UNeHealth Guidebook

2022

UNeHealth

University of Nebraska Medical Center℠

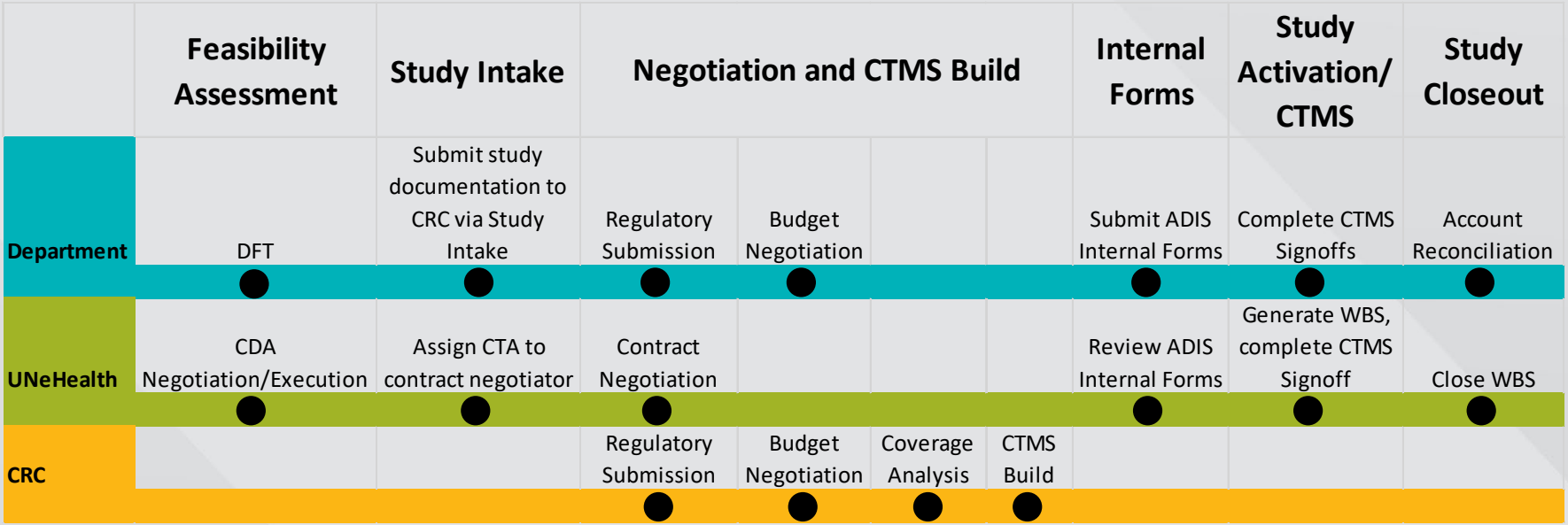
Agenda

- UNeHealth Scope
- Contract Process Workflow
- Contract Process Workflow Detail
- Conflict of Interest Review Process
- IRB Interaction
- Key Terms and Definitions
- Contact Information

UNeHealth Scope

- CDAs (Confidentiality Disclosure Agreements)
- Industry Sponsored Clinical Trial Agreements, Phase 1-4
- Industry Sponsored Observational Studies
- Industry Sponsored Master Clinical Trial Agreements and corresponding Work Orders
- Compassionate Use Agreements
- Emergency Use Agreements
- Investigator Initiated Clinical Trial Agreements (IITs)
- Industry Sponsored Device Studies

Contract Process Workflow



Feasibility Assessment/CDA Execution

A CDA allows Sponsor to share confidential information for a limited time (normally one year) and obligates PI to keep all information disclosed under the CDA confidential

PI is required to maintain confidentiality of information received (typically the protocol) for 3-15 years after the termination of the CDA

Protocol review and feasibility assessment helps PI determine if Sponsor and Study are a good match for UNMC by reviewing the following variables:

- *Is Protocol viable?*
- *Do we have the patient population?*
- *Do we have the necessary personnel?*
- *Does PI have effort available?*
- *Are costs prohibitive or is Sponsor flexible on budget?*

1. CDA is received for a particular study
   a) If received by department, department sends to UNeHealth for review
   b) If received by UNeHealth, UNeHealth confirms interest with department prior to negotiation
2. PI Determines if they are interested in study
3. UNeHealth receives CDA for negotiation
4. Upon execution, PI receives protocol to determine their interest in pursuing the study

Study Intake

After the Protocol has been reviewed by the PI and the department has decided to move forward with the Study, the necessary Study documents are compiled and sent to studyintake@unmc.edu

