

## **Types of Agreements Negotiated by FACTS**

**Confidentiality Agreement:** also referred to as a non-disclosure agreement (CDA or NDA), is an agreement governing the exchange of confidential information. It is designed to protect the confidential information that may be released between a for-profit entity and the faculty and staff of the Icahn School of Medicine (ISMMS) so that they may determine whether or not to enter into a subsequent agreement for a clinical trial.

**Clinical Trial Agreement (CTA):** A Clinical Trial is defined by the FACTS Office as a research study where the objective is either the testing of drugs, devices, diagnostics, treatments, interventions or preventive measure. This includes testing for an unapproved indication or Data collection to increase knowledge that would lead to enhanced safety and efficacy of a drug or device. The study must involve contact with humans, inclusive of medical record reviews. The source of funding or support must be a for-profit entity.

**Letter of Indemnification (LOI):** A letter issued by a for-profit entity which promises by written confirmation to act as a 3rd-party on behalf of the first party in a transaction or contract. This 3rd-party covers loss or damage to the 2nd-party in the agreement caused by the first party.

**Investigator-Initiated Clinical Trial Agreement (IICTA):** An agreement governing the conduct of a study based upon a protocol authored by an ISMMS Investigator/Sponsor Investigator. A for profit entity provides funding and/or drug or device.

**Site Agreement:** An agreement governing an external site's participation in an Investigator Initiated clinical trial as provided above.

**Registry Agreement:** An agreement governing the conduct of a study that is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.

**Registry Committee Agreement:** An industry funded agreement by entities with an economic interest in the sale of a product where the study looks at the use and or outcomes of use of their product subsequent to selling to MSH at the full commercial price.

**Sub-award Agreement:** An agreement governing financial support from a for-profit entity/prime awardee or pass-through entity (i.e., ISMMS) for the performance of a substantive portion of the effort under the prime award. It does not include procurement of goods and services purchased under an award, as the providers of these goods and services have no programmatic responsibility.

**Amendment:** An agreement governing changes to the terms of an existing agreement.

**Master Clinical Trial Agreement (MCTA):** An agreement governing standard terms, pre-negotiated between parties that reduces the need to renegotiate common language and allows focus to be placed on specific individual study work orders, protocols, and budgets.

**Data Coordinating Center:** An agreement governing responsibilities for the overall data management, monitoring, communication, and general oversight for a Multi-Center clinical trial. The agreement may be designated either by a for profit entity or by mutual agreement of the participating sites.

**Academic Research Organization (ARO):** An agreement wherein an academic and/or nonprofit institution performs certain functions in the conduct of clinical trials. The research services that an ARO provides can range from academic leadership to full-service clinical trial management capabilities, including site monitoring, data management, statistical analysis, safety monitoring, and clinical events classification, in addition to clinical expertise.

**Study Start Up Agreement (SSUA):** An agreement used when a for-profit entity or clinical research organization (CRO) wants to assist the Investigator and his/her research team by providing startup funding while the clinical trial agreement is being negotiated.

**Equipment Loan/Lease Agreement:** An agreement governing the loan or lease of equipment to be used in conjunction with a specific Clinical Trial Agreement and at no cost to ISSMS. The agreement cannot be a prerequisite nor imply any future leasing or purchasing of the equipment between ISMMS and the company. Furthermore, loaned/leased products cannot be utilized simultaneously for clinical and research purposes.

**Letter of Authority (LOA):** An agreement governing negotiating an agreement with a third party who is not the Sponsor, i.e. CRO whereby the CRO is executing the agreement on behalf of the Sponsor.