

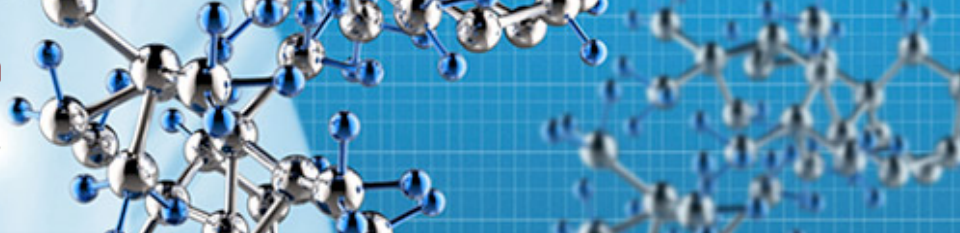
# Joint Clinical Trials Office New Initiatives and Updates

Alicia Lewis, Director, Cancer Clinical Trials

Erica Love, Associate Director, General Clinical Trials

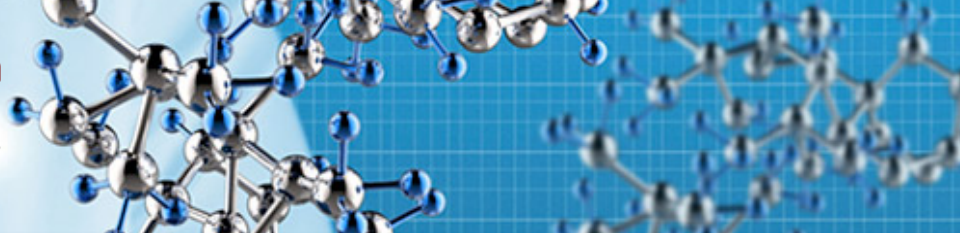
Nida Cassim, Assistant Director, Quality Assurance Unit

