Clinical Trial Initiation Timeline

Legend:

- Beginning of a Process
- A process or Step
- A document
- A bar to any next steps

Phases:
1. Non-Disclosure Agreement (NDA)
2. Feasibility
3. Negotiation*
4. Approval*

*This document shows two versions of the Negotiation & Approval stages: The first version (pg. 3) provides a high level Overview of the key steps. The second (pg. 4) shows a more detailed diagram of how the people or entities working on each item interact with each other.
NDA Phase

NDA Conversations Begin

Department obtains NDA template; submits to CCD

CCD & Sponsor negotiate NDA

Executed NDA

Dept. obtains contracts, regulatory, and budget documents from Sponsor

Feasibility meeting

PI decides whether to proceed

Feasibility Phase
Negotiation Phase
OVERVIEW

Essential Documents Timeline:
Dept. preps/sends Financial Disclosure forms & Investigator Agreement to Study Team for signatures

PI, Subl, Study Coordinator sign financial disclosure forms
PI, Subl sign Investigator Agreement
IRB approval
Final CTA (UofL-Sponsor)
CCD assists & finalizes SubK(s) (Hospital-UofL)
Final ULP Agreement (ULP-Sponsor)

IRB Timeline:
Dept. enters study in iRIS & begins work on ICF

1. PI approves
2. Scientific reviewer submits review
3. Dept. Chair approves

IRB approval release

Hospital Clearance
All agreements involving Sponsor executed

Sponsor Initiation; Study Starts

Facility Use Agreement(s) Timeline:
Dept. submits Sponsor documents to Hospital

If applicable

CTA Timeline:
Dept. submits to CCD

Budget Timeline:
Dept. reviews Sponsor budget template

If applicable

SubK(s) Timeline:
Dept. requests pricing from Hospital

If applicable

ULP Timeline:
CCD contacts Sponsor about ULP agreement

PI, Subs sign Investigator Agreement

If applicable

If applicable

Final FUA(s) (Hospital-Sponsor)

Final ULPS (Sponsor-UofL)
**Negotiation Phase**

**DETAILED; with interactions diagrammed**

**IRB Timeline:**
- Dept. enters study into iRIS & begins work on ICF
- Dept. routes draft ICF to PI & study coordinator, then sends to Sponsor for review

**Hospital Preliminary Review**
- Hospital introduces Hospital negotiator to Sponsor

**CTA Timeline:**
- Dept. submits to CCD
- CCD assigns negotiator; sends first draft

**Budget Timeline:**
- Dept. reviews Sponsor budget template

**If applicable Facility Use Agreement(s) Timeline:**
- Dept. submits Sponsor documents to Hospital

**Subject Injury/RRI Language Timeline:**
- CCD initiates RRI/S.I. language conversation with Hospital(s), Sponsor
- CCD, Hospital(s), Sponsor negotiate Subject Injury language

**PI, Subis sign Investigator Agreement**
- Sponsor approves draft ICF; Dept. loads draft ICF to iRIS
- Dept. & Sponsor negotiate the budget

**Essential Documents Timeline:**
- Dept. preps/sends Financial Disclosure forms & Investigator Agreement to Study Team for signatures

**IRB reviews & responds**
- 1. PI approves
- 2. Scientific reviewer submits review
- 3. Dept. Chair approves

**IRB approval**
- Sponsor pays IRB fee

**Final FUA(s) (Hospital-Sponsor)**
- CCD, Hospital(s), Sponsor negotiate FUA
- Dept. coordinates with Sponsor to resubmit to IRB; incorporates finalized RRI and cost/compensation

**Final CTA (UofL-Sponsor)**
- CCD, Hospital(s), Sponsor negotiate CTA language
- Dept. & CCD negotiator confirm RRI language

**Final budget**
- Dept. obtains Hospital pricing
- Dept. & Hospital negotiate pricing

**Hospital Clearance**
- All agreements involving Sponsor executed

**Sponsor Initiation; Study Starts**
- Sponsor pays IRB fee
- IRB approval release