Types of Agreements Negotiated by FACTS

**Confidentiality Agreement:** An agreement governing the exchange of confidential information that parties wish to share with one another with respect to a potential study, but wish to restrict access to or by third parties.

**Clinical Trial Agreement**: An agreement governing the conduct of a study sponsored by a for-profit entity.

**Letter of Indemnification (LOI):** An LOI is a letter issued by a Sponsor who is not a party to the CTA and is required by ISMMS. The LOI must contain the indemnification, subject injury and insurance provisions which are usually negotiated as part of the CTA. ISMMS requires that the Sponsor sign the LOI before ISMMS signs the CTA.

**Investigator-Initiated Trial (IIT) Agreement**: An agreement governing the conduct of a study sponsored by an ISMMS faculty member and a for-profit company is providing financial and/or product support.

**Registry Agreement**: An agreement governing a study where patients’ information is collected and added to a database.

**Site Agreement**: An agreement governing a site’s participation in a study initiated by a Sponsor-Investigator.

**Sub-award Agreement**: An agreement governing a site’s performance of services related to a Sponsor-Investigator’s study. The terms of the agreement are influenced by the prime agreement terms.

**Amendment:** It is a written document that modifies the original terms of an existing agreement.

**Master Agreement**: An agreement that sets forth the standard terms that will govern all subsequent clinical or research studies. The Master Agreement will contain a template Work Order/ Addendum that will set forth the particulars of the study such as budget/payment terms, schedule details, protocol name, and identity of the principal investigator, etc. A Master Agreement should be negotiated when the Sponsor or company estimates that ISMMS will participate in a number of studies during the term of the agreement and a cross section of our faculty be eligible to serve as principal investigators.

Summary of Miscellaneous Agreements Reviewed by FACTS

**CEC (Clinical Events Committee):** An agreement initiated by a sponsor for shared responsibilities of clinical monitoring and oversight of a clinical trial. All committee groups are components to ensure that the sponsor is compliant with conducting trials that are ethical, are safe for the subjects, and produce good, reliable data. For certain trials, sponsors may choose a CEC to review important endpoints reported by the investigators to determine if they meet protocol-specific criteria. Information that a CEC might be: (a) relatedness and seriousness of adverse events; (b)imaging data; (c) autopsy reports CECs are most valuable when endpoints are subjective; require the application of a complex definition, or when the intervention is not blinded. CEC assessments can help to ensure that data reviewed by other committees are accurate and as free of bias as possible.

**Data Coordinating Center:** An agreement wherein a Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of the conduct of a human subjects research project for a Multi-Center clinical trial. A Coordinating Center may be designated either by a sponsor or by mutual agreement of the participating sites. The Principal Investigator (PI) wishing to act as the Coordinating Center PI for a multi-site research effort must submit an IRB application. IRB review and approval in which s/he describes the Coordinating Center functions and responsibilities. The PI may submit either of the following: (a) for studies in which there will be no subject enrollment at the Icahn School of Medicine at Mount Sinai (“ISMMS”), a specific Coordinating Center application and protocol that outline the responsibilities of the Center and the Coordinating PI. This must be submitted to the IRB for review and approval prior to initiating the Center’s functions; or (b) for studies in which there will be subjects enrolled at ISMMS, an application and protocol in which the PI outlines the conduct of the research with participants at ISMMS. In such cases, a specific Coordinating Center protocol may or may not be available as a separate protocol submission. If not, the Coordinating Center functions should be described in protocol submitted or in a sub-protocol.

**ARO:** An agreement wherein an academic and/or nonprofit institution will perform one or more functions in the conduct of clinical trials. The 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. The concept of an ARO dates back several decades, when researchers recognized the need for large global clinical trials to answer important medical questions. Clinical scientists from several of the world's leading academic institutions formed teams of like-minded investigators with the goal of developing and conducting global clinical studies to improve patient care. AROs are focused on developing and sharing knowledge with the end goal of improving patient care. They accomplish this goal not only by leading and conducting multinational clinical trials but also by ensuring that the results from these trials are published and presented. These groups also focus on managing major national patient registries designed to collect data and determine best practices, which can then be incorporated into clinical practice guidelines. Education and development of clinical investigators is also a focus, with many of the leading AROs having fellowship programs whose influence extends around the globe.

**Data Use (in concert with a specific Clinical Trial Agreement):** An agreement used for the transfer of nonpublic data that is subject to some restriction on its use. DUAs serve to outline the terms and conditions of the transfer. Specifically, DUAs address important issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. The understanding established by a DUA can help avoid later issues by clearly setting forth the expectations of the parties (provider and recipient). Having a signed DUA in place may be a required precondition to transfers of certain data, or it may simply be a good idea. Determining whether a DUA is required is necessarily context dependent. When a DUA is required, it must be study specific – i.e. data cannot be transferred pursuant to “master” or blanket sharing agreements. DUAs must be signed by a Icahn School of Medicine at Mount Sinai official who has the appropriate delegated signature authority. The purpose of this guidance is to assist its users in assessing whether a proposed outgoing transfer of data that is in the possession of ISMMS and/or a ISMMS investigator (developed in his or her work for ISMMS) to a third party (i) is permissible; and (ii) if so, whether a DUA is necessary or recommended to effect the transfer. This guidance contemplates the outgoing transfer of data to third parties who have a bona fide research use or practical application for the data (e.g. collaborating research institutions, academicians, public policy makers, community service providers, etc.). **Note**: this guidance does not address incoming data to be a from a third party, nor does it address providing data to a web hosting service, which comes with a different set of considerations. Rather, this guidance contemplates the outgoing transfer of data to third parties who have a bona fide research use or practical application for the data (e.g. collaborating research institutions, academicians, public policy makers, community service providers, etc.). Where incoming transfer of data is proposed, the data provider will determine whether a DUA is necessary.

**Investigator Prototype for Research (IPR):** An agreement governing ongoing collaboration between Commercial Sponsor (“Company”) and Institution. Company is willing to make the following Investigator-requested Prototype for Research (“IPR”) available to Institution’s principal investigator, under the terms of a Master Research Agreement by and between Company and Institution

**Study Start Up Agreement (SSUA)**: An agreement typically used when a clinical sponsor or clinical research organization (CRO) wants to assist the PI and his/her research team by providing startup funding while the clinical trial agreement is being negotiated by the FACTS Team. Study Start-Up Agreements provide funds to help the PI with costs associated with IRB submission and/or to pay for salary/fringe of study research staff.

**Equipment Loan/Lease Agreement:** An agreement governing the loan or lease of equipment to be used in connection with clinical research. If a study involves a product being loaned or leased at no cost to ISSMS, the proposed agreement cannot condition or relate the loan/lease on/to a future leasing or purchasing agreement between ISMMS and the company. There must be a bona fide IRB approval for the study. Furthermore, loaned/leased products cannot be utilized simultaneously for clinical and research purposes.

**Letter of Authority**: An LOA is required when the SCS is negotiating a CTA with a third party who is not the Sponsor, i.e. CRO and the CRO is signing on behalf of the Sponsor.