UR-HRPP Ancillary Committee Updates

The University of Rochester’s Human Research Protection Program (UR-HRPP) is comprised of several integrated offices and committees aimed at ensuring individuals involved in conducting human subject research understand and apply their obligation to protect the rights, dignity, welfare and privacy of research subjects. An essential component of the UR-HRPP is the connection between the Research Subjects Review Board (RSRB) and the various ancillary committees. In addition to RSRB review, the purpose of these committees (listed in Table 1 on page 2) is to provide expertise in a given field and ensure applicable regulatory requirements are met and appropriate resources are available.

The Office for Human Subjects Protection’s Policy 503 Ancillary Committee Reviews, that describes ancillary review of human subject research activities, was recently revised (effective 4/25/2017) and corresponding updates to the RSRB Online Submission System (ROSS) were also implemented (effective 7/22/2017). Principal modifications to the policy include:

• Updated descriptions of when committee review and approval is required and clarity on when approval is given in relation to RSRB approval;
  
⇒ Before RSRB Review: Ancillary review and approval is granted before the RSRB begins review of the study.
  
⇒ Simultaneous to RSRB Review: Ancillary committee review is performed concurrently with RSRB review, but approval from each applicable ancillary committee is required prior to RSRB granting approval.
  
⇒ After RSRB Review: Ancillary committees are notified of the study during RSRB review, but approval is not required prior to RSRB approval.

• Splitting the former Perinatal Research Committee into the Obstetrical Research Committee and the Neonatal Clinical Trials Group;

• Additional amendment and annual renewal reviews by the Emergency Medicine Research Committee

• Updates to the Institutional Biosafety Committee’s review process reflective of current National Institutes of Health (NIH) guidelines; and

• Changes in how and when Surgical Pathology review is conducted. (continued on page 2)

Key Considerations:

• Plan Ahead & Do Your Homework – Each ancillary committee has their own application and review process, as well as their own review schedule. Knowing exactly what each applicable committee’s requirements are, what their review process is, and when their review occurs relative to RSRB review will help study teams plan sufficient time for review and avoid unnecessary frustration.

• Investigator Responsibilities – In regards to ancillary committee review, Investigators are responsible for:
  
◊ Ensuring all applicable ancillary committee approvals are in place prior to enrolling subjects;
  
◊ Adhering to applicable ancillary committee reporting requirements, as necessary; and
  
◊ Maintaining documentation of all ancillary committee approvals/acknowledgement.
# UR-HRPP Ancillary Committee Updates

## Table 1. Summary of Current Ancillary Committee Review Requirements

<table>
<thead>
<tr>
<th>Ancillary Committee</th>
<th>Review Timing#</th>
<th>Review Requirements</th>
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</table>
| Cancer Center Peer Review Committee (PRC)* | Before RSRB Review | • Reviews all hematology/oncology related studies  
• In addition to initial submission approval, review and acknowledgement must be obtained for each amendment  

| Obstetrical Research Committee (ORC)* | Before RSRB Review | • Reviews all research involving pregnant to post-partum women  

| Neonatal Clinical Trials Group (NCTG)* | Before RSRB Review | • Reviews all research involving planned study procedures on hospitalized newborns, including research involving newborns for which pregnant women will provide consent to prenatally  

| Emergency Medicine Research Committee (EMRC) | Simultaneously with RSRB Review | • Reviews all research involving:  
◊ Emergency Medicine faculty, residents, fellow or staff  
◊ Enrollment of emergency department patients  
• In addition to review and approval at initial submission:  
◊ Review and acknowledgement must be obtained for each amendment  
◊ Request for re-approval must be submitting annually, if the research continues beyond 1 year  

| Institutional Biosafety Committee (IBC) | Simultaneously with RSRB Review | • Reviews all research involving:  
◊ Introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors) into human subjects  
◊ Introduction of cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects  
◊ Introduction of genetically engineered micro-organisms into human subjects (including live vaccines if they are experimental in nature and/or not approved for use by the Food & Drug Administration)  
◊ Handling biohazardous organisms or materials at Biosafety Level 2 or higher, which includes the shipping of, analysis of, or experimentation with human specimens in any unaccredited UR lab  

