TITLE: LEGAL AGREEMENTS WITH SPONSORS/CROs, COLLABORATORS, OR FUNDERS FOR RESEARCH

1.0 OBJECTIVE:

1.1 This Standard Operating Procedure (SOP) describes the method for submission, review, resolution, execution, and distribution of legal documents binding either Florida Hospital (FH) and/or the Principal Investigator (PI) to another entity for the purposes of conducting research. These other entities may include, but are not limited to; industry or commercial sponsors, contract research organizations (CROs), or other research collaborators or funders, as well as agreements between the Principal Investigator and Florida Hospital, such as Letters of Agreement (LOAs).

1.2 This SOP is intended to ensure that Food and Drug Administration (FDA) Federal Regulations, the International Conference on Harmonization (ICH) Guidelines (E6) for Good Clinical Practices (GCPs), Department of Health & Human Services (DHHS) regulations, and the State of Florida associated laws and/or statutes, and any applicable FH Policies and Procedures are met regarding the legal responsibilities of the sponsor and investigator in conducting research.

1.3 This SOP is in place to ensure that both, Florida Hospital and the Principal Investigator, are legally protected in all necessary areas applicable to their specific project.

1.4 This Standard Operating Procedure (SOP) does not specify the legal requirements of any agreements with a Florida Hospital research department. The Florida Hospital Legal department is responsible for specific legal requirements including but not limited to research contracts.

2.0 DEFINITIONS:

2.1 Clinical Trial Agreement (CTA): A document used between the Institution and an outside party to define the terms and conditions associated with the conduct of a clinical trial. A protocol describing how patients will be treated is normally appended, as well as a budget, to the CTA (also referred to as a “Clinical Study Agreement” or “CSA”).

2.2 Confidentiality Disclosure Agreement (CDA): a document used between the Institution and an outside party that defines the terms and basic criteria used to assure that the party (or parties) receiving confidential information (i.e. data, methods, procedures) will maintain the information in confidentiality and will not
2.3 **Material Transfer Agreement (MTA):** A contract governing the transfer of tangible research materials between two organizations, when the recipient intends to use the materials for its own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. 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. Transfers may occur between the research institution, academia, and/or industry.

2.4 **Data Use Agreement (DUA):** Written agreement between a healthcare component and a person requesting a disclosure of PHI contained in a limited data set. Data use agreements must meet the requirements of limited data set procedure.

2.5 **Master Clinical Trial Agreement (MCTA):** An umbrella agreement between the Institution and an outside party in which both parties agree upon a set of contractual terms and conditions for future clinical trials contemplated by the agreement. This alleviates the need to negotiate the contractual terms for individual clinical trials. Instead, each subsequent clinical trial is contracted with a "Work Order", an "Amendment", or a "Schedule." This study-specific agreement would incorporate the terms of the master agreement and set forth the conditions that are unique to the particular study, such as protocol title, principal investigator name and budget.

2.6 **Letter of Agreement (LOA):** An agreement that establishes the obligations of the Investigator and Florida Hospital in order to properly conduct hospital approved research studies.

3.0 **RESPONSIBILITIES:**

3.1 The Principal Investigator's responsibilities regarding Legal Agreements for the purposes of conducting research under the auspices of Florida Hospital include the following:

3.1.1 Sign a LOA with FH, only if PI is a physician

3.1.2 Ensure that any necessary legal agreements are in place for the project prior to beginning enrollment. The PI may consult with the FH Office of Research Administration to identify which legal agreements are applicable and necessary for a given project.

3.2 Principal Investigator responsibilities that he/she may NOT delegate:
3.2.1 The PI’s own authentic signature, when required, may not be delegated to someone else, and it must be an authentic signature (an ink stamp is not acceptable).

3.2.2 The PI may not delegate or transfer all of his/her legally binding responsibilities identified in the agreement to someone else that is not named in the contract. Although the PI may delegate tasks to his/her research team to ensure that the project is implemented and conducted correctly, that does not free him/her of the ultimate responsibility for the overall conduct of the research study.

3.3 Principal Investigator responsibilities that he/she MAY choose to delegate:

3.3.1 Tasks associated with negotiating the language of legal agreements, and/or the negotiation of any budgets of monetary compensation associated with a legal agreement.

3.3.2 The task of submitting the legal document to the FH ORA, and ensuring that it goes through the proper FH procedures and departments in order to be negotiated, agreed upon, approved, finalized and signed.

3.3.3 The task of approved and finalized agreement is properly and fully executed prior to study enrollment beginning.

3.3.4 The task of ensuring that all fully executed agreements get distributed to the appropriate parties, and are filed correctly.

