

# CU Anschutz IND/IDE Program

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Clinical Research Operations and Services

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

# Central IND/IDE Program

The IND/IDE Program at CU Anschutz was established in 2023 under the directive of the Vice Chancellor for Research, Dr. Thomas Flaig.

## Purpose:

- Alleviate administrative burdens on investigators
- Standardize processes for research with FDA-regulated products
- Ensure that FDA-regulated projects are initiated with feasible goals and have appropriate resources and funding
- Facilitate efficient startup processes
- Minimize risk to participants and mitigate compliance risks





# Central IND/IDE Program

Consists of two branches:

1. IND / IDE Office (Vice Chancellor for Research)
2. Cancer Center (School of Medicine)

Research projects will be triaged to either entity based on project type and therapeutic area.



# Central IND/IDE Program

FDA submissions through one of these program branches is mandatory for all new projects as of July 1st, 2023.

Management of FDA submissions for active IND or IDE projects is decided on a case-by-case basis.





# Five Types of Projects

- Type 1 - Investigator-Initiated Studies (IIS) (even if some resources or funds are provided by an external partner) seeking to use an investigational product for which a University entity owns the manufacturing process and writes the CMC section of the IND
- Type 2 - Industry funded IIS where an external party controls the IP connected to the investigational product, but the product will be manufactured by a University entity
- Type 3 - Industry funded IIS where the DRUG manufacturing process is owned and controlled by an external entity, and the CMC information for the submission to the FDA is either provided in its entirety or via LOA to Cross-Reference an FDA filing or similar documentation.
- Type 4 - Industry funded IIS where an external party controls the IP and where the DEVICE manufacturing process is owned and controlled by an external entity, and the Design and Manufacturing information for the submission to the FDA is either provided in its entirety or via LOA to Cross-Reference an FDA filing or similar documentation
- Type 5 - Single patient and multi-patient compassionate use requests (both drug and device requests) where local investigator is regulatory sponsor for IND/Compassionate Use



# Sponsor Characteristics for Type 1-2 Projects

## CU Anschutz holds the IND/IDE

- CU Anschutz will retain all Sponsor responsibilities, but may delegate some of them to other campus entities (e.g. study monitoring)
- Approval needed from IND/IDE Governance Committee





# Sponsor Characteristics for Type 3-5 Projects

## PI holds the IND/IDE

- The Sponsor-Investigator will retain responsibility, scientific direction, and ownership of the project
- Risks and administrative burdens will be alleviated by central support, allowing researchers to focus on research and on protecting their human participants.



# Type 3-5 Projects continued

## Sponsor-Investigator will be responsible for (\*):

- Protocol development, and scientific justification
- Study budget development and securing of funding
- Completion of documents and forms as requested for submissions to FDA and local committees
- Recruitment and consent
- Data collection
- Adverse event (AE) documentation and AE assessment
- Data analysis including securing biostatistics support
- Communication with IND/IDE Office regarding IND/IDE amendments or expedited safety reporting to FDA
- Communication with the product manufacturer

(\* ) some tasks may be performed by an on-campus support team on a fee-for-service basis





# Program Highlights

At no cost to the PI, the IND/IDE Office's Regulatory Matter

Experts will:

- Help define the project's regulatory strategy (Type #3-5 projects)
- Manage and file all communication with FDA throughout the project's regulatory lifecycle
- Establish and train research teams on standardized electronic regulatory folders (eReg)
- Provide guidance and support for all regulatory questions related to projects
- Train research teams on responsibilities associated with projects under local regulatory sponsorship
- Assist with safety/pharmacovigilance-related issues



# Program Processes

- High level study budget review
  - Contact us before submitting to the HSR Portal, ideally during study budget development
  - Budget needed for:
    - Advarra EDC and study monitoring; risk assessment to determine if required
    - DSMB, if required
    - Statistician support as needed





# Program Processes continued

- Study Feasibility Assessment
  - Enrollment estimates for TriNetX facilitated by IND/IDE Office
  - Training for study staff to use tool going forward for all studies
- CU Anschutz Microsoft TEAMS for communication and document sharing
- Advarra eReg for TMF (coming soon!)



