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1. PURPOSE

- 1.1. The purpose of this **policy** is to describe the process to prepare for a convened Institutional Review Board (IRB) meeting and the primary reviewer system utilized at the University of Georgia (UGA).

2. DEFINITIONS

- 2.1. **Primary Reviewer:** the primary reviewer is the member with the most relevant expertise or experience pertaining to the study procedures, design, and/or targeted **human participants**.
- 2.2. **Secondary Reviewer:** the secondary reviewer is the member with similar relevant expertise or experience pertaining to the study procedures, design, or human participants. The secondary reviewer also conducts a full review of the submission and confirms the recommended determination or provides supplemental information for consideration.
- 2.3. **Quorum:** to achieve quorum at meetings, at least one more than half the number of **regular members** in the IRB Roster, including a **nonscientist** and a member who represents the general perspective of participants, must be present. When the membership roster consists of an even number (N), a quorum is defined as $(N/2)+1$.
 - 2.3.1. The nonscientist and the member who represents the general perspective of participants may be the same individual.

3. POLICY

- 3.1. A quorum must be established at least two weeks prior to the scheduled meeting date.
 - 3.1.1. If quorum for a meeting is not met, the meeting is re-scheduled or canceled. If appropriate expertise is not available for a study, the study is removed from the agenda and re-scheduled for another meeting when the expertise becomes available.
 - 3.2. The agenda for the meeting must be published no later than one week prior to the scheduled meeting date.
 - 3.3. A report of expedited reviews is available to IRB members on the meeting workspace in the portal.
 - 3.4. Meeting minutes from the previous convened meeting must be made available to IRB members at least two weeks prior to the meeting.
 - 3.5. Protocols must be reviewed by IRB members with relevant expertise.
 - 3.5.1. If the submission requires an expertise that is not held by any IRB member, a consultant with the appropriate expertise must supplement the need for relevant area/subject expertise.
 - 3.5.2. The consultant may attend the meeting or submit a report to be entered into record at the meeting.
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3.5.3.UGA utilizes a "Primary Reviewer" system to promote a thorough review. Under this system, studies are assigned to one or more IRB members for a full review of all materials.

3.5.4.At least one IRB member or consultant is responsible for scientific/scholarly review of research. Initial studies requiring committee review must be assigned to a Primary and a Secondary Reviewer.

3.5.5.**Modifications** and **continuing review** submissions requiring committee review must be assigned to a primary reviewer. The primary reviewer should be the individual who provided the initial review whenever possible.

3.6. When IRB members review research that involves **vulnerable populations**, at least one individual who is knowledgeable about or experienced in working with such subjects must be present at the meeting.

3.7. IRB members must be provided sufficient study information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

3.8. Study materials are provided to all attending IRB Members at least one week prior to the convened meeting by ensuring that the materials are accessible in the IRB portal record.

3.8.1.Upon request by an IRB member or during an electronic system failure, IRB members must be provided with an alternate means to access the sufficient information (e.g., email).

3.9. The **Principal Investigator (PI)** for the study must be invited to attend the IRB meeting, or be available by phone, when an initial study will be reviewed or when requested for other submissions such as modifications, reports of new information, or continuing reviews.

3.9.1.The PI may choose to invite another study team member to join him/her or attend as proxy.

4. PROCEDURES: IRB Staff

4.1. The designated IRB staff must send an email reminder to **regular members** no later than three weeks prior to the next scheduled meeting date requesting for them to confirm or decline attendance.

4.2. IRB staff must review attendance confirmations to determine that the requirements for quorum have been met. *Worksheet: Quorum and Expertise* may be used for guidance.

4.2.1.If a regular member declines attendance, delegated IRB staff must send an email invitation to that member's alternate.

4.2.2.If the IRB Chair declines attendance, delegated IRB staff must send an email invitation to the Vice Chair requesting attendance and/or requesting that the Vice Chair perform the functions of the IRB Chair.



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4.2.3.If neither the IRB Chair nor the Vice Chair can attend the meeting, delegated IRB staff must confirm that the HSO Director or another experienced IRB member will perform the functions of the IRB Chair.

4.2.4.The member who performs the functions of the IRB Chair will use the Chair Agenda.

4.3. IRB Staff must conduct a thorough pre-review of all submissions placed on the agenda no later than 3 weeks prior to the scheduled meeting to allow sufficient time for the PI to respond.

4.3.1.If IRB Staff are unsure whether a submission is ready to be placed on the agenda, the IRB Chair will be consulted.

4.4. Using the Agenda template, IRB Staff must prepare the meeting agenda:

4.4.1.Assign a primary reviewer and secondary reviewer who have scientific/scholarly expertise in the area of research to each initial study on the agenda.

4.4.2.Assign a primary reviewer to each continuing review and modification on the agenda.

4.4.3.Assign a primary reviewer to all other agenda items and prepare review materials for IRB members and consultants.

4.4.4.Contact a consultant with appropriate expertise, if necessary. *See Policy and Procedures: Consultation to the IRB.*

4.4.4.1. The consultation must be noted on the agenda.

4.5. The IRB Staff publishes the agenda no later than one week prior to the convened meeting.

When the agenda is published, the IRB Members who will be in attendance gain access to the electronic records which include: all responses to questions contained in the e-form; all supporting materials (recruitment scripts, consent documents, data collection instruments); pre-review items raised by HSO staff prior to assignment to the meeting; written consultant report, if any; and, in cases where the submission is a follow-on, access to all previous reviews.

4.6. A summary report listing all expedited studies approved within the previous 45 days is available in the electronic system to allow access to IRB members prior to the meeting.

4.7. IRB Staff must provide a list of acknowledged information items in the agenda.

4.8. If a training is part of the agenda, IRB Staff must provide the training materials to IRB members either before the meeting (if available) or following the meeting.

4.9. At least four days prior to the meeting, IRB Staff must invite the Principal Investigator (or proxy) to attend, or be available by phone or video call, on the day of the meeting.

4.10.Before the meeting, IRB staff must prepare the Chair Agenda.

5. PROCEDURES: Institutional Review Board

5.1. IRB members must confirm or decline attendance no later than two weeks prior to the scheduled meeting.



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5.2. If the primary or secondary reviewer contacts the PI before the meeting to request clarifications, a summary of that discussion should either be added to the submission as a review comment, or it should be verbally shared with the committee at the meeting.

6. MATERIALS

- 6.1. NOTIFICATION: Reviewer Assignment
- 6.2. ROSTER: IRB Members
- 6.3. TEMPLATE Email: IRB Meeting Reminder
- 6.4. TEMPLATE: IRB Meeting Agenda
- 6.5. TEMPLATE: Chair Agenda
- 6.6. WORKSHEET: Quorum and Expertise
- 6.7. WORKSHEET: IRB Meeting Checklist

7. REFERENCES

- 7.1. Policy and Procedures: Consultation to the IRB

Revision History:

11/13/2015: REV0 New Document

12/21/2016: REV1

08/04/2017: REV2

05/24/2021: REV3 minor revisions to match current procedures