| Surgical Pathology | Simultaneously with RSRB Review | • Reviews all research that involves receiving or obtaining fresh tissue, banked tissue or archived tissue blocks and slides  

| Human Use of Radiation Committee (HURC) | Simultaneously with RSRB Review | • Reviews all research involving radioisotopes or radiation-generating devices used for research purposes  
• In addition to review and approval at initial submission, review and re-approval must be obtained annually  

| Rochester Center for Brain Imaging (RCBI) | Simultaneously with RSRB Review | • Reviews all research involving activities requiring access to the RCBI  

| Clinical Research Center (CRC) | After RSRB Review | • Reviews all research procedures taking place in the CRC and/or utilization of CRC resources  

| Highland Hospital Administrative Research Review Committee (AARC) | After RSRB Review | • Reviews all research conducted at Highland Hospital  

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*Current contact information is available in Section 62 of the ROSS application.

#For studies utilizing an external IRB, other than the RSRB, ‘RSRB Review’ refers to the RSRB’s institutional review of the research that occurs prior to submission of the external reviewing IRB.

Have questions? Contact the relevant ancillary committee or your RSRB Specialist.
Utilizing MTurk: Considerations & Best Practices

Amazon Mechanical Turk (MTurk) is an online crowdsourcing platform available through Amazon.com; according to the website, it is a ‘marketplace for work that requires human intelligence’. Although it is not designed for conducting human subject research specifically, this unique ‘marketplace’ has become a popular recruitment tool for social science researchers as it provides access to a diverse population of potential subjects from many different locations.

How does the website work?

‘Requesters’ (i.e., Investigators) advertise a task, referred to as a Human Intelligence Task (HIT), which can include filling out a survey, watching a video, reading written material or performing a cognitive task. Requesters can design the HIT to be performed entirely within the MTurk platform or subjects can merely be recruited via MTurk and provided a hyperlink to perform the task elsewhere (e.g., an online survey platform such as Survey Monkey).

‘Workers’ (i.e., potential subjects) review a list of potential HITs and choose which HITs they wish to perform. Once a HIT is performed Requesters review the HIT and determine whether to approve or reject the work (i.e., accept or discard the data). Once a HIT has been approved, the Worker is paid, via their MTurk account, for completing the task.

What considerations do I need to be aware of?

Although interaction with subjects in this manner does not occur face-to-face, basic ethical principles that guide human subject research must still be adhered to. Common challenges with regards to respecting study subjects when utilizing MTurk include:

- Adequately Disclosing Information to Subjects – Based on the unique nature of the platform, it’s easy to overlook elements specific to the MTurk process that need to be disclosed to subjects. This includes clearly identifying:
  * What type of work is involved in completing the HIT;
  * How much time it will take to complete a HIT;
  * How much subjects will be paid to complete a HIT;
  * How much long it will take for a HIT to be approved (which affects when subjects will be paid);
  * Whether a screening process is involved in completing the HIT;
  * Under what circumstances a HIT might be rejected; and
  * Rejected HITs will affect a ‘Workers’ MTurk rating.

- Protecting Subject Data – Ultimately, all users are subject to conditions set forth in MTurk’s Privacy Notice (as well as the privacy conditions set forth for any other platform utilized to perform the HIT, such as an online survey service). Depending on the nature of these practices, anonymity of the subject cannot necessarily be guaranteed. Similarly, it’s possible for subject data to be shared with parties beyond that of the Investigator. While investigators can’t necessarily control the privacy practices of the online platforms utilizing, they can control what data is collected from the platform and how that data is managed once it’s been downloaded. This includes:
  * Excluding (or minimizing) the collection of identifiable data (including the MTurk Worker ID); (continued on page 4)
Utilizing MTurk (continued)

* (continued from page 3) Storing data in a secure manner (e.g., a secure network drive); and
* Eliminating any collected identifiers from the data set once analysis is complete.

Investigators should additionally be mindful of the quality of the data collected. Consider, for example, a subject that completes a HIT merely by selecting the first response of each question included in a survey versus a subject that reads each question and thoughtfully responds. ‘Bad’ data prevents Investigators from meeting the goals of their research. Therefore, considering how you’ll approve HITs and assess your data is something that needs to be thought through during the protocol development process. Some reports suggest that including attention check questions or merely asking subjects if they were attentive in performing the HIT can improve the quality of the data (Peer, et al., 2013; Rouse, 2015).