Erica Bersin, Manager, Subject Recruitment & Communications

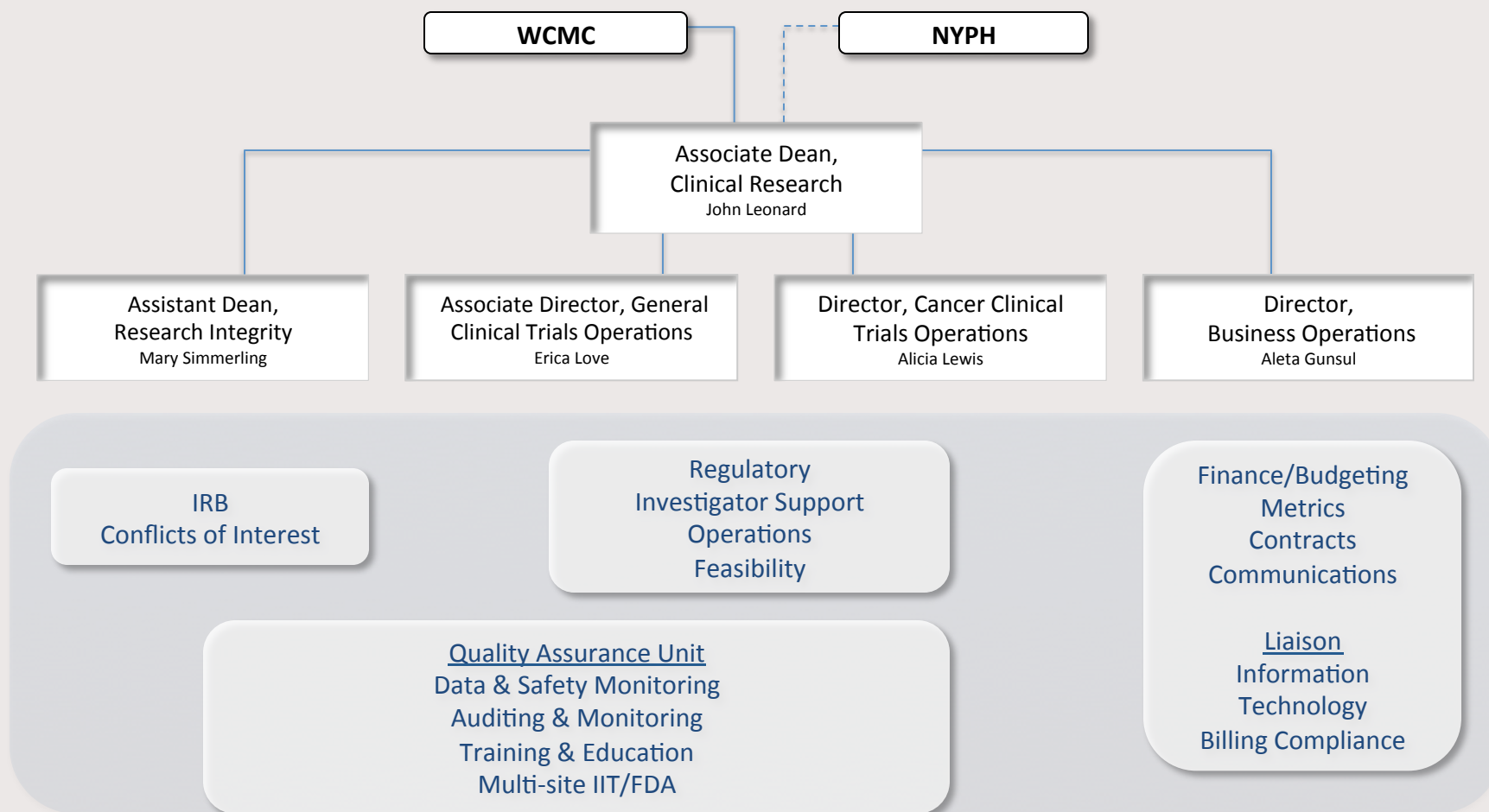


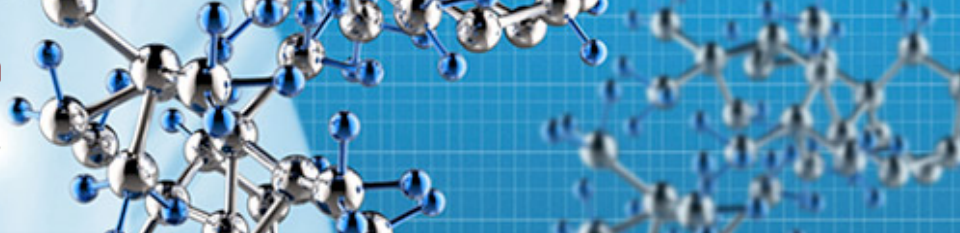
# Topics

- Quality Assurance Unit (QAU)
- ClinCard – Subject Compensation
- Subject Recruitment Advertising & Materials Policy
- JCTO website – Phase II



## JCTO Organizational Structure





## Quality Assurance Unit

Assistant Director,  
Quality Assurance Unit  
Nida Cassim, MPH

Program Managers,  
Safety & Monitoring /  
Audit & Monitoring  
Lauren Odynocki – General  
TBH – Cancer

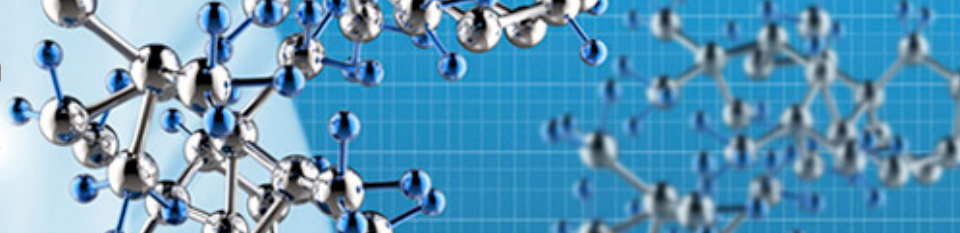
Program Manager  
Training & Education  
TBH

Safety Officer  
TBN

Program Manager  
IIT/Multi-Site/FDA  
TBH

Program Coordinator  
Safety & Monitoring /  
Audit & Monitoring  
TBH

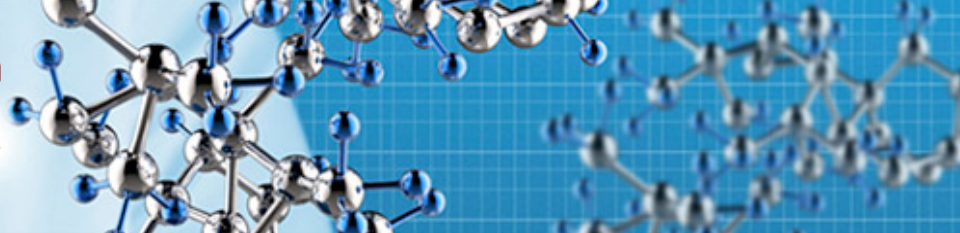
Program Coordinator  
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# Purpose

