2.2 Full IRB Review

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for: 1) submission of items required for full IRB review; 2) organization, scheduling, and conduct of full IRB meetings; 3) IRB approval criteria; 4) IRB actions; and 5) IRB documentation of actions.

2.0 Policy

It is the policy of the Organization that:

- 2.1. IRB review will be conducted in accordance with HHS regulations at 45 CFR 46.109; FDA regulations at 21 CFR 56.109; and will satisfy the criteria for IRB approval described in HRPP policy 2.5 (Criteria for Approval) and in 45 CFR 46.111 and 21 CFR 56.111, as applicable.
- 2.2. The HRPP will apply equivalent protections to non-federally funded research. These protections will be based upon the ethical principles in the Belmont Report. In addition, the requirements in 45 CFR 46, Subpart A, B, C, and D will be applied to the greatest extent possible in consideration of the nature of the research.
- 2.3. The Organization that will apply the ICH-Good Clinical Practice (GCP) E-6 Guidelines to studies where the sponsored agreement requires compliance with ICH GCP for clinical trials conducted internationally in accordance with HRPP policy 1.13 (Compliance with ICH-GCP Guidelines).
- 2.4. The IRB will conduct continuing review of research at intervals appropriate to the degree of risk, in accordance with 45 CFR 46.109 and HRPP policy 2.7 (Continuing Review of Research).

3.0 Definitions

- 3.1. Controverted issues are issues that cause controversy and dispute among the IRB membership during a convened meeting. Controverted issues that arise during the convened meeting may be the result of opposition to some aspect of the proposed research or may regard applicability or interpretation of ethics or regulation.

4.0 Procedures

- 4.1. All IRB applications are submitted to the ORA and processed in accordance with HRPP policy 2.1 (Submission of Items for Review by the IRB).
- 4.2. IRB Meeting Schedule
  - 4.2.1. The schedule of IRB meeting dates is posted on the IRB website.
    - 4.2.1.1. IRB-01 meets the first Thursday of every month (except January and July), and IRB-02 meets the third Thursday of every month.
    - 4.2.1.2. IRB-04 (Joint Pediatric IRB) meets the fourth Tuesday of every month (unless such date conflicts with a University holiday).
    - 4.2.1.3. IRB-03 (Rapid Response IRB) meetings are held on demand and convened as soon as possible, as per HRPP policy 1.30 (Use of the Rapid Response IRB).
    - 4.2.1.4. IRB-05 (Single IRB) meets the second Friday of every month, as required, based on items for review.
- 4.3. Quorum
  - 4.3.1. A full IRB meeting cannot be convened without the presence of a quorum. A quorum must represent a majority of the voting membership of the IRB, including at least one member whose primary concerns are in nonscientific areas.
  - 4.3.2. Each IRB includes one member that is not affiliated with the Institution. It is expected that least one unaffiliated member will be present at each meeting of each IRB as per HRPP policy 1.6 (IRB Composition, Leadership, Qualifications, & Responsibilities).
  - 4.3.3. IRB meetings may be conducted in person, or via video conferencing, as appropriate. Members will have access to all relevant materials prior to the meeting and will be able to participate actively and equally in all discussions.

- 4.3.4. When the IRB reviews any research involving children, or cognitively impaired persons, an IRB member who is knowledgeable about and/or experienced in working with that specific population will be present in accordance with HRPP policy 1.6 (IRB Composition, Leadership, Qualifications, & Responsibilities).
- 4.3.5. When the IRB reviews any research involving other vulnerable populations, an IRB member who is knowledgeable about and/or experienced in working with vulnerable populations (preferably but not exclusively the particular population in question) will be present in accordance with HRPP policy 1.6 (IRB Composition, Leadership, Qualifications, & Responsibilities).
- 4.3.6. When the IRB reviews any research involving prisoners, a prisoner representative must be present in accordance with HRPP policy 4.3 (Research Involving Prisoners).
- 4.3.7. Any IRB member who abstains from voting for reasons other than a COI (as defined in HRPP policy 1.7) is included in the quorum. This is recorded as an abstention in the minutes.
- 4.3.8. Any IRB member who has a COI will be recused in accordance with HRPP policy 1.7 (IRB Member, Consultant, Staff COI Identification & Management). This is recorded in the minutes as “recused due to conflict of interest” and the quorum is decreased accordingly. The name of the individual recused will be recorded in the minutes.
- 4.3.9. A designated IRB Analyst is responsible for determining quorum requirements, monitoring attendance at the meeting to verify maintenance of quorum, and recording the actions taken on all protocols and other items under review.
- 4.3.10. If attendance at a convened full IRB meeting falls below quorum (including losing all non-scientist members, or another required member), the meeting will be immediately suspended and no official business will be conducted until a quorum is re-established. If it is not possible to re-establish the quorum, the meeting will be adjourned and the remaining reviews will be conducted at the next available full IRB meeting.

