Clinical Research Center Resources

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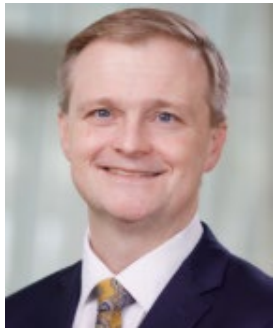
Clinical Research Center (CRC)
Mission & Leadership Team

Mission statement:

"The Clinical Research Center will provide exemplary research support and education to the University of Nebraska Medical Center/Nebraska Medicine, fostering a world-class environment that improves outcomes."

Leadership Team:



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Matt Lunning, DO

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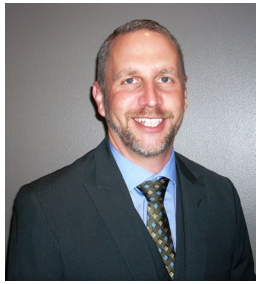

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A note before we get started:

- CRC resources will be presented through the life cycle of a clinical trial

CRC Resources

- Cellular Therapy Support Service ★
- Investigator Initiated Trial (IIT) Budget Development

★ = Mandatory Centralized service

CRC Resources

- Study Intake inbox owner ★
- Study triage ★

★ = Mandatory Centralized service

What is the Study Intake Process?

A centralized process to initiate the following study start-up activities:

- Clinical Trials Management System (CTMS) study build
- Contract negotiation
- Coverage analysis
- Budget negotiation (if CRC services requested)
- Regulatory submission (if CRC services requested)
- One Chart study build

The study intake process facilitates information sharing amongst the various teams involved in the start-up process and provides a consistent date to “start the clock” when tracking campus-wide activation timelines.

Which Studies Require a Study Intake Form?

- Meet the NIH definition of a clinical trial
- FDA regulated
- Include NM billable items
- Require cancer center tracking
- Utilize the CTMS for tracking and invoicing
- Use CRC services
- Require a clinical trial agreement

Study Intake Form Recipients

By submitting the form all pertinent personnel will automatically get emailed the form along with required documentation.

Recipients include:

- CTMS Team
- Study Intake Team
- Sponsored Programs Administration
- UNeHealth
- Investigational Device Review Committee
- PRMS Office
- Export Control
- IT Assessment
- Institutional Biosafety Committee
- Investigational Drug Services
- CRC Study Finance
- Clinical Research Recruitment
- CRC Clinic
- Radiology
- Ophthalmology
- Pediatric Research Office
- Clinical Research Support Fund

UNeHealth Decision Tree for 100% Industry Funded Clinical Research

100% Industry Funded Clinical Research – submitted through centralized intake process

UNeHealth reviews study intake form

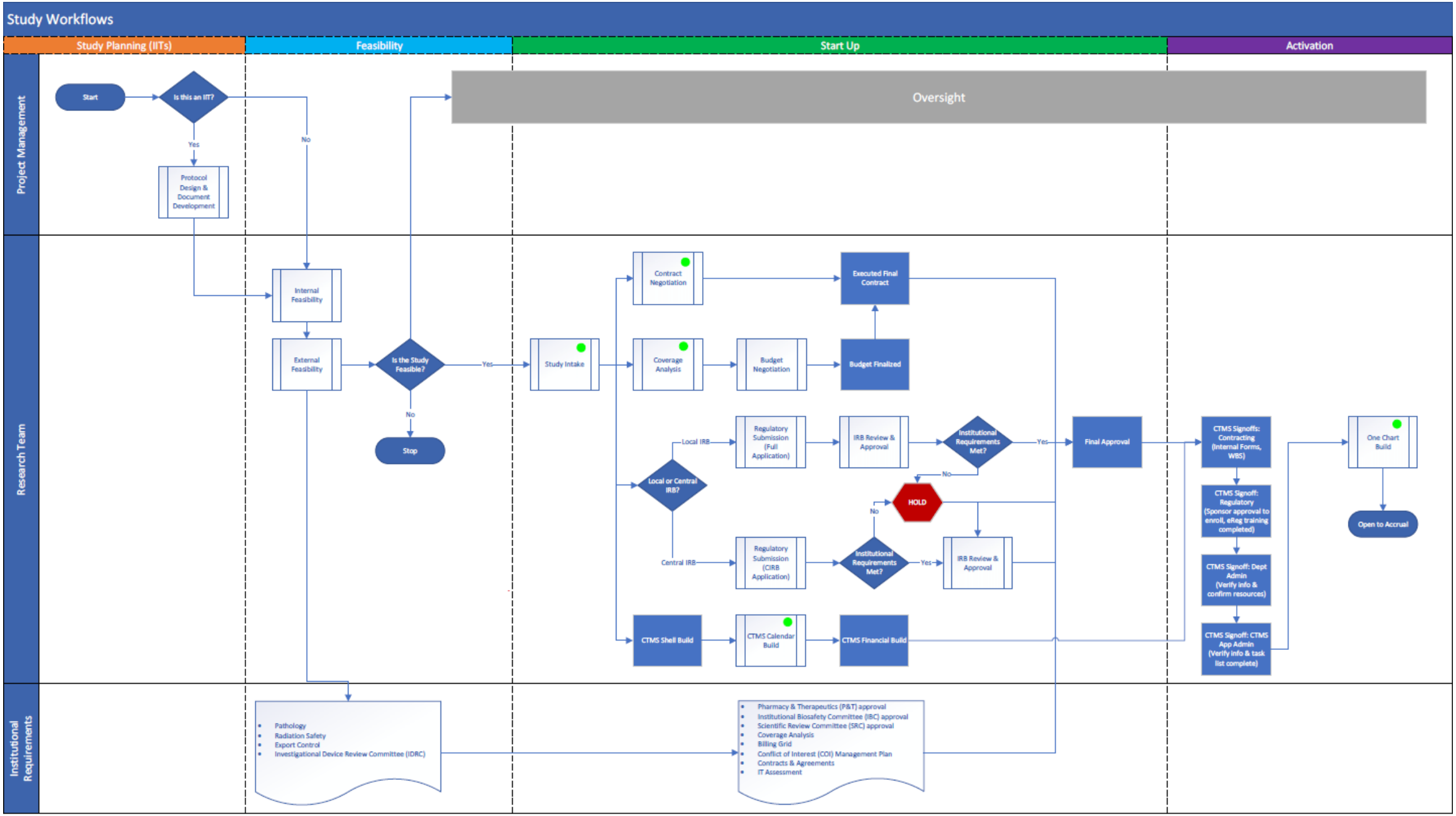
UNeHealth will negotiate the contract and assign 30% F&A to studies that meet the following criteria:

