HRP-801 | 3/15/2024

SOP: Establishing Authorization Agreements

1 PURPOSE

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

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 CCH Policy # RA.011.01 - Human Research Protection Program Policy details the criteria for relying on other institutions/organizations.

3.2 The institution may leverage an existing Institutional Profile to collect information requested in HRP-861 - WORKBOOK - Institutional Profiles For example, Institutional Profiles created for iREX or the SMART IRB platform are acceptable.

3.3 The institution may leverage the SMART IRB agreement, the OHRP Authorization Agreement template or create a local Authorization Agreement to establish reliance.

4 RESPONSIBILITIES

4.1 The IRB Reliance Coordinator or Director generally carries out these procedures. The IO/OO 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 HRP-803 - SOP - Reliance Pre-Review.

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

5.2 Determine whether the criteria for reviewing for or relying on other institutions/organizations are met:

5.2.1 Review CCH Policy # RA.011.01 - Human Research Protection Program Policy to determine if basic criteria are met.

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

5.2.2 If there is a request for your institution to rely on another institution's IRB, use HRP-832 - WORKSHEET - Considerations for Ceding IRB Review to inform your determination of whether your institution will rely on another institution's IRB.

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 that institution/organization will serve as the IRB of record for you.

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

5.3.2.1 A communication plan. Use HRP-830 - WORKSHEET - Communication and Responsibilities to create a communication plan.

5.3.2.2 Consent form instructions, including instructions for the institution/organization to provide local contact information and details regarding compensation for research-related injuries.

5.3.2.3 Recruitment material instructions.

5.3.2.4 New information reporting instructions.

5.3.2.5 Required terms.

5.3.2.6 Negotiable terms.

5.3.2.7 The process for adding participating sites or additional research to existing agreements.

5.3.2.8 Relevant tribal, state, or non-US laws, regulations, or policies, such as age of majority, circumstances that affect the age of consent, who can serve as a Legally Authorized Representative, and other information that may not be identified elsewhere in the Authorization Agreement.

5.3.3 Record the collected information in HRP-861 - WORKBOOK - Institutional Profiles.

5.3.4 File the HRP-815 - FORM - Institutional Profile and the Authorization Agreement (and any addendums) together for future reference.

6 MATERIALS

6.1 CCH Policy # RA.011.01 - Human Research Protection Program Policy

6.2 HRP-803 - Reliance Pre-Review

6.3 HRP-815 - FORM - Institutional Profile

6.4 HRP-830 - WORKSHEET - Communication and Responsibilities

6.5 HRP-832 - WORKSHEET - Considerations for Ceding IRB Review

6.6 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 SMART IRB Agreement: https://smartirb.org/agreement/

7.2 OHRP Authorization Agreement template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

[i] 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.