1 PURPOSE

1.1 The purpose of this process is to execute Authorization Agreements with other institutions.

1.2 This process begins when an institution/organization has been identified for a potential Authorization Agreement.

1.3 This process ends when an Institutional Profile has been established.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 1.001 (HRP-101) - Human Research Protection Program Plan details the criteria for reviewing for, or relying on, other institutions/organizations.

3.2 The institution utilizes the SMART IRB Portal and version 1 and 2 agreements, and the Rutgers Single Study Authorization Agreement template.

3.2.1 The Rutgers University IRB to cede IRB review to (i.e. rely on) an External IRB from another institution/organization, in alignment with the requirements outlined in 13.001 (HRP-892) – SOP - External IRBs.

3.2.2 The Rutgers IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study, in alignment with the requirements outlined in 13.006 (HRP-893) – SOP – RU As IRB of Record.

4 RESPONSIBILITIES

4.1 The Senior Reliance Manager and Reliance Administrator generally carries out these procedures. The IRB Reliance Assistant Director may also participate in reliance determinations.

5 PROCEDURE

5.1 Determine whether an Authorization Agreement is already in place between or among the institutions in question.

5.1.1 If a valid Authorization Agreement is already in place, proceed with 13.003 (HRP-803) - SOP - Site Validation.

5.1.2 If no Authorization Agreement is in place, and one is required, proceed with step 5.2 below.

5.2 Determine whether an Authorization Agreement should be executed with an institution/organization using one of the following worksheets:[i]

5.2.1 Using the 13.202 (HRP-832) – WORKSHEET – Considerations for Ceding IRB Review document, determine if reliance on a commercial IRB or external IRB is appropriate.

5.2.2 Using the 13.203 (HRP-833) – WORKSHEET – Considerations for serving as the sIRB document, determine if serving as the sIRB is appropriate.

5.3 If the criteria have been met, execute an Authorization Agreement with that institution/organization.

5.3.1 Indicate in the agreement the conditions under which you serve as the IRB of record for that institution/organization.

5.3.2 Indicate in the agreement the conditions under which that institution/organization will serve as the IRB of record for you.

5.3.3 Include the following in the Authorization Agreement, or as (an) addendum(s):

5.3.3.1 Consent form instructions.

5.3.3.2 Recruitment material instructions.

5.3.3.3 New information reporting instructions.

5.3.3.4 13.304 – FORM - Relying Site Local Considerations form to collect the information above about the institution/organization.

5.4 If the criteria have not been met, do not execute an Authorization Agreement. Communicate this to the other institution/organization.

6 MATERIALS

6.1 1.001 (HRP-101) - Human Research Protection Program Plan.
6.2 13.001 (HRP-892) - WORKSHEET: Considerations for Ceding IRB Review.
6.3 13.006 (HRP-893) - WORKSHEET: Considerations for serving as the sIRB.
6.4 13.204 (HRP-1801) - WORKSHEET: Authorization Agreement Review.
6.5 Relying Site Local Considerations.
6.6 One Drive Institutional Profile Record Folder.

7 REFERENCES

7.1 SMART IRB Agreement.
7.2 13.302 (HRP 890) - FORM - Single Study Authorization Agreement: Human Research Protection Program Toolkit | Rutgers Research.