HRP-801 | 2/2/2024| Author: T. Bechert | Approver: I. Irizarry

SOP: Establishing Authorization Agreements

1 PURPOSE

1.1 The purpose of this process is to execute Authorization Agreements with other institutions and agreements with individuals for reliance for non-exempt human research.[1]

1.2 This process begins when an institution/organization or collaborating independent investigator or collaborating institutional investigator at a non-assured institution has been identified for a potential Authorization Agreement.

1.3 This process ends when an Institutional Profile has been established or an Individual Investigator Agreement (IIA) has been executed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

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

3.2 An institution or individual must be engaged in non-exempt Human Research as determined by using HRP-311 - WORKSHEET – Engagement Determination for IRB reliance to occur.

3.3 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm. For example, Institutional Profiles created for IREx or the SMART IRB platform are acceptable.

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

3.5 This institution does/does not allow an unaffiliated individual or individual affiliated with an organization that does not have an Federalwide Assurance (FWA) to request reliance on this institution's FWA and IRB via an IIA.

3.6 This institution may leverage the OHRP IIA template or create a local IIA to establish reliance.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carry out these procedures. The IO/OO or HRPP Director may also participate in reliance determinations.

5 PROCEDURE

5.1 If the request is for IRB reliance on or by an institution, determine whether the criteria for reviewing for or relying on other institutions/organizations are met:

5.1.1 Review HRP-101 - Human Research Protection Program Plan to determine if basic criteria are met.

[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.

5.1.1.1 If the criteria have not been met, do not execute an Authorization Agreement. Prepare HRP-856 – LETTER – Decline Reliance on an External IRB, or HRP- 850 - LETTER - Decline to Serve and send to the other institution/organization.

5.1.1.2 If the request is 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.

5.1.1.3 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.

5.1.2 If the criteria have been met, for an institution/organization, execute an Authorization Agreement with that institution/organization. (Use of the SMART IRB Agreement is documented via a letter of acknowledgement or use of their Online Reliance System on a study specific basis.)

5.1.2.1 Indicate in the Authorization Agreement the conditions under which you serve as the IRB of record for that institution/organization.

5.1.2.2 Indicate in the Authorization Agreement the conditions under which that institution/organization will serve as the IRB of record for you.

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

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

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

5.1.2.3.3 Recruitment material instructions.

5.1.2.3.4 New information reporting instructions.

5.1.2.3.5 Required terms.

5.1.2.3.6 Negotiable terms.

5.1.2.3.7 The process for adding participating sites or additional research to existing Authorization Agreement (if this is a master agreement).

5.1.2.3.8 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.

5.1.2.3.9 Use HRP-802 - SOP - Management of Institutional Profiles to record the collected information in the Institutional Profile SmartForm. File the HRP-815 - FORM - Institutional Profile if applicable and the Authorization Agreement (and any addendums) together for future reference.

5.1.3 If the criteria within HRP-832- WORKSHEET - Considerations for Ceding IRB Review or HRP-8

5.1.4 33- WORKSHEET - Considerations for Serving as the sIRB have not been met, do not execute an Authorization Agreement. Prepare HRP-856 – LETTER – Decline Reliance on an External IRB, or HRP-850 - LETTER – Decline to Serve and send to the other institution/organization.

5.2 If the request is for an unaffiliated individual or individual affiliated with an organization that does not have an FWA to rely on your institution, determine whether the criteria have been met:

5.2.1 Confirm the individual does not need their institution to obtain its own FWA (e.g., they are the prime awardee, or routinely conduct human subjects research).[2]

[2] Extending an FWA to Cover Collaborating Investigators (2005) | HHS.gov: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html

5.2.2 Review HRP-101 - Human Research Protection Program Plan to determine if basic criteria are met.

5.2.2.1 If the criteria have not been met, do not execute an IIA. Prepare HRP-850 - LETTER – Decline to Serve and send to this institution's study team.

5.2.2.2 If the criteria have been met, execute IIA with the individual.

5.2.3

5.2.4 Upload the finalized IIA under "Other Attachments" in the study application.

6 MATERIALS

6.1 HRP-021 - SOP - Pre-Review

6.2 HRP-101 - Human Research Protection Program Plan

6.3 HRP-802 - SOP - Management of Institutional Profiles

6.4 HRP-815 - FORM - Institutional Profile

6.5 HRP-830 - WORKSHEET - Communication and Responsibilities

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

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

6.8 HRP-850 - LETTER - Decline to Serve

6.9 HRP-856 - LETTER - Decline Reliance on an External IRB

6.10 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 Single IRB Exception Determinations: https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/index.html

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

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

7.4 Extending an FWA to Cover Collaborating Investigators (2005): https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html