- *Editable contract and Protocol are required by UNeHealth for submission*

The contracting documents are uploaded to the UNeHealth Contract queue and assigned to a Contract Negotiator so that negotiations can begin

1. Contract documentation is submitted to studyintake@unmc.edu to allow contract negotiations to begin
2. Documents required by UNeHealth for submission:
   a) *Protocol*
   b) *Fully editable contract*

Negotiation & CTMS Build

After all study documents are submitted, the budget, contract, and IRB processes are assigned to negotiators

- Negotiations may be done by the CRC or individual departments
- All studies must be submitted to CRC regardless of budget/regulatory negotiation assignment, as a Coverage Analysis is still required

The Protocol Calendar is entered into CTMS by the CTMS team

UNeHealth performs initial COI check

1. The submitting department will identify which CRC services are being requested on the Study Intake form. This will determine which elements are assigned to CRC negotiators, and which will be handled within the department

2. Documents required by UNeHealth for submission:
   a) *Protocol*
   b) *Fully editable contract*

Contract Finalization & Execution

When the budget is approved and an IRB number has been assigned, a final contract document will be provided for signature.

The final document is reviewed by both the contract and budget negotiator to ensure accuracy and consistency with approved revisions.

UNeHealth will coordinate the signature process, routing to the PI, Institution signee, and back to the Sponsor for full execution.

1. Contract language and budget are finalized
2. UNeHealth receives signature ready document
    a) UNeHealth reviews language for accuracy
    b) Budget negotiator review budget for accuracy
3. UNeHealth coordinates signatures from PI, UNMC, and Sponsor
4. Final, fully executed contract is received and IRB is notified to allow IRB to grant full approval

Internal Forms

Once the budget has been approved, the Department Administrator or Coordinator translates the contract budget into ADIS

ADIS Internal Forms require entering some basic information about the study (number of patients, per patient costs, and startup costs) and assigning effort for each person on the budget

The IRB fees will automatically be included in the ‘exempt’ category. All other study-related expenses will fall into the “Operating” category

1. ADIS Internal Forms are entered upon budget approval
2. PI reviews/approves electronic budget and sends to UNeHealth
3. UNeHealth reviews/approves ADIS Internal Forms electronically and sends to Chair/Dean and Authorized Official
4. Chair/Dean and Authorized Official review/approve electronically
5. UNeHealth is notified by ADIS that the Internal Forms have been completed. If IRB has been approved and CTMS Signoffs are at “Contracting Signoff” stage, the WBS will be set up

Study Activation / CTMS Signoff

A WBS account number is required to be established prior to subject enrollment to ensure proper billing

UNeHealth will assign the WBS as soon as:

- The IRB is released
- ADIS Internal Forms are fully approved
- UNeHealth receives Contract Signoff notification from CTMS

UNeHealth will complete the CTMS signoff, entering the WBS and ensuring the full executed contract is uploaded

1. Only after the IRB is released, Internal Forms are fully approved, and CTMS signoff notification is received, will UNeHealth generate a WBS number
2. WBS number is based on the four-digit department code identified on the Internal forms
3. UNeHealth sends a bundle of Study-related documents to SPA Accounting who will enter the WBS number into SAP
4. Study staff will receive a notification that the bundle of Study-related documents is available in ADIS. This bundle can be accessed by approved personnel

