The Ins and Outs of Re-consenting:
When to Re-consent and Methods for Doing So

At some point during the life-cycle of any given study, study teams will likely encounter a situation where they need to re-consent a subject. Such circumstances may include:

- Changes in study objectives, procedures, payment or HIPAA authorization are being made;
- New information regarding potential risks and anticipated benefits emerges (e.g., the likelihood of a potential risk occurring or the magnitude of a potential risk increases);
- New alternative procedures or courses of treatment become available;
- A minor turns 18 during study participation;
- An adult subject loses capacity during participation (or regains capacity when originally enrolled by an authorized representative);
- Consent was originally obtained in a non-compliant manner (e.g., the incorrect version of the document was used); or

- The IRB or study sponsor determines that re-consent is required.

In addition to the circumstances of re-consent identified above, it is important to remember that the process of consent is ongoing and should continue through each subjects’ course of participation. The longer a subject participates, the more important it is to keep this point in mind. It is good practice to document these conversations, reconfirming the subjects agreement to continue participation, in your study records. To that end, with some longitudinal research, though it is not required, you may consider having subjects re-sign a consent at regular intervals (e.g., every 5 years).

**Methods for Re-Consenting**

Methods for re-consenting include:

- Presenting subjects with a consent addendum. A consent addendum is an effective method for providing new or revised information to subjects in a clear and concise manner as it is less dense than a full consent form. Documentation of re-consent from the subject, and the person obtaining consent, is typically obtained by signature and date.
- Presenting subjects with a revised version of the full consent form.
- Mailing subjects an informational letter. Special consideration must be given to whether documentation of re-consent is required with this method. If documentation is required, a second copy of the document and instructions for returning a signed copy must be provided with the letter.

Once you determine that re-consent is necessary, thoughtfully consider how you will re-consent subjects. The method of re-consent should be appropriate given: 1) the circumstance requiring re-consent and 2) the population you are re-consenting. In some cases, you may consider utilizing more than one method (e.g., a circumstance that requires notification to subjects still actively participating, as well as, subjects who completed participation).

As IRB review is required for amendments, study teams will need to submit their proposed process of re-consent with the amendment and the IRB will ultimately determine the
The Ins and Outs of Re-consenting

(continued from page 1)

appropriate method for re-consent.

Case Study Examples

1. A Data Safety Monitoring Board has identified a trend in elevated blood pressure among study subjects (this risk was not previously identified in the consent form) - An appropriate method for re-consent would be to contact subjects via telephone to discuss the newly identified risk with them (documenting this conversation in the study record) and then following-up with a mailed consent addendum describing the new potential risk for subjects to review.

2. Changes to the study design, procedures, number of subjects and payment have been made - Given the number of changes, it would be appropriate to utilize either a consent addendum or full version of the revised consent to re-consent subjects. If a full version of the consent is used, special care should be taken to emphasize the revised portions of the document when discussing the changes with the subject (e.g., highlighting or specifically pointing out revisions).

3. A minor turns 18 during the course of participation - As this subject has only provided assent previously, a full version of the consent form should be utilized to re-consent the subject.

If you encounter a situation where you are unsure whether re-consent is needed or are unsure of which method of re-consent is most appropriate, please contact your IRB and your study sponsor, if appropriate.

As a reminder, consent form, consent addendum and information sheet templates are available on the RSRB and WIRB website.

Did You Know...

- The OHSP website is now easily accessible from the URMC intranet providers website (see “Research (OHSP)” under “SMH Resources”).
- The Office for Research Integrity within the Department of Health and Human Services has developed a new interactive training video for study teams conducting human subject research. The video allows viewers to assume 1 of 4 critical roles within a human subject protection program. As the storyline of each role is revealed, viewers are presented with decision-making scenarios that determine the story outcome. The video can be accessed at: http://ori.hhs.gov/TheResearchClinic
- The Clinical Trials Processing Lab & Cold Storage Core is a fee-for-service resource, available within the UR, that provides support to both clinical trials and basic science research. Laboratory services include blood and tissue sample processing and shipping, for PI-initiated, industry and NIH-funded studies. The Cold Storage Core is also available for secure, on-site, long-term storage of research materials. Contact Carrie Dykes for more information.

Current Events

As a new feature to the OHSP Newsletter, we’ll be including local, national and international news articles and publications. 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.

- I Had My DNA Picture Taken, With Varying Results (Peikoff, K. (2013, December 30). I Had My DNA Picture Taken, With Varying Results. The New York Times.)
- Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem? (Steinsbekk, K. S., Myskja, B. K., & Solberg, B. Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?. European Journal of Human Genetics, 21, 897-902.)
Obtaining consent for participation in a research study is a process. The process begins at the first point of contact with the subject, continues throughout the subject’s participation with routine review of the research at study visits, and possibly also, follow-up after the subject completes the research study.

