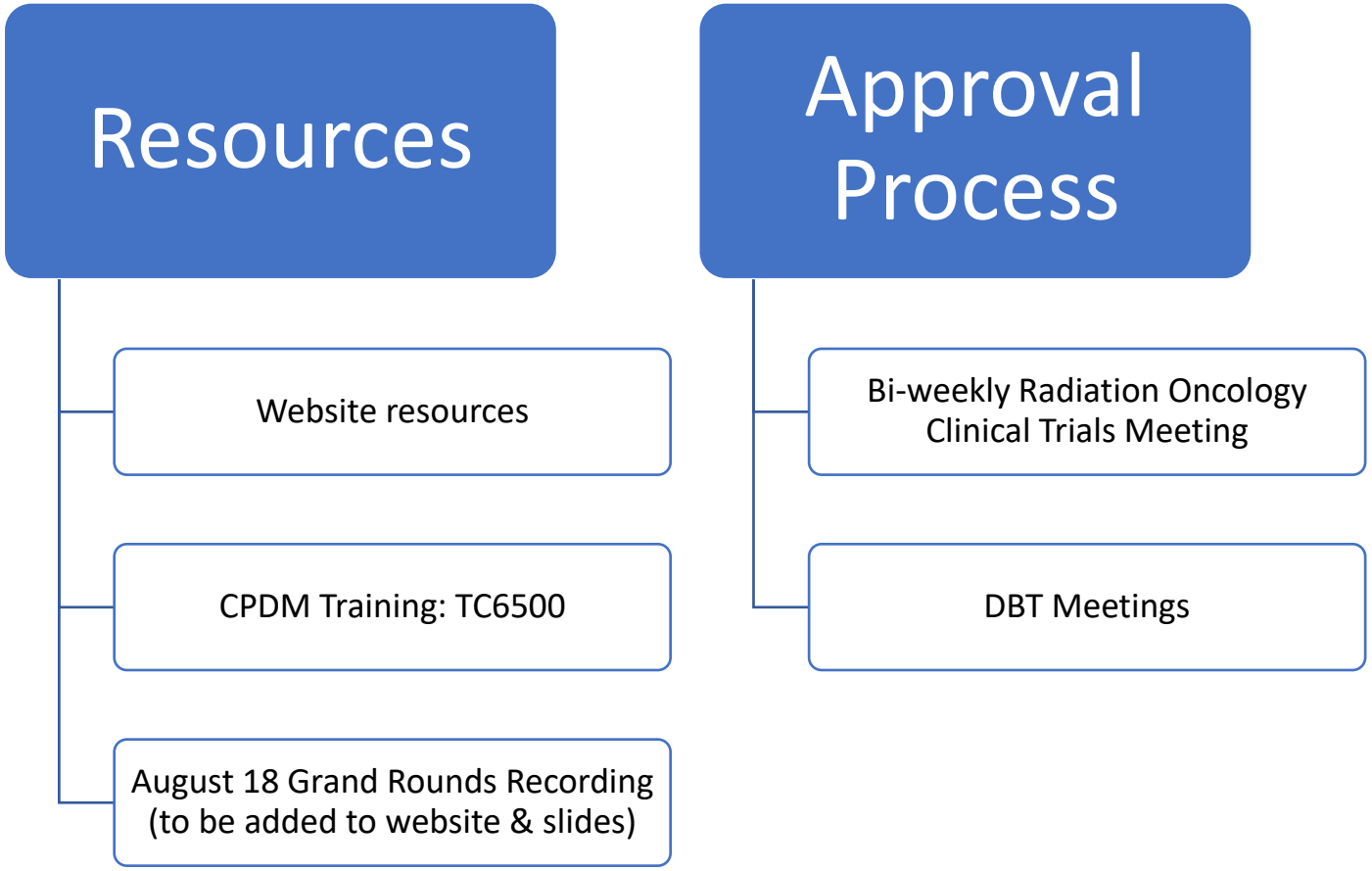
Rad Onc Clinical Trials Process & Resources

August 18, 2023

Eileen Connolly MD PhD
Assistant Professor of Radiation Oncology

COLUMBIA | COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

CPDM and Department of Radiation Oncology – Joint Clinical Trials Management



Website Resources

COLUMBIA | RADIATION ONCOLOGY

About Us ⌄ Education ⌄ Patient Care Research ⌄

Home > Departments & Centers > Radiation Oncology > Research

Radiation Oncology

- **About Us**
- **Education**
- **Patient Care**
- **Research**
  - Our Researchers
  - Research Labs
  - Clinical Trials Resources for Principal Investigators
  - Clinical Trials Resources for Patients
  - Announcements
  - Contact Us
- **Make a Gift**

https://www.vagelos.columbia.edu/departments-centers/radiation-oncology/research/clinical-trials-resources-principal-investigators

https://www.vagelos.columbia.edu/departments-centers/radiation-oncology/research/clinical-trials-resources-patients

Website Resources Cont'd-

Clinical Trials Resources for Principal Investigators

- Research trainings
- Approval & process workflows
- Checklists
- Study proposal survey link
- DBT meeting schedule & directory
- CPDM directory & slides
- Templates & examples
- Helpful links

https://www.vagelos.columbia.edu/departments-centers/radiation-oncology/research/clinical-trials-resources-principal-investigators

New CPDM Required Training: TC6500

REQUIRED RESEARCH TRAININGS:

RASCAL:

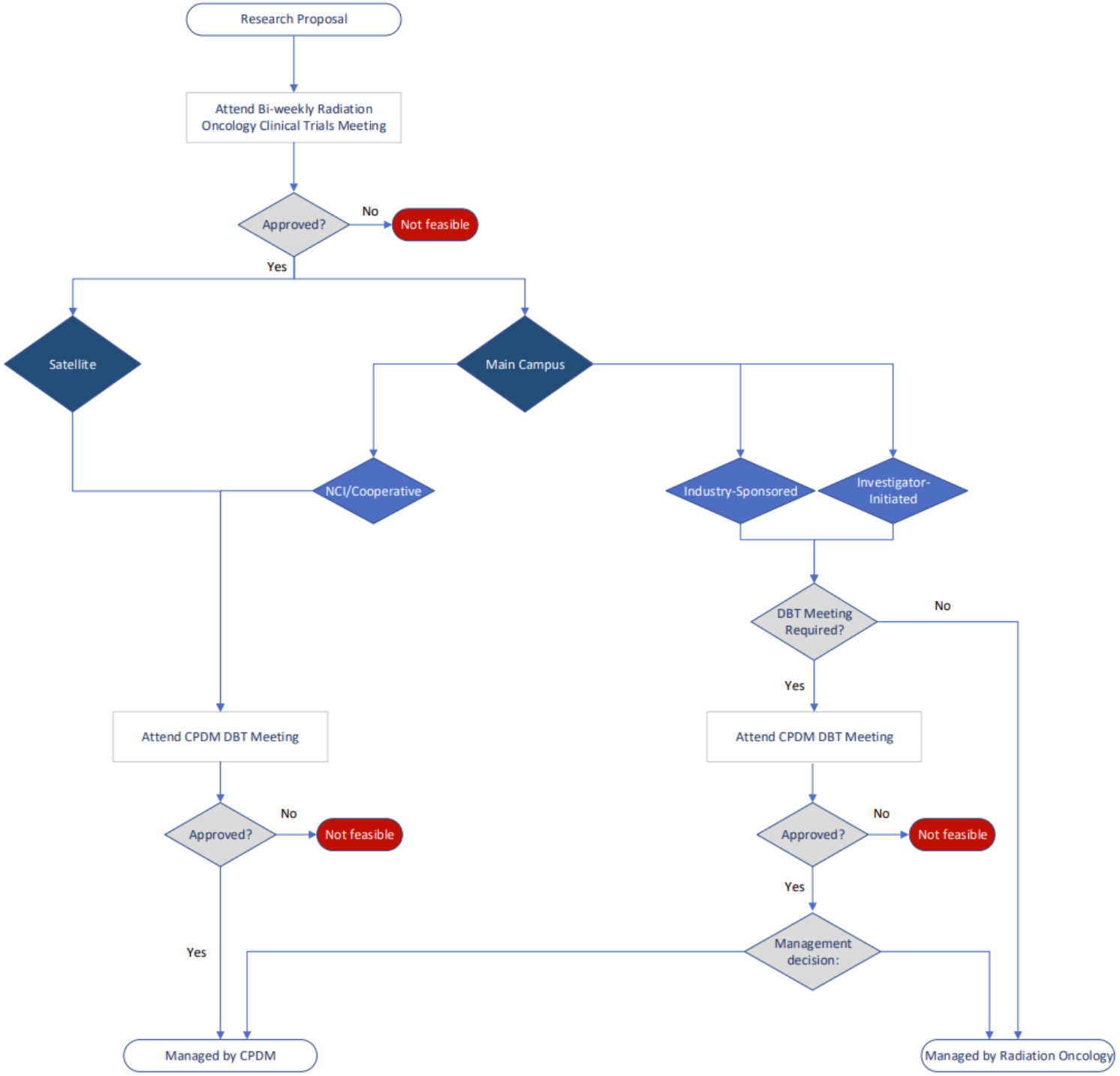
- TC0019 - HIPAA: Health Insurance Portability Accountability Act Research Training Course
- TC6500 - HICCC Clinical Protocol and Data Management Investigator Standard Operating Procedure Training

New CPDM required training

REDIRECTED TO CITI:

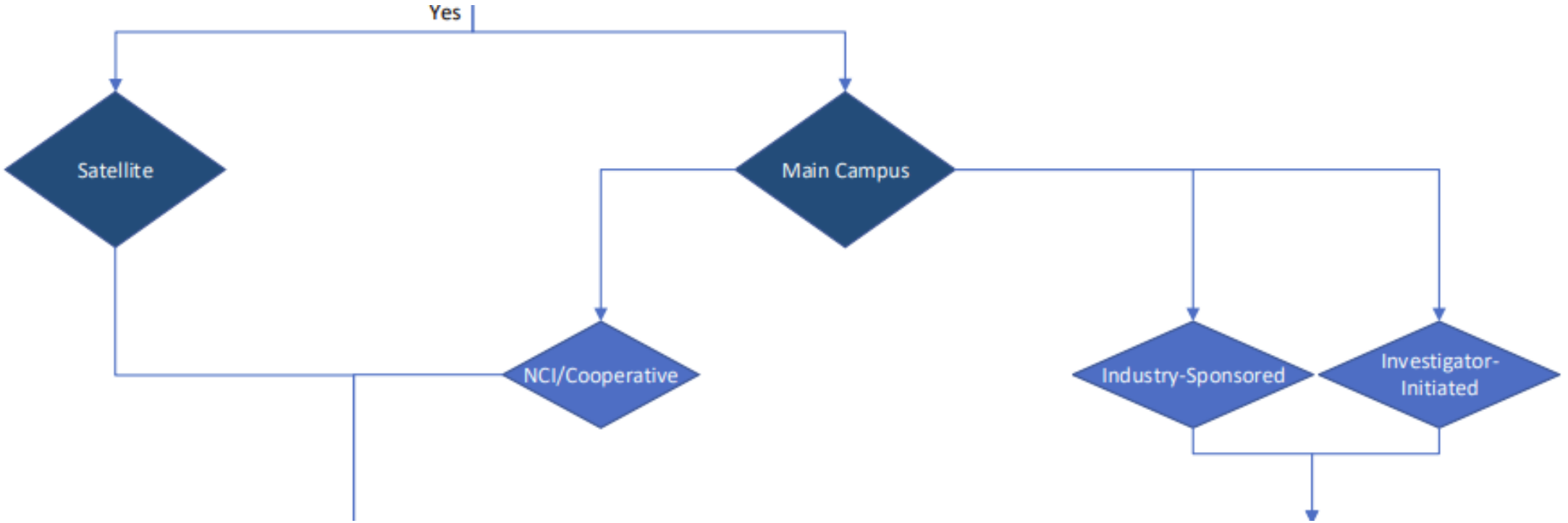
- TC0087 - Human Subjects Protection (HSP) Training
- TC0094 - Responsible Conduct of Research (RCR) Training
- TC3450 - Good Clinical Practice (GCP) Training
    - FDA-Regulated Research
    - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
    - Human Subjects Protection Biomed
    - RCR Biomedical
    - Research with Minors - BIOMED