- 4.4. Assignment of Reviewers and Creation of the Agenda
  - 4.4.1. Reviewers will be assigned by the IRB analysts with advice from the IRB Executive Chair/designee as necessary.
  - 4.4.2. For new IRB Applications and tabled IRB Applications, at least a primary and secondary reviewer, and usually a non-scientist reviewer, will be assigned. At least one of the assigned reviewers will have relevant scientific, medical, or other expertise in order to perform an in-depth review of the protocol.
    - 4.4.2.1. For IRB-03 (Rapid Response IRB) a non-scientist reviewer may not be specifically assigned; however, a non-scientist is always present during the meeting.
    - 4.4.2.2. For IRB-04 (Joint Pediatric IRB), a pharmacy reviewer is generally also assigned to research involving drugs.
  - 4.4.3. For applications for continuing review, one reviewer will be assigned, unless it is determined by the IRB Executive Chair/designee that more than one reviewer is necessary.
    - 4.4.3.1. Continuing review of protocols in which subjects are in standard follow-up (all research interventions are completed) may be assigned to a non-scientist, provided there is a scientist present during the meeting with relevant scientific, medical, or other expertise.

    - 4.4.4. For requests for change in protocol and/or ICF, reviews of internal adverse event reports, incident reports (including potential unanticipated problems involving risk to the subject or others, or noncompliance or complaints), or other special review items, one reviewer will be assigned, unless it is determined by the IRB Executive Chair/designee that more than one reviewer is necessary.
    - 4.4.5. If during the pre-review process, the IRB Analyst or reviewer determines that the board will require additional expertise, the services of an expert consultant will be obtained prior to the meeting, as described in HRPP policy 1.6 (IRB Composition, Leadership, Qualifications, & Responsibilities).
    - 4.4.6. All IRB members will be notified by email that a detailed agenda is available in RSS. This agenda contains: 1) education, policy, and informational items; 2) a categorized list of review items; 3) IRB reviewer assignment for each of the items under review, 4) notification of items approved by expedited review (in accordance with HRPP policy 2.3 Expedited Review) and per requirements of 45 CFR 46.110(c), 21 CFR 56.110(c), 5) IRB approval criteria, and 6) description of IRB actions.
- 4.5. Review Materials Distributed to IRB Members
    - 4.5.1. All members and alternates scheduled to attend an IRB meeting (in person or by videoconference) will have access through RSS to all submitted items described in HRPP policy 2.1 (Submission for Items for Review by the IRB), as well as all previously submitted materials, correspondence and IRB determinations related to protocols under consideration by the board.
    - 4.5.2. Materials will be available at least 7 days prior to the meeting with the following exceptions:
        - 4.5.2.1. Materials for IRB-03 (Rapid Response IRB) will be made available as soon before the meeting as is feasible.
        - 4.5.2.2. Occasional review items may be presented to the board at the time of the meeting. In all cases, the reviewer of these items (usually the Executive Chair, or other chair/vice-chair) will have had access to these items in advance of the meeting.
    - 4.5.3. At least two days prior to each meeting, all members and alternates of all Boards will have access through RSS to the following:
        - 4.5.3.1. IRB minutes of the last meeting of that Board
        - 4.5.3.2. Education, Policy and Information items
        - 4.5.3.3. Full agenda for that meeting
- 4.6. IRB Member Review Procedures
    - 4.6.1. All IRB members must be satisfied that they have sufficient information to make the determinations required for IRB approval in accordance with 45 CFR 46.111; 21 CFR 56.111, and HRPP policy 2.5 (Criteria for IRB Approval).
        - 4.6.1.1. IRB members must be satisfied that they have the appropriate expertise to review the protocol. If they do not, then the reviewer or any IRB member may request that the review be deferred and a consultant with appropriate expertise be obtaining, in accordance with HRPP 1.6 (IRB Composition, Leadership, Qualifications, and Responsibilities) section 3.1.3.
    - 4.6.2. IRB members are expected to consult the IRB study files in RSS (including but not limited to the IRB application, full protocol, investigator's brochure, questionnaires and surveys, recruitment and other subject facing materials, and consent documents), applicable regulations, and HRPP policies, as necessary during their review of the protocol.