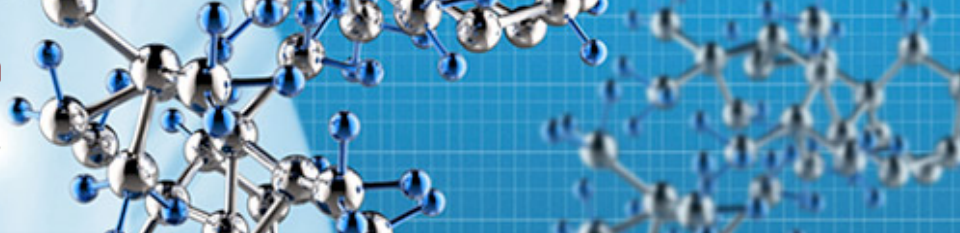
- Independent unit for audit and monitoring.
- Administrative support to the Data and Safety Monitoring Board.
- Investigator and study team support for investigator-initiated studies.
- Standardized education and training for investigators and study teams.





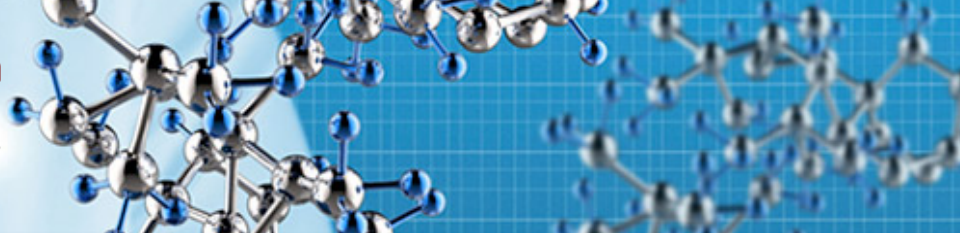
# Quality Assurance Unit Components

- Audit & Monitoring Committee
- Safety & Monitoring Core
  - Data & Safety Monitoring Board
- Investigator Initiated & Multi-Site Protocol Operations
- Clinical Research Education Office



# Audit & Monitoring Committee

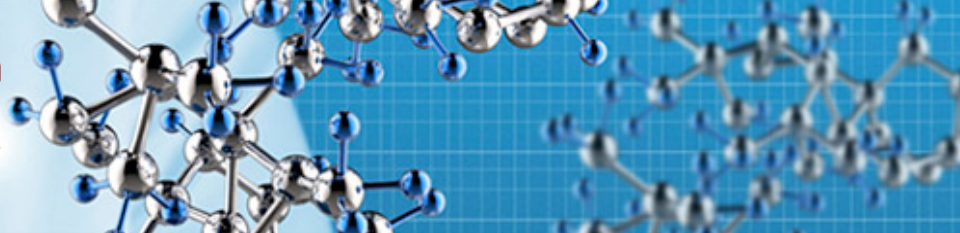
- Routine audits and monitoring (annual/periodic)
  - Adherence to protocol/study plan, informed consent, eligibility
- For Cause audits (as needed)
  - IRB requested, preparatory (pre-FDA audit), etc.
- Multi-Site audits(periodic)
  - Partner with Multi-Site Office to monitor outside sites (remotely or on-site)



# Safety & Monitoring Core

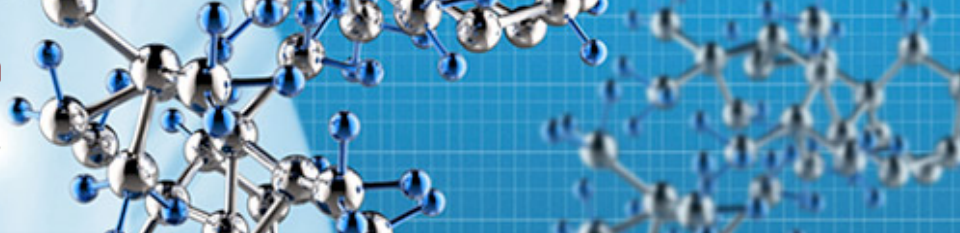
- Monitor data and safety of Investigator-Initiated and WCMC/NYPH sponsored clinical trials (i.e. high risk, IND/IDE held by WCMC/NYPH, Phase III).
- Review protocol progress, early stopping rules, dose escalations, interim analyses, etc.
- Review unexpected SAEs, cumulative AEs, unanticipated problems for WCMC/NYP investigator initiated trials.





