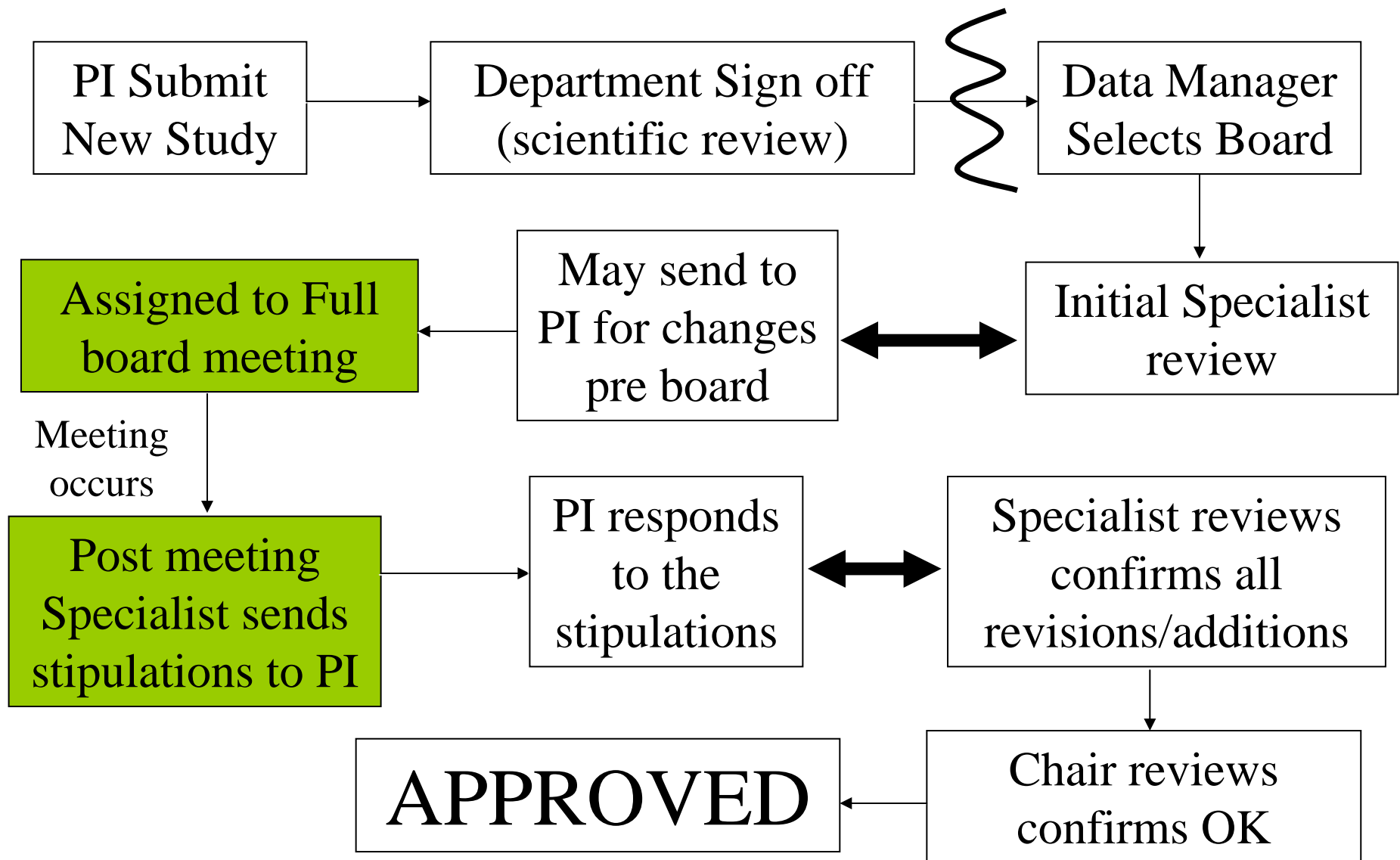