Approval Process

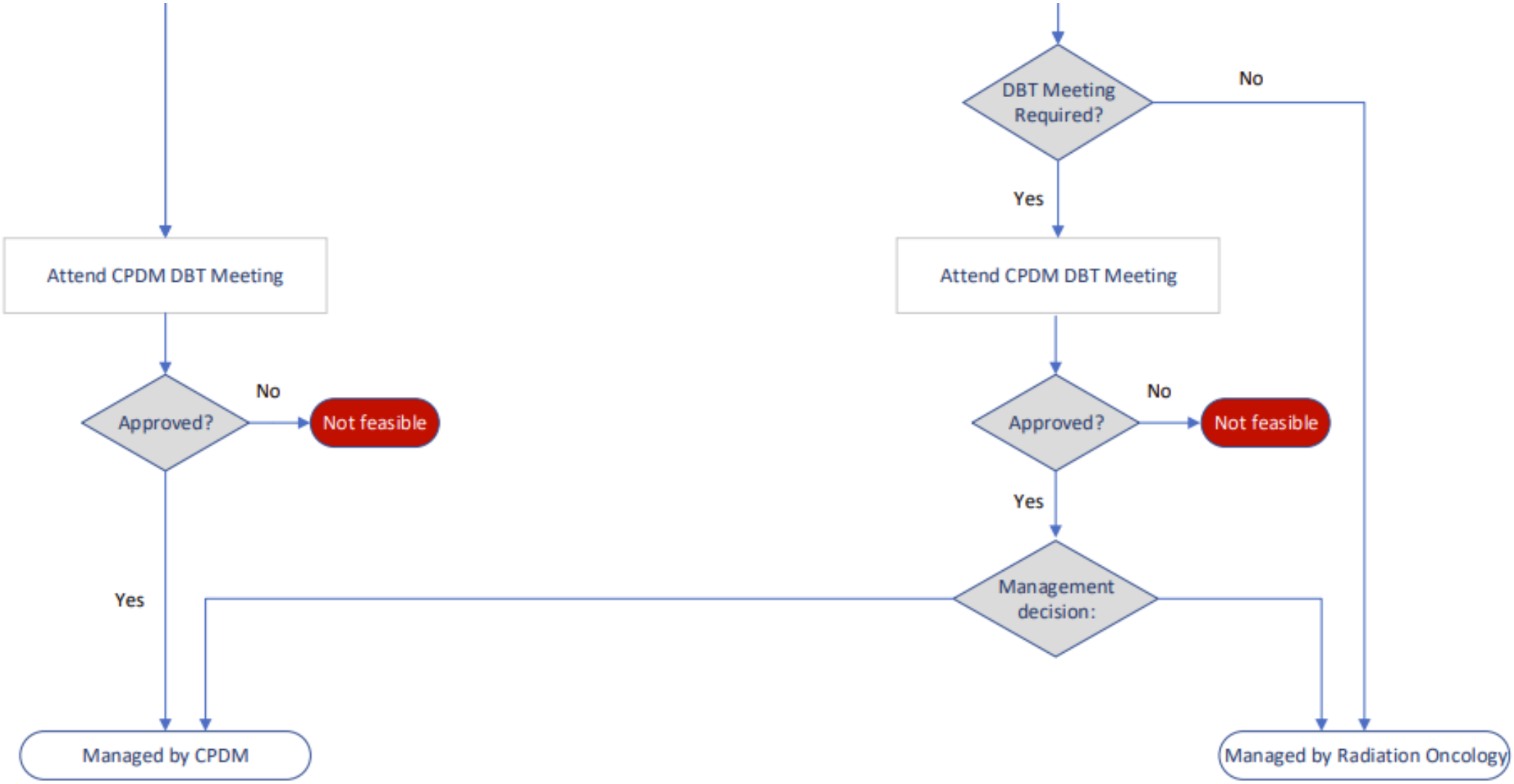


Approval Process

Approval Process



Approval Process



Bi-weekly Radiation Oncology Clinical Trials Meeting

Wednesday • 8:00-9:00am

Attend as needed for:

- Research proposals
- Review of ongoing studies
- Questions

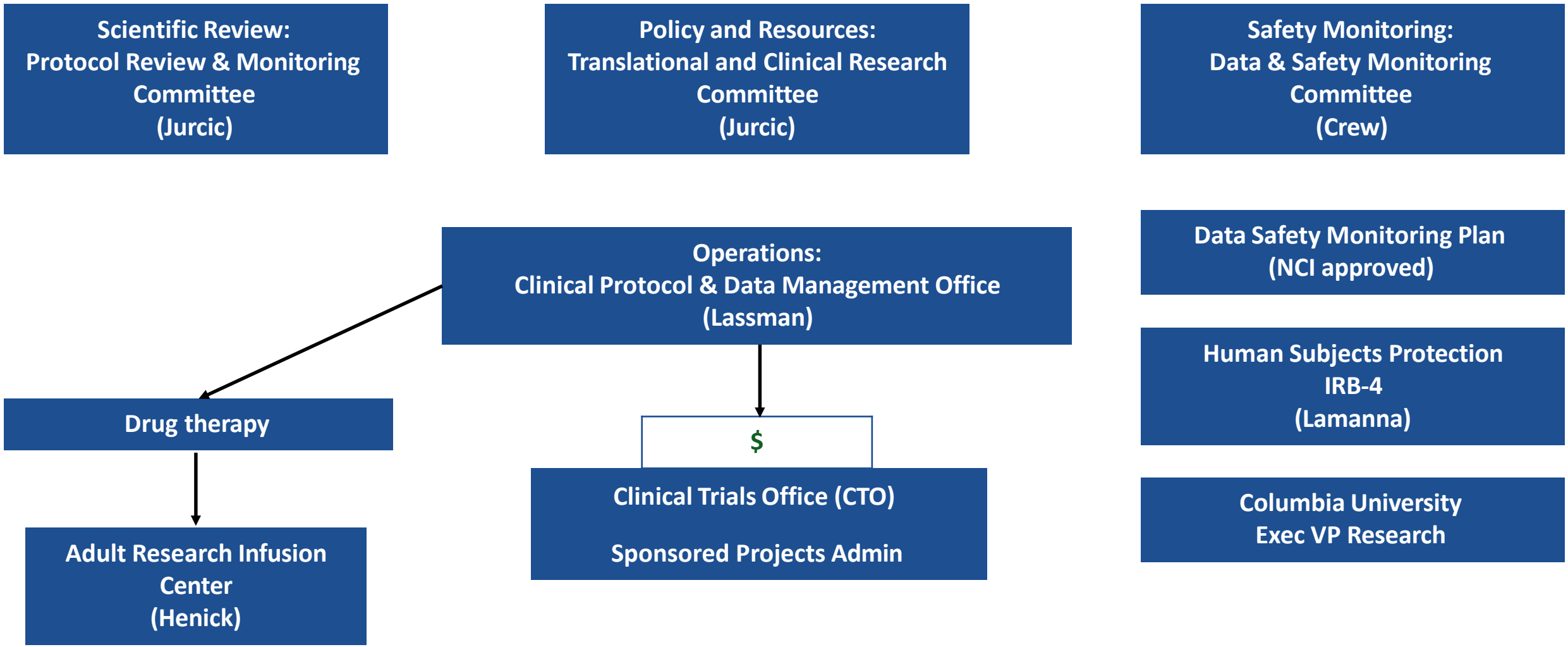
https://columbiacuimc.zoom.us/j/94402558184?pwd=K0dlaWdtdHIwUzZlMm1LMTcwaGhuUT09#success