    - 4.6.3. IRB members are expected to submit written reviews, as early as possible, to ORA.
    - 4.6.4. Deficiencies and/or major points of clarification which require revision of the IRB application or other review item should be described fully, and referenced to sections of the submitted application, to the Reviewer Template, or to the Criteria for Approval at 45 CFR 46.111.
    - 4.6.5. Deficiencies, errors, inadequate explanations, and excessively high readability level should be described sequentially according to the section of the ICF.
- 4.7. IRB Meeting Procedures
    - 4.7.1. When a quorum of the Board is present, the IRB meeting is called to order by the IRB Executive Chair, Chair, Vice Chair, or designee (subsequently referred to as “Chair” in this policy) and each item on the agenda is acted upon.
    - 4.7.2. The Primary Reviewer will present the review followed by the other assigned reviewers (secondary reviewer, non-scientist reviewer, pharmacy reviewer) as applicable. The protocol is then open for discussion by all IRB members. When the discussion is completed, a separate vote will be taken on each application or other item under consideration.
    - 4.7.3. When appropriate, IRB staff will present submitted materials from RSS or information from other sources (including applicable federal, state, and local regulations, and HRPP policies) to assist IRB members in their deliberation.
    - 4.7.4. Relevant regulatory information, including criteria for IRB approval, Subpart B, C, and D determinations, will be available to members, as part of the agenda, or when meeting in person, as placemats or other physical items, to assist IRB members.
    - 4.7.5. Whenever a controverted issue arises during an IRB meeting, or when the vote is less than unanimous, members will be asked if they wish to submit written comments or minority opinion. These items will be appended to the minutes of the meeting.
- 4.8. Voting Requirements
    - 4.8.1. The Primary Reviewer will recommend an action which must be seconded by another IRB member, normally the Secondary Reviewer.
    - 4.8.2. IRB voting on each motion will be recorded as the number of members in favor, the number against, and the number of abstentions. Separate votes for each action will be recorded.
    - 4.8.3. Except as specified in other sections of this policy, no motion shall pass unless two-thirds of the IRB members which constitute the quorum are present during the discussion and vote in favor of the motion.
    - 4.8.4. If a member must leave the meeting temporarily before the vote is taken, the vote can be delayed. If the vote is not delayed, the name of the absent member will be recorded in the minutes.
    - 4.8.5. Only those members physically in the room or attending by videoconference may vote. Absentee voting is not permitted.
    - 4.8.6. If a motion fails to pass by a two-thirds vote, other motions will be entertained. If no further motions are made, the protocol or issue under discussion shall automatically be deemed to have been tabled and shall be referred, as needed, to an IRB subcommittee for further study.
    - 4.8.7. If a protocol or issue has been referred to an IRB subcommittee, the Chair or a member of the subcommittee will present the results of the subcommittee meeting at any subsequent full Board meeting.
    - 4.8.8. The Chair will abstain from voting, except as needed to break a tie vote.

