

INSTRUCTIONS TO REQUEST THAT AN EXTERNAL INSTITUTION SERVE AS IRB OF RECORD

The following are the steps to request a Reliance Agreement for an external institution to serve as IRB of Record.

Submit the UPR MSC New Study application in the electronic system and provide OPPHI with the information required in order to assess for approval an External IRB as IRB of Record for the study. For NIH grants that meet the requirements for the Single IRB policy, the decision to rely upon an External IRB would occur at time of grant submission.

a. In the electronic application complete only the followings sections:

- **Section I. General Protocol Information** [(A) Protocol Title (**The External IRB should be named in parenthesis at the beginning of the full study title in the electronic application**), (B) Research Personnel (local site), (C) Protocol Description, (D) Protocol Department, (E) Research Funding, (F) Research Locations]
- **Section III. Subject Information** [(A) Human Subject Interaction -> If YES, Subject Information, Population Information, Subjects (Questions identified as *required*), (B) Proposed Consent Procedures, (C) HIPAA Questions, (D) Subjects Data]
- **Section IV. Other Questions** (all questions that apply)

b. Upload the following documents in section **VI. Attach Documents**:

- Proposal
- Informed consent form (if applicable)
- Instruments/Questionnaires/Data collection sheets/Diaries
- FDA Form 1572 (if applicable)
- Investigator Brochure/ Package Inserts (if applicable)
- Institutional Biosafety Committee approval (evidence of submission is accepted)
- Copy of IRB of Record Certification (if the study is already approved)
- Letters of support / collaboration (if applicable)
- CVs and certifications of the researchers/staff (if personnel is not affiliated with UPR MSC)
- IAA document with the information of the IRB of Record (WORD document) – Does not apply if the sIRB is WIRB or Advarra.
- Document “**Application for an External Institution to Serve as IRB of Record**” signed by UPR MSC PI.
- Any other document related to the study considered necessary to process the request of the agreement between the IRBs.

c. Complete **Section of Conflict of Interest** in the electronic application

d. Request the required **electronic signatures**

- The signature of the PI in the electronic application endorsement section, this ensures accuracy of the information contained within the submitted materials and, upon approval, assures compliance with all aspects of the section titled "Endorsement".
- If the PI is a faculty member, the signature of the Department Chair is needed to warrant that he/she is aware that the PI intends to conduct the proposed research in his/her department. If the Department Chair is unavailable, the acting chair, or the Dean of the school or designated representative may electronically sign the application.