Clinical and Translational
Research Town Hall

Demystifying Clinical Research Administration

November 24, 2025

Duke University School of Medicine

Agenda

Topic	Speakers
Introduction to Duke Research Administration	Charles D. Scales Jr, MD MSHS FACS *Associate Dean for Clinical Research Initiatives*
Office of Research Administration (ORA)	Jennifer McCallister, JD *Assistant Dean for Research Administration*
Research Administration Support Resource (RASR)	Tim Lee, MBA *Director for Research Administration*
Office of Research Contracts (ORC)	Mitchell E. Yelverton, JD *Director, Site-Based Research*
Panel Discussion	All speakers above • Monica Lemmon, MD *Associate Dean for Scientific Integrity* • Denise Snyder, MS, RD, LDN *Associate Dean for Clinical Research*

Some Research Support Offices operate at the Institutional level, whereas others are dependent upon School or Department

Institutional Level

- Office of Counsel
- Procurement & Supply Chain
- Office for Translation and Commercialization
- Office of Audit, Risk, and Compliance
- Office of Animal Welfare & Assurance
- Export Controls
- …and many more

Provost Area

- Office of Research Support (ORS)

School of Medicine

Administration

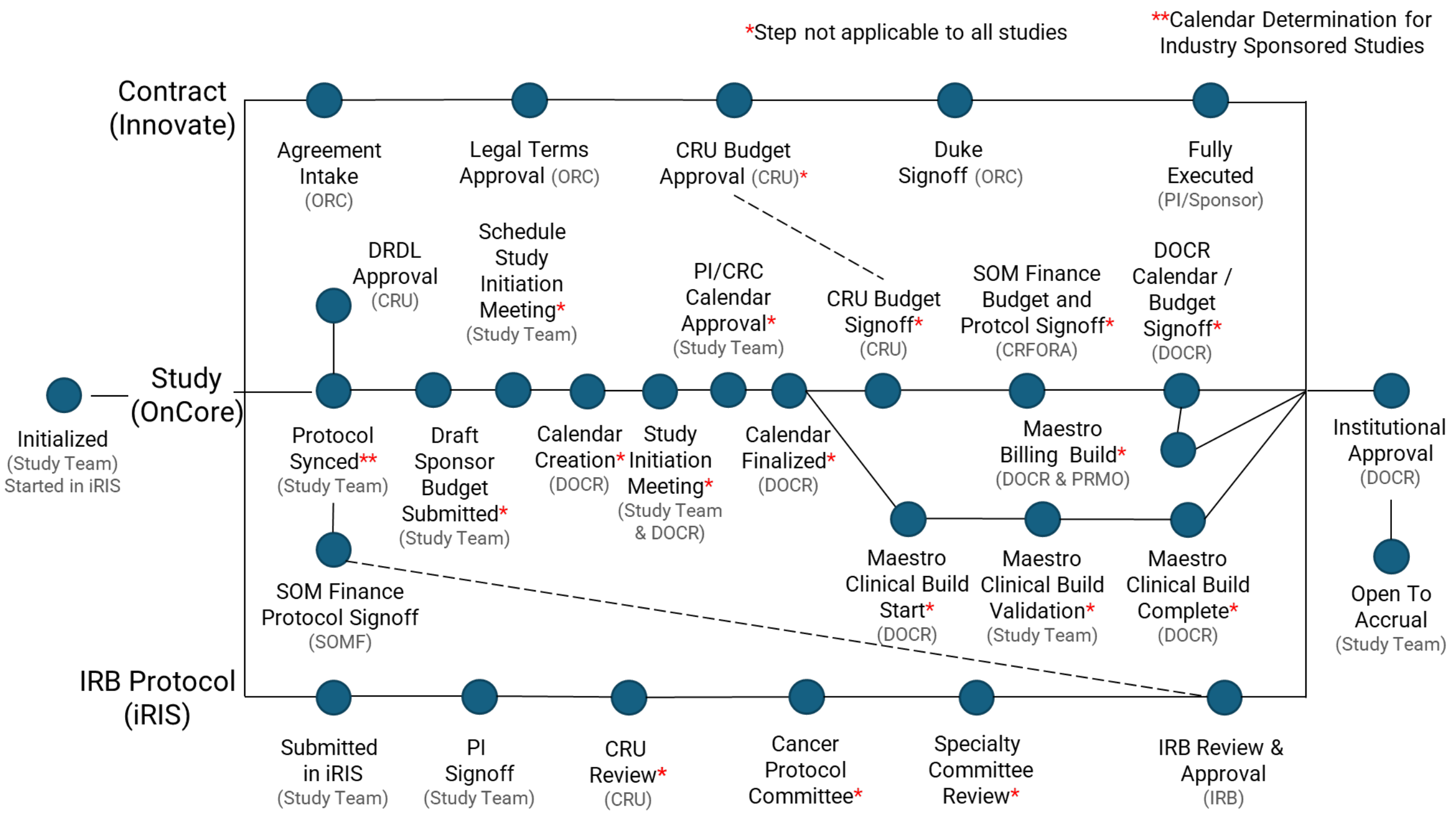
- Office of Research Administration (ORA)
- Research Administration Support Resource (RASR)
- Office of Research Contracts (ORC)

