



SOP: Annual HRPP Evaluation				
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1 PURPOSE

- 1.1 This procedure establishes the process to conduct annual evaluations of the human research program.
- 1.2 The process begins the first business day of each January.
- 1.3 The process ends by March 31.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDING PRINCIPLES

- 3.1 The human research program is evaluated annually.
- 3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects and communities is accomplished by making the webpage, [Research Participants](#), available. This webpage includes resources for individuals and groups interested in becoming research participants.

4 RESPONSIBILITIES

- 4.1 The Institutional Official and HSRO staff ensure completion of these procedures..

5 PROCEDURE

- 5.1 The Institutional 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 Employee Resources
 - 5.1.3 HRPP education program
 - 5.1.4 Legal counsel
 - 5.1.5 Conflicts of interests
 - 5.1.6 Quality improvement plan
- 5.2 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
 - 5.2.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.2.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the Institutional Official or designee to modify the IRB structure.
 - 5.2.3 Use the "WORKSHEET: IRB Composition (HRP-304)" to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
 - 5.2.4 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.2.5 If the composition of the IRB does not meet regulatory or organizational requirements, work with the Institutional official or designee to modify the IRB composition.
- 5.3 Have the Executive Director of the HSRO and Chairs evaluate the knowledge, skills and performance of each regular and alternate IRB member.
 - 5.3.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.3.2 Provide each member with a copy of his or her evaluation.
 - 5.3.3 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills and performance.
- 5.4 Have the Executive Director and HSRO Associate Directors and managers evaluate the knowledge, skills and performance of each IRB chair.
 - 5.4.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.4.2 Provide each IRB chair with a copy of his or her evaluation.
 - 5.4.3 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills and performance.



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- 5.5 Follow the University of Miami Human Resources annual employee evaluation process to evaluate the knowledge, skills and performance of IRB staff.
- 5.6 Evaluate the IRB Outreach Program
 - 5.6.1 Consider the following areas when evaluating the outreach plan:
 - 5.6.1.1 Whether the existing scope and content of the HRPP outreach materials continue to be adequate;
 - 5.6.1.2 Whether modifications to existing outreach materials are necessary;
 - 5.6.1.3 Whether there are new opportunities to provide outreach activities to the community.
 - 5.6.1.4 If the outreach program is not meeting the organizational goals, work with the Institutional Official or designee to modify the plan.
 - 5.6.2 Provide a copy of the evaluation to the Institutional Official or designee.

6 MATERIALS

- 6.1 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

- 7.1 None