LOMA LINDA UNIVERSITY

ADVENTIST HEALTH SCIENCES CENTER

OPERATING PROCEDURES

CATEGORY:	RESEARCH AFFAIRS	**CODE:**	H-27A
		APPROVED:	8/17/2010
SUBJECT:	PROCEDURES FOR CONDUCT OF CONVENED INSTITUTIONAL REVIEW BOARD (IRB) MEETINGS	**IMPLEMENTED:**	11/2010
		REPLACES:	
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Please note: Definitions are found at the end of this document. Words used will be underlined the first time they appear.

Convened meetings of the IRB shall be conducted in accord with applicable federal regulations, 45 CFR 46.108, 45 CFR 46.109, 21 CFR 56.108, and 21 CFR 56.109. The following procedures describe the conduct of IRB meetings:

1. Institutional Review Board (IRB) Administrator Pre-meeting Responsibilities:

   1.1 Develops, maintains, and revises, as appropriate, the IRB meeting schedule.

   1.2 Arranges IRB meeting location and catering after confirming meeting dates.

   1.3 Screens incoming IRB Application Packages.

   1.4 Assigns primary reviewer, and if applicable, a secondary reviewer.

   1.5 Prepares the agenda, in consultation with the IRB Chair.

   NOTE: The IRB Chair has the authority to alter the agenda anytime.

   1.6 Assembles the IRB member agenda packet.

   1.7 Distributes materials to IRB members planning to attend that specific meeting, and Ex-Officio (non-voting members) prior to the meeting, and in a time frame sufficient for review, as follows:

   a. All Members: IRB member agenda packet

   b. Primary/Secondary Reviewers: IRB Member agenda packet, IRB Application Package for all studies these members serve as the primary or secondary reviewer on, Full Board Reviewer's Worksheet, amendment review checklist and continuing review checklist, and PI's continuing review report and attachments.

c. Consultants: If a consultant is assisting in the review of a specific agenda item, s/he will be provided a copy of the IRB Application Package for that protocol, similar to that sent to the primary reviewer.

d. IRB Chair: IRB Member agenda packet and IRB Application Package for all studies.

1.8 Prepares and distributes an addendum to the agenda prior to the beginning of the IRB meeting, at the discretion of the IRB Chair, if applicable.

2. Institutional Review Board (IRB) Administrator Responsibilities During Meeting:

2.1 Assures IRB meeting room is set up for logistics of meeting.

2.2 Obtains signed Confidentiality Agreements from any attendees who have not previously signed one.

2.3 Records information for the IRB minutes (per IRB Minutes procedure – in progress).

2.4 Advises attendees on regulatory issues and institutional policies and procedures, as needed.

2.5 Obtains reviewers' notes, copies of related materials, and marked-up documents and arranges for appropriate disposal of non-reviewers' materials.

2.6 Provides other administrative support to IRB Chair and members as directed or required.

3. IRB Chair Responsibilities:

3.1 Confirms a quorum is present, in accord with federal regulations and institutional policy.

3.2 Invites individuals such as faculty, students, or other guests to attend as observers, or accepts recommendations from members to do so.

3.3 Invites the Principal Investigator (PI) to attend a convened IRB meeting, when appropriate, to aid in protocol review and to facilitate an efficient or adequate review.

3.4 Oversees the conduct of the IRB meeting, following the agenda as a guideline.

3.5 Excuses invitees and guests, at his/her discretion, to ensure a protective environment.

3.6 Excuses members who have a conflict of interest (per IRB Member Conflict of Interest Policy & Procedure – In Progress).

3.7 Confirms that individuals with appropriate expertise participate in the review process.

4. Primary Reviewer Responsibilities (During Meeting)

NOTE: In the absence of the primary reviewer, the secondary reviewer assumes his/her responsibilities. In the absence of both assigned reviewers, the IRB Chair may designate another member to assume those responsibilities, may assume those responsibilities himself, or may defer discussion to the next IRB meeting.

4.1 Presents the protocol in accord with LLU IRB Primary Reviewer's Worksheet.

4.2 Prepares a motion that includes the following:

a. one of the following approval categories:

i. Approved
ii. Conditionally Approved
iii. Tabled
iv. Disapproved

b. one of the following risk categories:

i. minimal risk
ii. minimal additional risk
iii. minor increase over minimal risk
iv. moderate risk
v. high risk

c. an approval period (if approved or conditionally approved) appropriate to the degree of risk but not longer than one year. If proposing the review be conducted more often than annually, other consideration factors include:

i. risk category
ii. the investigator's level of experience related to the study
iii. the institution's awareness of the investigator's ability to conduct human subject research in a compliant manner
iv. investigator-initiated – study may need shorter approval period and more oversight and monitoring
v. the nature of the provisions for safety monitoring, which includes the Data Safety Monitoring Board (DSMB) See policy – in progress.
vi. use of an investigational drug, device, or biologic with greater than minimal risk involved
vii. complexity of study design