- The study will prospectively consent human subjects to clinical research **or** the study has been granted a waiver of consent by the IRB

AND

- The location(s) of service either occurs in a patient care area (i.e.: can be scheduled in Epic) **or** subjects will not have encounters at UNMC/NM facilities (i.e.: phones calls, surveys, chart reviews, etc.)

All other studies will be routed to Sponsored Programs Administration



● Denotes a required centralized service

Institutional Requirements (ORA)

- Committee Reviews (5)
  - Scientific Review Committee (SRC)
  - Pharmacy & Therapeutics (P&T) Approval
  - Institutional Biosafety (IBC) Approval
  - Investigational Device Review Committee (IDRC)
  - Conflict of Interest (COI) Committee
- Institutional Sign-offs (7)
  - Pathology Approval
  - Radiation Safety Approval
  - Export Control
  - Coverage Analysis
  - Billing Grid/Matrix
  - Contracts & Agreements
  - IT Assessment

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CRC Resources

- Coverage analysis ★
- Billing grid development ★
- Budget development & negotiation
- Regulatory submission (including coordination of institutional requirements)
- Regulatory binder development
- CTMS financial entry
  - Required for UNeHealth studies ★
- Internal form completion
  - Required for UNeHealth studies ★
- CRC clinic feasibility
- Clinical coordination

★ = CRC Centralized service

CRC Resources

- Coverage analysis modifications ★
- Billing grid modifications ★
- Budget modifications
- Regulatory Maintenance (continuing reviews, personnel changes, amendments)
- Regulatory Binder Maintenance

- Research billing (hospital charge routing) ★
- CTMS financial build modifications
- Invoicing & Payment reconciliation
  - Required for UNeHealth studies ★
- Stipend/Travel reimbursement

- Clinical coordination
  - Nurse coordination
  - Non-nurse coordination
  - Data coordination
- Clinical Services
  - APP services
  - Space (UT & GCHS)
  - EKG
  - Collection/process/ship
  - Drug administration & monitoring
  - OGTT
  - Vitals
  - NP swabs
  - Pregnancy testing

★ = CRC Centralized service

Clinical Research Units (CRUs)

- University Tower 3480
  - 5 Exam Rooms
  - 2 Infusion Rooms
  - Phlebotomy Room
  - Processing Lab
- Global Center for Health Security- 39th and Dewey Street
  - 8 Exam Rooms
  - 2 Negative Pressure Biocontainment Rooms

CRC Resources

- Regulatory Closeout

- Invoicing
- Reconciliation of all payments and accounts
- Closure of financial account
  - Required for UNeHealth studies ★

- Clinical coordination
  - Nurse coordination
  - Non-nurse coordination
  - Data coordination

★ = CRC Centralized service

Questions?

University of Nebraska Medical Center