Subject Recruitment Plans:

Key Concepts for IRB Review

The key to any study’s success often lies in the study team’s ability to recruit and enroll subjects. Meeting that challenge requires considerable planning prior to the initiation of a study and, while IRB review and approval is only one step in the process of developing a subject recruitment plan, it’s an important one. Consider the following key concepts regarding IRB review and approval of subject recruitment plans:

**Selection of Subjects Must Be Equitable**

In determining whether the selection of subjects is equitable consider whether the criteria for selecting the study population are directly related to the goal of the research:

- Is the study population the population that will most likely benefit from the research or is the population selected out of convenience?
- Does the eligibility criteria appropriately protect subjects by eliminating those that may be at increased risk?
- If you require the enrollment of vulnerable subjects to address your study question, have you explained why this is required? Have you justified the burden of participating in the research in consideration of other burdens that may already be placed on the population?

**Plans Must Be Free of Undue Influence & Coercion**

Undue influence and coercion can be introduced via multiple avenues in subject recruitment. Consider how:

- a pre-existing relationship with a potential subject may affect their decision-making process;
- the material is conveyed in a study advertisement or recruitment letter (including the method of communication, information included, and visual effects); and
- subject payments and other forms of compensation may be interpreted by the study population.

**Case Study:** A colleague at a peer institution initiates a multi-study to evaluate the use of a contrast agent in a population undergoing routine MRI imaging. While the contrast agent is approved by the FDA, it is not approved for use in the study population. Rather than randomize individual subjects, the investigator plans to randomize by enrolling sites (e.g., subjects enrolled at Site A will receive routine care while subjects at Site B will receive the investigational contrast agent). Is the selection of subjects equitable, if the burden of risk is not evenly distributed across enrolling sites?

**OHSP Response:** No, this study would not likely be approvable in its current form as subjects enrolling at the institution administering the investigational contrast agent would unduly carry the burden of risk.
(continued from page 1) staff meetings to aid in the recruitment of healthy controls. How might the presentation of this study affect the willingness of potential subjects to enroll?

OHSP Response: In this scenario, the presentation of the study by senior leadership to recruit junior faculty, employees, students (potentially including medical students, residents, graduate and post-doctoral students), etc., would be viewed as potentially coercive. Undue influence and coercion could be minimized by having an individual who is not in a position of authority present the study and enroll these potentially vulnerable subjects (while explicitly expressing the voluntary nature of the research).

Subject Privacy Must Be Protected

Only Investigators with routine access to their prospective subjects (or subject records) may recruit these individuals directly (i.e., contact in-person or via phone/writing). “Routine access” means the Investigator already has a clinical/academic reason for knowing the subject or reviewing a subject’s record. Investigators who wish to recruit subjects from populations where they do not have routine access (e.g., patients of another physician), may not contact potential subjects directly; alternative methods for identifying and contacting these subjects must be formulated.

Case Study: A faculty member and graduate student in the Department of Clinical & Social Sciences in Psychology have initiated a new study on individuals with low back pain. Recruitment flyers have been placed in public locations but enrollment has been slow. To address this, the study team would like to recruit patients from local physical therapy clinics. What would be the best approach for recruiting these subjects?

OHSP Response: As the study team does not have routine access to these subjects, the initial point of contact must come from someone within the physical therapy clinic in order to maintain patient privacy. Appropriate methods of recruiting these subjects would include providing recruitment brochures to physical therapy clinics for providers to give to potential subjects or drafting a recruitment letter that includes study team contact information for providers to mail to potential subjects.

For additional information regarding IRB review of subject recruitment plans, please see OHSP Policy 703 and OHSP Guideline for Recruitment Materials and Payment of Research Subjects.

Save the Date! Upcoming Educational Opportunities

OHSP Research Education & Training Sessions

“Research Boot Camp”
Friday, July 31st 8:00am-12:00pm, Location TBD
To register, please email Kelly Unsworth

“Core Training”
Core Training Module 8: Subject Safety
Wednesday July 29th, 12:00-1:30pm, HWH 1W-509
Core Training Module 9: Essential Documentation
Wednesday July 29th, 12:00-1:30pm, HWH 1W-509

Achieving High Quality Clinical Research Seminar Series
The Achieving High Quality Clinical Research Seminar Series will resume in September. Save the date for our Fall seminars: September 22, October 27, & November 17. All seminars are held from 12:00-1:00pm in Helen Wood Hall Auditorium (1W-304).

Miss a Previous Seminar?
Presentation materials and links to videos of previous seminar series presentations are available on the OHSP and CTSI Websites.
Preparations for AAHRPP

Re-Accreditation Underway

The University of Rochester’s Human Research Protection Program (UR-HRPP) was originally granted full accreditation status by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) on June 15th 2007. This accreditation program acts as a “gold seal” among HRPPs worldwide, demonstrating an institution’s rigorous standards for the protection of human research subjects, as well as, their commitment to scientifically and ethically sound research and continuous program improvement.

The UR-HRPP is currently in the process of applying for re-accreditation, a process that takes approximately 1 year to complete. To date, the initial re-accreditation application (of over 1000 pages!) has been submitted and an AAHRPP site visit has been scheduled. During the site visit, representatives from peer institutions (e.g., IRB and compliance professionals from other AAHRPP-accredited sites) conduct an evaluation to ensure everyday practice within the UR-HRPP is consistent with UR policies and guidelines. At this time, members of the UR-HRPP, including senior leadership, key personnel from offices overseeing the conduct of research, board members, principal investigators and study coordinators (both biomedical & behavioral) will be interviewed. Individuals selected by AAHRPP for interviews will be notified by OHSP staff approximately 2 months prior to the site visit. Further instructions and training will be forthcoming at that time.

