Title: HRRC Meeting Preparation

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Reviewed/Recommended for Approval:
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Approved:
Richard Larson, MD PhD Vice Chancellor for Research

Date: 7/10/15

1 PURPOSE
1.1 This procedure establishes the process to prepare for a convened HRRC meeting.
1.2 The process begins when the agenda is closed, approximately 10 business days before a meeting date.
1.3 The process ends when HRRC meeting agenda materials are made available to HRRC members for review.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Section 3 Policy: Removed specific committee meeting times so SOP does not have to be updated when meeting time is changed.
2.2 Section 3.9: Increased number of days prior to meeting from 5 to 7 for providing materials to committee members.
2.3 Section 3.10: Clarified criteria for re-opening an agenda.

3 POLICY
3.1 HRRC members are informed of committee assignment, including the regularly scheduled meeting time, in the member's appointment letter.
3.2 At least one HRRC member or consultant is responsible for scientific/scholarly review of research.
   3.2.1 Review by a funding agency, an organizational scientific review committee or department chair may be used in combination with scientific/scholarly review by the HRRC.
3.3 Protocols are reviewed by HRRC members and consultants with sufficient expertise.
3.4 When HRRC members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
3.5 HRRC members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
3.6 For new submissions, a primary and a secondary reviewer are assigned.
3.7 For follow-on submissions, at a minimum, a primary reviewer is assigned.
3.8 Alternate HRRC members serve the same function as other HRRC members, except that if the alternate HRRC member and the regular HRRC member for whom the alternate member is substituting are both present only one member may vote.
3.9 Review materials are provided to all HRRC members at least 7 days before convened meetings.
At the request of the HRRC chair or HRRC manager, a closed agenda may be re-opened between 5 and 7 days before a convened meeting (but not less than 5 days) in order to accommodate emergent items where there is a possibility of increased risk to participants.

4 RESPONSIBILITIES
4.1 HRPO staff members carry out these procedures.

5 PROCEDURE
5.1 The Pre-Team staff member carries out the following procedures upon completion of the Pre-Review in advance of closing the agenda:

5.1.1 Assign the submission to an HRRC meeting.
5.1.2 Consult “DATABASE: HRRC Roster (HRP-601)” to be aware of the experience, expertise, and representational capacity of the HRRC.
5.1.3 Execute the “Assign Reviewers” activity in the submission workspace to assign a primary (and secondary, if applicable) reviewer.

5.1.3.1 Using a “Private Comment:"

5.1.3.1.1 Attach the completed Pre-Review Checklist (HRP-401)
5.1.3.1.2 Attach the appropriate Committee Review Recommendations Checklist
5.1.3.1.3 Attach other relevant checklist(s) and worksheet(s) as indicated by Pre-Review.
5.1.3.1.4 Attach any other relevant minutes or correspondence.

5.1.4 Instruct primary reviewer to upload the associated, completed checklist(s) as a private comment in advance of the meeting. Execute the “Assign Reviewers” activity in the submission workspace to assign a scientific/scholarly reviewer. The primary reviewer and the scientific/scholarly reviewer may be the same individual.

5.1.5 Assign the submission to the appropriate Post-Team staff member in the submission workspace.

5.2 The Post-Team staff member carries out the following procedures:

5.2.1 Confirm which HRRC members (regular, alternate, and chairs) will be present at the meeting.
5.2.2 Review all submissions placed on the agenda for a convened HRRC meeting. Ensure that all assigned primary reviewers will be present at the meeting.

5.2.2.1 If an assigned primary or secondary reviewer will not be present at the meeting, reassign the submission following steps 5.1.2-5.1.4.

5.2.3 Prepare an agenda for the meeting.

5.3 Use “WORKSHEET: Quorum and Expertise (HRP-305)” to ensure that the meeting will be appropriately convened and to ensure the HRRC will have the appropriate expertise for each protocol.

5.3.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.
5.3.2 Follow the procedures in “SOP: Consultation (HRP-051)” to obtain consultants. Note any consultants on the agenda.

5.4 For individuals who are provided materials (IRB members, consultants):
University of New Mexico Health Sciences Center
Human Research Protections Office

5.4.1 Execute the “Send Agenda” activity in the meeting workspace to deliver review materials to reviewers.

5.4.2 WORKSHEET: Review materials (HRP-301) may be used as an optional resource to provide support for HRPO staff that prepare materials for committee review.

6 MATERIALS
6.1 DATABASE: HRRC Roster (HRP-601)
6.2 SOP: Consultation (HRP-051)
6.3 SOP: Definitions (HRP-001)
6.4 CHECKLIST: Committee Review Recommendations (various)
6.5 WORKSHEET: Review Materials (HRP-301)
6.6 WORKSHEET: Quorum and Expertise (HRP-305)

7 REFERENCES
7.1 45 CFR §46.108(b)
7.2 21 CFR §56.108(b)