- 4.9. Criteria for IRB Approval and Other Determinations
  - 4.9.1. During all reviews, the IRB must determine whether the criteria for IRB approval have been (or continue to be) met, per HRPP policy 2.5 (Criteria for IRB Approval).
  - 4.9.2. As appropriate and as relevant to specific board reviews (such as review of new protocols, continuing reviews, review of requests for change in protocol or ICF or other types of IRB reviews as described previously) the IRB must also determine:
    - 4.9.2.1. Whether the research requires continuing review more often than annually, as required at 45 CFR 46.108(a)(3)(ii); 21 CFR 56.109(a)(2), as appropriate to the degree of risk. In making this determination the IRB may consider factors including but not limited to: the nature of the risks associated with the research; the degree of uncertainty regarding the risks involved; the vulnerability of the participants; the experience of the investigator in conducting the research; the IRB's previous experience with that researcher or sponsor; the projected rate of enrollment.
    - 4.9.2.2. Whether the research should have a third party observe the consent process in accordance with HRPP policy 1.2, Section 2.7 (Authority Granted to the IRB by the Organization).
    - 4.9.2.3. If the research involves an FDA regulated investigational device, the IRB will also determine and document the basis for determination that the investigation involves a significant risk device or non-significant risk device (in accordance with 21 CFR 812.66 and HRPP policy 6.2 (Research involving Investigational and Marketed Devices)).
    - 4.9.2.4. Whether the research needs verification from sources other than the PI that no material changes have occurred since the previous IRB review, as required at 45 CFR 46.108(a)(3)(ii) and 21 CFR 56.108(a)(2).
    - 4.9.2.5. Whether the current consent form is still accurate and complete.
    - 4.9.2.6. Whether the research requires an audit of research records in accordance with HRPP policies 1.21 (Post Approval Monitoring of Research) and 8.4 (Review of Noncompliance Involving Risk to the Subject or Others).
    - 4.9.2.7. Whether there are any significant new findings that arise from the review process that might relate to a subject's willingness to continue participation in the study.
    - 4.9.2.8. When the PI is the lead researcher of a multi-site trial, whether the management of information to the protection of human subjects is adequate, such as reporting of unanticipated problems, interim results, and protocol modifications.
  - 4.9.3. The IRB may determine that some components of the research have met the IRB criteria for approval whereas other components require minor or substantive changes, or are unacceptable. In this case, the IRB may choose to approve or conditionally approve those components that satisfy the IRB approval criteria. For those components that do not meet the IRB approval criteria the IRB may table or disapprove that component (as per IRB actions described below).
- 4.10. IRB Actions
  - 4.10.1. Approval; initiation of the research is authorized (when institutional requirements are satisfied).
    - 4.10.1.1. All of the criteria for IRB approval are satisfied and no changes are required.

- 4.10.2. Conditional approval; final IRB approval contingent upon IRB Executive Chair/designee review and acceptance of specified modifications and/or submission of additional documents.
  - 4.10.2.1. All of the criteria for IRB approval are satisfied provided the investigator makes the specified changes. The IRB requirements for final approval and release are considered minor and not substantive in nature.
- 4.10.3. Tabled, full IRB re-review required.
  - 4.10.3.1. The IRB requires additional information in order to determine whether the criteria for approval have been satisfied, and/or the IRB had concerns which warrant re-review by the full IRB.
  - 4.10.3.2. If the protocol and application are revised by the investigator in response to the IRB's comments, the protocol will be returned to the full convened IRB for re-review.
- 4.10.4. Disapproved
  - 4.10.4.1. Applications may be disapproved if (1) the IRB finds serious ethical concerns that cannot be resolved after discussions with the investigator, or (2) the protocol does not meet regulatory criteria for approval or institutional policy or requirements, and the investigator is unable to make modifications to meet the criteria or requirements.
  - 4.10.4.2. The investigator shall have an opportunity to appeal before the Board; however, the IRB has the final authority to act on any appeals and the decision of the Board cannot be overturned.
- 4.10.5. Suspension of IRB approval
  - 4.10.5.1. The IRB requires all research activities be halted immediately in accordance with HRPP policy 8.6 (Study Hold, Suspension, and Termination). This action may be taken in relation to continuing review, complaints, noncompliance, adverse events, and unanticipated problems involving risk to the subject or others.
- 4.10.6. Termination of the research
  - 4.10.6.1. The IRB requires the study be terminated in accordance with HRPP policy 8.6 (Study Hold, Suspension, and Termination). This action may be taken in relation to continuing review, complaints, noncompliance, adverse events, and unanticipated problems involving risk to the subject or others.

