1 PURPOSE
   1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.
   1.2 The objective of these evaluations is to measure and improve the program’s quality, efficiency and effectiveness.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 Revisions for AAHRPP accreditation; replaces version 8/6/13.

3 POLICY
   3.1 The human research protection program is evaluated annually.
   3.2 The evaluation plan includes internal directed audits, random internal compliance reviews, review and assessment of comments and concerns submitted by the research community, review and assessment of “IRB Member Self-Assessments”, and a review of HRPP metrics as prescribed by AAHRPP.

4 RESPONSIBILITIES
   4.1 Organizational Official or designee ensures completion of these procedures.

5 PROCEDURE
   5.1 Evaluate the resources provided to the human research protection program and make adjustments as part of the budgeting process. These resources may include:
      5.1.1 Space
      5.1.2 HRPP educational program
      5.1.3 Legal counsel
      5.1.4 Conflicts of interest
      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 IRB staff to modify the IRB structure.
   5.3 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of the IRB staff.
      5.3.1 Provide a copy of the evaluation to each IRB staff person.
      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 IRB Chairs and members who attended meetings during the evaluation period complete a self-evaluation of their performance once a year using the IRB Member Self-Evaluation Worksheet. Input also includes attendance at scheduled meetings, number/type of reviews conducted, working knowledge of regulations, and institutional support.
      5.4.1 Evaluation results are reviewed by the Organizational Official. Results, issues, and trends are shared with the IRB, IRB staff, and Research Compliance Officer.
      5.4.2 Send a copy of the “TEMPLATE LETTER: IRB Member Appreciation” to the IRB member’s supervisor.
      5.4.3 If needed, work with each IRB Chair and/or member to develop a plan to improve the individual’s knowledge, skills, and performance.
   5.5 Complete the “WORKSHEET: IRB Composition” to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
      5.5.1 If the composition of an IRB does not meet regulatory and organizational requirements, work with the IRB staff to modify the IRB composition.
5.6 Research Compliance Officer conducts audit activities at least every 6 months to assess IRB compliance with applicable federal, state, and local laws as well as institutional policies and procedures.

5.6.1 Activities may include but are not limited to the following:

5.6.1.1 Observation of IRB meetings or other related activities
5.6.1.2 Review of IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures
5.6.1.3 Review the IRB database to assure all fields are completed accurately
5.6.1.4 Other monitoring or auditing activities deemed appropriate by the IRB and HRPP

5.6.2 Results of internal IRB compliance audits are reviewed with Organizational Official. If any deficiencies are noted, a corrective action plan is developed by the Research Compliance Officer and IRB Chair and approved by the Organizational Official. The IRB and IRB staff are responsible for implementing the corrective action plan, the results of which are evaluated by the Research Compliance Officer.

5.7 Research Compliance Officer in conjunction with IRB members and/or the IRB Chair conducts audits of IRB protocols at least quarterly. Results of the audits are shared with IRB members and Organizational Official.

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

5.10 Metrics, as prescribed by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) are tracked, assessed and reported yearly.

5.10.1 The following metrics are measured:

5.10.1.1 Number of active protocols (exempt, expedited, full board)
5.10.1.2 Mean number of days from submission to review and approval for new studies for full board and expedited.
5.10.1.3 Mean number of days from submission to exempt determination
5.10.1.4 Percentage of protocols disapproved by the IRB
5.10.1.5 Number of complaints received from research participants
5.10.1.6 Number of cases of alleged non-compliance investigated
5.10.1.7 Number of determinations of serious non-compliance
5.10.1.8 Number of determinations of continuing non-compliance
5.10.1.9 Number of unanticipated problems involving risks to participants or others
5.10.1.10 Number of “for cause” audits of investigator protocols
5.10.1.11 Number of random audits of investigator protocols
5.10.1.12 Number of audits of IRB records
5.10.1.13 Number of FDA inspections of investigators or the IRB

5.10.2 Metrics will be used to assess the overall HRPP program and trends will be examined to determine where changes are needed or if more education is necessary.

5.11 Evaluate research community outreach plan.
5.11.1 Research community feedback is encouraged by wide publication of contact information for IRB Chair and IRB staff. Concerns and suggestions are welcomed.
5.11.2 Contact information for the IRB staff is included on the checklists for IRB submissions.
5.11.3 Concerns and suggestions received during the presentation of seminars and other educational events are welcomed.
5.11.4 Feedback is discussed with the IRB Chair and Organizational Official as appropriate and changes are made to the outreach plan as needed.
5.11.5 IRB Advisory Committee provides advice and consultation regarding changes to HRPP. The committee consists of representative investigators, IRB members, study coordinators and administrators. The Research Compliance Officer, IRB Chair and Organizational Official are ex-officio members.

5.12 Evaluate the subject outreach plan.
5.12.1 Concerns and questions are welcomed.
5.12.2 Contact information for the IRB Chair is provided in every consent form.
5.12.3 The document “BROCHURE – Should I Take Part in Research” is made available to researchers for distribution to their patient populations.
5.12.4 Feedback is discussed with the IRB Chair and Organizational Official as appropriate and changes are made to the outreach plan as needed.

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

7 REFERENCES
7.1 None