3.4 Florida Hospital Research departments are responsible for submitting legal documents to the Office of Research Administration (ORA) along with sponsor/CRO/collaborator contact information through the electronic submission system. The person submitting the documents will communicate any specific requirements and/or instructions from the sponsor/CRO/collaborator to the ORA at the time of submission.

3.5 The Office of Research Administration (ORA), in conjunction with the Florida Hospital Legal department, is responsible for the review or preparation, and approval of sponsor/CRO/collaborator legal documents.

3.6 The ORA will ensure that the protocol, informed consent and legal agreements are consistent regarding payment to research subjects for study participation and payment in the event of a research related injury, if applicable, prior to giving institutional clearance for that project.

3.7 Legal documents are signed by the Florida Hospital institution official signatory. The official signatory is the Vice President of Research. In the absence of the Vice President, the Chief Medical Officer will sign all applicable Legal documents.
4.0 PROCEDURES:

4.1 When the sponsor/CRO or FH Research Department provides the legal agreement, the Office of Research Administration will send the legal agreement along with the study protocol to the Florida Hospital Legal department for review. The Legal department will correspond directly with the sponsor/CRO/collaborator contact regarding any revisions that are required to the legal document. The ORA will be included in all correspondence between the Legal department and sponsor/CRO/collaborator.

4.2 The following elements, when applicable (for example CTAs or MCTAs), should be included in the contract to cover GCP and other responsibilities:

4.2.1 Sponsor's name and address

4.2.2 Protocol title with test article name.

4.2.3 A listing of the study, clinical, and legal responsibilities of Investigator site.

4.2.4 Estimated study start and finish dates.

4.2.5 Terms of payment including terms for delays and termination of the study.

4.2.6 Number of study subjects required to enter and complete the study and the criteria for a "completed" (fully paid) study subject.

4.2.7 Confidentiality agreement.

4.2.8 Dissemination of findings, and publication rights.

4.2.9 Data ownership rights

4.2.10 Indemnification

4.2.11 Research related injury responsibilities including the provision and payment and/or reimbursement of necessary medical care for research participants when appropriate

4.2.12 Guidelines or requirements for promptly reporting findings that could affect the safety of participants or influence the conduct of the study.

4.2.13 Data and safety monitoring process and reporting requirements.
4.2.14 The notification of the FH research department by the Sponsor and/or CRO of study results after the study has ended when participant safety could be directly affected by those study results, in order to consider informing participants.

4.2.15 Other legal issues as necessary per FH Legal.

4.2.16 Please note that most of the items listed above do not involve financial compensation, and that most research projects that involves collaboration with any entity outside of FH, even non-funded projects, will require some type of legal agreement to ensure the above elements are addressed when applicable, for example: data ownership, indemnification, subject injury expenses, legal responsibilities of each entity, confidentiality agreement, publication rights, and/or intellectual property. Please consult with the FH ORA if you are not sure what type of agreement you need for your project.

4.3 All agreements must be reviewed by Florida Hospital Legal department for the Institution and/or Investigator, as applicable.

4.4 A minimum of three originals are prepared or as many originals as the Sponsor/CRO/collaborator specifies. Together the ORA and Research Department are responsible for assuring all required signatures are obtained. All originals should mimic one another exactly and have consistent signatures and dates. When the three identical, original legal documents are fully executed, one is retained by the FH Research Department or Principal Investigator, one is retained by ORA and the other is provided to the Sponsor. Prior to sending the documents to the Sponsor/CRO the mailing address should be confirmed and the documents sent by a courier/carrier with a tracking number (i.e. Federal Express) The FH research department should keep the signed Legal documents separate from other regulatory documentation.

4.5 Fully executed legal documents (containing all required signatures) will be uploaded in a PDF format into the electronic submission system by the ORA once they are received. The uploaded PDF document cannot be altered and therefore there is no possibility that changes can be made to the final document.

4.6 Access to the final executed legal documents. After the document has been uploaded to the electronic submission system, anyone given authorization within the electronic submission system for that particular project will have the ability to view the document.

4.7 Florida Hospital Research Department studies must have a fully-executed signed agreement prior to receiving ORA clearance (if applicable).
5.0 Circumstances in which additional requirements may apply:

5.1 Grants: If the study is sponsored by a Grant, please contact the Office of Research Administration for direction.

5.2 Electronic Signatures

REFERENCES:

FDA Code of Federal Regulations: 21 CFR Part 312.53

International Conference on Harmonization (ICH) Guidelines (E6) for Good Clinical Practices (GCPs): 4.5.1, and 4.9.6

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