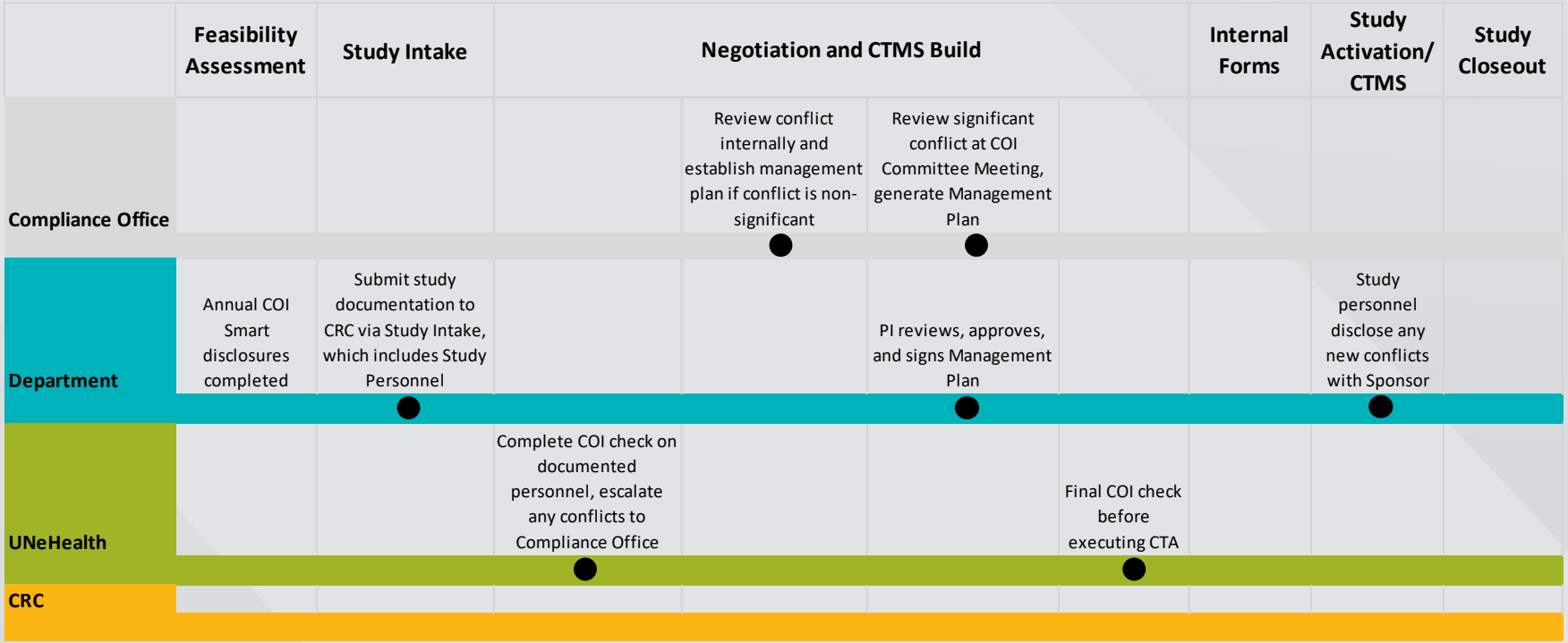
Study Closeout

At the conclusion of the Study or if the Study is terminated, the WBS will need to be fully reconciled and closed in SAP

The WBS cannot be fully closed until final payment has been received from the Sponsor

1. SPA Accounting will reconcile WBS and SAP account
2. Once the SAP Account has been locked (LKD), SPA Accounting will notify UNeHealth
3. UNeHealth will reconcile budget per SPA Accounting's instructions and close out study in Research Admin Database

Conflict of Interest Workflow



Conflict of Interest Review Process

Annual COI Smart disclosures are required per UNMC policy

Upon Study Intake submission to the CRC, UNeHealth completes COI Smart check on document personnel

- Conflicts are escalated to Compliance Office

Compliance Office reviews conflict internally and establishes management plan if conflict is non-significant

- Significant conflicts are reviewed at COI Committee meeting, and management plans are generated as appropriate

PI reviews, approves, and signs management plan, which is then forwarded to UNeHealth

Prior to executing the CTA, UNeHealth completes a final COI check

- IRB submission is reviewed, COI Smart check is completed for all personnel listed on IRB application

During Study Activation and CTMS signoffs, Study personnel disclose any new conflicts with Sponsor

IRB Interaction

- Once contract language is finalized, UNeHealth sends certain sections of the contract to UNMC's IRB to ensure consistency between contract and Informed Consent form
  - Study conduct language (ICH/GCP, Applicable Laws)
  - Biological samples language (if applicable)
  - Subject injury language
  - AHRPP language
- UNeHealth notifies the UNMC IRB via email as soon as the fully executed CTA is received

Key Terms and Definitions

Clinical Trial Agreement (CTA) – legal document governing the conduct of the Study in accordance with the Protocol

Confidential Disclosure Agreement (CDA) – legal document for the protection of proprietary information (ie. Protocol, Investigator's Brochure)

Sponsor – the person or entity who takes responsibility for and initiates the research study

Contract Research Organization (CRO) – separate entity often used by Sponsor's to manage various aspects of the Study (ie. CDA/CTA negotiations, monitoring, payments)

Principal Investigator (PI) – the primary individual responsible for the preparation, conduct, and administration of a study in compliance with the laws and regulations and institutional policy governing the conduct of a study

Facilities and Administrative Rates (F&A) – also known and indirect or overhead costs. Assist with the administrative costs related to the study. UNMC's current F&A rate is 28%.

Work Breakdown Structure (WBS) - corresponds to the financial account where transactions related to the study and other study-related expenses are tracked

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