Communication Component of the Data Safety Monitoring Plan (DSMP)

Monitoring the progress of the research and the safety of participants are key components to a Data Safety and Monitoring Plan (DSMP).

The IRB Guidance for developing a DSMP outlines the following five key components and provides essential elements for each:

1. Monitoring the progress of clinical investigations and the safety of participants.
2. Assuring compliance with the requirements regarding the reporting of unanticipated problems or adverse experiences.
3. Assuring that any action resulting in a temporary or permanent suspension of the study is reported to the appropriate entities (i.e., funding agency, IRB).
4. Assuring data accuracy and protocol compliance.
5. Assuring communication among multi-center sites adequately protects participants.

In conducting its review of the DSMP, the IRB considers who, what, when, and how information will be shared to monitor safety.

Communication Considerations for Data Safety Monitoring Plans

- Sites
- Sponsor
- IRB

- Scientific developments
- Unanticipated problems
- Data Safety Monitoring Reports

- Risk determined intervals for routine communications
- Triggers for prompt alerts

Obtaining Data and Safety Information From Lead Centers

If a DSMP describes monitoring by an independent individual or entity such as a Data Safety Monitoring Board (DSMB), investigators provide the IRB with documentation of activities from the external monitoring entity (reports, meeting minutes, etc). Such monitoring entities are in the unique position of having information for the entire project, including project-wide events, subject withdrawals, interim findings, relevant literature, or assessment information that may assist the IRBs in reviewing the research and protecting subjects.

In situations where a multi-site clinical trial does not have a Data Safety Monitoring Board, the IRB may suggest that the UK site initiate periodic requests for information from the lead coordinating site or center.

Documentation evidencing DSMP or DSMB activities may be submitted by the investigator as a modification request. At continuation review the investigator submits any documentation not previously submitted. The IRB reviews to reassess the risk category and determine whether any additional information should be shared with research participants or added to the informed consent document.
UK INVESTIGATOR QUICK GUIDE TO IRB REPORTING REQUIREMENTS

While conducting human research, investigators are responsible for ongoing IRB reporting and communications designed to keep the IRB informed about the research. Much of the communication includes correspondence the investigator prospectively submits for review by the IRB during the conduct of a human study, such as protocol modifications or continuing and final review submissions.

However, like life in general, new information becomes available or unanticipated events occur which needs to be reported for review by the IRB. ORI has developed an abbreviated guide of common events that may occur during the conduct of a human research study which require reporting to the IRB.

Designed as a quick “bulletin board” reference, the one-page guide outlines reporting categories and provides web addresses to applicable policies, procedures, or forms for obtaining reporting details and timelines.

Policy for Scheduling Runner Pick–Up of Time-Sensitive/Confidential Material

While campus mail is sufficient for the majority of correspondence between the ORI office and investigators, there are ORI/IRB materials that warrant pick up or delivery by the UK Research Department Runner. The Research Runner is employed by Research Administrative & Fiscal Affairs for the delivery of time sensitive and confidential information and serves all units under the Vice President for Research (VPR).

**Please note: The information below is for areas that are non VPR units and for areas that are not mandatory daily stops.

Research runner pick-up requests from investigator offices external to the VPR units must be arranged by ORI to prevent duplicate requests. Call the main ORI line (257-9428) with your protocol number so that we may direct your request to the applicable staff. ORI staff will arrange for IRB related material that meets Research Runner criteria below to be picked up from the investigator for delivery to ORI. To meet the Research Runner policy, the material must be:

- Time sensitive (≤24 hour) information; or
- Confidential Information (information of sensitive nature or identifiable subject information* such as signed consent forms)

*subject records, such as medical records submitted as supporting documents, should have identifiers removed or blacked out and replaced with study subject codes.

As always, a research investigator may contact ORI if he/she has an urgent need for IRB correspondence to be sent electronically.

If you have questions regarding the UK Research Runner policy, please contact Toni Smith (257-8288) at UK Research Administrative and Fiscal Affairs.

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Registration information to come soon.

2012 Human Research Protection Regional Conference
Friday, October 5, 2012
Northern Kentucky Convention Center

“Human Subject Protection: With A Little Help From Our Friends”

The 2012 conference will feature a diverse group of speakers discussing cutting edge topics such as:

- Research ethics, vaccine misinformation and other lessons from “The Panic Virus”
- Improving Informed Consent
- Internet research
- Ethical relativism and its impact on research
- Returning genetic research results to subjects
- Human Subject Protection update from OHRP

Configurer education credits and nursing credits available. Attendance also counts as UK human subject protection refresher training.

Co-sponsored by Schulman Associates IRB, Cincinnati Children’s Hospital Medical Center, the University of Cincinnati and the University of Kentucky