1 PURPOSE
1.1 This procedure establishes the process to add a new HRRC member.
1.2 The process begins when the Vice Chancellor for Research has identified an individual to serve as a HRRC member. (This may be a completely new member, or the addition of a previous member to another HRRC.)
1.3 The process ends when the new member has completed training and the IRB registration is updated with OHRP.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Replaces SOP HRP-085, HRP-086

3 POLICY
3.1 All University of New Mexico Health Sciences Center (UNM HSC) HRRCs shall maintain a membership that complies with Federal regulations at 45 CFR 46.107 and 21 CFR 56.107. Membership shall be appropriate in size and expertise to fulfill the HRRC’s obligations to safeguard the rights and welfare of human research participants, and to conduct the scientific and ethical review of protocols. Appointment, terms, and evaluation of the HRRC members shall be conducted in a manner that supports the responsibilities of the HRRC.
3.2 The Chancellor serves as the Institutional Official with oversight of research and HRRC functions. The Chancellor delegates his federally-granted authority to the Vice Chancellor for Research to appoint, evaluate and remove HRRC members (including Chairs) and to ensure that composition of the HRRC is in compliance with federal regulations.
3.3 HRRC rosters are maintained using the "DATABASE: HRRC Roster (HRP-601)."
3.4 Term of appointment is 3 years.
3.5 Chairs may serve for consecutive terms.
3.6 A HRRC Chair must be an employee of the University of New Mexico.
3.7 Members may serve for more than two consecutive terms only at the recommendation of the chair and with the approval of the Vice Chancellor for Research. The decision to waive the term limitation will be made based upon the determination that continued participation of a particular person is for the overall benefit of the HRRC. The individual must have a history of good performance in meeting the responsibilities of a member of the HRRC as outlined in SOP HRP-060. The decision whether to grant a waiver of this term limitation rests with and in the sole discretion of the Institutional Official or designee, as appropriate.
3.8 No member of the HRRC shall have a vested right to continue as a voting member beyond the term limitation contained in this section.
3.9 Following the completion of a term, members may be appointed by the Institutional Official or designee, as appropriate, to serve as an alternate member for additional term(s).
3.10 New HRRC members must satisfy the following initial training requirements before assuming their role as a committee member:
   3.10.1 CITI (Collaborative Institutional Training Initiative) Human Research Protections online training modules:
3.10.1.1 Biomedical Responsible Conduct of Research
3.10.1.2 IRB Members & Staff Basic Course
3.10.2 Click IRB online training
3.10.3 In-person training with a senior staff member to review responsibilities of a HRRC member and completion of Click IRB Reviewer Workbook and competency test.
3.10.4 Additional training may be scheduled for a new member to supplement the minimum required training listed above based to ensure optimum performance as a member.

4 RESPONSIBILITIES
4.1 HRPP Director or designee carries out these procedures.
4.2 The Institutional Official delegates to the Vice Chancellor of Research the authority to appoint HRRC members, alternate members, HRRC chairs, and vice chairs.

5 PROCEDURE
5.1 Determine from the Vice Chancellor for Research whether the individual will be a regular HRRC member, alternate HRRC member, HRRC chair or HRRC vice chair.
5.2 Have the individual complete the “FORM: HRRC Member Information (HRP-202).”
5.3 Obtain a copy of the individual’s résumé or curriculum vitae.
5.4 Update “DATABASE: HRRC Roster (HRP-601)”: 
   5.4.1 Set the End Date and save.
   5.4.2 Set the Start Date, make the End Date blank, update with the new member information, and save as a new file.
5.5 Complete "WORKSHEET: HRRC Composition (HRP-304)" and revise the membership as needed to ensure that the HRRC is appropriately constituted.
5.6 Prepare a "TEMPLATE LETTER: HRRC Member Appointment (HRP-560)" for the individual.
5.7 Provide to the Vice Chancellor for Research for review approval and signature:
   5.7.1 FORM: HRRC Member Information (HRP-202).
   5.7.2 Résumé or curriculum vitae.
   5.7.3 Completed “TEMPLATE LETTER: HRRC Member Appointment (HRP-560)"
5.8 If not approved, select another individual and restart at 5.2.
5.9 Once the appointment letter is signed:
   5.9.1 Send the signed “TEMPLATE LETTER: HRRC Member Appointment (HRP-560)" to the individual.
   5.9.2 If the individual requires training, schedule the individual for training.
   5.9.3 Update the registration of all affected HRRCs on the IRB Registration with OHRP.¹
5.10 File:
   5.10.1 Old and new DATABASE: HRRC Roster (HRP-601)
   5.10.2 TEMPLATE LETTER: HRRC Member Appointment (HRP-560)
5.11 Notify the appropriate HRRC Chair(s) and HRPO staff members when the individual has completed training.

6 MATERIALS
6.1 DATABASE: IRB Roster (HRP-601)
6.2 FORM: IRB Member Information (HRP-202)
6.3 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
6.4 WORKSHEET: IRB Composition (HRP-304)
6.5 Click IRB Reviewer Workbook

7 REFERENCES
7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).