PART 2: Agreements at a glance[1]

Agreements with Institutional Review Boards (IRB) or between institutions/organizations and IRBs are NOT the same as FWAs. IRB agreements DO NOT substitute for or replace FWAs.

IRBs are a *component* of an institution's assurance of compliance (FWA). They are not themselves an FWA.

HRPO has found great confusion on these points.

All U.S. federally funded non-exempt[2] research involving human subjects:
(1) must be approved by an IRB
AND
(2) must be conducted under a Federalwide Assurance (FWA).

BOTH of these criteria apply! Not "either/or". IRBs and FWAs are NOT interchangeable.

IRB Agreements	
Terms	For the purposes of this Guidance, the following terms are used. **Relying institution/organization**: The institution, organization, or individual that enters into an agreement with an external IRB in which the external IRB will review, approve, and oversee the research of the relying institution/organization. **Approving IRB**: The external IRB that has agreed to review, approve, and oversee the research or research project of the relying institution/organization. **Assuring institution/organization**: An institution/organization that has its own FWA and that agrees to "assure" the research activities performed by individuals who are not employed by an assured institution/organization or who are not acting under the assurance of their assured employer. **Non-assured institution/organization**: An institution/organization that does not have its own FWA. **Reliance agreement, IRB Authorization Agreement (IAA), Institutional Agreement For Institutional Review Board Review (IAIR)**: See below **Institution/organization**: Means "institution **or** organization". This is to acknowledged that there are non-institutional entities that conduct human subjects research, such as companies, foundations, non-profit organizations, governmental organizations, non-governmental organizations, etc.

[1] HRPO companion to "Part 1: IRBs v. FWAs at a glance". HRPO recommends that the reader reviews "Part 1: IRBs v. FWAs at a glance"

[2] Research that has received a determination of 'exempt from IRB oversight' or a determination of 'research not involving human subjects' (RNIHS) is not required to be covered under an FWA.

IRB Agreements	
Overview	There are a number of terms used for the written agreements that designate an external IRB to review an institution's/organization's research, for example: - Reliance agreement - IRB Authorization Agreement (IAA) - Institutional Agreement For Institutional Review Board Review (IAIR) These are different names for the same basic purpose of establishing a formal relationship between two institutions/organizations for the services of an approving IRB. ALL OF THESE AGREEMENTS ASSUME THAT THE RELYING INSTITUTION **HAS** AN FWA. (See the attached OHRP IAA template). **Having a reliance agreement or an IAA or an IAIR does NOT take the place of having an FWA.** Organizations relying on an external IRB must still have their own FWA or be included within another institution's/organization's FWA or have other assurance arrangements in place (see the FWA section below). If an institution/organization does not have an FWA **or if their engaged partners/collaborators do not have FWAs**, it may be possible to arrange for Individual Investigator Agreements (IIA). See "Agreements for FWA coverage" below. If FWA or other assurance arrangements cannot be made, the federally funded research at the "non-assured" facility may not be possible. See the FWA section below. Agreements must be kept on file at both institutions/organizations and made available to OHRP or any U.S. federal department or agency conducting or supporting research covered by the FWA upon request
IRB Authorization Agreement (IAA) / Institutional Agreement For Institutional Review Board Review (IAIR)	Whenever the institution/organization relies upon an IRB operated by another institution or organization for review of research covered by the FWA, the institutions/organizations must ensure that this arrangement is documented by a written agreement between the "**relying**" institution/organization and the "**approving**" institution/organization operating the IRB. The agreement must outline their relationship and must include a **commitment that the approving IRB will adhere to the requirements of the relying Institution's FWA**. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. See the attached HRPO-notated copy of the OHRP IAA template.
Reliance Agreement	Reliance agreements, IAAs or IAIRs apply to agreements between relying institutions/organizations and approving IRBs. **These agreements do not substitute for an FWA**. See the IAA section above. When approving IRBs require a Reliance Agreement (or other agreement) from a relying institution/organization, they are assuming that the relying institution/organization **HAS an FWA**.

Federalwide Assurances (FWA)	
Agreements for FWA coverage	If an institution/organization does not have an FWA or if their engaged partners/collaborators do not have FWAs, it may be possible to arrange for Individual Investigator Agreements (IIA). These are agreements between an assured institution/organization and the INDIVIDUALS who are performing the research activities. The "assuring" institution/organization agrees to ensure that the applicable individuals who are performing research activities are aware of (trained in) and follow human research protections requirements (informed consent, compliance with the approved protocol, reportable events, etc.) See "Individual Investigator Agreement (IIA)" below.
Individual Investigator Agreement (IIA)	An institution may extend its FWA to cover a collaborating individual investigator by establishing an "**Individual Investigator Agreement**" (IIA). See OHRP's sample "Individual Investigator Agreement". A comparable agreement can be developed by the institution/organization. http://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html NOTE: "Investigator" is not limited to the roles of Principal Investigator, Sub-Investigator, etc. For the purposes of the FWA, an "investigator" is anyone who is performing research activities that involve interaction or intervention with human subject or their identifiable information while not employed by an assured institution/organization or who is not acting as an agent of their assured institution/organization. IIAs therefore are needed for applicable personnel such as clinical staff, survey-takers, recruiters, etc. Basically, the assured institution/organization is taking on the responsibility of ensuring that the human research protections requirements of the Common Rule are being followed by the non-assured investigator/employee. **There are 14 conditions that must be met in order an assured institution/organization to extend its FWA** to cover a collaborating independent or institutional investigator. The conditions are listed in the OHRP page above. If HHS (or DOD)-conducted or -supported human subjects research activities routinely occur at a non-assured institution/organization, the institution/organization should obtain an OHRP-approved FWA, and the IIA (or similar agreements) should not be used. =
Alternative arrangement	If it is not possible for a performance site/collaborator/personnel to be assured by any of the mechanisms above, it may not be possible for the research to be conducted at that site or with those individuals. A solution to this problem could be for the staff/personnel of an assured institution/organization to perform the research activities at the non-assured site. This would require an access agreement from the non-assured site to allow the assured staff to perform the research activities in its facilities.