Finally, be aware that MTurk is a moving target; Investigators should not assume that MTurk policies and practices remain consistent from one study to the next. Investigators wishing to utilize the platform should familiarize themselves with current standards with each new study being initiated. Similarly, as the RSRB becomes aware of changes in practice, their MTurk Information Letter Template gets updated, as appropriate. As such, Investigators should reference the template directly from the RSRB in drafting information letters with each new study.

What additional information do I need to include in my protocol?

As with all study protocols, all procedures pertaining the research must be described in the study protocol. This includes identifying how MTurk will be utilized (i.e., to recruit subjects only or perform the entire HIT), as well as addressing the considerations identified above.

What’s the difference between MTurk & TurkPrime?

TurkPrime is a partnering MTurk platform designed specifically for social science researchers. At an additional cost, TurkPrime provides Requesters additional features not available in MTurk (e.g., study customization, targeted recruitment).

References:

Research QI ‘Gold Star’ Award

The QI division is recognizing Richard Barbano, MD and Ashley Owens for their quality work on the ‘Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study with an Open Label Phase to determine efficacy and safety of Tozadenant as Adjunctive Therapy in Levodopa-treated Patients with Parkinson’s Disease Experiencing End of Dose ‘Wearing Off’ study.

The study site received the 3rd Quarter, 2017 OHSP-QI ‘Gold Star’ award for their commendable work in serving a challenging subject base, demonstrated attention to regulatory compliance/protocol adherence, having very good Investigator oversight, consenting processes, outstanding inclusion/exclusion criteria documentation, and high quality, organized study-related documentation.

Congratulations!
Federal regulations require Institutional Review Boards (IRB) to monitor the conduct of human subject research. One mechanism through which this responsibility is met is via the continuing review process (i.e., progress report). When completing the progress report for continuing review, a common source of confusion is how to accurately report the status of both the study as whole and the individual study subjects. Tables 2 and 3 below provide descriptions of the study and subject statuses provided within the RSRB Online Submission System (ROSS), respectively. Note that other reviewing IRBs may utilize a slightly different process or different status descriptions. When completing progress reports for other reviewing IRBs, study teams must adhere to the expectations of the reviewing IRBs rather than the RSRB.

**Common Pitfalls in Status Reporting:**

- Reporting study and/or subject statuses that are inconsistent with other information provided within the current report or information provided with prior progress reports. For example: *(continued on page 6)*

<table>
<thead>
<tr>
<th>Table 2. Study Status Descriptions</th>
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<tbody>
<tr>
<td><strong>Active Studies</strong></td>
</tr>
<tr>
<td>- No local accrual to date; however, accrual is possible = While no enrollment has occurred since the study’s initial approval, the study team intends to enroll subjects in the future.</td>
</tr>
<tr>
<td>- Accrual continues = Subject have been enrolled and the study team intends to continue enrolling subjects.</td>
</tr>
<tr>
<td>- Open to accrual but no enrollment has occurred since last review = At least 1 subject has been enrolled since the study’s initial approval but no subjects have been enrolled during the current reporting period. The study team intends to continue enrolling subjects.</td>
</tr>
<tr>
<td>- Accrual complete, but research activity continues = All subjects have been enrolled (i.e., no further enrollment will occur) but data continues to be collected via approved study procedures (e.g., survey completion, intervention activities and monitoring, chart review, specimen analysis).</td>
</tr>
<tr>
<td>- Data analysis only = All subjects have been enrolled, all interventions are complete, and all data has been collected but the data continue to be analyzed.</td>
</tr>
<tr>
<td>- Umbrella study = Study was initially approved as an ‘umbrella’ study; all subject enrollment and data collection occurs via separately approved protocols.</td>
</tr>
<tr>
<td>- Multi-site coordination center study = Study was initially approved as a ‘coordination center’; all subject enrollment and data collection occurs via separately approved protocols.</td>
</tr>
<tr>
<td>- Completed study = Study has been completed as described in the approved study protocol, including primary analysis of the data.</td>
</tr>
<tr>
<td>- Study closed before completion = Study was initiated (i.e., some subjects were enrolled and procedures completed) but was stopped prior to completing the study as described in the protocol.</td>
</tr>
<tr>
<td>- Study has not been/will not be conducted = Study was never initiated; no subjects were enrolled, no data was collected.</td>
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<tr>
<th>Table 3. Subject Status Descriptions</th>
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<tr>
<td>- Screen failure = Subject provided consent but during screening it was determined that the subject did not meet eligibility criteria; no procedures beyond screening were performed.</td>
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<tr>
<td>- Currently undergoing study intervention procedures = Subject is currently undergoing intervention/interaction and participating actively in study procedures.</td>
</tr>
<tr>
<td>- Non-interventional follow up data collection = Subject has completed all active participation, contact with the subject has ceased, and only follow up data (e.g., survival data) is being collected.</td>
</tr>
<tr>
<td>- Completed study procedures and follow-up = Subject has completed all active participation and all follow up data collection is complete.</td>
</tr>
<tr>
<td>- Withdrawn from study = Subject provided consent but either chose to withdraw their consent or was withdrawn from the study by the Investigator. No additional or follow up data will be collected.</td>
</tr>
<tr>
<td>- Death (related to study) = Subject provided consent and died while participating in the study. The cause of death was possibly or probably related to study participation.</td>
</tr>
<tr>
<td>- Death (unrelated to study) = Subject provided consent and died while participating in the study. The cause of death was not related to study participation.</td>
</tr>
</tbody>
</table>
What’s the Status? (continued)

