DSMPs are written plans that describe how the conduct and progress of a study is overseen and monitored. The goal of this plan is to:

1. Ensure that important information that may affect the safety or welfare of subjects is collected, reviewed, and acted upon as quickly as possible; and
2. Ensure the validity and integrity of the research data.

Per OHSP Policy 506, DSMPs are required for all research posing greater than minimal risk and may be required for studies involving minimal risk, depending on the nature of the study.

Developing an Appropriate DSMP

Principal Investigators (PI) are responsible for the development of DSMPs. Based on the nature, size, and complexity of the research, DSMPs can range from a simple plan where the PI periodically reviews safety data to a more extensive plan that involves a Data & Safety Monitoring Committee (DSMC).

At a minimum, DSMPs should identify the individual(s) responsible for monitoring; the process for conducting the monitoring; the mechanism for documenting the monitoring; and who will be notified of the monitoring activity outcome (e.g., IRB, study sites, sponsor).

In developing a DSMP, consider the following:

- Have you complied with all of the applicable policies/requirements? DSMPs must comply with institutional requirements, as well as, any other applicable regulatory agencies and study sponsors (e.g., the Food & Drug Administration; the National Institutes of Health).
- Are you confusing DSMPs with general safety monitoring? All studies, regardless of risk level or intervention require monitoring and reporting of research events to ensure subject safety (see OHSP Policy 801—Reporting Research Events). Only those studies that are greater than minimal risk, require formal DSMPs.
- Have you critically assessed the appropriateness of the DSMP based upon the study procedures and their associated risks? The level of monitoring must be commensurate with the nature of the study. DSMPs that are insufficient may inadvertently increase risks to subjects while DSMPs that are too extensive may run ineffectively, thereby increasing risks to subjects, or set study teams up for a compliance problem by not following the plan. Examples of appropriate monitoring levels based on risk are provided in Appendix 1 of OHSP Policy 506.
- If a DSMC will be formed, what will be their responsibilities? The responsibilities of a committee will depend on the nature of the study. Generally, responsibilities should include interim monitoring for efficacy, safety, study conduct (e.g., recruitment & retention, non-compliance, completeness of the data) and continued relevance of the study question.

(continued on page 2)
Who will act as a Safety Monitor or serve on the DSMC? Generally, safety monitors and committee members should be free of any conflicts of interest (either with the study or study sponsors) and have relevant expertise based on the role they serve within the DSMP.

Complying with a DSMP
Once a study is approved, the PI is responsible for ensuring adherence to the DSMP plan, as described in the study protocol and IRB application. As with all study procedures, documentation to demonstrate the execution of the DSMP must be maintained. Best documentation practices include maintaining:

- A written summary of each meeting or data review, noting the date/time and venue of communication (e.g., in-person, teleconference, etc.), participant list and any recommendations resulting from the meeting (see Figure 1).
- Documentation of communications to study sites, IRBs, sponsors and regulatory agencies.
- Documentation of DSMC member or Safety Monitor training/experience (e.g., curriculum vitae) and conflict of interest disclosure.

Additional data and safety monitoring information can be found in the FDA guidance document “Establishment and Operation of Clinical Trial Data Monitoring Committees” or guidance provided by the appropriate National Institutes of Health division. Data and safety monitoring will also be reviewed at an upcoming Office for Human Subject Protection seminar.

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Figure 1. Sample Data & Safety Monitoring Plan Documentation

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<td>Description of Meeting:</td>
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<td>Overview of Study:</td>
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<tr>
<td>Adverse Events Evaluation:</td>
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<tr>
<td>Additional Information:</td>
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</table>
OHSP Policies

As you’ve likely noticed through the Office for Human Subject Protection (OHSP) listserv, the office has been busy updating their policies over the past year. It is important to stay up-to-date on these policies and refer to them as necessary both during project development and throughout the lifecycle of a study. All OHSP policies and corresponding guidelines are available on the OHSP website. If you have any questions regarding the information provided in the policies/guidelines, please contact your RSRB specialist.

Reminders

Professional Certification Maintenance

If you hold a research-related professional certification through ACRP, SOCRA or PRIM&R, it is your responsibility to maintain that certification. Each certifying organization establishes their own certification maintenance requirements. Careful consideration should be paid to:

- What re-certification requirements are set forth;
- How long the certification period is;
- What standards the certifying organization sets forth concerning acceptable providers of continuing education credits;
- What continuing education supporting documentation should be maintained (most certifying organizations conduct random audits of continuing education activities); and
- Application deadlines.

Several opportunities exist within the University to obtain continuing education activity credits for re-certification purposes. This includes regularly scheduled OHSP and CTSI seminars as well as the annual SCORE half-day workshop. Typically these events are advertised through departmental/group listservs (see the hyperlinks provided above). Additional continuing education opportunities can be identified through the Center for Experiential Learning and the URMC Scientific Events Calendar. Note however, that the content of these opportunities (beyond those offered by OHSP, CTSI and SCORE) are NOT likely to be directly related to clinical research and therefore may not be accepted by your certifying organization, depending on their requirements.