DBT Meetings & Contact Information

Disease Based Team (DBT) Meetings & Contacts							
Disease Team	**Day**	**Time**	**Recurrence**	**Notes**	**Manager**	**UNI**	**Phone**
BMT	Monday	3-4PM	Weekly		Deeksha Kaura	dk3195	305-0454
Breast	Friday	7:30-8:30AM	Weekly	*every 3rd week at 8AM	Erik Harden	eh2828	305-6361
GI	Thursday	4-5PM	Weekly		Kriti Bagri Manjrekar	kb3315	304-5579
GU	Thursday	10-11AM	Biweekly		Jill Gray	jg4400	304-7991
Myeloid - Heme	Tuesday	3-4PM	Weekly		Beatriz Raposo Corradini	br2469	305-6679
Lymphoid- Heme	Wednesday	12-1PM	Weekly		Beatriz Raposo Corradini	br2469	305-6679
Melamona/Sarcoma	Thursday	4-5PM	Weekly		Moury Minhaz	mm3597	305-8487
Myeloma	Wednesday	2-2:45PM	Weekly		Deeksha Kaura	dk3195	305-0454
Neuro	Wednesday	8:15-9:15AM	Weekly		Kriti Bagri Manjrekar	kb3315	304-5579
Phase 1	Friday	8-9AM	Weekly		Kim Roman, Alyssa Schumpp	lr2787, as6498	342-3970, 342-0139
Thoracic	Friday	3-4PM	Weekly		Moury Minhaz	mm3597	305-8487
Hudson Valley	Monday	3-4PM	Monthly	*every 2nd Monday	Erik Harden	eh2828	305-6361
Westchester	Thursday	12-1PM	Monthly	*every 4th Thursday	Erik Harden	eh2828	305-6361