- 4.11. IRB Review Letters
  - 4.11.1. IRB review letters, which reflect the deliberations and decisions of the Board, are developed by the IRB Analysts, in consultation with the IRB Executive Chair/designee and reviewers as appropriate.
  - 4.11.2. IRB review letters must be written in a clear, explanatory, and facilitative fashion in order to assist PIs in understanding the rationale for any IRB concerns, clarifications and mandated changes to the IRB application, ICF(s)/information sheet(s) and/or other associated documents.
  - 4.11.3. The IRB review letters will clearly document the following:
    - 4.11.3.1. The decision to approve, require modifications, table, or disapprove.
    - 4.11.3.2. A list of any modifications or clarifications required by the Board.
    - 4.11.3.3. If the IRB disapproves the action, a statement providing the rationale for the disapproval, and an invitation for the investigator to appeal.
  - 4.11.4. Review letters are signed by the IRB Analyst in accordance with HRPP policy 1.19 (IRB Signature Authority).

- 4.12. IRB Meeting Minutes
  - 4.12.1. Basic Information
    - 4.12.1.1. The IRB minutes are based upon the actions of the IRB recorded in detail by the assigned IRB Analyst. The minutes are then developed after the meeting by the IRB Analysts in consultation with the IRB Executive Chair/designee.
    - 4.12.1.2. The IRB minutes consist of the core minutes and addenda (which contain the detailed review letters provided to the investigator for all protocol related activities).
    - 4.12.1.3. Copies of the core IRB minutes and addenda are available on RSS to IRB members (including alternates) and the Institutional Official, before the next meeting of the board.
    - 4.12.1.4. IRB members for each board have the opportunity to review and correct minutes for the previous convened meeting of that board.
    - 4.12.1.5. The complete IRB minutes will be provided to OHRP, FDA, auditing groups, and other entities in accordance with all applicable federal, state, and Organizational requirements.
  - 4.12.2. The minutes (core and addended review letters) will contain the following information, as appropriate:
    - 4.12.2.1. Identification of the individuals present at the meeting: IRB members, non-voting IRB member alternates, consultants, IRB administrative staff, and guests.
      Note: If consultants are present, a brief description of the consultant expertise will be noted as well as documentation that the consultant did not vote on any actions.
    - 4.12.2.2. Identification of IRB members classified as non-scientists.
    - 4.12.2.3. If the meeting was conducted in-person, the minutes will note by name any IRB members, non-voting IRB member alternates and consultants who attended videoconferencing. If the entire meeting was conducted via teleconferencing, the minutes will so note.
    - 4.12.2.4. Identification of alternate IRB members and the IRB member for whom they are substituting.
    - 4.12.2.5. The names of IRB members who have a COI and are recused at the time of the discussion and vote on each board action.
    - 4.12.2.6. The names of IRB members who do not have a COI but are absent from the room for other reasons at the time of the vote on each board action.
    - 4.12.2.7. IRB special notification items per IRB minutes template.
    - 4.12.2.8. Documentation of quorum for each separate vote count for all board actions (in favor, opposed, and abstentions).
    - 4.12.2.9. In the event a consultant provided an in-depth review of research the agenda will document the information provided by the consultant and verify that the consultant did not vote.
    - 4.12.2.10. Verification that all IRB members who attended through videoconferencing were able to actively participate in all discussions and votes.
    - 4.12.2.11. A written summary of the discussion and resolution of controverted issues.
    - 4.12.2.12. A written summary of the discussion and resolution of actions taken with regard to significant new findings either provided by the investigator or provided by other sources, which may relate to the subject’s willingness to continue participation in the research.