Operations

- Duke Office of Clinical Research (DOCR)
- Office of Regulatory Affairs and Quality (ORAQ)

Department-Specific

- Clinical Research Units
- Dept of Medicine Research Administration (DoM-RA)
- Surgery Office of Clinical Research (SOCR)
- …and many more


*Step not applicable to all studies
**Calendar Determination for Industry Sponsored Studies
Contract (Innovate)
Agreement Intake (ORC)
Legal Terms Approval (ORC)
CRU Budget Approval (CRU)*
Duke Signoff (ORC)
Fully Executed (PI/Sponsor)
DRDL Approval (CRU)
Schedule Study Initiation Meeting* (Study Team)
PI/CRC Calendar Approval* (Study Team)
CRU Budget Signoff* (CRU)
SOM Finance Budget and Protcol Signoff* (CRFORA)
DOCR Calendar / Budget Signoff* (DOCR)
Study (OnCore)
Initialized (Study Team) Started in iRIS
Protocol Synced** (Study Team)
Draft Sponsor Budget Submitted* (Study Team)
Calendar Creation* (DOCR)
Study Initiation Meeting* (Study Team & DOCR)
Calendar Finalized* (DOCR)
Maestro Billing Build* (DOCR & PRMO)
Institutional Approval (DOCR)
SOM Finance Protocol Signoff (SOMF)
Maestro Clinical Build Start* (DOCR)
Maestro Clinical Build Validation* (Study Team)
Maestro Clinical Build Complete* (DOCR)
Open To Accrual (Study Team)
IRB Protocol (iRIS)
Submitted in iRIS (Study Team)
PI Signoff (Study Team)
CRU Review* (CRU)
Cancer Protocol Committee*
Specialty Committee Review*
IRB Review & Approval (IRB)

Charge for Our Speakers

1. What is the entity you represent?
   – Broadly speaking, what does your entity do?

2. How is your entity working to reduce complexity and minimize research start-up times?

3. What is the best way for faculty/researchers to partner with you and/or your entity?

Office of Research Administration (ORA)

Jennifer McCallister, JD

Duke University School of Medicine

What is ORA?

- Oversee pre-award activities at the central level
  - Review full applications to ensure true, complete, and accurate
  - Ensure institutional clearances (e.g. IRB, IACUC, etc)
  - Act as institutional signing official
- Manages award acceptance and activities during award
  - Reviews and sets-up NOAs
  - Reviews and submits prior approval requests, NCEs, etc.
  - Manages components of closeout
- Agreement management – government and foundation
  - Review and negotiate incoming agreements
  - Draft and issue subawards on SOM awards

Preaward – Clinical Projects

- Understand the rules/requirements for human subjects vs. human data/samples
- Work with CRU to create appropriate budgets for clinical project
- Clinical trial coordination
  - START EARLY
  - Poll sites on costs needed to implement protocol
  - Consult with grant manager/ORA on payment type before building budget
  - Budget as subawards to include correct indirects

Award Management – Clinical Projects

- Managing fixed/capitation residual balances prior to end of project
- Review milestones prior to contract execution
- Ensure all trial expenses are put on WBSE
- Understand payment terms when Duke is a subrecipient (fixed/cost reimbursable/hybrid)
- For coordinating centers, monitor site enrollment and spending across sites

Contracts - Clinical Projects

- Coordinating centers –
  - Create a feasible payment schedule for sites
  - Use appropriate payment mechanism
  - Determine how enrollment will be managed
  - Manage sIRB (if applicable)
- Manage IRB submission – often holds up contract/data transfer

Creating efficiencies

- Working on AI tools for applications/RPPRs
  - Budget justification tool
  - Other support tool
- Streamlined reviews for certain types of projects
- Additional flexibilities in contract terms
- Data front door for HS data in contracts (replaces former DTIF process)

Research Administration Support Resource (RASR)

Tim Lee, MBA

Duke University School of Medicine

What is RASR?

