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1. PURPOSE

- 1.1. The purpose of this *policy* is to establish the process to add a new Institutional Review Board (IRB) member to the University of Georgia (UGA) IRB Roster and IRB registration with Office for Human Research Protections (OHRP).

2. DEFINITIONS

- 2.1. **IRB Roster:** A list of all active IRB Members and their contact information.
- 2.2. **Regular member:** A primary member of the IRB.
- 2.3. **Alternate member:** A member who is designated to substitute for a regular IRB member for an entire meeting or at any time during a meeting. Alternate members have qualifications comparable to the applicable regular member and may serve as alternate for more than one regular IRB member.
- 2.4. **Scientist:** Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline.
- 2.5. **Non-Scientist:** Members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline.
- 2.6. **Affiliated:** A UGA employee or agent (or a member of this person’s immediate family). They include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB.
- 2.7. **Unaffiliated:** An individual who has no affiliation with UGA, other than as an IRB member. They may include people whose only association with the institution is that of a patient, subject, or alumni/former student at UGA. Paying unaffiliated members for their services would not make the member “otherwise affiliated” as stated in the regulations, or cause the member to have a conflicting interest.

3. POLICY

- 3.1. In consultation with the IRB Chairperson, the Human Subject s Office (HSO) Director and **Institutional Official** or designee will appoint new members and determine if the individual will be a regular IRB member, alternate IRB member, or IRB chair, scientist or non-scientist, affiliated or unaffiliated.
- 3.2. The IRB Roster will be promptly updated upon the IRB member addition.

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- 3.3. The IRB Roster is located on the shared network drive and maintained by the HSO designated staff member.
- 3.4. IRB Members are appointed for terms of one to three years with the option for renewal or extension.
- 3.5. The new IRB member must complete IRB member training prior to attending a convened board meeting as a voting member or being assigned to review a full board or expedited submission. See *IRB Member Training Manual*.

4. PROCEDURES

- 4.1. The HSO Director and/or the Institutional Official must interview the potential new IRB member and obtain a copy of the individual's resume or curriculum vitae.
 - 4.1.1. In consultation with the IRB Chairperson, the HSO Director and Institutional Official or designee must determine whether the individual will be a regular or alternate member, scientist or non-scientist, affiliated or unaffiliated. *WORKSHEET: IRB Composition* may be used as a guide to ensure that the IRB is appropriately constituted.
- 4.2. The HSO Director must prepare and provide the new member with a draft IRB Member Appointment Letter that will describe expectations.
- 4.3. Upon the new member's acceptance and signature of the letter, the HSO Director will provide the IRB Member Appointment Letter to the Institutional Official for review and approval signature.
- 4.4. Upon receipt of the signed appointment letter, the HSO Director must notify the IRB staff and IRB Board Members via email of the addition of the new member.
 - 4.4.1. The designated IRB staff member must send the signed letter to the new member and designated recipients and upload a copy to the appropriate shared drive folder.
- 4.5. The designated IRB staff member must update and upload the IRB Roster and the new IRB Members resume or curriculum vita to the appropriate shared drive folder.
- 4.6. The designated IRB staff must send the new member an e-mail with links to regulations, the Click IRB manual, and the *IRB Member Training Manual*.
- 4.7. The designated IRB staff member must update the electronic system to include the new member.
- 4.8. The HSO Director must update the online IRB registration with OHRP within 90 days of adding the new member to the UGA IRB Roster.

5. MATERIALS

- 5.1. IRB Roster
 - 5.2. WORKSHEET: IRB Composition
 - 5.3. IRB Member Training Manual
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5.4. Template Letter: IRB Member Appointment

5.5. Template Letter: IRB Chairperson Appointment Letter

6. REFERENCES

6.1. OHRP IRB Registration Process FAQs, <http://www.hhs.gov/ohrp/policy/faq/irb-registration/various-categories-members-for-irb-roster.html>