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1. PURPOSE

- 1.1. The purpose of this **policy** is to define **Principal Investigator** eligibility for University of Georgia Institutional Review Board (UGA IRB) submissions. Individuals who do not meet the criteria to be a PI may still participate as Co-Investigators.

2. DEFINITIONS

- 2.1. **Principal Investigator (PI):** is the individual primarily responsible for overseeing the preparation, conduct, and administration of **human subjects research**.
- 2.2. **Affiliated Institution:** a hospital or institution in the vicinity of UGA which does not have an internal IRB and where an existing Memorandum of Understanding or Agreement exists between UGA and the affiliated institution designating UGA IRB as the Reviewing IRB.
- 2.3. **Faculty Sponsor:** is a mentor who provides direct supervision to a post-graduate professional trainee and who shares in the responsibility for the ethical conduct of the research with the professional trainee. Used interchangeably with Faculty Advisor or Preceptor.

3. POLICY

- 3.1. All **human subjects research** studies conducted at UGA must designate an individual qualified to serve as the Principal Investigator (PI).
- 3.2. The Principal Investigator is ultimately responsible for the appropriate oversight and conduct of research. The PI may delegate certain responsibilities and functions of the research; however, he/she must maintain oversight and retain ultimate responsibility for the conduct of research and of those to whom responsibilities were delegated.
- 3.3. The PI must, therefore, be sufficiently qualified by education, training, and experience to assume responsibility for the proper oversight and conduct of the research, including the protection of the rights, welfare, and safety of each human research subject.
- 3.4. Any individual who holds one of the following appointments at UGA is eligible to serve as the PI on IRB submissions:
 - 3.4.1. Tenured or Tenure-Track Faculty: Assistant Professor, Associate Professor, Professor, and Professor Emeritus
 - 3.4.2. Non-Tenure-Track or Temporary Faculty and eligible staff: Assistant Research Scientist, Associate Research Scientist, Senior Research Scientist, Senior Research Associate, Public Service Representative, Public Service Assistant, Public Service Associate, Senior Public Service Associate, Academic Professionals, Clinical Assistant Professor, Clinical Associate Professor, Clinical Professor, Adjunct Faculty with Primary Federal Appointments, and Instructor/Lecturer
 - 3.4.3. Adjunct Faculty if any of the following criteria has been satisfied:
 - 3.4.3.1. Submission of a Certification of Support for Adjunct Faculty from the Dean or Department Head (or other appropriate documentation)
 - 3.4.3.2. IRB review and approval of the person's Curriculum Vitae (CV)



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3.4.4. Individuals in the categories below are eligible to serve as PI if they have obtained written approval from the appropriate Dean, Department Head or Director. Written approval for these individuals to submit to the IRB is granted for a single submission only. Exceptions to this single project approval condition may be made in certain circumstances (for example, for individuals who submit multiple submissions).

3.4.4.1. Temporary Assistant Professor, Visiting Faculty, Postdoctoral Research Associates, and Postdoctoral Research Fellows

3.4.4.2. The written approval must include:

3.4.4.2.1. the reason why an exception should be made,

3.4.4.2.2. the individual's qualifications for being PI, and

3.4.4.2.3. a statement that the Department Head or Director (or another specifically identified eligible individual) will assume responsibility for and ensure compliance with all applicable requirements for conduct of the study should the PI fail to do so.

3.4.5. Residents at Affiliated Institutions who holds an appointment at UGA if the following criteria have been satisfied:

3.4.5.1. an appropriate Faculty Sponsor is identified in the submission, and

3.4.5.2. the Medical Partnership Resident Program Director has granted written authorization.

3.4.6. Professional Pharmacist Trainees (PharmD) on clinical rotations if an appropriate Faculty Sponsor is identified in the submission.

3.4.7. The Faculty Sponsor must be sufficiently qualified by education, training, and experience to assume responsibility for the proper oversight and conduct of the research, including the protection of the rights, welfare, and safety of each human research subject.

Individuals eligible to serve as Faculty Sponsor include:

3.4.7.1. Individuals with any of the UGA faculty appointments above (section 3.4) and with appropriate supporting authorization, if applicable;

3.4.7.2. Clinical preceptors for pharmacists in the PharmD Professional Program with written documentation of this person's qualifications to serve as PI from the Clinical and Administrative Pharmacy Department Head; and,

3.4.7.3. Other individuals with faculty appointments at other institutions as determined by an Institutional **Memorandum of Understanding** criteria.

3.5. Medical Professionals employed by or with admitting privileges in an affiliated institution if one of the following criteria has been satisfied:

3.5.1. IRB review and approval of the person's Curriculum Vitae (CV), or

3.5.2. written documentation of this person's qualifications to serve as PI from the affiliated institution.

3.6. UGA **students**, with the exception of post-graduate professional trainees, may not serve as PI and should seek an eligible individual to serve this role on an IRB submission.

3.6.1. For projects that do not meet the definition of human subjects research or where the IRB will rely on the review of an **External IRB**, students may serve as PI. See **Policy and**



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Procedure: Determination of Human Subject Research and Policy and Procedure: Reliance on an External IRB.

- 3.7. When an individual is no longer eligible to serve as PI on ongoing projects at UGA, this individual should select an eligible investigator to serve as the new PI for each of his/her IRB-approved projects.

4. PROCEDURES: Researchers

- 4.1. The researcher must complete the submission form through the IRB's electronic application system.
- 4.2. The researcher must identify the eligible investigator who will serve as PI where prompted.
- 4.3. To obtain approval for the exceptions described in Section 3.3, an email with the required information or a Certification of Support (for [Postdoctoral Associate](#) or [Adjunct Faculty](#)) must be submitted.
- 4.4. The PI is responsible for submitting new applications for review as well as all **modifications** and **continuing reviews** to approved research.
- 4.5. If an individual is no longer eligible to serve as PI, this individual should submit modifications through the IRB's electronic application system for each ongoing project in which he/she is PI in order to update the system and alert the IRB of the change in PI. In the submission, the PI must indicate whether or not he/she will remain on the study team.

5. PROCEDURES: Institutional Review Board

- 5.1. The IRB Staff will review the submission to ensure that the PI meets eligibility requirements.
- 5.2. For individuals without an appointment at UGA, the IRB Staff will review supporting documentation for PI eligibility. If the individual is deemed eligible to be PI, the submission will be accepted. If not, the IRB Staff will communicate this determination to the individual.
- 5.3. If an individual who is no longer eligible to serve as PI has not submitted modifications to ongoing projects to alert the IRB Staff of a PI change, the IRB will contact the Head of the PI's Department/Unit to identify a new PI and provide the IRB with a letter giving the IRB permission to act on his/her behalf in submitting the modifications for PI change.
- 5.4. For **non-committee reviews**, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence.
- 5.5. For committee reviews, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence that describes missing information or required modifications.
- 5.6. IRB Staff will document information pertaining to determinations that the requirements of this policy have been met in the review history for non-committee reviews and in the meeting minutes by recording the motion to approve for research reviewed by committee.

6. MATERIALS

- 6.1. [Template: Certification of Support for Postdoctoral Associate](#)
- 6.2. [Template: Certification of Support for Adjunct Faculty](#)



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7. REFERENCES

- 7.1. Policy and Procedure: Determination of Human Subject Research
- 7.2. Policy and Procedure: Reliance on an External IRB