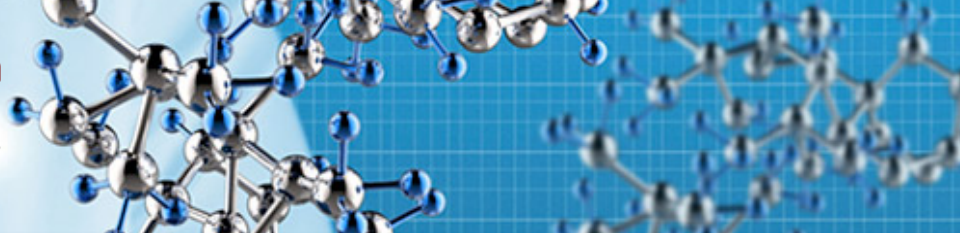
# Investigator Initiated & Multi-Site Protocol Operations

- Review all Investigator-Initiated clinical trials to ensure compliance with Institutional elements and requirements (i.e. DSMB, SAE reporting, registration).
- Oversight of [clinicaltrials.gov](http://clinicaltrials.gov) updates.
- Prepare and review IND/IDE applications, including exemptions and single patient use, sent to FDA.
- Serve as central resource and point of contact for Investigators and Study Teams for Multi-Site protocols.



# Clinical Research Education Office

- Introductory training for new staff working in clinical research
  - General research training requirements
  - Study activation process
  - Systems access and workflows
- Orientation of new clinical research faculty
- Continuing education
- Re-training as part of corrective action plans/audit findings.
- Develop and distribute guidance and standard operating procedures for clinical research.



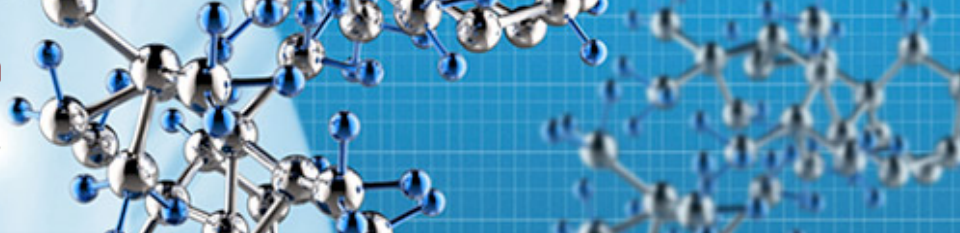
# Current Activities

## Audit & Monitoring Committee

- Conducted two internal QA audits
- FDA inspections
  - Attended close out visits
  - Drafted correspondence
- Developed FDA inspection guide

## Investigator-Initiated & Multi-Site Protocol Operations

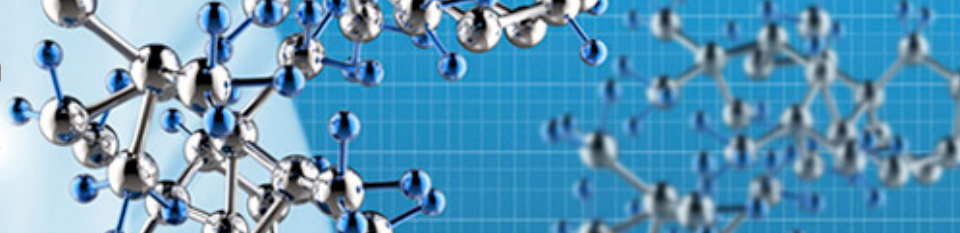
- Prepared IND application/exemption
- Created protocol template for investigator-initiated trials



# Current Activities

## Safety & Monitoring Core

- Data and Safety Monitoring Board
  - Business Process Solutions Review:
    - Creating appropriate data and safety monitoring plans
    - Timeliness of submissions, dispositions and response
  - Developing tools to facilitate review process and evaluate risk level of studies.

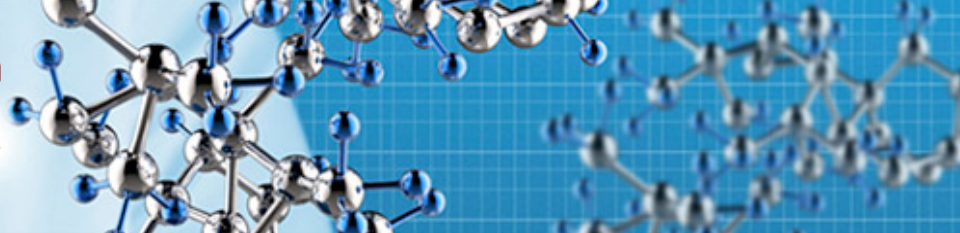


# ClinCard – Subject Compensation

- Launched August 2014
- Almost 400 cards distributed across 16 studies (General Medicine & Oncology)
- Secure reloadable debit card
- Provides real-time processing of subject compensation & reimbursement
- Subjects receive compensation immediately; less time spent following up = more efficient outcomes