HICCC CLINICAL TRIAL INFRASTRUCTURE

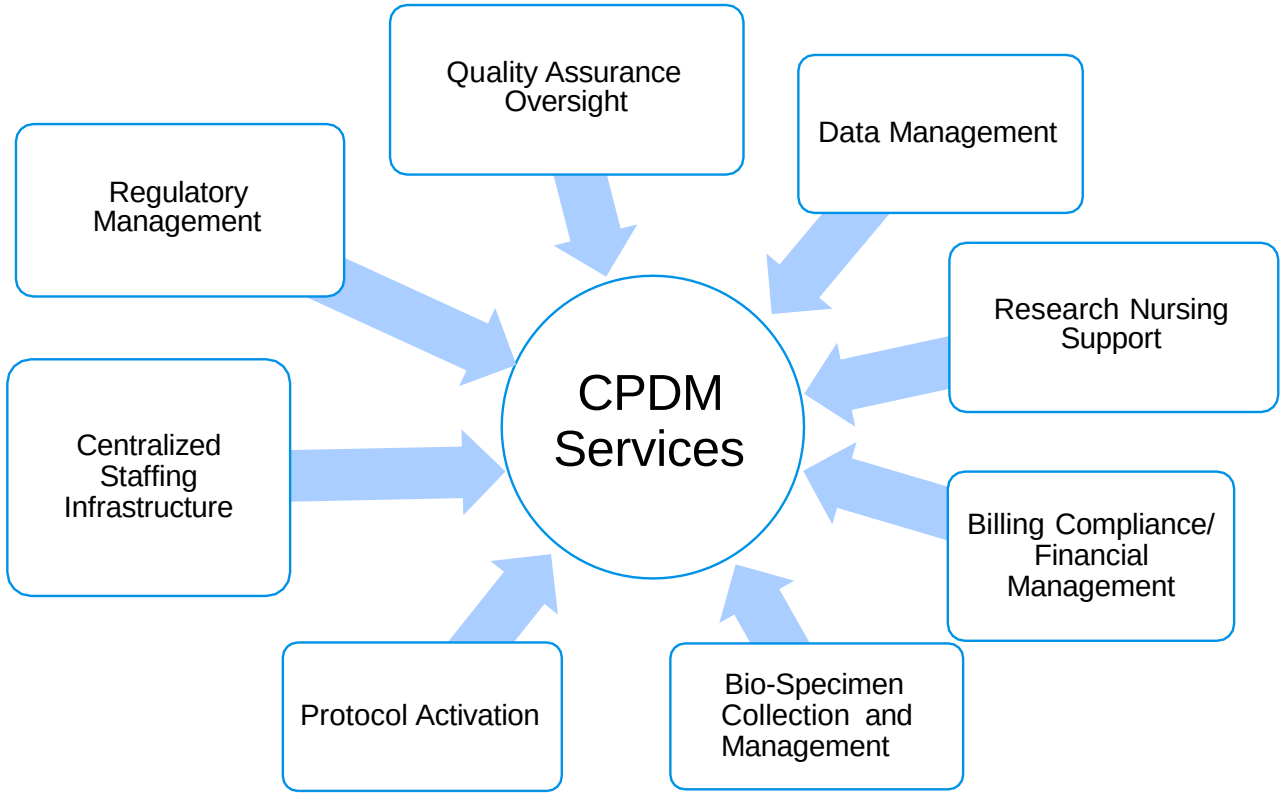
HICCC Clinical Trial Infrastructure



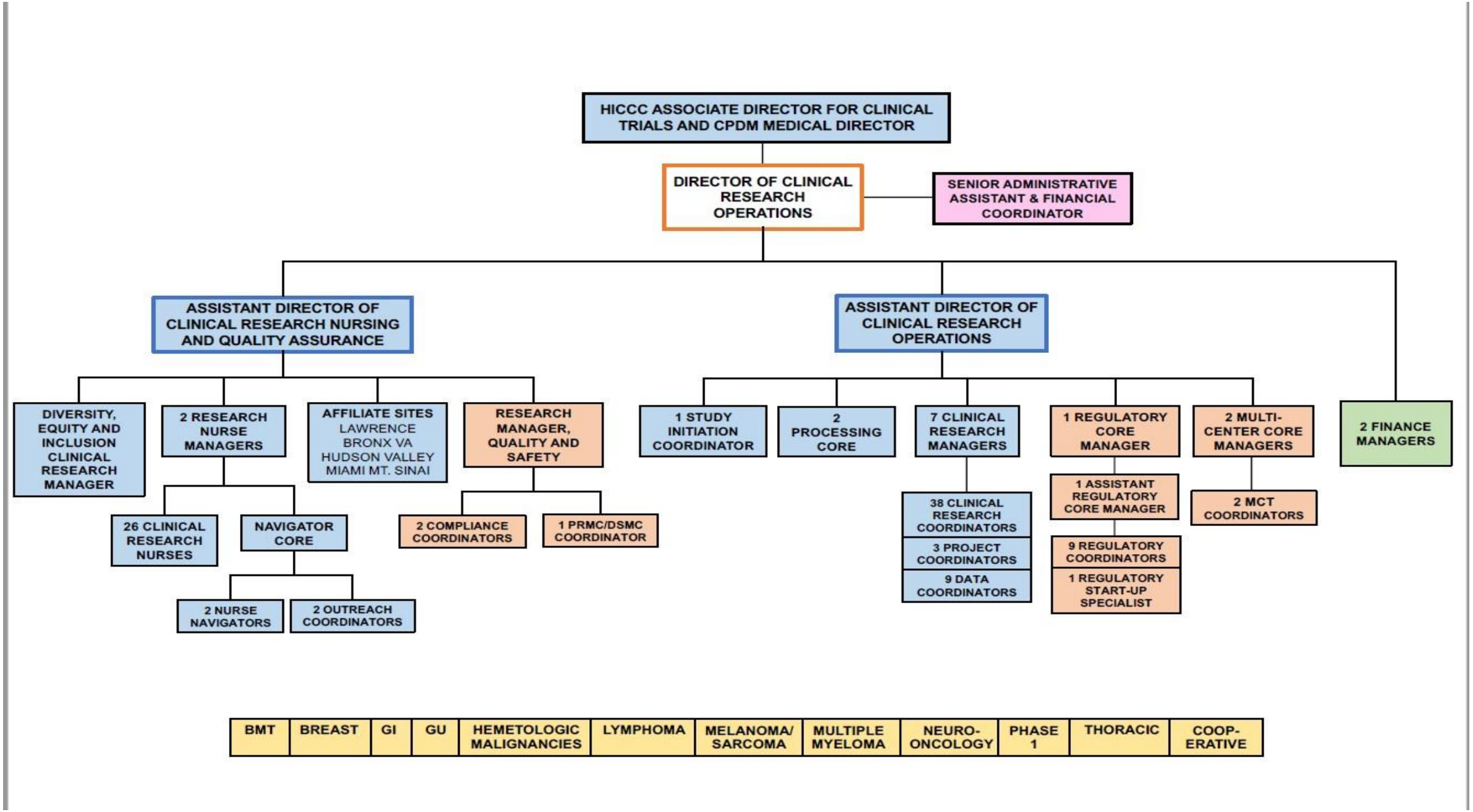
What is the CPDM?

The CPDM comprises 120 FTEs who provide centralized research support services to more than 60 HICCC members.

- Centralized office of
- Well-trained personnel supporting
  - Regulatory
  - Nursing
  - Study Management
  - Compliance
- Promote Uniformity and consistency to support
- PIs and patients



CPDM Organizational Structure



Disease Based Team(DBT) Meetings

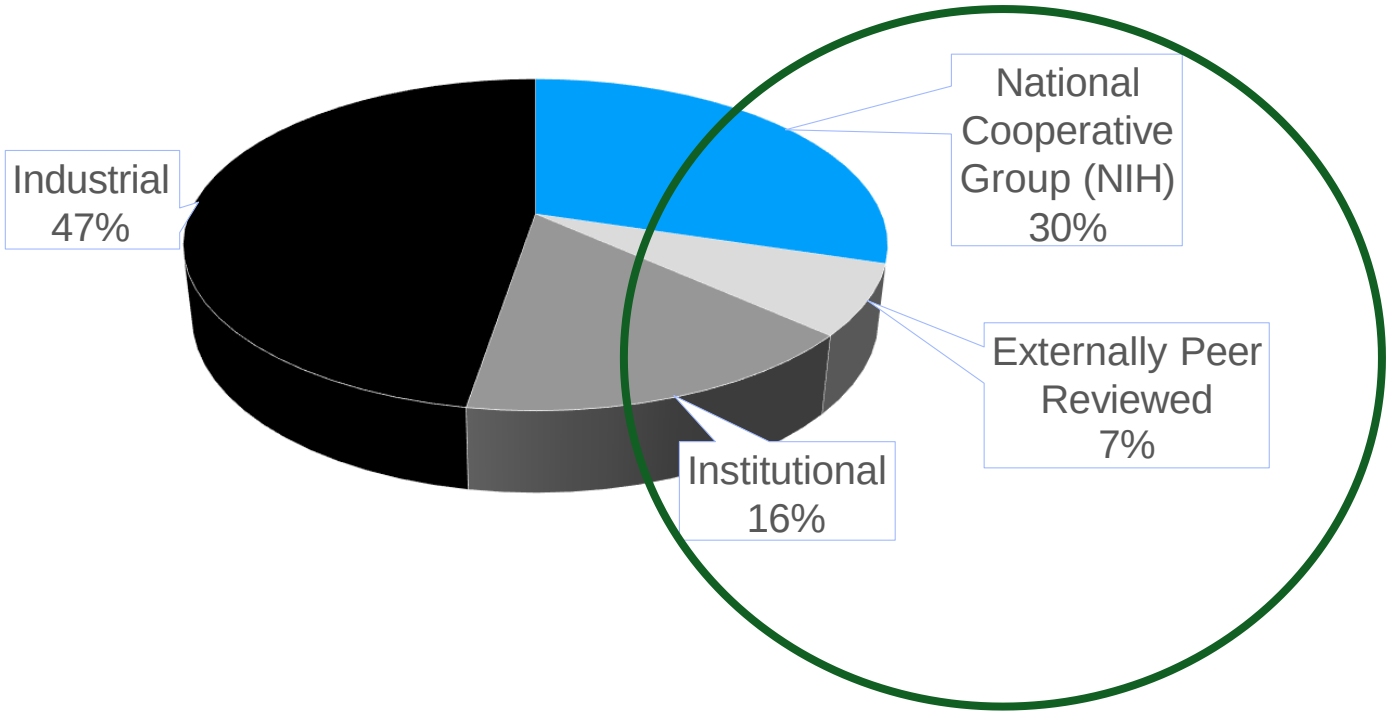
- Breast – every Friday 7:30 am
- BMT- every Monday at 3:00 pm
- GI – every Thursday 4:00 pm
- GU – every other Thursday at 10 am
- Heme – Myeloid – every Tuesday at 3 pm
- Heme- Lymphoid – every Wednesday at 12 noon
- Melanoma/Sarcoma – every Thursday at 4 pm
- Neuro Oncology – every Wednesday at 8:15 am
- Phase 1- every Friday at 8 am
- Thoracic- every Friday at 3 pm
- Hudson Valley – monthly – 2nd Monday at 3 pm
- Westchester(Lawrence) – monthly- 4th Thursday at 12 noon

