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.
1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Replaces version dated 7/18/2012.

3 POLICY
3.1 The human research protection 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 document “BROCHURE - Should I Take Part in Research” available to the patient population.

4 RESPONSIBILITIES
4.1 IRB staff ensure 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 Provide a copy of the evaluation to the Organizational 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 Organizational Official or designee to modify the IRB structure.
5.3 Have the IRB chair or IRB manager evaluate the knowledge, skills, and performance of each regular and alternate IRB member.
   5.3.1 Provide a copy of the evaluation to the Organizational Official or designee.
   5.3.2 Provide a copy of the evaluation to each IRB member.
   5.3.3 Send a copy of the “TEMPLATE LETTER: IRB Member Appreciation” to the IRB member’s supervisor.
   5.3.4 If needed, work with each IRB member to develop a plan to improve the individual’s knowledge, skills, and performance.
5.4 Have the Organizational Official or designee evaluate the knowledge, skills, and performance of each IRB chair.
   5.4.1 Provide a copy of the evaluation to the Organizational Official or designee.
   5.4.2 Provide a copy of the evaluation to each IRB chair.
   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 Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.
   5.5.1 Provide a copy of the evaluation to the Organizational Official or designee.
5.5.2 Provide a copy of the evaluation to each IRB staff.
5.5.3 If needed, work with each IRB staff person to develop a plan to improve the individual’s knowledge, skills, and performance.

5.6 Complete the “WORKSHEET: IRB Composition” to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
5.6.1 Provide a copy of the evaluation to the Organizational Official or designee.
5.6.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the Organizational Official or designee to modify the IRB composition.

5.7 Evaluate the subject outreach plan.
5.7.1 Provide a copy of the evaluation to the Organizational Official or designee.
5.7.2 If the subject outreach program is not meeting organizational goals, work with the Organizational Official or designee to modify the plan.

5.8 Check when the last time each IRB was registered. If more than 2 years, update the registration.1
5.9 Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 2 years, update/renew the federalwide assurance (FWA).2

6 MATERIALS
6.1 BROCHURE - Should I Take Part in Research
6.2 TEMPLATE LETTER: IRB Member Appreciation
6.3 WORKSHEET: IRB Composition

7 REFERENCES
7.1 None

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