- 4.12.2.13. The reason(s) for disapproval of research.
- 4.12.2.14. A determination of when continuing review is required more often than annually.
- 4.12.2.15. A determination of which projects need verification from sources other than the PI that no material changes have occurred since the previous IRB review.
- 4.12.2.16. A determination of which projects should have a third party observe the consent process.
- 4.12.2.17. A determination of which projects require an audit of research records.
- 4.12.2.18. Rationale for conducting continuing review on research that otherwise would not require continuing review.
- 4.12.2.19. Rationale for an expedited reviewer's determination that research appearing on the expedited reviewer list is more than minimal risk.

5.0 Deadlines for PI Responses

- 5.1. The PI is given 60 days from the date of the IRB review letter to respond to the IRB's review by submitting appropriately revised documents. If no response is received by the end of the 60-day period, or by the expiration of an extension provided granted by the IRB Executive Chair/designee) the study may be withdrawn or closed.

6.0 Review of PI Responses

- 6.1. If the IRB required only minor, directed modifications, the IRB Analyst serves as the designated reviewer and is authorized to review and determine the acceptability of the PI's response. The IRB Analyst will consult with the IRB Executive Chair/designee or IRB reviewers as necessary.
- 6.2. If, on consultation with the Executive Chair, the Analyst determines that the investigator's response to the IRB review is inadequate or incomplete they may correspond with the investigator to resolve those issues or may refer the submission for review by the full convened IRB.
- 6.3. If, on consultation with the Executive Chair, the Analyst determines that the investigator's response to the IRB review contains significant changes not initially reviewed by the IRB, they will refer the submission for review by the full convened IRB.

- 6.4. If the IRB required modifications/clarifications that are more than minor in nature (that is, if the submission was tabled), the investigator's response will be returned to the full convened IRB for re-review. If possible, the revised submission is assigned to both the IRB that performed the initial review and the original primary and secondary reviewers.

7.0 IRB Approval Periods

- 7.1. The approval period for protocols for which continuing review is required is based on the date that the convened IRB gave conditional approval of the research. Studies approved with annual continuing review are valid for 364 days from the date of conditional approval; the approval period expires on the 365th day.

8.0 Final IRB Approval Letter

- 8.1. Once all modifications or clarifications required by the Board (as per section 4.11) have been satisfied, and all outstanding Institutional Requirements have been met (section 9.) the ORA will inform the PI that the research may commence.
- 8.2. The final approval letter from ORA will document the following determinations:
  - 8.2.1. Pertinent dates:
    - 8.2.1.1. Date of full Board review.
    - 8.2.1.2. Date all conditions set by the IRB were determined to be met and the study was granted IRB approval.
    - 8.2.1.3. Expiration Date for which continuing review is required (per section 7.1 above).
  - 8.2.2. Compliance with applicable HHS and FDA regulations, HRPP policies and Institutional Requirements.
  - 8.2.3. Documentation of the level of risk (minimal risk or greater than minimal risk).
  - 8.2.4. Documentation that the IRB determined that the research satisfies the requirements of 45 CFR 46, Subpart B and the designated category (46.204; 46.205; 46.206). Per Section 2.2 of this policy the IRB will apply Subpart B as required for federally funded research and for non-federally funded research to the greatest extent possible. Any alteration of Subpart B requirements as applied to non-federally funded research will be documented.
  - 8.2.5. Documentation that the IRB determined that the research satisfies the requirements of 45 CFR 46, Subpart C (46.305) and is appropriately classified under