Disease Based Team(DBT) Meetings

- Investigators-multidisciplinary, regulatory, nursing, CRC, MCT, and Data meet either weekly/biweekly/monthly to review DBT portfolio
- Review of protocols in pipeline, start-up, open and closed to enrollment
- Studies open/closed to enrollment- review of patients on study
- **Priority score for those studies being considered**
- Accrual to trial goal – at least 3 accruals/study open to accrual per year

Statistical Summary

- NCI expects a balanced portfolio and active participation on National Cooperative Group Networks as well as innovation through institutional trials
- However, the COST of research is the same, regardless of trial type
- Approximately $40,000 per patient



Translational and Clinical Research Committee

Initially formed to deal with reopening trials following the Covid outbreak but now has a larger mission to ensure that Cancer Center resources are being appropriately allocated to studies with the highest potential impact.

Disease Based Team Prioritization

- Scientific merit: Will this study lead to impactful discoveries and advances in the field?
- Clinical need: Is the intent of the study curative or palliative? Does the study offer the possibility of meaningful clinical benefit? Are other treatment options available?
- Feasibility: What is the anticipated rate of recruitment? Can the study be completed in a reasonable period of time? What is the complexity of the trial regarding number of patient visits, route of administration, pharmacokinetic sampling, etc.?
- Academic output: Will the study result in publications, grants, and presentations? Is it important for career development?
- Funding: Has funding been secured to complete the study? Is the source internal or external?
- Resources: Is there adequate research staff available to complete the study?
- Overall score: This should reflect the overall priority of the study and not simply be an average of the above.

Fiscal Support Council(FSC)

Cancer Center revised the process by which investigators can seek internal funding for clinical trials from the HICCC. These requests are be reviewed monthly by the committee, Studies eligible for HICCC funding include: CUIMC Investigator-Sponsored Trials; Cooperative Group Trials (including NCORP, NCI, and ETCTN), Externally Peer-Reviewed Trials, and Other(Investigator sponsored trial from Outside institution). The HICCC will not support underfunded industry-sponsored trials.

https://cumc.co1.qualtrics.com/jfe/form/SV_6LTd0Ah2A5w1sK9

Members:

Joseph Jurcic, MD- Chair

Eileen Connolly, MD

Joel De Castro, MD

Dawn Hershman, MD

Nobuko Hijiya, MD

Fabio Iwamoto, MD

Leah Katz, MD

Gulam Manji, MD

Appeals: Andrew Lassman, MD and Anil Rustgi, MD

Medicare Clinical Trial Policy

Medicare Clinical Trial Policy:

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

The investigational item or service, itself unless otherwise covered outside of the clinical trial;

Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

Items and services customarily provided by the research sponsors free-of-charge for any

enrollee in the trial. Routine costs in clinical trials include:

Items or services that are typically provided absent a clinical trial (e.g., conventional care);

Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

Coverage of Phase 1 Trials:

The Medicare policy does not specify the phases of trials that are covered but instead states that a trial "must have therapeutic intent." It is the position of ASCO and other leading cancer organizations that phase 1 cancer clinical trials have therapeutic intent and therefore should be covered by Medicare. In the past, ASCO has worked with other cancer organizations to provide information to assist research sites with coverage denials related to phase 1 participation. For assistance on this issue, please contact ASCO at ResearchPolicy@asco.org.

Post-Award Process

PI/Faculty Salary Support – Industry Projects

Calculated on a quarterly basis:

$7500 for study start-up payments

$2500 for renewal payments

Set amount($300) per accrual based on trial complexity score (OPAL)

Closure- 25% of surplus

Award Reconciliation

Industry Projects Surplus

25% – Additional PI/Faculty Salary Support

25% – HICCC for reinvestment into underfunded, high priority clinical trials

50% – Disease Based Team Discretionary Funds with HICCC retaining fiduciary oversight

Principal Investigator Responsibilities

The PI is responsible for the overall conduct and management of the clinical research project, including all administrative, fiscal and scientific matters. Depending on the type of research study, the PI's responsibilities include:

- Assuming overall responsibility for the management of the study;
- Determining protocol feasibility;
- Ensuring that all of the information in the proposal or research protocol is presented in a manner that is complete, accurate and developed according to the practices commonly accepted within the academic community;
- Ensuring that all required approvals are obtained and University forms and certifications are completed in a timely manner; • Knowing and abiding by the terms and conditions of the award;
- Conducting the work on the project according to the research protocol and investigational plan that was submitted with the original proposal or as subsequently modified by the sponsor in agreement with the PI and the University;

Principal Investigator Responsibilities

- Prospectively obtaining IRB approval of any changes to the research protocol or investigational plan, except when implementation before IRB approval is required to avoid imminent harm to research participants;
- Ensuring that all work meets the highest ethical standards and is conducted without real or apparent conflicts of interest, in accordance with the University's policies;
- Ensuring that all work performed is conducted in compliance with applicable federal, state and local laws and regulations and with University policies and requirements;
- Ensuring that all research personnel are qualified, have an appropriate appointment or position, have met necessary training requirements, are fully familiar with the research protocol and are kept informed about any modifications of the research protocol;
- Ensuring that non-Columbia collaborators have the appropriate approvals, whether from their home institution, a commercial entity or by agreement through Columbia;
- Ensuring that the delegation of responsibilities is in accordance with the protocol and any applicable regulations and policies, and that all members of the study team are aware of the delegations;

