LOMA LINDA UNIVERSITY

ADVENTIST HEALTH SCIENCES CENTER

OPERATING POLICY

CATEGORY:	RESEARCH AFFAIRS	**CODE:**	H-27
		APPROVED:	8/17/2010
SUBJECT:	CONDUCT OF CONVENED INSTITUTIONAL REVIEW BOARD (IRB) MEETINGS	**IMPLEMENTED:**	11/2010
		REPLACES:	02/2009
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Please note: Definitions are found at the end of the associated procedure. Words used will be underlined the first time they appear in a document.

1. Convened meetings of the LLUAHSC 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.

2. Convened meetings of the IRB shall meet the following federal and institutional requirements for attendance and quorum:

   2.1 The IRB Chair shall chair the meeting.

      a. For planned absences, the IRB Chair may designate an experienced IRB member to serve as chair of the meeting.

      b. For an unexpected absence of the IRB Chair, the IRB administrative staff shall recruit an experienced member to serve.

   2.2 A quorum of the IRB voting members shall be present (or simultaneously connected via speakerphone/video) for all reviews/actions that must be voted upon.

   2.3 At least one member whose primary concerns are in non-scientific areas shall be present [45 CFR 46.108(b) and, if applicable, 21 CFR 56.108(c)].

   2.4 At least one physician shall be present for vote on FDA-regulated research.

   2.5 When research involves prisoners, the following federal regulations apply [45 CFR 46.304]:

      a. a majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

      b. at least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. Where a particular research project is reviewed by more than one Board, only one Board need satisfy this requirement.

2.6 Convened meetings may be conducted by tele/video conferencing as long as IRB member(s) have received copies of all the documents to be reviewed at the meeting, a quorum is met, and discussion occurs in real-time.

2.7 IRB Members with conflict(s) of interest related to a specific protocol may be permitted to answer questions during IRB's review of that protocol. However, any conflicted members shall not be present during discussion, shall not vote upon and shall not count towards meeting quorum for the vote on the particular protocol for which the members have conflict(s) of interest [45 CFR 46.107(e), and, if applicable, 21 CFR 56.107(e)]. See IRB Member Conflict of Interest Policy – in progress.

2.8 If a quorum is lost during a meeting, the IRB shall not take further protocol actions that require a vote unless the quorum is restored [45 CFR 46.108(b), and, if applicable, 21 CFR 56.108(c)].

2.9 If a primary and his/her alternate member are both present, only the primary shall count towards the quorum and vote.

2.10 Ad hoc consultants may attend in person or send written comments for IRB consideration, but shall not count towards a quorum for voting purposes [45 CFR 46.107(f), and, if applicable, 21 CFR 56.107(f)].

3. Review of Protocols:

3.1 The Chair of the IRB meeting shall foster a protective environment, where members may engage in free and open dialogue without the fear of personal recrimination or reprisal.

3.2 The IRB shall determine that all of the following applicable requirements are satisfied, before approving any research protocol [45 CFR 46.111(a)(1-7) and 21 CFR 56.111(a)(1-7)]:

a. Risks to subjects are minimized.

b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result.

c. Selection of subjects is equitable.

d. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative, unless specifically waived by the IRB [45 CFR 46.116(d), and, if applicable, 21 CFR 50.24].

e. Informed consent will be appropriately documented, per (policy in development).

f. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

g. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

3.3 The IRB shall assure that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects [45 CFR 46.111(b) and, if applicable, 21 CFR 56.111(b)(c)].

3.4 The IRB shall determine the interval for continuing review of research appropriate to the degree of risk, but not less than once per year [45 CFR 46.109(e), and if applicable, 21 CFR 56.109(f)].

4. Voting:

4.1 Only IRB members present at the convened meeting or participating in the conference/video call may vote.

NOTE: Although voting by proxy is not allowed, absentee members may provide written comments for IRB consideration.

4.2 A motion shall pass when a majority of the quorum votes in favor of the motion [45 CFR 46.108(b), and, if applicable, 21 CFR 56.108(c)].

Approved: LLUAHSC President's Council – August 17, 2010

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Vice President, Research Affairs	Date
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President	Date
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Corporate Secretary	Date