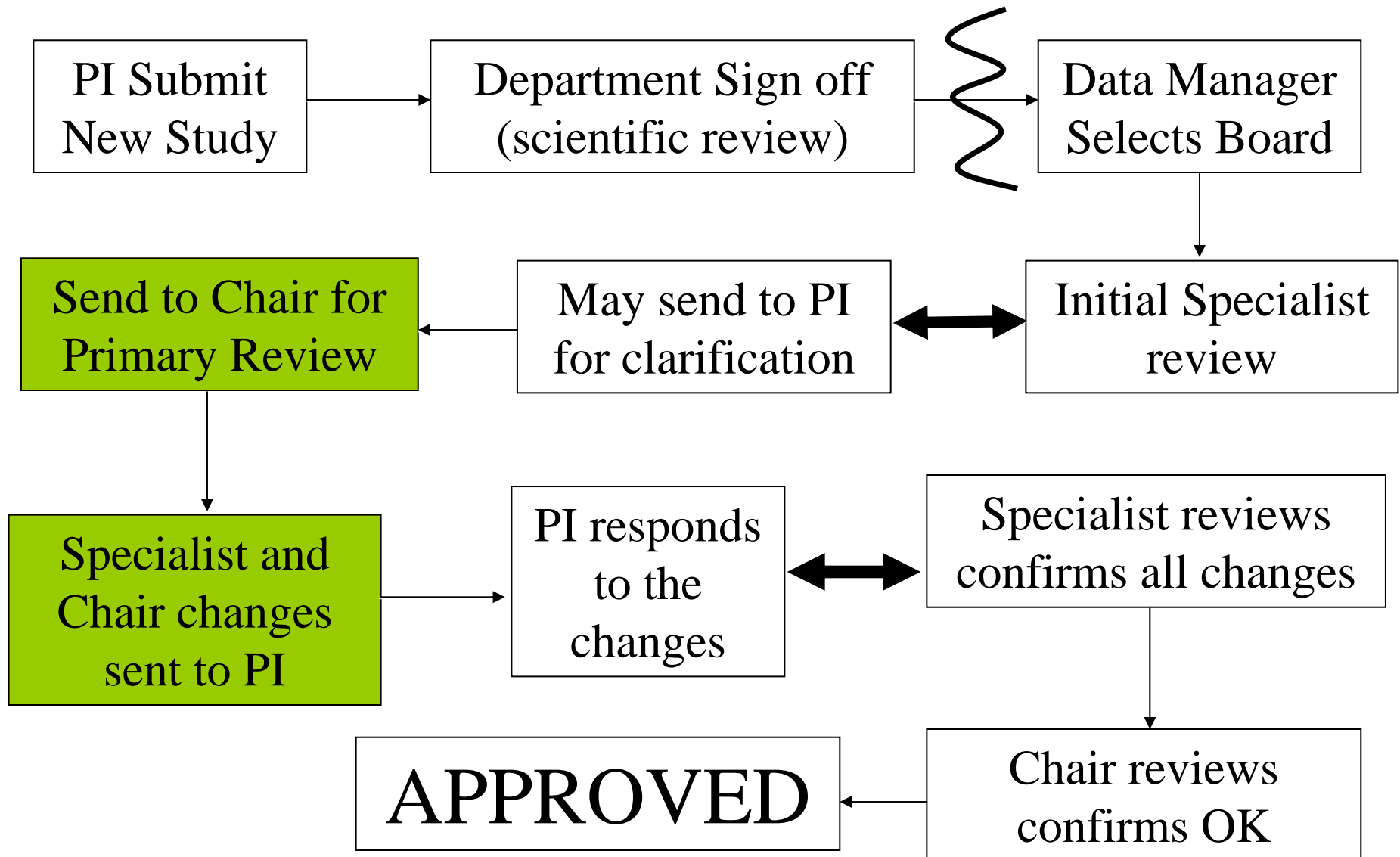