- RASR stands for the Research Administration Support Resource. It is a centralized administrative unit within the School of Medicine that provides essential "cradle-to-grave" support for research grants and contracts

- RASR personnel work closely with faculty, principal investigators (PIs), and central offices to manage all financial aspects of sponsored research, from the initial proposal stage to project closeout

- The RASR group serves as a shared resource to streamline administrative processes and promote research excellence across various departments at Duke

RASR Services Based on Funding Type

	Service	Federal/State	Foundation	Industry	Internal
Pre-Award	SPS Entry	✓	✓	✓	n/a
	Internal Cost Assessment	✓	✓	✓	✓
	Budget Development	✓	✓	✓	✓
	Participate in OnCore Calendar Build Meeting			✓	
	Contract Payment Terms Negotiation	n/a	n/a	✓	n/a
	Budget Negotiation	n/a	n/a	✓	n/a
	Negotiate Future Budget Amendments	n/a	n/a	✓	n/a
	Application Submission	✓	✓		n/a
Post-Award	**Service**	**Federal/State**	**Foundation**	**Industry**	**Internal**
	Effort Management	✓	✓	✓	✓
	Subrecipient Monitoring	✓	✓		
	Subrecipient Invoicing/Payment			✓	
	Compliance & Oversight	✓	✓	✓	✓
	Financial Reporting	✓	✓	✓	✓
	Revenue Management & Collection			✓	n/a
	Financial Management	✓	✓	✓	✓
	FAM	✓	✓	✓	

RASR Requirements Based on Funding Type & Protocol Source

Protocol Source - IST vs IIT	Industry Sponsored Trials (IST)	Investigator Initiated Trials (IIT)
	Industry Sponsor writes the protocol	Duke Investigator writes the protocol
	Industry Sponsor / CRO provides CTA, Budget, and all study documents needed	Duke PI / study team provides study documents RASR provides ICA and budget if seeking external funding (Industry)
	All institutional fees for industry apply	Certain institutional fees are waived
		Can be Industry, Federal, Foundation, Internal/Dept, or Philanthropic Funded

	Federal	Foundation	Industry IST	Industry IIT	Internal
Schedule of Events*	✓	✓	✓	✓	✓
CPT Codes	✓	✓			✓
Protocol			✓		
Contract with Payment Terms			✓	✓	
Manuals (Pharmacy, Lab, Imaging) & CRFs			✓		

***Schedule of Events** are required to help the Study Team and RASR determine the appropriate amount of effort needed to be budgeted for: Regulatory, Nursing, Data, and Study Oversight.

Definition of Clinical Trial vs Clinical Research – F&A

Duke Definition:

- The controlled, clinical testing in human subjects (must include **prospective** data collection) of a drug, device, treatment, diagnostic, intervention, or preventive measure to assess its safety, efficacy, benefits, costs, adverse reactions, and/or outcomes
- Industry Sponsored Clinical Trials – 33%
- Industry Sponsored Clinical Research – Federal F&A Rate

NIH Definition:

- A research study in which one or more human subjects are prospectively assigned to one or more interventions(which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Streamlining of Support

- Centralized Start-Up
- Rate Cards
  - Abbvie Rate Card (Oncology)
  - Amgen Rate Card (Oncology)
  - BMS Rate Card (Oncology)
- Standardization of Fees within RASR CRUs
  - Maintenance Fees
  - IRB Regulatory Effort Fees
- Kick-Off Meetings

Key Issues Causing Delays

- Involving incorrect Pre-Award Office (ORC vs ORA)
- Missing or incomplete necessary documents
  - Schedule of Events, Protocol, etc.
- Lack of feasibility assessment and planning
  - Do we have the patient population?
  - Are physicians prescribing the drug / using the device?
  - Operational plan – what will be needed to carry out all steps? Who will help?
- Budgeting Incorrect F&A