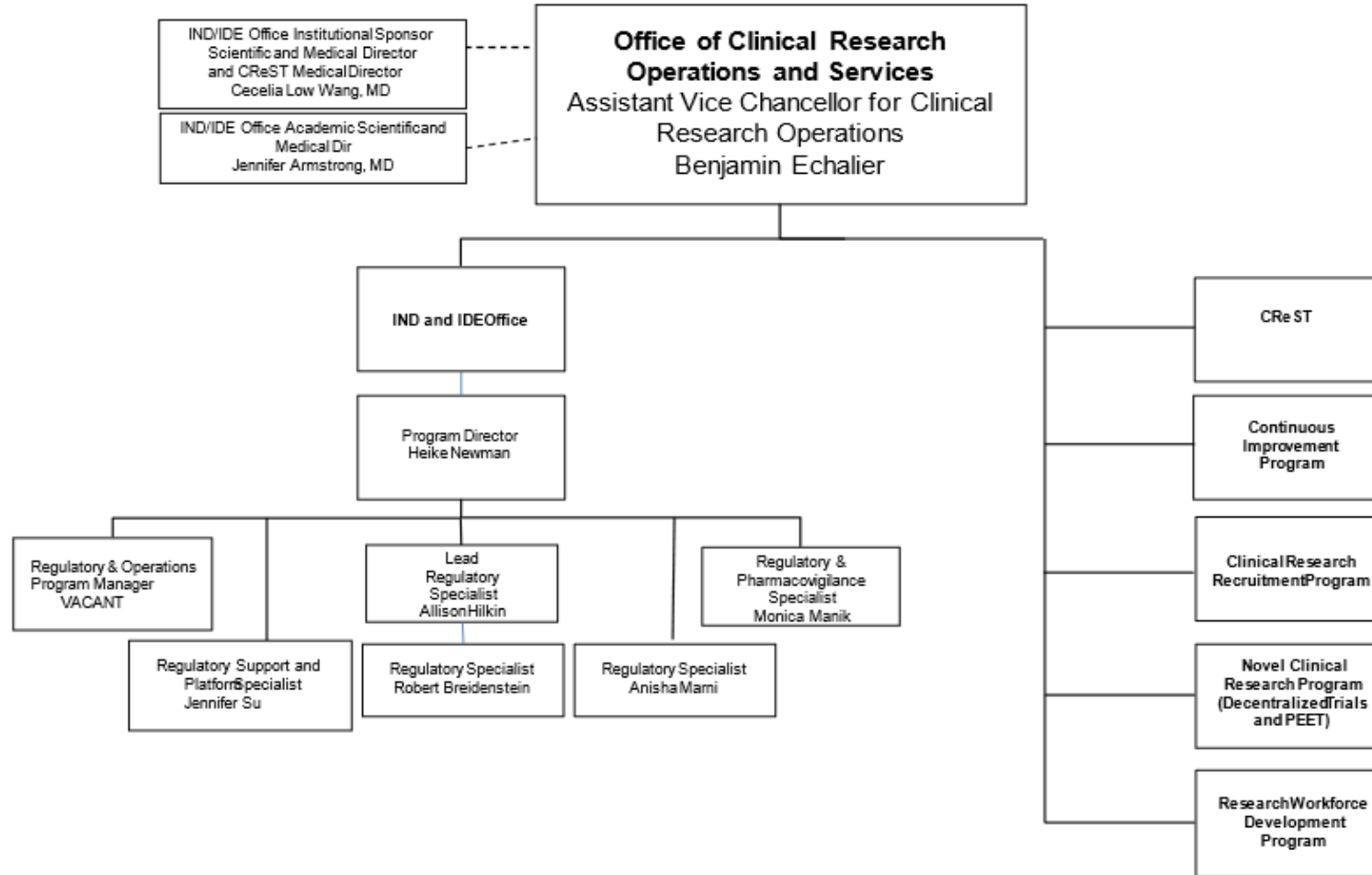
# IND/IDE Office Structure



Clinical Research Operations and Services

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UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



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## Heike Newman

- Assist PIs with defining regulatory path, strategy and process for Type #3-5 projects
- Provide guidance on FDA-related questions
- Provide oversight over use of DEA Schedule 1 controlled substances (also hemp products) at the CU Anschutz Campus
- Primary Contact at the IND/IDE Office for Type #1-2 projects



# Medical Directors

**Dr. Cecilia Low Wang will serve as the IND/IDE sponsor's authorized representative for projects where products are manufactured by an entity affiliated with CU Anschutz (Type #1 and #2 projects).**

- Sign FDA form 1571 for each FDA communication
- Review and approve selected sponsor SOPs
- Close collaboration with project's Medical Lead on:
  - Study product quality and patient safety related issues
  - Protocol and IND/IDE amendments
  - Review of monitoring reports and trends
  - Escalating issues of noncompliance





# Cecilia Low Wng



Cecilia C. Low Wang, MD, FACP, FACE, is a physician scientist and Professor in the Department of Medicine, Division of Endocrinology, Diabetes and Metabolism, at the University of Colorado Anschutz Medical Campus School of Medicine. After completing fellowship at CU, Dr. Low Wang (pronounced “lowwong”) set up her laboratory as a VA-funded investigator studying cellular mechanisms of atherosclerosis, and began her work in medical education. She later joined the CU Anschutz faculty, and CPC Clinical Research as Clinician-Scientist. Dr. Low Wang is a national leader in diabetes and endocrinology. She is Chairperson of the FDA Endocrinologic and Metabolic Drugs Advisory Committee. She has been involved in numerous clinical trials of drugs, devices, and biologics at all levels including trial

design, operations, medical safety and pharmacovigilance, endpoint adjudication, data structure and analysis, and final CSR preparation. She has extensive experience in human subjects research through her work as a COMIRB panel member, extensive FDA interactions as lead investigator, and serving as principal investigator of various trials. Dr. Low Wang directs the inpatient Glucose Management Team at the University of Colorado Hospital. She is a member of the Academy of Medical Educators, the founding Program Director of the Diabetes Fellowship Program, Associate Director of the Mentored | Scholarly Activity, co-founder of the American College of Diabetology, and former Associate Director of the Fellowship in Endocrinology, Diabetes and Metabolism. She contributes her expertise on key task forces and committees for the Endocrine Society and American Heart Association, and in leadership roles at the American Association of Clinical Endocrinology.



