1 PURPOSE
   1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.
   1.2 The process begins the first business day of each June – in conjunction with the fiscal budget process.
   1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 Minor revisions for AAHRPP accreditation; replaces version dated 03/07/2013.

3 POLICY
   3.1 The human research protection program is evaluated annually.
   3.2 Documentation of this annual evaluation is maintained in the IRB office.

4 RESPONSIBILITIES
   4.1 The IRB Manager ensures completion of these procedures.

5 PROCEDURE
   5.1 Have the Organizational Official or designee evaluate the following resources provided to the human research protection program, and make adjustments as part of the budgeting process.
      5.1.1 Space
      5.1.2 HRPP educational program
      5.1.3 Legal counsel
      5.1.4 Conflicts of interests
      5.1.5 Quality improvement plan
   5.2 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
      5.2.1 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the Organizational Official to modify the IRB structure.
   5.3 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.
      5.3.1 Provide a copy of the evaluation to each IRB staff.
      5.3.2 If needed, work with each IRB staff person to develop a plan to improve the individual’s knowledge, skills, and performance.
   5.4 Complete the “CHECKLIST: IRB Composition” to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
      5.4.1 If the composition of an IRB does not meet regulatory and organizational requirements, work with the Organizational Official to modify the IRB composition.
   5.5 Evaluate the participant outreach plan.
      5.5.1 Consider the following areas when evaluating the outreach plan:
         5.5.1.1 Whether the existing scope and content of UCF’s outreach materials continue to be adequate;
         5.5.1.2 Whether modifications to existing outreach materials are necessary;
         5.5.1.3 Whether or not UCF’s existing materials are being regularly utilized by the IRB Office or by members of the UCF research community in their own interaction with the communities in which they conduct research;
         5.5.1.4 Whether there are new opportunities to provide outreach activities to the community, and ;
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5.5.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.

5.5.2 If the participant outreach program is not meeting organizational goals, work with the Organizational Official to modify the plan. Modifications may include, but are not limited to:

5.5.2.1 Modifying existing outreach materials;
5.5.2.2 Developing new materials;
5.5.2.3 Surveying the UCF research community to identify and participate in additional outreach opportunities, and;
5.5.2.4 Working directly with community organizations to identify and participate in additional outreach opportunities.

5.6 Check when the last time each IRB was registered. If more than 2 years, update the registration.¹

5.7 Check when the last time the federalwide assurance (FWA) was updated/renewed. If more than 3 years, update/renew the FWA.²

5.8 Have the IRB chair evaluate the knowledge, skills, and performance of each regular and alternate IRB member.

5.8.1 Provide a copy of the evaluation to each IRB member.
5.8.2 Send a copy of the “TEMPLATE LETTER: IRB Member Appreciation” to the IRB member’s supervisor.
5.8.3 If needed, work with each IRB member to develop a plan to improve the individual’s knowledge, skills, and performance.

5.9 Have the Organizational Official evaluate the resources provided to the human research protection program and make adjustments as part of the budgeting process.

5.10 Have the Organizational Official evaluate the knowledge, skills, and performance of each IRB chair.

5.10.1 Provide a copy of the evaluation to each IRB chair.
5.10.2 If needed, work with each IRB chair to develop a plan to improve the individual’s knowledge, skills, and performance.

5.11 Prepare an initial written assessment of all items in this SOP and provides it to the Organizational Official.

5.12 Have the Organizational Official review and determine in writing whether any corrective action is required.

5.13 Retain the documentation of this annual process in the IRB Office’s records.

6 MATERIALS

6.1 CHECKLIST: IRB Composition
6.2 TEMPLATE LETTER: IRB Member Appreciation
6.3 TEMPLATE HRPP Assessment Report

7 REFERENCES

7.1 45 CFR §46.103(b)(2).
7.2 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).
7.3 21 CFR §56.107, 21 CFR §56.115(a)(5).