Principal Investigator Responsibilities

- Holding regular research team meetings and ensuring communication among all member of the team;
- Determining eligibility of subjects;
- Ensuring that informed consent is properly obtained from study subjects;
- Ensuring appropriate monitoring of subjects;
- Ensuring that all data is obtained, maintained and reported in accordance with the protocol and investigational plan;
- Making medical assessments, evaluating the efficacy of the study medication and determining whether adverse events or unanticipated problems have occurred;
- Submitting reports on the research in a timely manner, according to the sponsor or IRB requirements, including reports of unanticipated problems, adverse events and protocol deviations and violations;

Principal Investigator Responsibilities

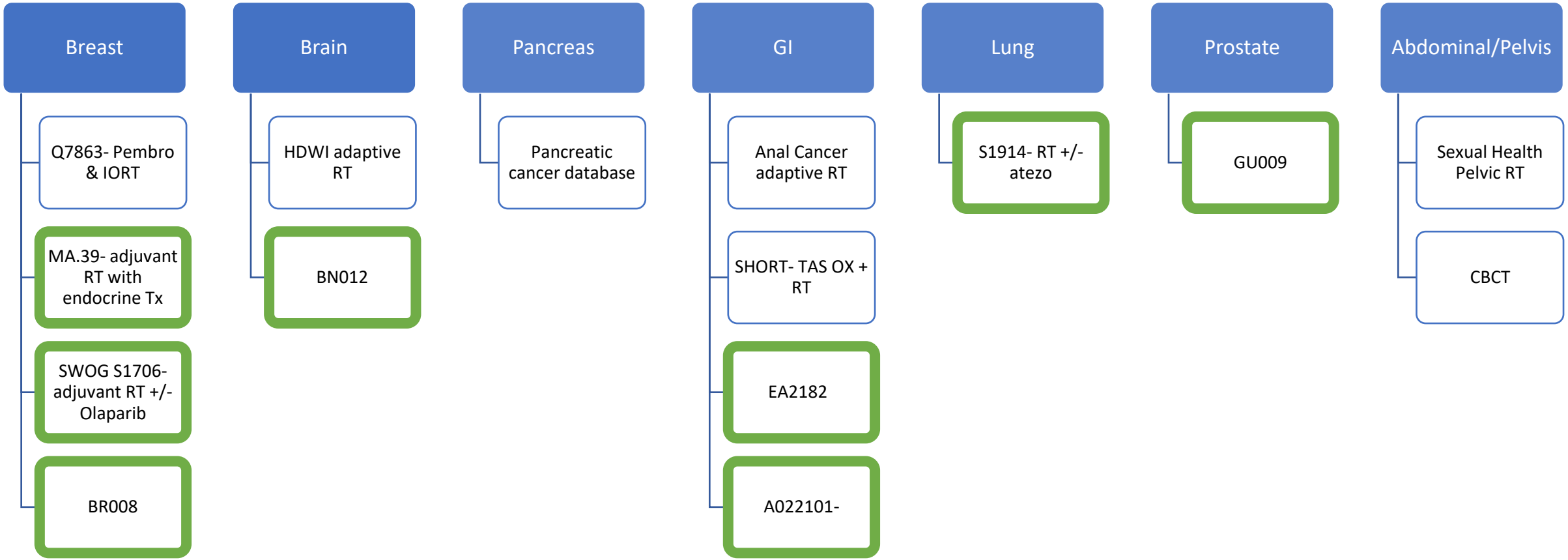
- Managing the project's budget so that funds are spent correctly, taking into account any restrictions imposed by the sponsor and avoiding cost overruns;
- Ensuring that all financial records and reports are accurate and auditable;
- Monitoring the activities of subrecipients, if any; and
- Completing the formal closeout of the project.

- **RASCAL TC6500 CPDM** Investigator Standard Operating Procedure Training

- New Study
  - Review protocol and priority score at team meeting
  - Feasibility submission in collaboration with Clinical Research Manager
  - Fiscal Support Council submission in collaboration with Clinical Research Manager
  - Review and sign study activation checklist
  - Review and sign Eligibility checklist