the designated category {46.306(2)(i); 46.306(2)(ii); 46.306(2)(iii); 46.306(2)(iv)}, as applicable. Per Section 2.2 of this policy the IRB will apply Subpart C as required for federally funded research and for non-federally funded research to the greatest extent possible. Any alteration of Subpart C requirements as applied to non-federally funded research will be documented.
    - 8.2.6. Documentation that the IRB determined that the research satisfies the requirements of 45 CFR 46, Subpart D and has met all the requirements for the designated category (46.404; 46.405; 46.406; 46.407), as applicable. Per Section 2.2 of this policy the IRB will apply Subpart D as required for federally funded research and for non-federally funded research to the greatest extent possible. Any alteration of Subpart D requirements as applied to non-federally funded research will be documented.
    - 8.2.7. Documentation that the IRB determined that the research satisfies the requirements of 21 CFR.50, Subpart D and has met all the requirements for the designated category (50.51, 50.52. 50.53, 50.54), as applicable.
    - 8.2.8. Documentation that the IRB considered protocol specific findings for research involving decisionally impaired subjects, as per HRPP policy 4.6 (Review of Research Involving Subjects with Impaired Decision-Making Capacity).
    - 8.2.9. Documentation of the nonsignificant or significant risk device determinations.
    - 8.2.10. Documentation that the IRB determined that the research satisfies the requirements for waiver of informed consent/ HIPAA authorization as per HRPP policy 5.2 (Waiver or Alteration of Informed Consent and HIPAA Authorization).
    - 8.2.11. Documentation that the IRB determined that the research satisfies the requirements for waiver of child assent as per HRPP policy 4.4 (Research Involving Children).
    - 8.2.12. Documentation that the IRB determined that the research satisfies the requirements for waiver of signed consent as per HRPP policy 5.4 (Waiver of the Requirement to Obtain Signed Consent Form).
- 8.3. The Final approval letter from ORA will note that the determinations were made by the convened IRB, and the specific justifications for the determinations can be found in the approved IRB application, accompanying submitted materials, and/or minutes.

9.0 Review by Other Organizational Committees

- 9.1. Before the ORA will grant final approval and release, the ORA must receive verification of approval or completion of review by components of the HRPP as described in HRPP Policy 1.10 (Scientific and Other Committee Review of Research) and as required by the organization.

DOCUMENT HISTORY:

? Written: 4/4/2016 (Approved: 4/4/2016) - original author not recorded

? Revised: 3/29/2018 - revision not documented

? Revised: 6/2/2021 - Added IRB-05; added definitions (section 3.0); simplified overall by referencing other policies where appropriate; revised procedures to reflect activities during teleconference meetings; clarified when meeting materials will be available (especially for RR-IRB and special review items); revised to delete references to paper copy distribution of materials (all materials available thru RSS); clarified assignment of reviewers; added that chair may vote to break a tie vote; clarified types of other IRB determinations (section 4.9); deleted list of types of items for which documentation of quorum required (section 4.12); revised deadlines for PI responses to be consistent with Policy 2.3. (Expedited Review); clarified that IRB administrator authorized to communicate with investigator to resolve inadequate or incomplete responses to request for minor modifications or clarifications; revised description of contents of condition approval and final approval letters; deleted references to pre-2018 Common Rule and corrected regulatory citations.

? Revised: 10/13/2022 - Modified definition of “controverted issues”; revised throughout to reflect meetings by video conference; clarified identification of members recused; deleted list of materials supplied to members and clarified that materials available in RSS; deleted 20 minute discussion time limit; clarified that IRB approval is distinct from ORA release; deleted IRB action “decline to review”; clarified criteria for disapproval; combined descriptions of contents of core minutes and addended letters; revised policy to require documentation of findings and determinations in the final ORA approval letter as opposed to the initial IRB review letter. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised: 10/13/2022 - amended section numbers due to removal of 4.10.5, amended 8.1.1 to align with heading 8.2, amended 8.2 sequentially to 8.3 (Robert Lewis - IRB Assoc)

? Board Notified: 11/22/2022

? Revised: 11/30/2022 - corrected language in 4.3.3 from: “IRB meetings may be conducted in person, or via video conferencing, as appropriate. In either case If meetings are conducted by video conference, Members will have access to all relevant materials prior to the meeting and will be able to participate actively and equally in all discussions.”, to: “IRB meetings may be conducted in person, or via video conferencing, as appropriate. Members will have access to all relevant materials prior to the meeting and will be able to participate actively and equally in all discussions.” (Robert Lewis - IRB Assoc)

? Revised: 7/31/2023 – revised sections 4.4.5 and 4.6.1.1 to more fully describe the assessment of the need for an expert consultant; added description of items to be reviewed (section 4.6.2); revised 4.10.3.2 to state explicitly that tabled protocols will be returned to the convened IRB for further review. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 3/29/2024 – revised criteria for disapproval (section 4.10.4). {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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