RASR Zones and Directors

Zone 1- Dana Sanders	Zone 2 – Deborah Martin	Zone 3 – Chelsea Penumarthy	Zone 4 – Broderick Grady	Zone 6 – Shannon Wood	Zone 7 – Tiffany Cervi	Zone 8 – Tim Lee
Biochemistry	Population Health Sciences	Surgery	International Research	OB/GYN	CTSI	Industry Sponsored Clinical Research
Biostatistics & Bioinformatics	Dermatology	Emergency Medicine		Pediatrics	MC3	
Cell Biology	Family Medicine & Community Health	Head and Neck Surgery		Anesthesiology	Center for Aging	
Integrative Immunobiology	Medicine	Orthopaedic Surgery		Ophthalmology	BIAC	
Neurobiology	Neurology	Neurosurgery		Psychiatry		
Pharmacology & Cancer Biology	Pathology	Radiology				
DMPI	Duke Cancer Institute	Urology				
Molecular Genetics & Microbiology	Heart Center					
	Radiation Oncology					
	DEPRU					

Office of Research Contracts (ORC)

Mitchell E. Yelverton, JD

Duke University School of Medicine

University Central Administration Contracting Responsibilities

Entity	Scope
Office of Research Administration (ORA)	Government and non-profit agreements for SOM & SON
Office of Research Contracts (ORC)	Industry agreements for SOM & SON, all Material Transfer Agreements (MTAs) for the University
Office of Research Support (ORS)	Agreements for Provost Area
Procurement	University-wide purchase of goods and services
Office for Translation and Commercialization (OTC)	University-wide licensing and commercialization

ORC Portfolio Overview

Duke Site-Based Research

- Industry-funded clinical projects enrolling Duke subjects
- Clinical trials and general clinical research

Basic and Preclinical Science

- Preclinical and bench/animal science
- Material transfers: biological samples, animal models, cell lines, and similar

Research Programs Collaborations

- Data agreements: data transfer and data use, data research collaborations with other academic institutions, retrospective data research, consortium agreements, educational programs

“Contracts” - Not Just ORC

- ORC - legal terms and conditions
- Risk Management (liability concerns)
- Scope of Work
- Budgets/Payment Schedules
- Sponsored Projects System (SPS) administrative holds (PI training, PI status, SPS status)
- Sponsor delays

It ALL flows downhill to the last gate . . .ORC signing the contract

Duke Contracting Agility Initiative

Goal is to be focused and agile – only negotiate for what we

(1) Must have

or

2. Must not have

Subject to

- Internal Revenue Service
- Food & Drug Administration
- Association for Accreditation of Human Research Protection Programs (AAHRPP)
- Health Insurance Portability and Accountability Act (HIPAA)
- Duke Institutional Review Board
- Other Duke Policies

Partners in Agility Initiative

- University Counsel
- University Treasury/Finance/Tax
- Office for Translation and Commercialization (OTC)
- Duke Office of Clinical research (DOCR)
- Office of Audit, Risk, and Compliance (OARC)
- Office of Research Administration
- Office of Research Support
- Clinical Research Units/Departments/Principal Investigators

Examples of Recent Changes

- New approach to intellectual property (IP) terms - Private Business Use (~40 new projects since Jan 2023 @ >$27M)
- Confidentiality
  - Expanded terms (3 years, 5 years, 7 years, 10 years)
  - No requirement for marking information as confidential
  - Long term confidentiality allowed if not required for research
  - Extended period in CDAs (tied to subsequent study even if Duke doesn't participate)
- Publications
  - Acceptance of deletion of confidential information from publications under certain circumstances
  - Publication delays
    - For multi-center studies (12-24 months from end of study)
    - For review and IP protection (up to 120 days)

ORC Negotiation Time - SRAs

Executed Sept – Nov 2025

Negotiation Time	# of Agreements	% of Total	Cumulative %
≤ 2 weeks	103	60%	
≤ 3 weeks	13	7%	67%
≤ 4 weeks	9	5%	72%
≤ 60 days	21	12%	84%
≤ 90 days	16	9%	93%
>90 days	10	6%	
Total SRAs	**172**		
Average time	**24.5 days**		

Panel Discussion

Thank You!