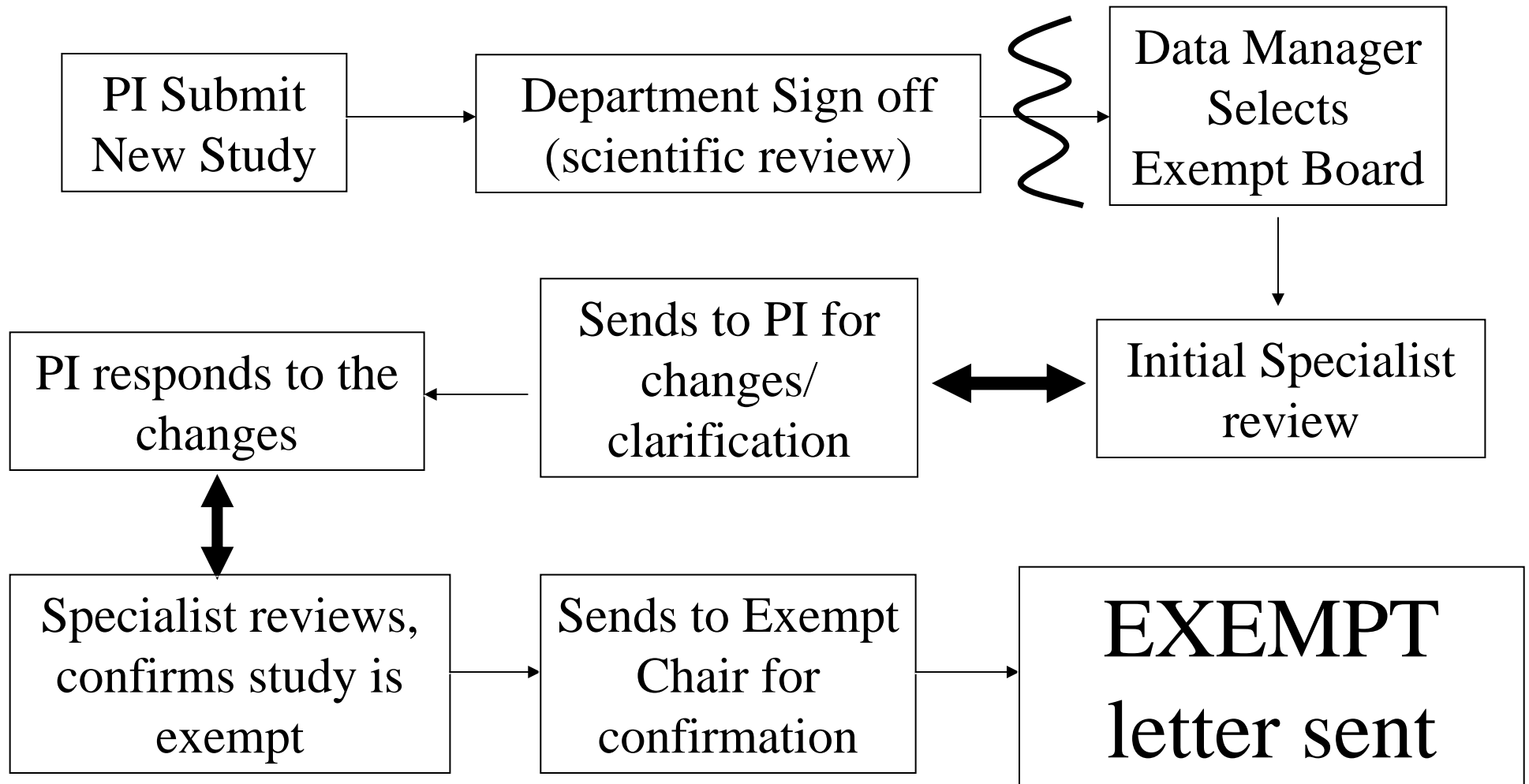
Process for **FULL BOARD** Review



Process for **EXPEDITED** Review



Process for **EXEMPT** Review



Informed Consent: Additional Resources

UR:

- RSRB Website: www.rochester.edu/rsrb
 - Investigator Guidance (Available under “Guidance Documents”):
<http://www.rochester.edu/rsrb/documents/pdf/invguidance.pdf#pagemode=bookmarks&page=1>
 - Consent Templates (Available under “Document Templates”):
<http://www.rochester.edu/rsrb/submission-documents/index.html>
- Glossary of Lay Terms: <http://www.rochester.edu/rsrb/documents/pdf/layterms.pdf>
- Miner Library - Health Literacy Toolkit:
http://www.urmc.rochester.edu/hslt/miner/selected_topics/HealthLiteracyToolkit.cfm
- CTSI Research Subject Advocacy Program (Nancy Needler):
<http://www.urmc.rochester.edu/ctsi/research/regulatory-support/rsa-program.cfm>

