DUKE UNIVERSITY

Project Tracker for Institutional Approval

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OVERVIEW

Problem

The Clinical Trial Institutional Approval process is complex, involving numerous offices, overlapping workflows, and multiple different systems.

Overall Aims & Scope

- Provide transparency into Duke's process

- Reduce timelines in main three areas of startup:

    ▪ IRB approval

    ▪ Contract execution

    ▪ Billing/Calendar setup

- Focus initially on industry-funded clinical trials, but plan to expand in the future

Methods

Partnered process owners, investigators, research teams, and IT developers through a series of focus groups and working sessions during discovery and development.

DISCOVERY

Audience

Engagement with Clinical Research Study Teams and Research Administrators revealed common needs with a slightly different scope:

SIMILARITIES

- Hindered by data captured across multiple systems.
- Limited understanding of the entire process.
- Absence of reliable, widely accessible indicators for delays or outstanding requirements.

DIFFERENCES

- Study Teams interested in the progress of individual projects.
- Research Administrators needed an aggregate view of start-up metrics across a unit over time.

IMPLEMENTATION

Solution

Project Tracker system accessible via Duke's myRESEARCHhome portal comprised of 2 main components:

Tableau Metrics Dashboard
- Retrospective view of data across units
- Primarily for Research Administrators

Project Status Tracker
- Status information for a project awaiting approval
- Primarily for Study Teams

Both tools leverage the same defined milestones, mapped application variables, and combined data source. Study Teams and Research Administrators can access both tools.

TABLEAU METRICS DASHBOARD

Consolidate retrospective data from multiple systems

Visualize milestone time to completion across a unit

Indicate areas of delay for strategic response

Specialty Committee Trends for Institutionally Approved Protocols
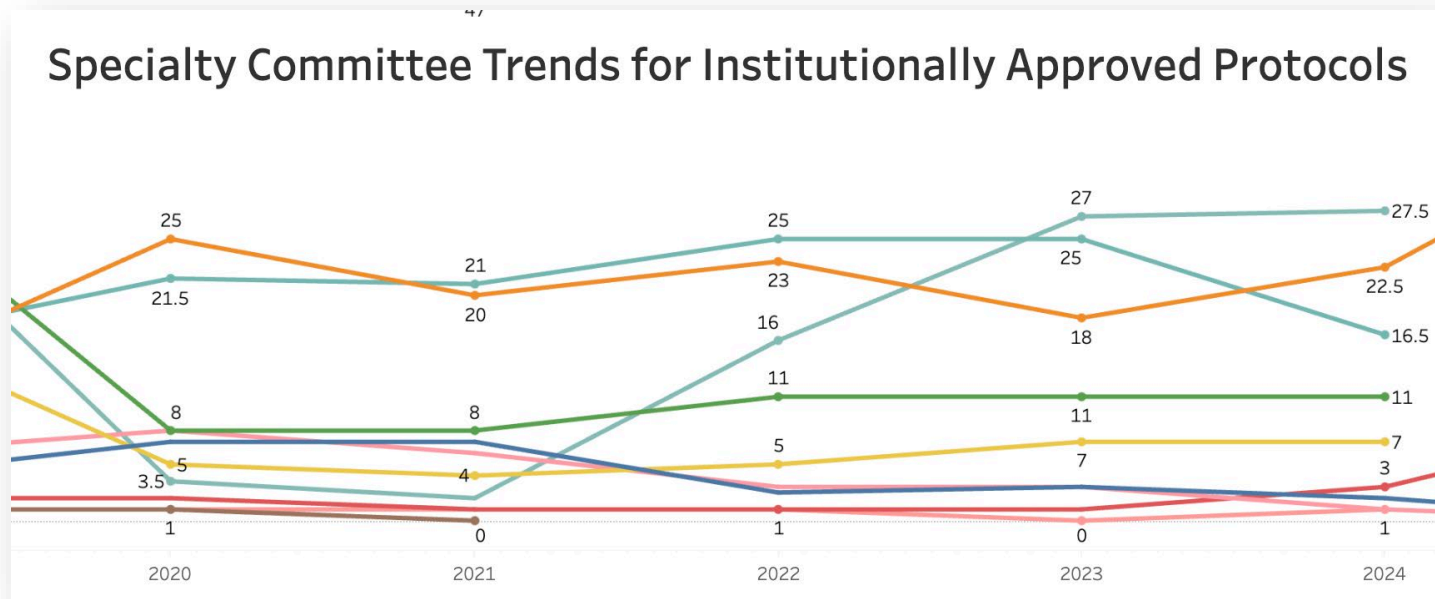
Awaiting Institutional Approval

Percent of Studies waiting for Institutional Approval
- 60 Days or Less
- 61 to 85 Days
- 86 to 120 Days
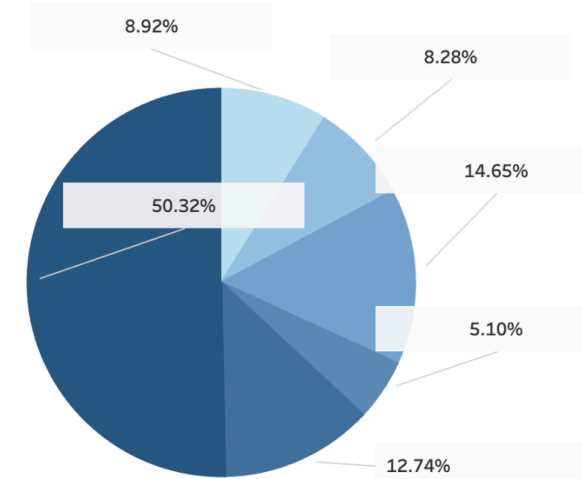- 121 to 150 Days
- 151 to 180 Days
- Over 180 Days

