University Hospitals
Clinical Research Center

What types of contracts does the Pre-Award Grants & Contracts office review?

Amendment
An agreement that modifies any aspect of an existing agreement. Common modifications include: adding new terms or conditions, extending the project period, increasing the funding, etc.

Business Associate Agreement associated with Clinical Research
This is an agreement between a covered entity (the holder of the PHI) and the recipient of the PHI (such as a service provider) in which the covered entity discloses PHI or in which the business associate creates, receives, maintains, or transmits PHI on behalf of the covered entity or another business associate. HIPAA generally requires that covered entities and business associates enter into a Business Associate Agreement to ensure that the business associate will appropriately safeguard protected health information. The business associate contract also serves to clarify and limit, as appropriate, the permissible uses and disclosures of protected health information by the business associate, based on the relationship between the parties and the activities or services being performed by the business associate. A business associate may use or disclose PHI only as permitted by the agreement or as required by law.

Clinical Trial Agreement
This agreement is between at least two parties and typically includes an industry sponsor, who is designated as the Sponsor per FDA guidelines. Other parties may include a contract research organization (CRO) designated by the Sponsor. Common terms generally include; confidentiality of proprietary information, data rights and HIPAA protections, certain regulatory terms, publication rights, inventions and patents, payment schedules, indemnification, subject protection, research injury and budget.

- **ACTA** – The Accelerated Clinical Trial Agreement was developed to streamline the negotiation process. The ACTA represents a straightforward and unambiguous position that sets forth regulatory and contractual obligations, acceptable to both parties. The ACTA can be chosen when used in template form with no modifications or when slight modifications are made and approved by UH legal.
- **Work Order** – A project specific clinical trial agreement that rolls up under a Master Agreement. Work Orders, or Statements of Work, define the work activities, deliverables, timelines, pricing and other requirements. All terms not defined in the work order are governed by the Master Agreement.

Collaboration Agreement
A contract between UH and one or more organizations that are cooperating in the conduct of a research program. In these agreements, there is generally no transfer or funds between organizations (referred to as a “No Cost Collaboration”). Instead, the agreement describes the actions that each organization has agreed to undertake, and defines the obligations each party has to the others participating in the collaborative research effort.

Confidentiality/Non-Disclosure Agreement
A confidentiality agreement is sometimes referred to as a non-disclosure agreement (NDA) or a confidential disclosure agreement (CDA). This agreement is between at least two parties and describes confidential material, knowledge, or information that the parties wish to share with one another for a specific purpose, but wish to restrict access to third parties. It is a contract through which the parties agree not to disclose information covered by the agreement. After execution of a confidentiality agreement, the protocol, the clinical trial agreement and other study materials will be released to the participating site.

Consulting Agreement
An agreement between a consultant and a sponsor in which the sponsor desires to engage the consultant to provide and perform certain services related to a research project in the area of the consultant’s expertise. This ONLY includes consulting agreements that transfer money to Institution. All consulting agreements that pay a physician directly go to the Compliance Office for CE-20 review.

Data Use Agreement
This is an agreement between a covered entity (the holder of the PHI) and the recipient of the PHI (such as a research investigator) in which the covered entity discloses data in the form of a Limited Data Set or a de-identified data set for purposes of research. Data use agreements are required to restrict the use of the PHI in the applicable data set to a specified purpose, to safeguard the PHI, and to assure that the individuals whose PHI is included in the data set will not be identified by the recipient. Sometimes a DUA is attached to an underlying agreement that specifies other terms of the project. Policy: PH-16

Grant Agreement
An agreement that outlines the award terms and conditions of a grant award.

Investigator Initiated Clinical Trial Agreement

This agreement is for a research study that is initiated by a non-industrial sponsor (e.g., an investigator at UH, other academic medical centers, and/or cooperative groups). Generally, the Principal Investigator is also the Sponsor of the Study per FDA guidelines. Common terms in this agreement are similar to those included in a clinical trial agreement; however, certain obligations and liabilities are shifted to the Principal Investigator.

Laboratory Services Agreement

An agreement entered into when a sponsor provides funding to support a specific research project related to laboratory analysis or other laboratory services, with an expectation of receiving reports or certain deliverables.

Letter of Indemnification (LOI)

A document detailing an obligation contractually assumed by one party to protect another against loss or damage from specific liabilities. In the case of a clinical trial, a Letter of Indemnification is used when the Clinical Trial Agreement is between an institution and a Contract Research Organization and not directly with the Sponsor of a study. Due to the fact that the Sponsor is not a party to the Clinical Trial Agreement a separate agreement is required to contractually ensure that the institution and study subjects are appropriately covered for losses resulting from the their participation in a clinical trial.

License Agreement associated with Clinical Research

A contract under which the owner of a copyright, know how, patent, service mark, trademark, or other intellectual property, allows a license to use, make, or sell copies of the original. Such agreements usually limit the scope or field of the licensee and specify whether the license is exclusive or non-exclusive. In relation to clinical research, a License Agreement may be necessary in order for an institution or physician to obtain the rights to use specific computer software, surveys, or items that are required to complete a clinical trial or clinical research.

Master Agreement

A contract reached between parties, in which the parties agree to most of the terms that will govern future transactions or future agreements. A Master Agreement permits the parties to quickly negotiate future agreements (see Clinical Trial Agreement – Work Order), because they can rely on the terms of the master agreement and not be repetitively negotiated.

Material Transfer Agreement

This is an agreement that governs the transfer of tangible research materials between two organizations. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives, including intellectual property. Biological materials, such as reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials, but MTAs may also be used for other types of materials, such as chemical compounds and even some types of software. An MTA may also require a Business Associate Agreement (BAA) when the transaction involves the release or exchange of protected health information. A BAA may not be required if the materials are de-identified in accordance with HIPAA and/or released pursuant to a valid patient authorization approved by the Institutional Review Board.

Service Agreement

This agreement is required when a service is provided from one party to another and is formally defined in writing. Common terms typically include; scope of work, budget and terms and conditions affecting confidential information, if any, data rights, payment schedules, and indemnification. An example scenario that would require a service provider agreement might be one party engaging another party to perform statistical analysis that is beyond the expertise of an internal employee. If the service involves the release or exchange or protected health information or the service provider will have access or exposure to patients or patient data, a business associate agreement must be attached to the service provider agreement.

Study Start-up Agreement

An agreement that is executed prior to the review of a Clinical Trial Agreement. It is a brief agreement that ensures that the institution will receive payment for study start-up activities even if the parties are unable to fully execute a Clinical Trial Agreement (e.g., a study is terminated by the FDA, the Sponsor terminates the study, or a department decides not to move forward with a study). An example of start-up fees include: 1) Department start-up fee, 2) Department - preparation and submission of documentation required for initial IRB review fee, 3) CRC administration/financial management fee, and 4) UH/Advarra IRB initial review fee.

Subcontractor/Subsite Agreement

An agreement in which UH transfers a portion of the research or effort out to another institution or organization.