Assurances, Agreements & Reliance

As protocols become increasingly complex, so do to the assurances and agreements that they require. Unfortunately, navigating what types of agreements are required, based on the nature and scope of a research proposal, can be confusing. Below is a quick tutorial of the most commonly used agreements among University of Rochester Investigators. Bear in mind, obtaining Institutional Review Board (IRB) approval does not equate to executing/obtaining any of the agreements identified; IRB approval must still be obtained. Furthermore, in some cases, an agreement may still be required even though IRB approval isn't (e.g., when a proposal does not meet the definition of human subject research).

Type of Document	Description	Required For…	Executed By…
Federalwide Assurance (FWA)	A written declaration confirming an institution's commitment to comply with the requirements set forth in 45 CFR 46 (as well as the terms identified in the assurance document).	• Institutions engaged in human subject research conducted or supported by the Department of Health and Human Service (HHS) • Note that FWAs pertain to institutions, *not* IRBs; external awardees and/or sub-contractors engaged in the research are required to file their own FWA with HHS.	Institutional Official (via Office for Human Subject Protection)
Confidential Disclosure Agreement (aka Non-Disclosure Agreement)	A legal contract between two parties (e.g., sponsor and investigator) defining information that will be shared between the two parties and restrictions on wider dissemination.	Industry-sponsored clinical trials (note that this agreement is executed during the site selection phase of the research; prior to Clinical Trial Agreement execution)	Office of Research and Project Administration
Clinical Trial Agreement	A legal contract that manages the relationship (e.g., responsibilities, risk allocation, protection of legal/intellectual property) between a study sponsor and the institution conducting the clinical trial.	Clinical trials sponsored via mechanisms other than grant funding	Office of Research and Project Administration

Data Use Agreement	A legal contract required by the HIPAA Privacy Rule for the transfer of limited data sets that sets forth terms for maintaining the confidentiality of the shared data.	Sharing of a limited data set (a 'limited data set' includes protected health information [PHI] that excludes direct identifiers, but may include city, state, 5-digit zip code, and dates, and other unique codes that are not direct identifiers)	Office of Research and Project Administration
Material Transfer Agreement	A legal contract that governs the transfer of materials between entities, including the scope of work as well as the rights/obligations regarding intellectual property, ownership, publication, confidentiality and research results.	Projects that require the transfer tangible material (e.g., biological materials such as cell lines and vectors, data, software, chemical compounds) between entities	Office of Research and Project Administration
Reliance (or IRB Authorization) Agreement	A written agreement that provides a mechanism for an institution engaged in research to delegate IRB review to another IRB.	Human subject research proposals requesting IRB review by an external IRB (i.e., other than the Research Subjects Review Board)	Office for Human Subject Protection

ADDITIONAL RESOURCES:

- OHSP Guideline for Determining Engagement in Research
- OHSP Policy 504 IRB Reliance and Collaborative Research
- OHSP Guideline for When UR is the Reviewing IRB
- OHSP Guideline for When UR Relies on a Non-UR IRB
- Office of Research and Project Administration Website