# Medical Directors

**Dr. Jennifer Armstrong will support projects that have products manufactured by an entity not affiliated with CU (Type #3 and #4 projects).**

- Risk Assessment for each project to determine Advarra EDC and independent monitoring requirements
- Review of protocol changes to determine if IND amendment is needed
- Assistance to Sponsor-Investigator in review of SAEs to determine proper reporting processes
- Assistance with protocol development
- Support to CU Sponsor-Investigators for regulatory and IRB questions





# Jennifer Armstrong



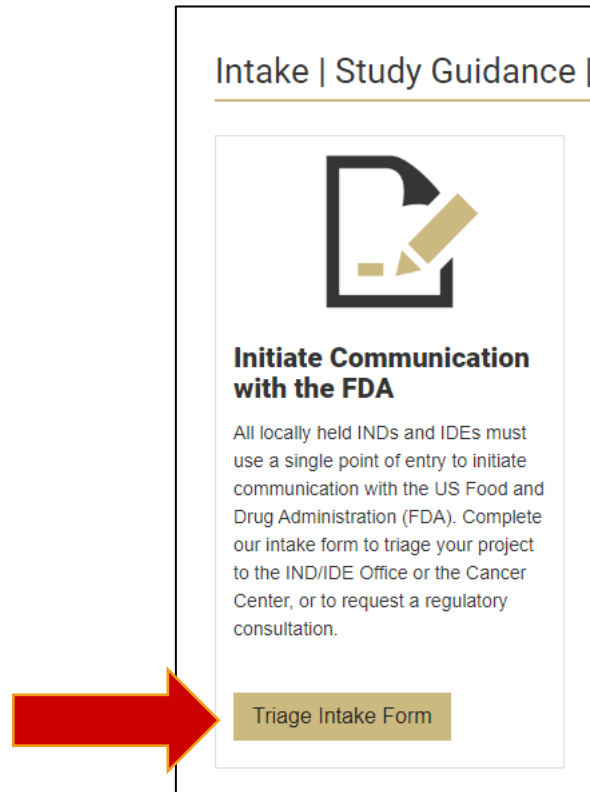
Jennifer Armstrong MD, MPH, FAHA (she/her) has been a physician-scientist at CU-Anschutz and Children's Hospital Colorado since 2008 in the Departments of Pediatrics (Section of Neurology), Neurology, and OB/GYN (Division of Basic Reproductive Sciences). Dr. Armstrong is a leader in clinical research trials and regulatory/compliance at CU-Anschutz, including serving as a COMIRB Chair and pregnancy, fetal/neonatal, neuroscience, and DEI content expert. She has extensive research administration, clinical trials, and pharmacovigilance experience in thrombosis/hemostasis, stroke and cardiovascular research as the former Director of Clinical Research at the CU-Anschutz Hemophilia and Thrombosis Center and faculty at CPC Clinical Research. Most recently, Dr. Armstrong co-chaired - along with Alison Lakin - the CU-Anschutz Clinical Research Reactivation endeavors during COVID-19 ensuring safe and equitable clinical research operations for participants and staff throughout the pandemic and beyond. As a leader in research operations and compliance during an international crisis, Dr. Armstrong has consulted for other global institutions as well as the CTTC consortium to develop standardized clinical trials and safety guidelines. Dr. Armstrong is moreover an internationally recognized expert for her own research and clinical expertise in neuroplacentology, maternal, fetal and neonatal coagulation and inflammatory disorders, and perinatal stroke and brain injury.




# Central Intake Form

<https://research.cuanschutz.edu/cros/ind-ide-office>

[IND.IDE.Office@cuanschutz.edu](mailto:IND.IDE.Office@cuanschutz.edu)



Intake | Study Guidance |



**Initiate Communication with the FDA**

All locally held INDs and IDEs must use a single point of entry to initiate communication with the US Food and Drug Administration (FDA). Complete our intake form to triage your project to the IND/IDE Office or the Cancer Center, or to request a regulatory consultation.

Triage Intake Form





# What We Ask of PI/Study Team

- Familiarize yourself with FDA regulations
- Designate Delegation of Authority
- Understand and follow AE/SAE/SUSAR reporting requirements, including determination assessments
- Maintain professional communications. Our office is here to help you.



# Resources

- [FDA Investigator-Initiated IND Resources](#)
- [NIH Introduction to the Principles and Practice of Clinical Research](#)
- [NIH Clinical Research Education](#)





# Contact Us

## IND/IDE Central Inbox

- [ind.ide.office@cuanschutz.edu](mailto:ind.ide.office@cuanschutz.edu)

## IND/IDE Program Director

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**THANK YOU**



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