Institutional Authorization Agreements, Collaborations, Reliance, and More

George Washington University
IRB Forum
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What is Collaboration?

- Engagement by two or more entities in human subject research by virtue of subject accrual, transfer of identifiable information, and/or in exchange of something of value, such as material support (e.g., funding, resources, drugs, identifiable specimens), intellectual property, or credits.
- Examples:
  - Multi-investigator projects
  - Multi-institutional projects
  - Virtual research partnership (remote student research)
  - Subcontracting
  - Co-authorship

What is Engagement?

- An institution becomes "engaged" in human subjects research when its employees or agents
  - (i) intervene or interact with living individuals for research purposes; or
  - (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

When is an Institution Engaged?

- Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution;
- Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures;
- Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment;
- Institutions whose employees or agents obtain the informed consent of human subjects for the research;
- Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research.

Engagement in Research: Funding

- When GW is the primary money holder, GW IRB will be the IRB of record;
- GW will ensure collaborative institutions operate under a Federalwide Assurance (FWA) via "Assurance of Compliance" and have IRB approval;
- FWA is the only type of assurance accepted by GW and approved by Office of Human Research Protections (OHRP).

FederalWide Assurance (FWA)

What is a FWA?

- “License” to conduct federally supported human subjects research;
- Required of every institution that is engaged in human subjects research;
- Contract with DHHS that establishes the standards for research conduct, formalizing your commitment to follow the regulations and protect human subjects including adherence to the Common Rule (45CFR46) and Belmont Report.

When is an FWA Needed?

- When an institution is engaged in human subjects research (not exempt from the regulations);
- An institution may extend its FWA to cover a collaborating individual investigator under certain conditions using certain types of agreements;
- Individuals collaborate must complete CITI training and agree to follow the regulations and GW IRB requirements.

Examples of When an FWA is Required

- GW listed as prime awardee on a grant from NIMH. The research will be conducted at clinical sites in the DC area. Clinics do not routinely perform research, but will be recruiting, consenting, and collecting subject data. Clinics need FWAs.
- GW faculty serves as co-PI on a study. Howard is the prime awardee but GW students are recruited. Both institutions will share identifiable data. Both require an FWA.

How to Apply for a FWA

- How to file a new FWA:
  - http://www.hhs.gov/ohrp/assurances/assurances/file/in dex.html
- Note: When filing an FWA, the institution will have to list an IRB. If the IRB is external, the institution should ALWAYS check with the external IRB first;
- How to check on the status of a FWA:
  - http://www.hhs.gov/ohrp/assurances/status/index.html
- Your application must designate:
  - Institutional Official
  - Human Protections Administrator

Who is an Institutional Official?

- Not OHR or the GWU IRB.
- An individual legally authorized to:
  - Act for, or on behalf, of the institution to obligate said institution to the terms of the FWA;
  - Legally bind the institution in agreements;
- This person is responsible for all research conducted at the institution;
- IOs are usually people with titles like: VP, Medical Director, Executive Director, etc.

Institutional Authorization Agreements

What are they?

When can they be used?

What about individuals?

What is an Institutional Authorization Agreement (IAA)?

- An IAA- or IRB reliance- is an agreement between two institutions, each with an FWA (usually), that allows one IRB to rely on another for review and approval;
- Must be approved and signed by the Institutional Officials at each institution;
- They can only be used for expedited (minimal risk) studies;
- Exempt studies are an exception and should still be submitted to the OHR for “concurrence”.

When Can an IAA be Used?

- Reliance may be set up when one institution is more engaged than the other. For example:
  - A GWU based researcher is conducting data analysis for a study taking place at another institution
  - A GWU doctoral candidate is conducting research at his/her home institution and obtains IRB approval there
  - Collaborative research (work with Dept of Defense, DC Dept of Health, etc)

What if There is Not Another IRB?

- Individual Investigator Agreements (IIAs) can only be used in circumstances where one person at the institution is engaged in human subjects research AND the institution does not typically conduct research;
  - A collaborating investigator who is not affiliated with GWU;
  - A collaborating investigator who is affiliated with an institution/hospital/clinic that may not have its own IRB to review the study;
  - A collaborating investigator who is not acting as an employee of any institution with respect to his or her involvement in the research being conducted by GWU.

What is Considered for an Agreement?

- Risk level: Typically not used for studies that are greater than minimal risk (full board).
- Does the other institution require IRB review?
- Does the other institution have an IRB?
- What research activities happening at GW?
  - Consenting of subjects
  - Recruitment
  - Data collection
  - Identifiable data analysis

When Can an Agreement NOT be Implemented?

- GW investigator is lead for whole study (i.e., designed the project);
- Other IRB has poor performance history (cited by FDA or OHRP for violations);
- Institutional Officials (IOs) do not approve agreement. Some institutions will not enter into an IAA (Veterans Affairs, NYU, George Mason);
- Note: If the IOs do not agree to rely, the PI is responsible for ensuring that all documents are consistent between IRBs. There should be one consent form, one protocol, etc.

How do I get an Agreement?

- The PI or primary contact should contact both institutions to determine if an IAA is appropriate. IAAs may only be used for studies that are considered minimal risk. Research determined to be Exempt and greater than minimal risk studies cannot enter into this sort of agreement.
- Once both institutions agree to enter into the agreement, complete the appropriate IAA form and IRB of Record Request form.
  - 2.a:If GWU is to be lead, no other documents should be necessary as we will have already reviewed the study.
  - 2.b:If GWU is to rely, please submit the other institution's IRB approval and any other study related documents such as consents.
- Submit all pertinent documents to ohrirb@gwu.edu. An IRB staff member will route for signatures accordingly. Please be certain to have the form completed in its entirely prior to submission. Federalwide Assurance and IRB numbers may be found here: http://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc
- After signature from both intuitions has been obtained, provide GWU with a final copy for our records.

Does it matter Which Approval I get First?

- Regulations don't dictate in which order collaborating institutions provide approval;
- Submission may be concurrent, however, it is advised that the institution on which the others will rely be first to approve;
- Always follow lead IRB policies and inform relying IRBs to any changes.

Questions?

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