Regulatory File Documentation

IRB approval letters, all approved versions of the study protocol, as well as, watermarked versions of informed consent forms and recruitment materials must be maintained for all studies, regardless of risk-level. Only the current versions of watermarked materials are available for study teams to access in the RSRB Online Submission System (ROSS); previously approved documents CANNOT be accessed directly. As such, study teams should print and/or save these documents AS SOON AS THEY ARE APPROVED. Additional information on what must be maintained in your regulatory file can be found here.

Study Documentation & Self Audit Tools

Study documentation templates and self audit tools are available on the OHSP Quality Improvement (QI) website. Questions regarding the use of these templates/tools can be directed to the QI team.
The QI division would like to recognize Carla Casulo, M.D. and Michael Brady, Ph.D. for their quality work on the ‘ULYM-13105 ~ A Phase II Study of Doxycycline in Relapsed Non-Hodgkin Lymphoma’ trial. This dynamic study team also includes the James P. Wilmot Cancer Center Research Team and is located within the Cancer Center. They received the 3rd Quarter, 2014 ‘Gold Star’ award for demonstrating attention to regulatory compliance, exceptional subject recruitment/retention practices, and high quality, organized study-related documentation. The consenting process and inclusion/exclusion criteria documentation was outstanding.

Congratulations!

Save the Date! Upcoming Educational Opportunities

OHSP Research Education & Training Sessions

“Research Boot Camp”
Presented by: OHSP Staff
October 10, 2014 8:00am-12:00pm
Helen Wood Hall Classroom 1W-509
To register, please email Kelly Unsworth

ROSS Training
The RSRB Office provides training for the RSRB Online Submission System (ROSS) the 3rd Monday of every month from 2-3pm. To sign-up for this training, please email Sue Flanigan.

Achieving High Quality Clinical Research
Seminar Series
Upcoming seminars will be held on October 21st, November 18th and December 16th from 12:00-1:00pm. All seminars will be announced via the Office for Human Subject Protection’s listserv. To subscribe to the listserv, please email Kelly Unsworth your name, study team role and email address.

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

Current Events

- **Oldest Patients Are Often Left Out of Drug Trials** (Lamas, D. [2014, May 12]. Oldest patients are often left out of drug trials. The Boston Globe.)
- **Are Therapeutic Motivation and Having One’s Own Doctor as Researcher Sources of Therapeutic Misconception?** (Kim SYH, De Vries R, Parnami S, et al. Journal of Medical Ethics. Published Online First: May 22, 2014 as 10.1136/medethics-2013-101987)
- **The Ice Bucket Challenge...Research Has Been Cut By Billions** (Segal, M. [2014, August 18.] The Ice Bucket Challenge Has Raised More Than $13 Million -- Meanwhile, Medical Research Has Been Cut By Billions. The Huffington Post.)
- **Clinical Trials May Be Compromised By Online Patient Chatter** (Silverman, E. [2014, July 30.] Clinical Trials May Be Compromised By Online Patient Chatter. The Wall Street Journal.)

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.

Research QI ‘Gold Star’ Award

The QI division would like to recognize Carla Casulo, M.D. and Michael Brady, Ph.D. for their quality work on the ‘ULYM-13105 ~ A Phase II Study of Doxycycline in Relapsed Non-Hodgkin Lymphoma’ trial. This dynamic study team also includes the James P. Wilmot Cancer Center Research Team and is located within the Cancer Center.

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Congratulations!
How do I complete the “Oversight” section when I enter a study into ClinicalTrials.gov?

If you are the owner of a record, responsible for registering a study on ClinicalTrials.gov, complete the “Oversight” box as follows:

- FDA Regulated? - Answer yes, if the study involves a drug (including supplements), device or biologic
- IND/IDE Protocol? - Answer yes, if an Investigational New Drug or Investigational Device Exemption application has been filed with the Food & Drug Administration
- Review Board? - Enter the approval status, RSRB number and the following contact information:
  
  Board Name: Research Subjects Review Board
  Board Affiliation: University of Rochester
  Phone: (585) 275-2398
  Email: rsrb@urmc.rochester.edu

  *Note that the contact information provided is generic to the RSRB office; study teams should avoid providing direct contact information for specific RSRB personnel (i.e., your RSRB specialist).
- Data Monitoring? - Answer yes, if an independent data monitoring committee is being utilized
- Oversight Authorities? - Select: 1) “United States: Institutional Review Board”; 2) “United States: Data & Safety Monitoring Committee”, if a DSMC is being utilized; 3) “United States: Food & Drug Administration”, if the study involves a drug, device or biologic (more that 1 item can be selected from the dropdown menu).

Additional support for ClinicalTrials.gov registration information is available through the CTSI’s Office of Regulatory Support and Research Help.