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### 1. PURPOSE

- 1.1. The purpose of this policy and procedures is to establish the process in conducting the annual evaluations of the University of Georgia's Human Research Protections Program (UGA HRPP).

### 2. POLICY

- 2.1. The UGA HRPP is evaluated annually.
- 2.2. The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making the document BROCHURE: Should I Take Part in Research available to the subject population.

### 3. PROCEDURES: HRPP

- 3.1. The *Institutional Official* (IO) meets at least annually with the Human Subjects Office (HSO) Director, IRB Chairs and Vice Chairs (if available), and the Associate Vice President for Research Compliance to evaluate the adequacy of resources provided to the HRPP, including but not limited to, administrative resources such as space and personnel. Adjustments are made as necessary to maintain adequate resources.
- 3.2. The IRB Chairs and HSO Director must evaluate whether the number of IRBs is appropriate to the volume and types of human research reviewed and overseen.
  - 3.2.1. The results of this evaluation must be provided to the IO or Designee.
  - 3.2.2. If the number of IRBs is not appropriate to the volume and types of research reviewed and overseen, the IRB Chairs and HSO Director must work with the IO or Designee to address the situation.
- 3.3. The IRB Chairs and Human Subjects Office (HSO) Director must evaluate whether the composition of the IRB meets regulatory and organizational requirements using the *WORKSHEET: IRB Composition*.
  - 3.3.1. The results of this evaluation must be provided to the IO or Designee.
  - 3.3.2. If the composition of the IRB does not meet regulatory and organizational requirements, the IRB Chairs and HSO Director must work with the IO or Designee to modify the IRB composition.
- 3.4. The IRB Chairs and HSO Director must evaluate the knowledge, skills, and performance of each regular and alternate IRB member using the *Checklist: IRB Member Annual Evaluation*.
  - 3.4.1. The results of the evaluations must be provided to the IO or Designee.
  - 3.4.2. A copy of his/her evaluation report must be provided to each IRB member.
  - 3.4.3. As needed, the IRB Chairs and HSO Director must work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.



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3.5. The IRB staff must ensure that the IO or Designee, in consultation with the HSO Director, evaluates the knowledge, skills, and performance of the IRB Chairs using the *IRB Member Annual Evaluation*.

3.5.1. A copy of his/her evaluation report must be provided to each IRB Chair.

3.5.2. If needed, the IO or Designee, in consultation with the HSO Director, develops a plan to improve the individual's knowledge, skills, and performance.

3.6. The HSO Director or Designee must evaluate the knowledge, skills, and performance of IRB staff following UGA's Human Resources annual employee evaluation process.

3.6.1. The results of the evaluations must be provided to the IO or Designee.

3.6.2. A copy of his/her evaluation report must be provided to each IRB staff.

3.6.3. If needed, the HSO Director must work with each IRB staff to develop a plan to improve the individual's knowledge, skills, and performance.

3.7. The IRB Chairs and HSO Director must evaluate the subject outreach plan.

3.7.1. The results of this evaluation report must be provided to the IO or Designee.

3.7.2. If the subject outreach program is not meeting organizational goals, the IRB Chairs and HSO Director must work with the IO or Designee to modify the plan.

#### **4. MATERIALS**

4.1. BROCHURE: Should I Take Part in Research

4.2. WORKSHEET: IRB Composition

4.3. Checklist: IRB Member Annual Evaluation

#### **5. REFERENCES**

5.1. §46.107 IRB Membership

Revision History:

12/11/2015: REV0 New Document

05/24/2021: REV1 minor revisions to improve clarity

08/17/2021: REV2 to clarify process to assess HRPP resources