Following the AAHRPP site visit, a report identifying any HRPP deficiencies will be issued, after which the UR-HRPP will have 30 days to provide a description of any corrective and preventative actions. The entire re-accreditation process, including the site visit report and institutional response will then be reviewed at an AAHRPP Council meeting for re-accreditation determination. Updates concerning the AAHRPP re-accreditation process will be provided via the OHSP listserv. To subscribe to the listserv, please email Kelly Unsworth, providing your name, study role and e-mail address.

Research QI ‘Gold Star’ Award

The QI division would like to recognize Alan Katz MD, MPH and Christine Huggins, PhD, CCRC for their quality work on the ‘Pilot Study of Short-Course Preoperative Stereotactic Body Radiation Therapy for Resectable Pancreatic Cancer’ trial. This dynamic study team is part of the Department of Radiation Oncology.

They received the OHSP-QI ‘Gold Star’ award for demonstrating attention to regulatory compliance, exceptional subject safety practices, and high quality, organized study-related documentation.

Congratulations!
Let's test your Quality Improvement knowledge! In lieu of an article, OHSP's Division of Quality Improvement (OHSP-QI) wants to challenge your memory (and scavenger) skills. The answers to the crossword puzzle below can be found on the OHSP-QI’s webpage, in their recent SCORE presentation and in previous 2014-2015 OHSP newsletters (the puzzle appears on page 5). The first 2 individuals to e-mail a scanned copy of the completed crossword puzzle (with the correct answers) to Jennifer Dolan will receive a nominal prize and mention in the next OHSP newsletter. (HINT: Some of the answers are more than one word.)

ACROSS
1) A type of study documentation used to clarify discrepancies.
2) Drug and device studies must document tasks ________ to study team members by the PI.
3) A central IRB.
4) The “rule book” by which OHSP-QI reviewers assess adherence.
5) Subject-specific files should include assessment of this OHSP-QI safety-related review parameter.
6) Corrections to study documentation should include this element.
7) A local IRB.
8) A type of OHSP-QI review.
9) The top QI rating of a study with consent and enrollment of subjects at the time of review.
10) A 2015 OHSP-QI initiative.
11) Signature dates of the subject and person obtaining consent should generally ______.
12) All OHSP-QI Investigator’s Meeting, regardless of review type or findings, discuss PI _____ of study activities.
13) An error or discrepancy identified during the review process.
14) A goal of OHSP-QI is to assess for ________.
15) An OHSP-QI review parameter.
16) A basis for routine (random) OHSP-QI review.
17) The method for notifying Investigators of a pending review.
18) An OHSP-QI tool available for sites to assess and review their own study documentation.
19) Corrections to study documentation should include this element.
20) The number of Routine QI reviews conducted in 2014.
21) A type of documentation log that demonstrates protocol-defined use of an investigational product.

DOWN
22) An OHSP-QI template resource.
23) Drug and device studies are reviewed under this guideline.
24) The approximate number of hours each OHSP-QI review cycle takes.
25) An OHSP-QI review parameter.
26) A type of documentation log that chronologically list subjects, by identification code, that have signed consent to participate.
27) The most common OHSP-QI review finding.
28) Drug and device studies are reviewed under this entity’s regulations from this entity.
29) OHSP-QI reviews are conducted to ensure this is protected.
30) This document requires an IRB watermark.
31) A plan developed in response to a review finding.
32) The location where OHSP-QI reviews are held.
33) A secondary goal of OHSP-QI.
34) Corrections to study documentation should include this element.
35) While reviewing signed consent forms, completion of any ______ options will be assessed.
36) An OHSP-QI review parameter.
37) The individual response for responding to OHSP-QI review findings.
38) All OHSP-QI Investigator’s Meeting, regardless of review type or findings, discuss the identification and management of potential ______.
39) The individual response for implementing the University’s HRPP (and therefore, ultimately the OHSP-QI program).
Current Events

- **Clinical Trial Data: Share and Share Alike?** (Mitka, M. [2015, March 3]. JAMA, 313 [9].)
- **Research Misconduct Identified by the US Food and Drug Administration: Out of Sight, Out of Mind, Out of Peer-Reviewed Literature** (Seife, C. [2015, April]. JAMA Internal Medicine, 175 [4].)
- **Ancestry.com is Quietly Transforming Itself into a Medical Research Juggernaut** (Hernandez, D. [2015, April 6]. The Huffington Post.)
- **Recruiting Patients for Research? Simple Explanations, Queries from Doctors are Best** (Newby, K. [2015, April 13]. Stanford Medicine New Center.)
- **A Drug Trial’s Frayed Promise** (Thomas, K. [2015, April 17]. The New York Times.)
- **Apple Makes Ethics Board Approval Mandatory for All Medical Research Apps** (Duhaime-Ross, A. [2015, April 29]. The Verge.)

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.

Office Updates

- After over 6 years of service, Igor Milosevic, RSRB Regulatory Specialist for Board 03, is leaving the University. Until a permanent replacement is hired and trained, various staff within the RSB will be covering Board 03. Questions regarding this transition can be directed to Tiffany Gommel or Emily Flagg. Best of luck to Igor and his family on their new adventure!
- OHSP recently expanded its library of resources, adding the “MediKidz Explain Clinical Trials” comic to the collection. MediKidz is a children’s medical education organization dedicated to helping children learn about various health topics in comic book format. “MediKidz Explain Clinical Trials” follows a young patient’s adventure in learning about Clinical Trials with the Mediland action heroes. The comic is available for sign-out in the OHSP office or can be purchased through the MediKidz website.

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