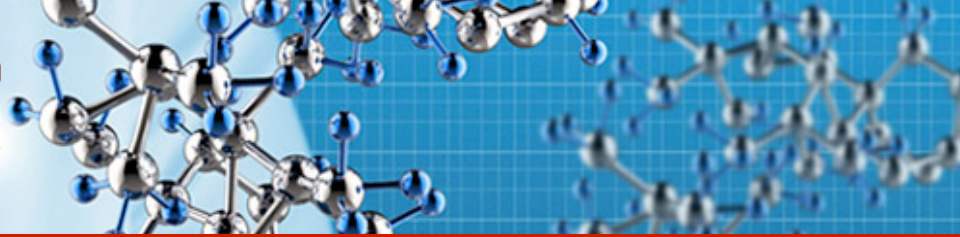






# Policy for Subject Recruitment Materials & Advertising

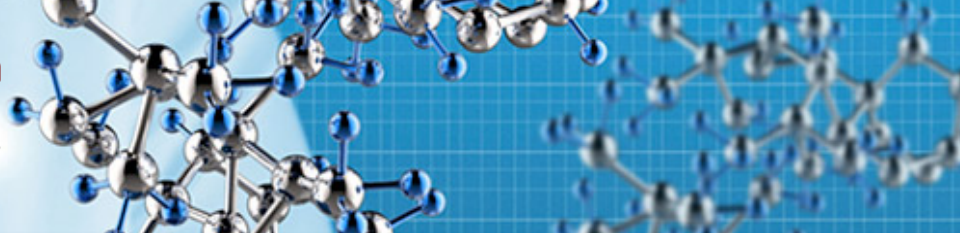
- WCMC IRB must review & approve recruitment materials & methods.
- Advertising includes print (brochures, flyers, newspapers), audio & online (websites, social media, video, blogs)
- Simple to understand lay language: study purpose, basic eligibility criteria, study contact details.
  - include “research study” at the top or beginning of material
  - no content that overpromises on end result or “cure”
  - do not use acronyms



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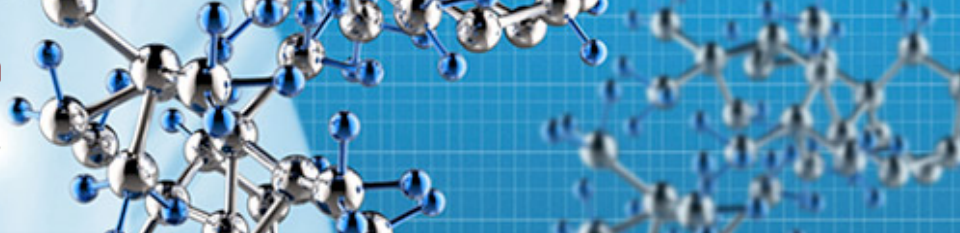
## **Getting the word out after IRB approval:**

- Sending e-mail communication - only WCMC-NYP e-mail addresses may be used, including listservs (i.e. News and Community)
- JCTO website
- Posting on campus
  - only post in designated frames outside of elevators or bulletin boards
  - postings must include the date posted
- Posting off-campus – as appropriate



## JCTO Website – Phase II

- Addition of active clinical trials to site
- Search functionality by disease area and free text fields
- Ability to sort results
- To add a study, complete the “Clinical Trials Summary Template” located in the Researcher’s Toolbox on the JCTO website



# Contact Information

## Quality Assurance Unit

- Nida Cassim – [ngc2002@med.cornell.edu](mailto:ngc2002@med.cornell.edu); 646-962-8281

## ClinCard

- [clincard@med.cornell.edu](mailto:clincard@med.cornell.edu)

## Subject Recruitment and Study Postings

- Erica Bersin, [erb3001@med.cornell.edu](mailto:erb3001@med.cornell.edu); 646-962-8232

## General Questions

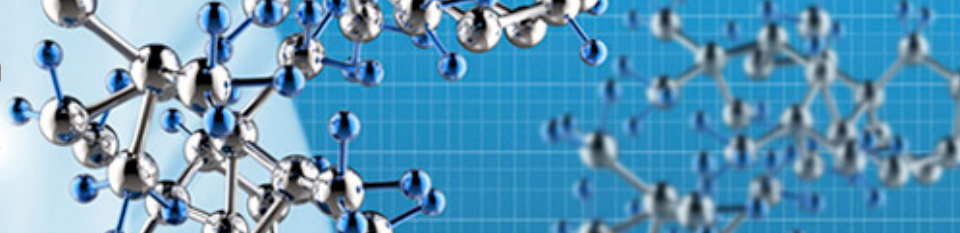
- [jctooperations@med.cornell.edu](mailto:jctooperations@med.cornell.edu)



Weill Cornell Medical College

 **NewYork-Presbyterian**

JOINT CLINICAL TRIALS OFFICE (JCTO)



# QUESTIONS?