(continued from page 5) a) the study status is reported as ‘accrual continues’ when the prior report indicated that accrual was complete; b) the study status is reported as ‘open to accrual with no enrollment since last review’ when 5 additional subjects are identified as enrolled later in the report; or c) the reports indicates that 5 additional subjects have been enrolled for a total of 20, when only 10 subjects were reported as enrolled on the prior report.

- Confusing sponsor, site and IRB terminology; while similar terminology may be used by various entities they may have different meanings. For example, the RSRB considers anyone who has signed a consent form as ‘enrolled’. Whereas a sponsor or other site, might only consider subjects ‘enrolled’ once they’ve signed consent and passed screening or completed randomization. Another common example pertains to reporting subjects who have withdrawn. While a sponsor might consider a subject who has withdrawn from an intervention, but is still completing outcome measures (or permitting data collection on them), as ‘withdrawn’, the RSRB would consider this subject as one who is undergoing ‘non-interventional follow up’ as data is still being collected from this subject.

If you are unsure of how to report information at the time of continuing review, reference the ‘gray box’ instructions provided with ROSS or contact your RSRB Specialist (or the reviewing IRB directly, for research reviewed and approved by IRBs other than the RSRB).

Frequently Asked Questions

How Do I Know if My Grant is ‘Just-in-Time’?

‘Just-in-Time’ (JIT) refers to a specific award procedure utilized by the National Institutes of Health (NIH), and some foundations. The JIT process allows some elements of a grant submission (e.g. IRB approval, other support) to be submitted later in the application process, thereby allowing the Investigator to initially focus on the science of a specific submission. Once an initial submission has been reviewed by the NIH, those receiving scores in a fundable range will receive notice from NIH requesting the submission of additional materials. At that time, the initial application for approval of the research should be submitted to the reviewing IRB with documentation pertaining to the initiation of the JIT process.

For further clarification, the ‘Just-in-Time’ process applies only to grants that have been: 1) submitted to NIH; 2) received a fundable score; and 3) received notification form NIH to initiate the JIT process.

Investigators unsure of whether this process applies to their grant submission should contact their Program Director at the NIH.
Summer (Research) Weather Forecast

From the Quality Improvement Team

- Review the study’s regulatory file while sipping ice cold lemonade on a sunny day.
- Read the current OHSP policies applicable to your study during a campfire on a clear, calm day.
- Consider ways to enhance Investigator oversight while grilling outside on a windy day.
- Implement a checklist to ensure the correct consent form version is used while spending time indoors on a rainy day.
- Contemplate recruitment ideas so the study stays afloat while swimming on a warm day.
- Schedule a consultation for a newly approved study or to implement quality measures on a hazy, hot, and humid day.