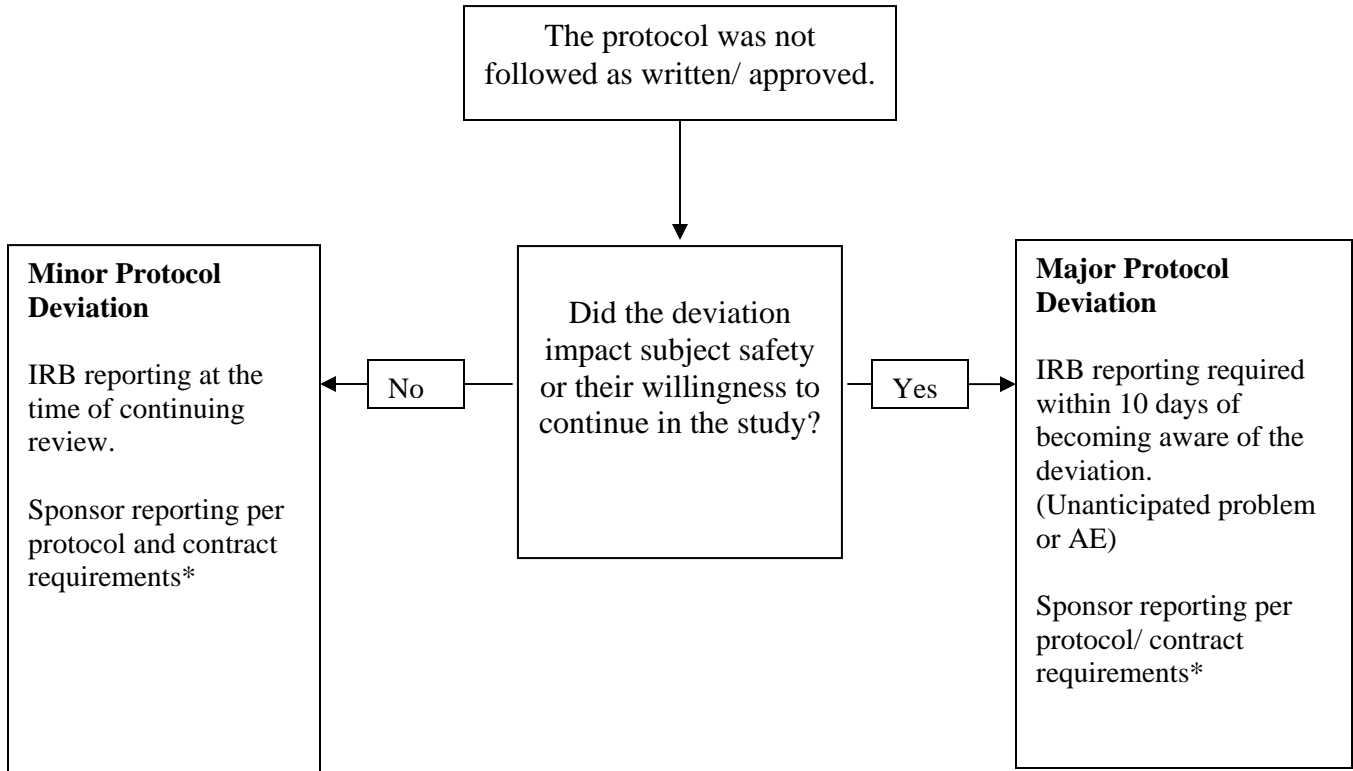
DHHS/FDA:

- The Belmont Report: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>
- OHRP Informed Consent Guidance: <http://www.hhs.gov/ohrp/policy/consent/index.html>
- OHRP Video – General IC Requirements:
<http://www.youtube.com/watch?v=URo4x4pv68A&p=5965CB14C2506914>
- FDA – A Guide to Informed Consent:
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>
- Agency for Healthcare Research and Quality – Informed Consent and Authorization Toolkit for Minimal Risk Research: <http://www.ahrq.gov/fund/informedconsent/>
- National Center for Health Marketing – Plain Language Thesaurus for Health Communications:
http://depts.washington.edu/respcare/public/info/Plain_Language_Thesaurus_for_Health_Communications.pdf
- E6 Good Clinical Practice – Consolidated Guidance:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>

Miscellaneous:

- Mathieu, Mark P., ed. Good Clinical Practice A Question & Answer Reference Guide, May 2010. Barnett Educational Services / Chi, 2010.