8.92% 8.28% 14.65% 50.32% 5.10% 12.74%

TABLEAU METRICS DASHBOARD

Consolidate retrospective data from multiple systems

Visualize milestone time to completion across a unit

Indicate areas of delay for strategic response

Institutionally Approved Studies by Fiscal Year

270

Fiscal Year	CRU/Primary Management Group	Oncore Financials
FY 2024	(All)	Yes

Quarter	Division	Investigator Initiated
(All)	(All)	(All)

Month		
(All)		

Click here to report an issue or suggest an enhancement

Approved Within 120 Days	Median Days for Approval	Minimum Days for Approval	Maximum Days for Approval
7.04%	267	37	1,202

Institutional Approval — FY 2024

- 90 Days or Less
- 91 to 120 Days
- 121 to 150 Days
- 151 to 180 Days
- Over 180 Days — 208

	OnCore Range	OnCore Median	OnCore 90 Day Target		iRIS Range	iRIS Median	iRIS 90 Day Target		Innovate Range	Innovate Median	Innovate 90 Day Target
Step 1: Protocol Synced	0 - 432	0	0								
Step 2: Draft Sponsor Budget Submitted	-32 - 544	12	7	Step 1: Submitted in iRIS	0 - 683	71	7	Step 1: Agreement Intake	-8 - 517	27	0
Step 3: Schedule Study Initiation Meeting	-19 - 123	1	1								
Step 4: Calendar Creation	88 - 40	12	7								

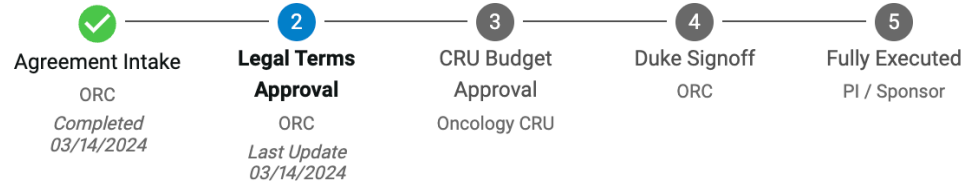**Duke** Clinical & Translational Science Institute

PROJECT STATUS TRACKER

Consolidate status info from multiple systems

Visualize the current status of my project
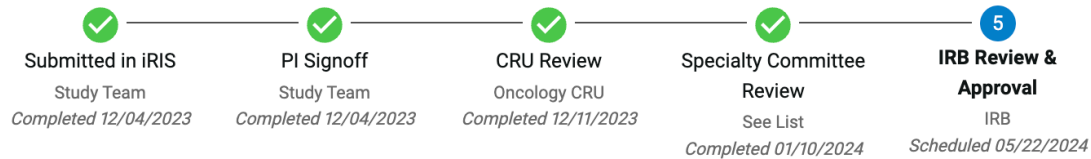
Indicate steps requiring study team action

CONTRACTS (INNOVATE)

✓ Agreement Intake — ORC — Completed 03/14/2024

2 **Legal Terms Approval** — ORC — Last Update 03/14/2024

3 CRU Budget Approval — Oncology CRU

4 Duke Signoff — ORC

5 Fully Executed — PI / Sponsor

BUDGET / CALENDAR (ONCORE)

✓ Protocol Synced — Study Team — Completed 05/18/2022

✓ Draft Budget Submitted — Study Team — Completed 08/16/2022

✓ Schedule Study Initiation Meeting — Study Team — Completed 08/16/2022

✓ Calendar Creation — DOCR — Completed 08/30/2022

✓ Study Initation Meeting — Study Team / DOCR — Completed 08/30/2022

❗ **PI / CRC Calendar Approval** — Study Team — Last Update 08/30/2022

7 Calendar Finalized — DOCR

8 CRU Budget Signoff — Heart Center CRU

9 SOM Finance Budget Signoff — SOM Finance

10 DOCR Calendar / Budget Signoff — DOCR

IRB PROTOCOL (IRIS)

✓ Submitted in iRIS — Study Team — Completed 12/04/2023

✓ PI Signoff — Study Team — Completed 12/04/2023

✓ CRU Review — Oncology CRU — Completed 12/11/2023

✓ Specialty Committee Review — See List — Completed 01/10/2024

5 **IRB Review & Approval** — IRB — Scheduled 05/22/2024

SPECIALTY COMMITTEES

✓ Pathology — Completed 01/08/2024

✓ Pregnancy — Completed 01/10/2024

✓ Protocol Review and Monitoring Committee — Completed 01/08/2024

How did we find this info before?

1. Contract System   3 steps
2. CTMS (Budget/Cal.)   6 steps
3. IRB System   5 steps

14 total steps across 3 systems + emails between 3-4 people