- Employers and on-line services may inspect e-mail transmitted through their systems;
- Backup copies of e-mail may exist even after the sender or recipient has deleted his/her copy;
- E-mail can be used to introduce viruses into computer systems.

To minimize these risks, all study teams must obtain consent from subjects prior to initiating e-mail communications. If the research is being conducted within the covered entity (i.e., URMC and Affiliates), this authorization is required to be obtained and documented via the ‘Research Subject E-mail Consent Form’ available through the Office for Human Subject Protection’s website. When using this form, similar to research consent, the original signed e-mail consent must be maintained by the study team in the research record and a copy must be provided to the study subject. Note however that, because this is a standardized form, it does not need to be approved by the Research Subjects Review Board for use. For research conducted outside the covered entity (i.e., River Campus), information concerning e-mail communications must be included in the research consent.

The research consent should clarify that: a) e-mail communications will be used (and whether it is optional); b) what type of information will be communicated via e-mail; c) risks related to e-mail communications; and d) how the study team will protect against those risks.

In addition to obtaining consent from study subjects, consider the following measures to minimize risks related to email communications:

- Generate and send subject e-mails via your designated University of Rochester e-mail account to ensure additional security measures inherent to the University’s e-mail servers. Do not use personal Gmail, Yahoo, Hotmail, etc. accounts to e-mail study subjects.
- Minimize the content (and subject line) of e-mails to the minimum necessary to convey the intended message. Do not communicate sensitive information via e-mail. (continued on page 6)
Communicating via E-mail with Study Subjects

- (continued from page 5) If you are sending an e-mail that includes protected health information (PHI) and are part of the covered entity, encrypt the e-mail by typing ‘SECURE’ at the beginning of your subject line (additional information on this process is available here).
- Add a confidentiality notice to the signature block of e-mails generated to study subjects. E.g., “This message contains information that may be confidential and privileged. If you are not the addressee (or authorized to receive this e-mail for the addressee) you may not use, copy or disclose to anyone this message or any information in this message (including attachments). If you received this message in error, please advise sender by e-mail, and delete the message. Thank you.”
- Double-check the e-mail address has been entered correctly prior to transmitting the e-mail.

RSRB Process Changes & Clinical Trials.gov

The Department of Health and Human Services published a final ruling on the requirements for submitting registration and summary results for specified clinical trials to ClinicalTrials.gov on September 21, 2016. This ruling, which expands the original clinical trial registration requirements set forth in the Food and Drug Administration Amendments Acts (FDAAA), is intended to clarify the types of clinical trials that require registration, registration deadlines and results reporting requirements.

Based on this ruling, the Research Subjects Review Board (RSRB) has modified sections 3.2 of new applications and 2.8 of continuing review forms in the RSRB Online Submission System (ROSS). The revised sections clarify registration criteria and, for those studies that require registration, requests entry of the study’s ‘ClinicalTrials.gov Identifier’ number (NCT#). Submission of this identification number will be required prior to RSRB approval (including re-approvals of active studies). ‘ClinicalTrials.gov Identifier’ numbers can be found on the study record detail in ClinicalTrials.gov once the study has been registered (or may be provided by a study sponsor or coordinating center in the event the study is registered by an external entity). When entering this information into ROSS, note that all eight digits, including any/all zeros, must be entered into the ‘ClinicalTrials.gov Identifier’ (the ‘NCT’ prefix is already provided).

If you have questions pertaining to whether your study requires submission to ClinicalTrials.gov or need assistance completing trial registration, please contact ResearchHelp@urmc.rochester.edu. Questions regarding the submission of the ‘ClinicalTrials.gov Identifier’ to the RSRB can be directed to your RSRB Specialist.
I need to add an additional revision to an amendment that’s already been submitted to the RSRB (but not yet approved). Can I ‘recall’ the amendment to add the additional item?

In most cases, as long as it’s appropriate to do so given the type of change and where the amendment is in the review process, amendments can typically be sent back to the study team for the additional changes. In order to do so, contact the RSRB Specialist reviewing the amendment directly; they can evaluate whether the timing is appropriate, based on the additional change, and send the amendment back to you for revision. **DO NOT** select the ‘Withdrawal Amendment’ activity within the amendment workspace in the RSRB Online Submission System (ROSS). Selecting this does not recall the form, it withdraws the entire amendment from the submission and review process and requires study teams to start the entire process over with a new amendment.

Note that this process is also true for revisions pertaining to new applications, continuing reviews and reportable events.

**What does the RSRB consider reasonable in terms of payment to subjects for participation?**

Unfortunately, because the design and nature of research (including related ethical and legal concerns) can vary drastically, there are no definitive ‘rules’ about how much and in what form subjects should be paid for participation. Generally, determining subject payment should be approached from the perspective of compensating subjects for the time and inconvenience of completing study procedures, though this should also be evaluated within the context of the specific research study. What might be considered ‘reasonable’ to compensate one subject for 30 minutes of survey completion, for example, might not necessarily be equivalent to what might be ‘reasonable’ to compensate for 30 minutes of intense exercise testing.

When the RSRB reviews subject payments included in research protocols, they will primary consider whether the amount and method of disbursement is coercive or presents undue influence. This could include providing significant cash payment for simple procedures accomplished in relatively short period of time, providing necessary standard of care clinical procedures that would normally be billed to an insurer (or to the subject) free-of-charge or at reduced rates, or offering additional compensation for procedures that are strictly routine care. Payments should be commensurate with the procedure’s complexity, risk level and completion time.

The RSRB will also consider whether the timing of disbursement is coercive or presents undue influence. Typically, for longitudinal research or research that requires multiple visits, payment to subjects should be pro-rated based on the study visits and/or procedures completed. Providing one-time, lump-sum payments for a study that is completed over the course of 5 study visits could induce subjects wishing to withdraw to complete the study in order to receive payment. ‘Bonus’ payments for subjects who complete an entire study may permissible, provided they aren’t unnecessarily large or disproportionate to the nature of the research.
Upcoming Educational Opportunities

OHSP Research Education & Training Framework Courses:

Research Boot Camp will be held Friday, January 27th from 8:00am-12pm in Helen Wood Hall Classroom 1W-501. Course objectives, a content outline and recommendations regarding course completion are available here. The next session will be held Friday, January 27th from 8:00am-12:00pm in Helen Wood Hall Classroom 1W-501. Continuing education credit will not be provided. Breakfast and snacks are welcome. To register, please click here: Research Boot Camp.

Achieving High Quality Clinical Research Seminar Series:

Please note that the Achieving High Quality Clinical Research seminar series, in conjunction with the Clinical & Translational Science Institute (CTSI) seminar series, has moved from Tuesdays to Thursdays. All seminars are held from 12:00-1:00pm in Helen Wood Hall Auditorium. Save the following dates for our Spring seminars:

- January 26th: Annual Office for Human Subject Protection Updates & Introduction to ‘Site Quality Management Plan Reference Guide’
- February 23rd, March 30th and April 20th: To Be Determined

Not Able to Attend? Miss a Previous Seminar?

Live streaming of seminars is typically available through the CTSI. Presentation materials and videos of previously recorded seminars are also available on the OHSP and CTSI websites.

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