Section 300:	**FUNCTIONS AND OPERATIONS**		
Standard Operating Procedure (SOP):	**302 RESEARCH ETHICS BOARD (REB) MEETING ADMINISTRATION**		
This SOP pertains to:	REB Staff and Members		
Responsibility for executing this SOP:	Director, Research Ethics, Research Ethics Staff, the Chairs of the U of S Research Ethics Boards and the Vice-President Research		
Approval Authority	The Vice-President Research		
Effective Date:	July 1, 2012	**Superseded documents dated:**	

1. PURPOSE

This SOP provides the framework to ensure that REB Meetings are conducted and documented in a consistent manner in order to meet regulatory and institutional requirements.

2. POLICY

Except when a delegated / expedited review procedure is used, the REB will review proposed research at convened meetings at which a quorum is present.

3. SPECIFIC POLICIES

3.1 Quorum

3.1.1 A quorum is defined as including a minimum of five members representing the scientific, ethical, community and legal or non-scientific constituencies as set out in 3.1.2 below. Where applications must conform to US regulations, an additional quorum requirement of a majority (50% +1) of the regular and/or substitute members will pertain.

3.1.2 A quorum consists of regular and/or their substitute members and requires at least two members, whose primary concerns are in scientific areas, one member whose primary concern is in a nonscientific area, one member who is knowledgeable in ethics, one member who is knowledgeable in the relevant law and one community member who has no affiliation with the institution. For drug trials, one of the scientific members must be from a medical discipline, or if regarding a dental drug from a medical or dental discipline. A representative who is knowledgeable in complementary or alternative health care must be in attendance to review clinical trials involving natural health products for therapeutic purposes.

TCPS2 Article 6.4
45 CFR 46.107
21 CFR 56.107

The Natural Health Products Regulations part 4

3.1.3 In all cases the Chair will ensure that there is adequate expertise to provide appropriate ethical and scientific

review of the study (ies) in question. **3.1.4** A substitute member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above. **3.1.5** Ad hoc reviewers will not be used to establish quorum. **3.1.6** Non-voting members cannot be used to establish quorum. **3.1.7** No votes will be taken without a quorum	
3.2 Primary Reviewers Prior to the meeting, the Chair or designate will identify two primary reviewers for each research project or protocol as per SOP 203 Article 3.2.2. Amendments and annual renewals that are required to be reviewed by the Full Board in accordance with regulatory or sponsor requirements will be assigned to one primary reviewer. No member will be assigned a study in which she or he is a Principal or a co-investigator. If studies are inadvertently assigned to REB members with a conflict of interest, the REB member is required to notify REB administration immediately.	Primary Reviewers duties outlined in SOP 203 Article 3.2.2.
3.3 Meeting Materials Sent Prior to REB Meetings All REB members will have access to study documentation required for review in sufficient time prior to the meeting to allow for adequate review (normally 7 days). The documentation will be posted on the PAWS system and REB members will receive an e-mail notifying them that the material has been posted and may be viewed on PAWS. Meeting materials will include: **3.3.1 Agenda:** A meeting agenda will be prepared by REB staff. A copy of the agenda and attached materials will be maintained on the PAWS system. **3.3.2 Summary report of REB activities** for the preceding period. **3.3.3 Review materials:** All REB members will have access to all relevant study documentation including: • REB Applications • Proposed informed consent documents • Complete protocol for new and renewal applications • Questionnaires and assessment instruments • The Investigator's brochure • Any other supporting materials, such as examples of recruitment advertising, etc.	

- Minutes from the previous meeting
- Completed U of S REB Protocol Review Forms.

3.3.4 Access to Study Documentation during Meetings:
All REB members in attendance at REB meetings have access to a lap-top computer connected to the PAWS system to enable them to view all study documentation as listed in 3.3.2.

3.4 Minutes

3.4.1 Recording: The REB Facilitator or designate will take minutes of each meeting. Minutes will be in accordance with the applicable Board template. They will be written in sufficient detail to show the following:

- Meeting attendance; presence of any ad hoc reviewers, guests or observers;
- Declarations of conflicts of interest and recusals, if any;
- Actions taken by the REB on each agenda item requiring full REB action, including, the basis for requiring changes in or for disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Voting results, including for, against (if applicable) and members who abstain from voting.
- The minutes do not include reviewer comments submitted on PAWS that were not discussed at the meeting. The complete set of comments / issues for all studies are produced in a separate document and retained.

3.4.2 Approval: Minutes will be posted online prior to the next REB meeting for review and approval.

Corrections requested by the REB will be noted in the minutes of the next meeting and the minutes with corrections (if any) will be approved. REO Staff will amend the prior minutes in accordance with the approval.

3.5 Telephone Use

3.5.1 Convened meeting using speaker phone
In unusual circumstances, should a member not be able to be physically present during a convened meeting, but be available by telephone, or video-conference link, the meeting can be convened using a speaker phone or video-conference link. The member who is not physically present will be connected to the rest of the members via

speakerphone or video-conference link. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone call may vote provided they have had an opportunity to review all the material the other members have reviewed.	
3.5.2 Meeting Conducted Via Telephone Conference Calls Under very unusual circumstances (e.g. public health alerts and quarantines) the Chair may at his/her discretion convene an REB meeting via telephone conference call. A quorum (as defined in 3.1 above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place – "telephone polling" (where members are contacted individually) will not be accepted as a conference call.	
3.6 Approval by Consensus Members of the REB generally approve studies by consensus, which is noted as a unanimous vote in the REB minutes. Where consensus is not achieved the decision will be made by majority vote, with the minutes reflecting who was opposed to the majority decision. The REB may take the range of activities described in SOP 404. Members will also determine the level of risk, the frequency of review for each protocol, appropriate monitoring and whether third party assessment and follow up will be needed.	SOP 404
3.6.1 Exception for US Federally Funded and FDA Regulated Research If a U of S REB is reviewing a study that is funded by the US Federal Government or that is subject to the US Food and Drug Administration Regulations, study approvals shall be made by a formal counted vote specifying the number of REB members present at the time of approval, the number of members voting for, against and abstaining. The votes will be recorded in the minutes in the following format Total = 15; Vote: For – 14, Opposed – 0, Abstained – 1.	45 CFR 46.115(a)(2)