Protocol Deviation Decision Tree



***Sponsor and IRB reporting are typically not the same.**

****Planned protocol deviations MUST be approved by the sponsor AND IRB in advance.**

Reportable Events

Definitions:

- **Involving risks to subjects or others** - some harm (physical, psychological, social, financial, or legal) or discomfort has occurred or is/was possible and affects subjects or "others" (e.g., subject's family, research team, third parties, etc.).
- **Serious** - an event that results in any of the following outcomes:
 - Death
 - life-threatening event
 - inpatient hospitalization or prolongation of existing hospitalization
 - a persistent or significant disability/incapacity
 - congenital anomaly/birth defect,
 - requires medical or surgical intervention to prevent one of these outcomes

Non-drug/device studies SERIOUS - any event that caused a prolonged or permanent harm, which may be psychological, social, legal or financial, e.g. loss of identifiable, sensitive data.

- **Unanticipated/Unexpected** - the event was unforeseen and has not been previously encountered, known, or recognized and was not identified in nature, severity, or degree of incidence in the protocol (investigational plan), supporting documentation (e.g., Investigator Brochure), the informed consent document, or the RSRB application.
- **Related to the study** – the PI determines that the event occurred due to some aspect of the study;
 - research procedure - existence of a laptop database
 - study drug
 - study procedure

Guidance for Reporting Reportable Events to the RSRB

Available on the RSRB Website under “Reportable Events”

http://www.rochester.edu/rsrb/documents/pdf/Reporting_Reportable_Events_Guidance.pdf

Reportable Event Types in RSRB Online Submission System (ROSS):

- **Type 1: A locally occurring “serious adverse event” per FDA definitions** - Reports of adverse events that are Serious, Unexpected, Related and occur at UR or sites for which the UR-PI has responsibility.
- **Type 2: Batched report of several off-site adverse event reports.** No study changes requested - Sponsors (industry or federal) may send reports of adverse events occurring at any test site to investigators. There is no regulatory requirement to forward these to the RSRB.
- **Type 3: Not Currently Being Used**
- **Type 4: An unanticipated problem involving risks to subjects or others (UPIRTSO)** that occurs in a UR study or that impacts UR subjects or conduct of the UR study - Unanticipated problems involving risks to participants or others (UPIRTSO) may or may not be an “adverse event” per FDA regulations. Report “non-toxicity” events as UPIRTSOs. Examples include lost laptops with identifiable data, recruitment letters sent to the wrong people breaching privacy, overdoses, etc.
- **Type 5: Monitoring body report (Data Safety Monitoring Board – DSMB, Data Monitoring Committee – DMC)** - Formal monitoring bodies send to investigators summary reports on the status of studies (e.g., keep open, close early). These reports are reviewed when submitted and also in continuing review.
- **Type 6: Receipt of new information** (including changes in risks or benefits) that may impact the willingness of subjects to participate or continue to participate in the research study - New information of this type could need to be presented to all subjects (past, current, future). These reports may require a change in the consent process/form, if so, then file an amendment and do not continue this event report. (The event is reported as the reason for the amendment.)

- **Type 7: Changes made to the research without prior RSRB approval** in order to eliminate apparent immediate harm - Such investigator-initiated changes for safety reasons may show a need for a change in the study, if so, then file an amendment and do not continue this event report. (The event is reported as the reason for the amendment.). Use this Type to report one-time changes that do not call for changes to the study.
- **Type 8: An incident of non-compliance** with the University's policies or the requirements or determinations of the RSRB - Investigator self-reports of non-compliance with federal regulations or the requirements of the RSRB that affect the rights, safety, or welfare of subjects or others.
- **Type 9: Investigator-initiated voluntary suspension of research** - Investigators may suspend all or part (enrollment, test procedures, etc) of a research study to consider changes to the research, investigate risks to subjects or others, etc. These reports keep the RSRB apprised of the status of approved research.