**Clinical Trial Initiation Timeline**

The Timeline for initiating a Clinical Trial consists of four (4) Phases:

1. Non-Disclosure Agreement
2. Feasibility
3. Negotiation
4. Approval

This document was prepared to walk the reader through all Phases of the Clinical Trial Initiation Timeline in order to gain a better understanding of each Phase.

1. **Non-Disclosure Agreement**

Typically, a trial begins with conversations between a department and the Sponsor. In order to further those conversations, a Sponsor may request that a Non-Disclosure Agreement or NDA (also referred to as a Confidential Disclosure Agreement or CDA) be entered in order to protect Sponsor’s confidential and proprietary information.

The department should submit the Non-Disclosure Agreement template provided by Sponsor to the Clinical Contracts Division (CCD), along with basic information about the study and contact information for the Sponsor. This additional information can be submitted via a Non-Disclosure Agreement Disclosure Form or an email with the same information.

The Clinical Contracts Division negotiator will then reach out to Sponsor, both parties will agree on language for the Non-Disclosure Agreement, and once ready, the agreement will be routed for signatures. When all parties have signed, the PI/Department may begin the more in-depth discussions with Sponsor that take place at the Feasibility Phase.

1. **Feasibility**

At this Phase, the department should obtain all contractual, budgetary, and regulatory documents from Sponsor. After reviewing Sponsor’s information and assessing the department’s resources/access to patient population, the PI chooses whether or not to proceed with the Study.

1. **Negotiation**
* **CTA Timeline**: If the PI chooses to proceed, then the Negotiation Phase will begin once the Draft Clinical Trial Agreement (CTA), Protocol, Draft Budget, and Draft Informed Consent Form (ICF) are submitted to Clinical Contracts Division. The CTA will most likely be between UofL and the Sponsor, but sometimes, a 3-Party Agreement (between UofL, the Sponsor, and the Hospital) is necessary.

There are several timelines that should begin concurrent with this submission:

* **IRB Timeline**: The department’s regulatory coordinator enters the study in iRIS and begins reviewing the Informed Consent Form. This timeline will conclude with the IRB’s Approval/Approval Release.
* **Budget Timeline**: The department reviews the Sponsor’s budget and initiates contact with any hospital/facilities that it might need to work with in order to complete the Study. This timeline will conclude in (1) a final budget that is included in the CTA and (2) the pricing used for any hospital resources involved in the study.
* **Hospital Related; applicable when a Hospital is involved**:
	+ **Subcontract (or Hospital Purchase Services Agreement - HPSA) Timeline**: The department obtains pricing information from the Hospital for use in its own budget considerations and negotiations with the Sponsor. If the Hospital is contracting directly with the Sponsor via a Facility Use Agreement, then a subcontract is entered between UofL and the Hospital. If the Hospital is not contracting directly with the Sponsor then an HPSA would be used. This timeline will conclude in an executed agreement (Subcontract or Hospital Purchase Services Agreement) between UofL and the Hospital.
	+ **Facility Use Agreement (FUA) Timeline**: The department also submits the study information to the Hospital for its review. A Facility Use Agreement is entered when the Hospital contracts directly with the Sponsor. The Clinical Contracts Division will introduce the Hospital negotiator to Sponsor’s negotiator in order for the Facility Use Agreement negotiations to begin. This timeline will conclude in an executed Facility Use Agreement between the Sponsor and the Hospital.

There are two other timelines that can begin somewhat later in the process:

* **Essential Documents Timeline**: The Department prepares and returns to the Sponsor any executed Essential Documents which may include Financial Disclosure Forms or Investigator Agreement forms for Study Team signatures.
* **Subject Injury Language/Research Related Injury Language Timeline**: The Subject Injury language of the CTA (and FUA, if applicable) should mirror the Research Related Injury Language of the ICF. The CTA negotiator helps coordinate with the Hospital, Sponsor, and Department during the Negotiation Phase to achieve uniformity in the Subject Injury and Research Related Injury language.
* **ULP Timeline**: If the department will be working with ULP, then the CCD negotiator acts as liaison between ULP and Sponsor to implement a ULP Agreement or Exhibit to the CTA that addresses ULP.

There are four (4) places in the Negotiation Phase where delays could hold up a timeline or, if left unattended to for long enough, could delay Sponsor Initiation of the Study:

1. In the **Essential Documents Timeline**, delays in the Study Team signing the Essential Documents could delay Sponsor Initiation.
2. In the **Essential Documents Timeline**, delays in Investigators signing Investigator Agreement could delay Sponsor Initiation.
3. In the **IRB Timeline**, delays in PI, Scientific Reviewer, and Department Chair entering iRIS and providing their approval could delay the IRB Timeline.
4. In the **Agreements (CTA & Budget, FUA, ULP) Timelines**, a delay in any given agreement could delay the execution of all documents.
5. **Approval**

Once all agreements are executed and the IRB has approved the Study, then the Approval Phase begins.

* After IRB approval is given and the IRB review fee has been paid, the IRB will release its approval for the Study.
* This IRB Approval Release and all executed Agreements should be submitted to the Hospital so that the Hospital can review and provide its own Hospital Clearance for the Study.
* Once Hospital Clearance is provided and all of the Essential Documents are executed, the Sponsor can choose to approve initiation of the Study.