Food For Thought

Please note that the articles included in this feature by no means represent OHSP’s current viewpoints; they are merely meant to provoke thought and conversation on issues concerning human subject research.

- Some Social Scientists are Tired of Asking for Permission. (Murphy, K. [2017, May 22]. New York Times [online]).
- Scientist Screwed Up? Send ‘Em to Researcher Rehab. (Pickett, M. [2017, June 11]. Wired [online]).
- Giving children a voice in clinical trials. (Children's National Health System. [2017, June 15]. Science Daily [online]).
Grant Submission ≠ Protocol

A common mistake in preparing initial IRB submissions is assuming that the grant and the study protocol are one in the same when they’re not. Grants typically have page limitations and therefore, provides only a summary of the interventions and/or procedures involved in meeting the aims of the research and are not detailed enough to act as a study protocol. In some cases, multiple studies (each requiring their own separate protocol) may also be covered under one grant, in which case the grant would only provide a summary of each of the involved studies. Remember: in order to approve research, IRBs must confirm that the research meets the regulatory-defined criteria for approval (45 CFR 46.111).

Minimally, this means that protocols must thoroughly describe the purpose of the research, rationale and background information supporting conduct of the research, characteristics of the population under study, study procedures and methodologies, risks (including how risks will be monitored and minimized) and benefits, recruitment and informed consent procedures, and methods for protecting subject privacy. Applications failing to meet these requirements, including those that merely provide the grant application as the study protocol, will be returned for correction/clarification.

RSRB Welcomes New Staff

The RSRB is proud to welcome Kristin Dauenhauer. Kristin’s role as the Reliance Specialist will focus on facilitating IRB Authorization and IRB Reliance Agreements for research deferred to an external reviewing IRB (i.e., an IRB other than the Research Subjects Review Board [RSRB]) and when the RSRB will be the Reviewing IRB for external sites.

Welcome Kristin!!

NIH Extends the Single-IRB for Multi-Site Research Effective Date

The National Institutes of Health (NIH) has extended the effective date of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research to January 25, 2018. The policy will apply to all competing grant applications for due dates on or after January 25, 2018.

Adequately planning for these submissions is a critical key to the success of these proposals! All study teams are required to meet with Tiffany Gommel, RSRB Director and Kelley O’Donoghue, Associate VP for Human Subject Research, well in advance of submissions requesting to utilize the RSRB as the reviewing IRB, to ensure adequate budgeting and monitoring have been accounted for. The following resources are also available for your reference:

- A copy of the NIH policy on the use of single IRBs can be found here.
- Scenarios illustrating the use of direct and indirect costs for single IRB review under this policy are available here.
- Video recordings and copies of the slides presented during the 10/4/2016 (Using a Single IRB Model: Implications for Researchers at the UR) and 4/20/2017 (Preparing Single IRB Grant Submissions Utilizing the RSRB as the Reviewing IRB) OHSP seminars on the policy are available on the OHSP website.
Upcoming Educational Opportunities

Achieving High Quality Clinical Research Seminar Series:
The Achieving High Quality Clinical Research Seminar Series will resume in September 2017, with a new time and location. Fall seminars will be held the last Wednesday of the month from 12-1pm in Helen Wood Hall Auditorium. Save the date for the following seminar dates: September 27th, October 25th and November 29th!

OHSP Education & Training Framework Opportunities:
Course objectives, a content outline and recommendations regarding course completion, as well as instructions for self-enrolling in the course are available here.

- **Orientation to Conducting Human Subject Research**: This course is available through MyPath. Instructions for self-enrolling in the course are available here.
- **Research Boot Camp**: This course is available through MyPath. Instructions for self-enrolling in the course are available here.
- **Core Training**: Registration for these courses is required through MyPath. Registration hyperlinks for the courses listed below are available on the OHSP Research Education & Training homepage.
  * Module 9 Essential Documentation: August 10th, 2-4pm, HWH 1W-501
  * Module 10 Quality Management: September 11th, 9am-12pm, Med Ctr 2-7534

**Note that Core Training Modules are in the process of being ‘converted’ to online training modules available via MyPath (similar to the Orientation and Research Boot Camp courses referenced above). As modules become available, they will be announced via the OHSP listserv.**

Contact Information

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