SOP: Establishing Authorization Agreements				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-801	02/18/2022	Huron	D. Durbin	1 of 2

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 10/29/2020: Section 3.2 Added sentence to include SMART, OHRP, and local agreements. Section 4.1: changed reliance coordinator to "IRB staff members assigned to reliance duties" and added IO/OO and HRPP Director. Section 5.1 and 5.2 Procedure, further outlines the procedure to establish authorization agreements by determining if basic criteria are met by institutions. In section 5.3, outlines specific information to be included "with" the Authorization Agreement. Section 5.3.4 and 5.3.5 were added to collect and record Institutional Profiles. Added Worksheets Considerations for Ceding IRB Review and Serving as the sIRB. Added references. Added section 8 Previous Versions. Updated formatting and numbering.

3 POLICY

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

3.2 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm 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 staff members assigned to reliance duties generally carry out these procedures. The IO/OO or HRPP 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 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 HRP-101 - Human Research Protection Program Plan 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.

5.2.3 If an institution is requesting to rely on your institution's IRB, use HRP-833 - WORKSHEET - Considerations for Serving as the sIRB to inform your determination of whether your institution's IRB will serve as the sIRB.

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

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

5.3.3.3 Recruitment material instructions.

5.3.3.4 New information reporting instructions.

5.3.3.5 Required terms.

5.3.3.6 Negotiable terms.

5.3.3.7 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.

5.3.4 Record the collected information in the Institutional Profile SmartForm.

5.3.5 File the Authorization Agreement (and any addendums) together for future reference.

6 MATERIALS

6.1 HRP-101 - Human Research Protection Program Plan

6.2 HRP-830 - WORKSHEET - Communication and Responsibilities

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

6.4 HRP-833 - WORKSHEET - Considerations for Serving as the sIRB

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

8 PREVIOUS VERSIONS

8.1 10/29/2020

[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.