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.
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