1. PURPOSE
   1. The purpose of this process is to execute Authorization Agreements with other institutions.
   2. This process begins when an institution/organization has been identified for a potential Authorization Agreement.
   3. This process ends when an Institutional Profile has been established.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. The Human Research Protection Program Plan (HRP-101) details the criteria for reviewing for or relying on other institutions/organizations.
4. RESPONSIBILITIES
   1. The Reliance Coordinator generally carries out these procedures.
5. PROCEDURE
   1. Determine whether an Authorization Agreement should be executed with an institution/organization.[[1]](#endnote-1)
   2. If the criteria have been met, execute an Authorization Agreement with that institution/organization.
      1. Indicate in the agreement the conditions under which you serve as the IRB of record for that institution/organization.
      2. Indicate in the agreement the conditions under which that institution/organization will serve as the IRB of record for you.
      3. Include the following in the Authorization Agreement, or as (an) addendum(s):
         1. A communication plan. Use “WORKSHEET: Communication and Responsibilities (HRP-830)” to create a communication plan.
         2. Consent form instructions.
         3. Recruitment material instructions.
         4. New information reporting instructions.
      4. Use “FORM: Institutional Profile (HRP-815)” to collect the information above about the institution/organization.
      5. Record the collected information in “WORKBOOK: Institutional Profiles (HRP-861).”
      6. File the “FORM: Institutional Profile (HRP-815)” and the Authorization Agreement (and any addendums) together for future reference.
   3. If the criteria have not been met, do not execute an Authorization Agreement. Communicate this to the other institution/organization.
6. MATERIALS
   1. Human Research Protection Program Plan (HRP-101)
   2. FORM: Institutional Profile (HRP-815)
   3. WORKSHEET: Communication and Responsibilities (HRP-830)
   4. WORKBOOK: Institutional Profiles (HRP-861)
7. REFERENCES
   1. None.

1. If your institution participates in the NCATS SMART IRB program, then you may choose to replace this SOP with SMART IRB documentation or to supplement this SOP with SMART IRB documentation. [↑](#endnote-ref-1)