1 PURPOSE
1.1 This procedure establishes the process to conduct annual evaluations of the University of New Mexico Health Sciences Center Human Research Protections Program (HRPP). The process is conducted annually (July 1–June 30) to coincide with the budget cycle.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Correction of spelling and grammatical errors throughout SOP
2.2 Replaced all references to "IRB" with "HRRC"
2.3 Remove references to specific HRPP components throughout document
2.4 Replaced all references to Institutional Official or designee to Vice Chancellor for Research in accordance with Delegation of Authorities memo
2.5 Section 3 Revised policy statements.
2.6 Section 4.1 Changed responsible individual from HRPO staff to HRPP Director
2.7 Section 5.1 Modified resources to be evaluated by Vice Chancellor for Research.
2.8 Section 5.2 Revised to better reflect evaluation of appropriate number of HRRCs.
2.9 Section 5.3 Revised to clarify HRRC member evaluation process.
2.10 Section 5.4 Revised to clarify HRRC Chair evaluation process.
2.11 Section 5.5 Revised to clarify HRPO staff evaluation process.
2.12 Section 5.6 Revised to clarify evaluation of the HRRC composition.
2.13 Section 5.7 Revised to ensure current membership appointments and tracking
2.14 Section 6 Addition of HRRC Confidentiality Statement

3 POLICY
3.1 The Human Research Protection Program is evaluated annually.
3.2 The Institutional Official has the responsibility to ensure that the Human Research Protections Program has sufficient resources, including IRBs, appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
3.3 The Institutional Official delegates to the Vice Chancellor for Research the authority to perform periodic evaluation of the performance of the HRRC Executive Chair and the individual HRRC Chairs and administrative staff. In this connection, the HRPO and its staff shall report administratively to the HSC Office of Research under the auspices of the Vice Chancellor for Research.
3.4 The Institutional Official delegates to the Vice Chancellor for Research the authority to manage and administer funds and ensure that adequate personnel, space and other resources are allocated to the Human Research Protections Program.

4 RESPONSIBILITIES
4.1 The HRPP Director ensures completion of these procedures.

5 PROCEDURE
5.1 Have the Vice Chancellor for Research evaluate the following resources provided to the HRPP and make adjustments as part of the budgeting process.
   5.1.1 Space
   5.1.2 Personnel
   5.1.3 Other resources

5.2 Have the Vice Chancellor for Research evaluate whether the number of HRRCs is appropriate to the volume and types of research reviewed.
   5.2.1 If the number of HRRCs is not appropriate to the volume and types of research reviewed, the Vice Chancellor for Research will make recommendations to the Institutional Official for modifying the HRRC structure.

5.3 In conjunction with the HRRC Chairs, evaluate the knowledge, skills, and performance of each regular and alternate HRRC member.
   5.3.1 HRRC members will be provided the opportunity to complete a self-assessment of their knowledge, skills and performance using a Self-Evaluation tool.
   5.3.2 Have the Chair(s) evaluate each HRRC member and alternate on their demonstrated knowledge, skills and performance in carrying out their HRRC responsibilities. The self-evaluation should be considered in the Chair evaluation for each member. Responsibilities evaluated will include:
       5.3.2.1 Regular attendance at IRB meetings
           5.3.2.1.1 Members with a 50% absenteeism rate may be asked by the Chair to improve attendance or resign from the committee
       5.3.2.2 Regular attendance at training sessions, as appropriate to remain current with Federal, State and local regulations governing human subject research
       5.3.2.3 Adherence to expectations of confidentiality as outlined in the HRRC Confidentiality Statement.
       5.3.2.4 Adequate preparation for committee meetings including completion and proper documentation of assigned reviews.
       5.3.2.5 When applicable, timely completion and proper documentation non-committee reviews.

5.3.3 HRPP Director will provide a copy of membership recommendations for each HRRC to the Vice Chancellor for Research.
5.3.4 If the performance review indicates that a member is not performing adequately, the member may be removed from the committee by recommendation from the HRRC Chair to the Vice Chancellor for Research as described in SOP HRP-083.
5.3.5 If needed, work with each HRRC member to develop a plan to improve the committee member's knowledge, skills and performance.

5.4 Have the Vice Chancellor for Research evaluate the knowledge, skills, and performance of each HRRC Chair.

5.4.1 Have HRRC members (including alternate members) participate in an online evaluation of each HRRC Chair.

5.4.2 Responsibilities evaluated will include:

5.4.2.1 knowledge and consistent application of the ethical principles of the Belmont Report and the federal regulations and IRB policies governing human subject protections;

5.4.2.2 responsiveness to the concerns of HRRC committee members as described in the chair evaluation survey;

5.4.2.3 ability to interact constructively with other HRRC Chairs;

5.4.2.4 ability to manage the efficient and effective conduct of HRRC committee meetings;

5.4.2.5 attendance and/or participation in the Organization's human research protections program

5.4.3 Confidentially summarize evaluation results for review by the Vice Chancellor for Research.

5.4.4 Have the Vice Chancellor for Research provide feedback in one-on-one meetings with each Chair to improve and enhance performance.

5.5 Follow the UNM Human Resources annual employee evaluation process to evaluate the knowledge, skills and performance of the HRPO staff.

5.5.1 Inform the Vice Chancellor for Research of any HRPO staff member who receives an overall rating of "Needs Improvement" on the annual performance evaluation.

5.5.2 If appropriate, the HRPO staff supervisors will work with each HRPO staff person to develop a plan to improve the individual's knowledge, skills, and performance.

5.6 Use the “Worksheet: IRB Composition (HRP-304)” to evaluate whether the composition of the HRRC meets regulatory and organizational requirements.

5.6.1 Provide a copy of the evaluation to the Vice Chancellor for Research.

5.6.2 This process may be conducted more frequently than annually if the HRRC membership undergoes significant change.

5.6.3 If the composition of an HRRC does not meet regulatory and organizational requirements, work with the Vice Chancellor for Research to modify the HRRC composition.

5.7 Check whether each HRRC member has a current appointment letter on file that includes an active appointment term.

5.7.1 If the term for the HRRC member is expiring, reference and utilize SOP: HRP-082 Appointment and Terms of HRRC Members and HRP-083 HRRC Membership Removal.

5.8 Check when the last time each HRRC 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 WORKSHEET: HRRC Composition (HRP-304) or equivalent
6.2 HRRC Confidentiality Statement
6.3 Self-evaluation tool for HRRC members
6.4 Evaluation tool for HRRC Chairs

7 REFERENCES