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1. PURPOSE

- 1.1. This **policy** establishes the process to create a new internal University of Georgia Institutional Review Board (UGA IRB) or rely on an **external (commercial) IRB** to provide review of **human subjects research** conducted under the auspices of UGA.

2. POLICY

- 2.1. The **Institutional Official** or Designee determines the need for a new internal IRB or reliance on an external IRB in consultation with the Designated IRB staff.
- 2.2. The Institutional Official or Designee determines the types of reviews that the new internal or external IRB will conduct or if reviews will be conducted without any limitations in consultation with the Designated IRB staff.
- 2.3. The new internal or external IRB must be registered with the Office for Human Research Protections (OHRP) as an additional IRB and designated under UGA's **Federalwide Assurance** (FWA) before it reviews research conducted or supported by Department of Health and Human Services (HHS).
- 2.4. Appointment of new Members to an internal IRB will be carried on in accordance with *Policy and Procedures: IRB Membership Addition*.
- 2.5. IRB Members are maintained using the **IRB Roster**.
- 2.6. A commercial IRB that will be relied upon must be accredited with the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

3. PROCEDURES: IRB Staff

- 3.1. In consultation with the Designated IRB staff, the Institutional Official or Designee determines the need for a new internal IRB or reliance on an external IRB, and whether the IRB will be limited to certain types of reviews or will conduct all reviews without any limitations. This will be indicated on the "IRB Scope" tab of the **IRB Roster**.
- 3.2. For external (commercial) IRBs
 - 3.2.1. The Designated IRB staff consults the AAHRPP website and ensures that the commercial IRB is AAHRPP-accredited. Non-accredited commercial IRBs should not be relied upon.
 - 3.2.2. If the research is **federally funded**, or the relied upon organization requires an agreement or contract, the Designated IRB staff arranges for an agreement or contract.
- 3.3. For internal IRBs
 - 3.3.1. Select the following:
 - 3.3.1.1. At least five individuals to serve as **regular IRB Members**.
 - 3.3.1.2. Additional individuals to serve as **alternate IRB Members**, if needed.



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- 3.3.1.3. At least one of the individuals to be the IRB Chair.
- 3.3.2. For each new IRB Member, the *Policy and Procedures: IRB Membership Addition* must be followed.
- 3.3.3. Use “Worksheet: IRB Composition” to ensure that the composition of the IRB meets regulatory and organizational requirements, and make the appropriate adjustments as needed.
- 3.4. The Designated IRB staff registers the additional IRB with OHRP.
- 3.5. The Designated IRB staff designates the additional IRB under UGA’s FWA.

4. MATERIALS

- 4.1. IRB Roster
- 4.2. WORKSHEET: IRB Composition
- 4.3. TEMPLATE LETTER: IRB Member Appointment
- 4.4. TEMPLATE LETTER: IRB Chairperson Appointment

5. REFERENCES

- 5.1. 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5), 45 CFR 46 Subpart E
- 5.2. 21 CFR §56.107, 21 CFR §56.115(a)(5)
- 5.3. Policy and Procedures: IRB Membership Addition