Colorado Multiple Institutional Review Board
UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**

COMIRB

Colorado Multiple Institutional Review Board

Presentation to RAIN
March 18, 2021

John Heldens, RAC, CIP
Director

Our Leadership Team

John Heldens, Director

Cat Sutherland, Assistant Director

Matthew Hamilton, IRB Manager, Panel C

Ryan Lowry, IRB Manager, Panels A & B

Melissa Smith, IRB Manager, Panels D & S

[COMIRB staff listing]

COMIRB@ucdenver.edu

Contact us anytime

Services

- IRB Review and Privacy Board (HIPAA) for University of Colorado Denver | AMC, UCHealth, Children's, VAMC, Denver Health
- AAHRPP Accreditation for University
- Office Hours, every Monday from 12-1pm
- Ad hoc consultations: study design, level of review, human subjects research or not, QI vs. research, recruitment and consent strategies, help with FDA regulatory questions (need for IND/IDE)
- Trainings anytime: Institutions, Departments, Research teams, Students
- Single IRB Review
- Forms and Guidance
- Letters of support for multicenter grant proposals (Director)

IRB Panels

10 full board IRB meetings per month* [schedule]:

Panel A: Adult

Panel B: Adult & Children

Panel C: Children

Panel D: Oncology

Panel S: Social/Behavioral, Downtown Campus

*About 25-30% require full board review. Most research is eligible for review outside of full board ("expedited" and "exempt")

Levels of Review

- > 3000 active studies with COMIRB
- ~ 25-30% require full board review
  - Primarily clinical trials, Anschutz and affiliates
  - < 1% of research from downtown goes to full board
- ~ 30% eligible for “expedited review” (e.g., minimal risk procedures)
- ~40% “exempt” (e.g., educational research, surveys, secondary research)
- Expedited & Exempt studies are reviewed by one IRB member

Timelines (FY 19/20)

- Secondary research: ~ half approved same day or next
- Exempt median: 2 days
- Expedited median: 20 days
- Full board median: 28 days

Review process - NIH

- If proposal is for multicenter research requiring sIRB, PI may need a letter of support for the proposal from COMIRB Director. I will review proposal and if COMIRB can serve as sIRB, will provide a letter of support.
- IRB approval is not normally required prior to JIT
- As soon as JIT notification is received, PI should:
  - Submit an application for formal IRB review. Indicate JIT notice was received.
  - Email COMIRB@ucdenver.edu with the proposal and JIT notification if consultation is needed, or if any questions
- COMIRB will prioritize JIT submissions

Definition: Human Subject

- A living* individual about whom an investigator conducting research obtains
  - Data through intervention or interaction with the individual; OR
  - Identifiable private information [HIPAA identifiers]

* HIPAA covers Protected Health Information from deceased for 50 years

Human Subjects Research

Not human subjects research if:

- No intervention with a subject
- Researcher (anyone on the proposal) never had/has access to identifiers (dates are identifiers)
- Source data are publically available

Contact COMIRB@ucdenver.edu, Cat or John if questions about what to indicate on grant proposal

Levels of Review

- Research presenting more than minimal risk* requires full board review

  * Risk of daily life
- Defined categories for research eligible for expedited review [expedited categories]
- Minimal risk research that doesn't fit into a category needs to go to full board once
- Defined categories for exempt research [exempt categories]

FAQ: Single IRB

- Requests for COMIRB to serve as sIRB: Contact COMIRB@ucdenver.edu
- Requests to rely on an external IRB: Contact ExternalIRB@ucdenver.edu

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Other questions

- Budget for IRB costs
- Obtaining IRB documents
- Subaward requirements
- Continuing review requirements