While documentation of consent is only part of the process, it is extremely important to ensure that documentation of consent is legal, valid, and effective. As such, your consent process should be reviewed on a routine basis. Here are some helpful questions to ask yourself to aid your review:

- Is the approved consent form printed on department letterhead?
- Is the watermark present and valid (has not expired)?
- Was the correct version of the consent form used? Do you print a limited number of consent forms for use or do you print current versions directly from your share drive or the RSRB Online Submission System before signing to avoid using outdated consent forms?
- Are all signatures original, complete, legible, and in indelible ink?
- Do all the signature dates match? (Signature dates must be the same date, unless the IRB-approved protocol specifies differently).
- Did the subject sign and date the document for themselves?
- Is the person obtaining consent an RSRB-approved study member?
- Are corrections indicated with a single line through the error, dated, and initiated?
- Are all applicable checkbox options completed by the subject as specified (initials/date or check/circle)?
- Was a signed copy of the consent form given to the subject and the original form filed in the subject’s research chart?
- Was the process of consent documented in narrative or checklist format in addition to signing the consent?
- Are subjects updated on changes to the study and reminded they can withdraw at any time? How was this communication documented?

OHSP-QI is pleased to announce that revised Study Self-Audit Tools to assess and review research documentation are now available for PIs, Study Coordinators and Site Staff. Study Self-Audit Tools are available at: http://www.rochester.edu/ohsp/quality/studySelfAuditTools.html

The QI division would like to recognize Matthew Miller, MD for his quality work on the ‘Head and Neck Cancer Biospecimen Bank’ trial. This dynamic study team also includes Paul Allen, PhD and Mark Merkley, MD, PhD and is located in the Department of Otolaryngology-Head and Neck Surgery.

Dr. Miller and the clinical research team received the ‘Gold Star’ award for demonstrating attention to regulatory compliance and documentation, teamwork amongst site staff, and high quality, organized research.

CONGRATULATIONS!
OHSP Training Checklists Now Available

Training checklists meant to facilitate and document study team training are now available on the OHSP Division of Research Education & Training website. Four basic training checklist are provided based on role and type of research, each with a basic set of training activities. The basic human subject training conducted through CITI and other University-required training is identified with asterisks in each checklist. Any other required training will be dependant on individualized roles. As such, these checklists are meant to act as a guide only and should be modified to suit each individual department’s and/or study team’s needs; activities that do not apply to a trainee should be eliminated from the checklist. Similarly, additional training elements can be inserted to the checklist (additional training resources for your consideration are available in OHSP’s “Study Team Member Training & Resource Reference List”). If you would like guidance on developing departmental and/or study team training standards, contact Kelly Unsworth.

Checklist Modification Considerations

- What training activities will a study team member need soon after starting their position? Are there activities that team members might find more informative if they have some experience in their position? Is there a progression of training? (Note that OHSP provides guidelines for training activities that fall within their training framework.)
- Who is in charge of overseeing and documenting training within each department and/or study team?
- How often will training progress be reviewed with new trainees?
- Will you set forth training requirements for experienced study team members? How often will this be reviewed?
- How will the department and/or study team support team members in their training?

Figure 1. Utilizing the Checklists

OHSP Research Education & Training Sessions

“Research Boot Camp”

Presented by: Kelley O'Donoghue, Tiffany Gommel & Kelly Unsworth

July 16, 2014, 8:00am-12:00pm
Helen Wood Hall Classroom 1W-502

Achieving High Quality Clinical Research Seminar Series

The Achieving High Quality Clinical Research Seminar Series will resume in September. All seminars will be announced via the OHSP listserv. To subscribe to the listserv, please email Kelly Unsworth providing your name, study team role and email address.

ROSS Training

The RSRB Office provides training for the RSRB Online Submission System (ROSS) the 3rd Monday of every month from 2-3pm. Upcoming dates include July 21st, August 18th & September 15th. To sign-up for this training, please email Sue Flanigan.
Frequently Asked Questions

Question 3.2C of the RSRB Continuing Review Form asks how many subjects have been enrolled since the last Progress Report.

When are subjects considered “enrolled” in a study?
Subjects are considered “enrolled” in a study as soon as they have given their consent to participate (even if they have yet to undergo any study procedures). In cases where a screening process is involved, the number reported in section 3.2C should include subjects deemed eligible for participation as well as screen failures (study status is clarified further in section 3.5). If your study involves reviewing pre-existing data or specimens only, your response to 3.2C should reflect the number of records or specimens accessed to date.

How do I obtain approval to use ResearchMatch.org?
ResearchMatch is a national recruitment registry that brings together researchers and people who are interested in learning more about research studies via a secure website. This free, online tool is available to University of Rochester researchers.

As with any type of recruitment method, approval must be obtained from your IRB prior to use. To obtain IRB approval, study teams must complete and submit the “ResearchMatch Approval Form” to their IRB. Submissions requesting the use of ResearchMatch that do not include this form will be returned to the study team. The form must include the recruitment message that will be sent to potential volunteers and should not include study team contact information (all communications should remain within the ResearchMatch system until individual volunteers release their personal information).

Once IRB approval is provided, the study team’s recruitment researcher (e.g., coordinator) will need to create a profile in the ResearchMatch system, enter the study details and upload a copy of the IRB-approved form into ResearchMatch. Following verification of IRB approval by our University’s ResearchMatch Institutional Liaison, the recruitment researcher will be notified that ResearchMatch access has been granted. Additional information and assistance with ResearchMatch is available through the CTSI.

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