OFFICE OF CLINICAL RESEARCH
Non-Federal
INTAKE PROCESS

Acronym Glossary
- CDA – Confidentiality Disclosure Agreement
- CA – Contract Administrator
- IC – Intake Coordinator
- NDA – Non-Disclosure Agreement
- P&L – Patents & Licensing
- PI – Principal Investigator
- OCR – Office of Clinical Research
- FAST – USF Financial System
- AHRPP – Association for the Accreditation of Human Research Protection Programs
- ICF – Informed Consent Form
- CTA – Clinical Trial Agreement (contract)
- PL – Project Liaison
- WIRB – Western Institutional Review Board
- FDA – United States Food and Drug Administration
- IRB – Institutional Review Board
- NSQ – New Study Questionnaire
- LTP – Letter to Proceed to Commercial IRB

PI receives CDA/NDA from Sponsor
OCR receives CDA/NDA from Sponsor

CDA/NDA sent to Patents & Licensing (P&L)

P&L reviews, executes CDA/NDA and provides executed copy to PI & OCR

PI decision to move forward with trial?

Yes

No

STOP

NSQ completed

Contract and Budget Process
CA
- Sends CTA for Patents and Licensing review, inserts USF required language, sends to AHRPP, sends edited CTA to legal
- Negotiates CTA with Sponsor to Agreed-Upon Language
PLs
- Review Schedule of Events and Proposed Budget – arranges meeting with study team as needed. Completes Procedure Analysis for Budget
- Propose Budget to Study Team
- Negotiate Budget with Sponsor to Agreed-Upon Terms and notifies CA
CA
- Combines CTA and budget for executable document
- Receives executable document from sponsor and sends to legal for stamp
- Routes document to PI, DSR and sponsor
- Notifies PLs when contract is fully executed

PI or Sponsor emails documents to OCR
Intake email
OCR@health.usf.edu

Draft Budget
Protocol
Draft Consent Form
Clinical Trial Agreement (CTA)
OCR New Study Questionnaire

- IC opens in SharePoint and Intake Tracking and Sends Request for Needed Documents and NSQ Link, if Needed
- IC sends CTA and LOI to CA

Account Open in FAST with Initial Budget and Open for Enrollment
OCR sends Project over to DSR to setup in FAST system and distributes Notice with chartfield string to PI office
PL receives Internal Form
ClinCard Administrator Enters Study Into ClinCardSite (if required)
PL Sends Approval To Enroll Letter (ATE) when:
- Contract fully executed
- IRB Approved
- Hospital approval documents received (if applicable)
Requests submittal of Internal Form, provides IF budget numbers and prepares GBR

IRB Process Flow
OCR Reviews for IRB LTP

STOP

START

Last Updated 8/20/14