Department of Radiation Oncology Of Columbia University Research Studies

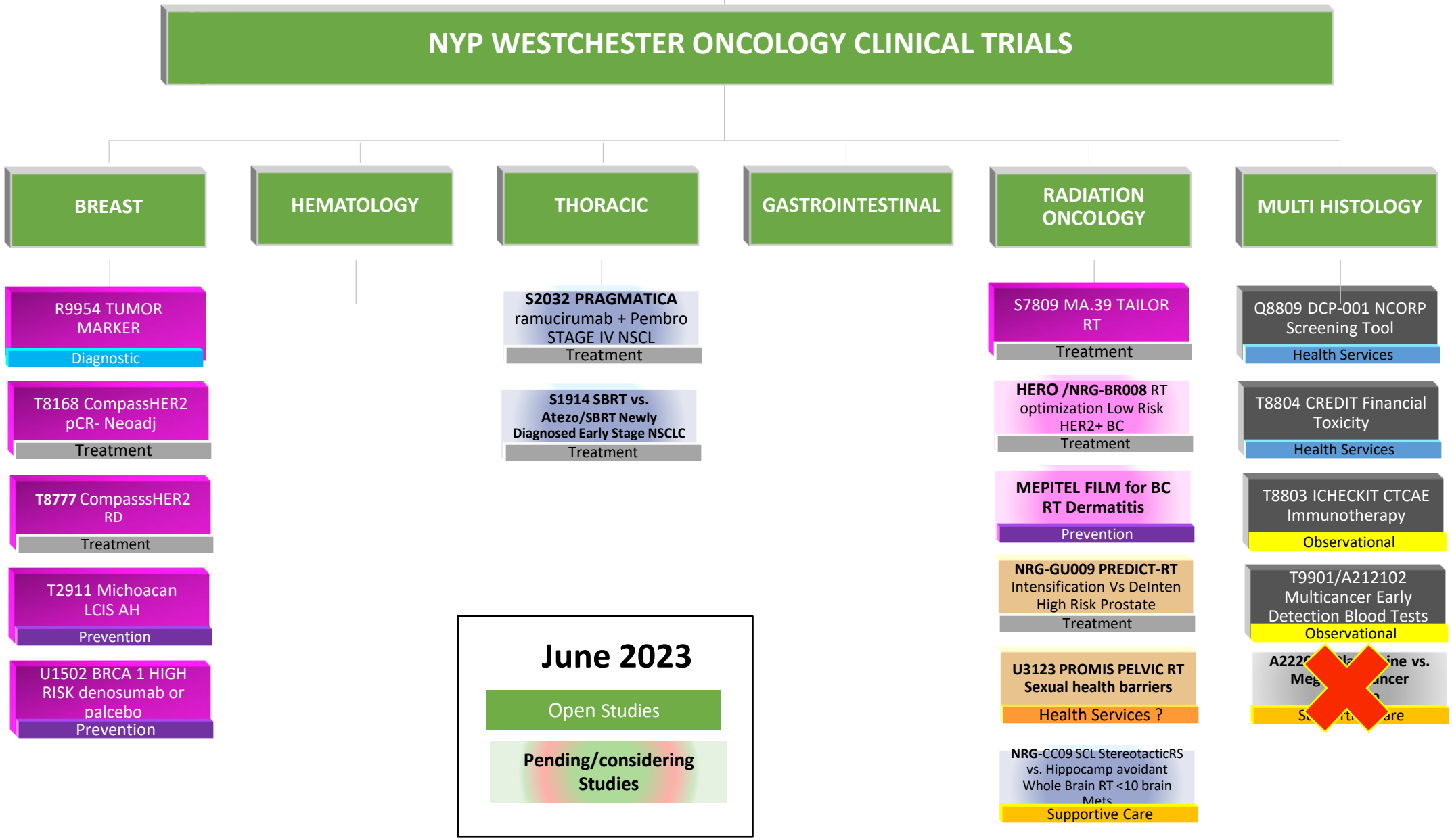
Clinical Trials at CUIMC



Research Studies at CUMC

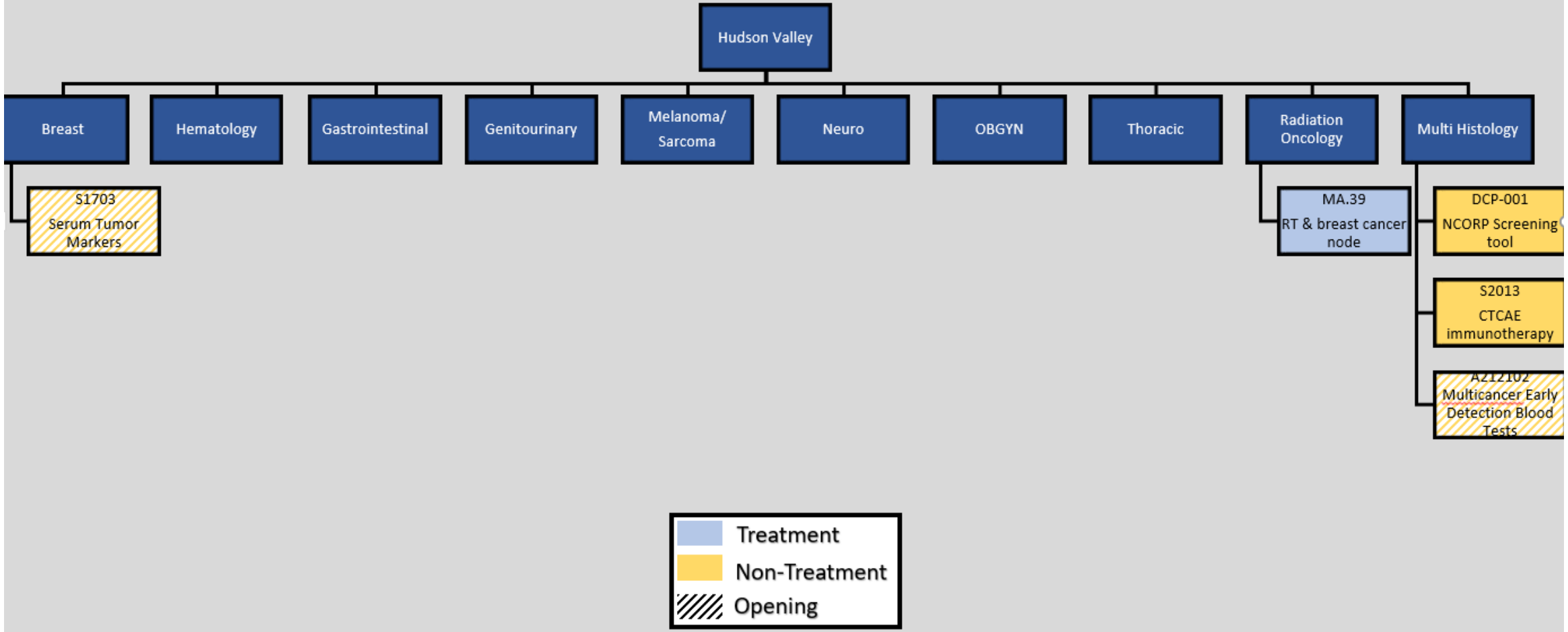
Investigator Initiated	Databases	NCI Cooperative Groups	NCI Cooperative Groups- Coming Soon	CPDM	Sponsored
ADELANTE (AAAT2490)	Brain Malignancy, Tumor and RT (AAAM2358)	SWOG S1706 (AAAT7675)	NRG-CC009 (AAAU7430)	Aerodigestive Biospecimens Protocol (AAAU3344)	SHORT Study /CRP18085 (AAAS9068)
MK-3475 on the breast tumor microenvironment (AAAQ7863)	AAAJ8512 – Breast cancer	EA2182 (AAAS9611)	NRG GU009 (AAAT6799)	Immune response to radiotherapy for prostate cancer (AAAU5087)	*TARGIT Phase IV Registry(AAAM5650)- Data clean up only*
IORT DCIS (AAAQ7853)	GU Malignancy Clinical Registry (AAAT7614)	MA.39 (AAAS7809)	NRG-BN012 (AAAU5925)		
Varian Adaptive RT Anal Cancer (AAAU0074)	Lung Cancer (AAAI0481)	*RTOG 1005 (Long term Follow-up only)*	A221803 (AAAU4852)		
Breast tumor microenvironment (AAAO7708)	Pancreas Cancer (AAAQ7437)	*RTOG 0815 (Long term Follow-up only)*	NRGBR008 (AAAU6554)		
Pelvic RT PROMIS NRG (AAAU3123)		*RTOG 0534 (Long term Follow-up only)*	S1916- no IRB # assigned		
HDWI Varian Grant (AAAU2309)		*A071801- Data clean up only*			
IV contrast-enhanced CBCT in radiotherapy (AAAS0632)					

NYP WESTCHESTER ONCOLOGY CLINICAL TRIALS



v. 5/19/23

NYP Hudson Valley Hospital Visual Portfolio:



Questions