1 PURPOSE
1.1 This procedure establishes the process to form or rely on a new IRB.
1.2 The process begins when the Institutional Official or designee determines the need for a new IRB.
1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated (if needed), and all members have completed training.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 HRRC rosters are maintained using the “DATABASE: HRRC Roster (HRP-601).”
3.2 In order to facilitate human research by allowing investigators to avoid duplicative IRB review while at the same time protecting the rights and welfare of human participants, the UNM HSC is willing to rely on external IRBs in limited circumstances.

4 RESPONSIBILITIES
4.1 The Institutional Official or designee has the authority to determine what IRBs the organization will rely upon. In this regard, the Institutional Official has the authority to determine whether the University may rely on any one or more external IRBs or central IRBs.
4.2 HRPO staff members carry out these procedures.
4.3 The Institutional Official or designee appoints HRRC members, alternate members, HRRC chairs, and if used, other officers (e.g., vice chairs.)

5 PROCEDURE
5.1 Determine from the Institutional Official or designee whether the HRRC will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the “IRB Scope” tab of the “DATABASE: HRRC Roster (HRP-601).”
5.2 For external IRBs:
   5.2.1 Ensure that one or more of the following are true:
   5.2.1.1 The Human Subject Review Boards are part of an AAHRPP accredited organization.
   5.2.1.2 The organization’s investigator is a collaborator on Human Research primarily conducted at another organization and the investigator’s role does not include interaction or intervention with subjects.
University of New Mexico Health Sciences Center
Human Research Protections Office

5.2.1.3 The organization is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

5.2.2 If the research is federally funded or the relied upon organization requires an agreement or contract, arrange for an agreement or contract.

5.2.3 File the agreement or contract if one exists.

5.3 For internal HRRCs:

5.3.1 Select:

5.3.1.1 At least five individuals to serve as IRB members.
5.3.1.2 Additional individuals to serve as alternate IRB members, if needed.
5.3.1.3 At least one of the individuals to be the HRRC chair.

5.3.2 Follow "SOP: Appointment of HRRC Members (HRP-082)" for each HRRC member.

5.3.3 Use "WORKSHEET: HRRC Composition (HRP-304)" and revise the selected individuals as needed to ensure that the HRRC is appropriately constituted.

5.3.4 Notify the HRPP Director when all individuals have completed training.

5.3.5 Using the "Create Committee" SmartForm, create the new committee in the system.

5.3.6 Once training is completed, add committee members to the system with the Committee Member role

6 MATERIALS

6.1 DATABASE: HRRC Roster (HRP-601)
6.2 FORM: HRRC Member Information (HRP-202)
6.3 SOP: Appointment of HRRC Members (HRP-082)
6.4 WORKSHEET: HRRC Composition (HRP-304)

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).