5. IRB Member Responsibilities (During Meeting):

5.1 Reviews and votes on IRB meeting minutes.

5.2 Reviews and acknowledges the Interim Report of Administrative Actions.

5.3 Discusses the motion proposed by the primary reviewer.

5.4 Makes determinations required by regulations and protocol-specific findings:

a. waiver or alteration of specific required elements in the informed consent
b. the rationale for significant risk/non-significant risk device
c. safety monitoring
d. benefits outweigh risks

5.5 Proposes a modification to the final motion to reflect discussion.

5.6 Votes formally on the proposed motion (for, against, or abstain).

6. Institutional Review Board (IRB) Administrator Responsibilities (Post-Meeting):

6.1 Provides administrative support and prepares IRB meeting minutes per 45 CFR 46.115(a)(2) or 21 CFR 56.115(a)(2) for review by the IRB Chair and formal adoption by the IRB in session.

6.2 Provides documentation to the PI describing the IRB's decision using the IRB approved template, per 45 CFR 46.109(d), and, if applicable, 21 CFR 56.109(e):

a. Approved: approval notice includes a list of any stipulations limiting approval. The following applicable items will be attached:

i. approved informed consent, including translations (stamped, with dates)
ii. assent (stamped, with dates)
iii. HIPAA authorization
iv. California Experimental Subjects Bill of Rights (stamped, without dates)
v. recruitment materials
vi. other subject related documents

b. Conditional Approval: an interim notice describing required revisions to be addressed before final IRB approval can be released.

c. Tabled: a notice listing the reasons for tabling and include a description of the revisions or clarifications requested (see Guidance on Investigator's Response to a Tabled Decision – in progress).

d. Disapproved: a notice describing the reasons for disapproving the protocol.

6.3 Maintains records of IRB decisions for each protocol in the institution's database (See Record Retention Policy – in progress).

7. Principal Investigator (PI) Responsibilities (Post-Meeting):

   7.1 Responds to requested revisions within approximately 3 months of the IRB meeting or the application may be withdrawn.

   7.2 Conducts the study in accord with IRB approval.

Definitions:

Institutional Review Board (IRB) Approval: the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. [45 CFR 46.102(h), and, if applicable, 21 CFR 56.102(m)].

IRB Member Agenda Packet: this includes the agenda, applicable educational materials, minutes, Report of Interim Administrative Actions, Outline of Research Reports – Full Board Review of Extension Requests; and for new protocol submissions, the application form, informed consent document(s), assent (if applicable), and protocol, or protocol summary).

Conditionally Approved: changes requiring only the concurrence of the principal investigator (PI) or non-substantive clarifications, that, when met, will allow the release of the IRB approval.

Disapproved: the determination of the IRB that the research reviewed does not meet regulatory and institutional requirements for approval, as submitted.

High Risk: used subjectively at the discretion of the IRB to convey a sense of magnitude of research-related risk that is greater than moderate risk. High risk studies may include those involving cardiac or back device implants.

IRB Application Package: includes the application form, abstract, informed consent document(s), protocol or protocol summary, investigator's brochure, recruitment materials, and appendices.

IRB Chair: the individual designated by the President to provide leadership and expertise for the overall IRB review process and serves as the primary representative of the IRB for the institution.

IRB Members: persons listed on the Office of Human Research Protection (OHRP) Membership Roster, and includes both primary and alternate voting members.

Majority: means greater than 50%.

Minimal Additional Risk: used subjectively at the discretion of the IRB to convey that the risks associated with research procedures are minimal regardless of the risk involved in standard care procedures associated with the subject's underlying condition. Thus for regulatory purposes, "minimal additional" is a minimal risk category.

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]

Minor Increase over Minimal Risk: regulatory term for studies involving children.

Moderate Risk: used subjectively at the discretion of the IRB to convey a sense of magnitude of research-related risk that is greater than minimal. Moderate risk studies may include those involving experimental drugs.

Primary Reviewer: a voting member of the IRB chosen based upon the appropriate level of experience, educational background, and expertise to serve as the leading reviewer and presenter of human subject research reviewed at convened IRB meetings.

Quorum: greater than 50% of the IRB voting members present in person or connected simultaneously via speakerphone or video, including one member whose primary concerns are in a non-scientific area [45 CFR 46.108(b)]. If both the primary and alternate member are present, only the primary member counts toward quorum and voting. Conflicted members cannot count towards quorum.

Secondary Reviewer: a voting member of the IRB chosen based upon the appropriate level of experience, educational background, and expertise to evaluate the assigned agenda item and serves to supplement the findings of the primary reviewer and second the motion.

Stipulations: narrower limits imposed by the IRB (e.g. more narrowly restricted inclusion/exclusion criteria, approval for only one stage of the study, approval of fewer recruitment sites, or limitations on recruitment mechanisms). The study may begin on this limited scale, but the PI retains the option to later submit a change request to reverse the stipulation, usually after additional information or effort is accomplished.

Tabled: the IRB has determined that the research reviewed has significant outstanding issues that cannot be resolved by way of requiring stipulations to the proposed research and must be resubmitted for further review.

Tele/video Conferencing: participation by IRB members, remote from the meeting site, being connected by telephone or video conference.