The Office of Clinical Research (OCR)

Ashlee Lang, MPH, Director

UNIVERSITY of ROCHESTER MEDICAL CENTER | CTSI CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

Agenda

- **OCR Overview**
  - OnCore
  - Feasibility
  - Research Finance
  - Payments
- **The Next 6 Months**
  - Communications
  - Working Groups
  - Start Up Manual
  - The Next 6 Months

OCR: Who We Are

Director: Ashlee Lang

Administrative Assistant: Karen Ely

CTMS Team: James Delmonico, Deborah Lamay, Gary Morton (Oncology)

Training Team: Meredith Perrin

Finance Team: Rebecca Dennis, Megan Wutzke, Erica Longbine and Josh Cook (Participant Payments)

Feasibility Team: Caledonia Banker

OCR: What We Do

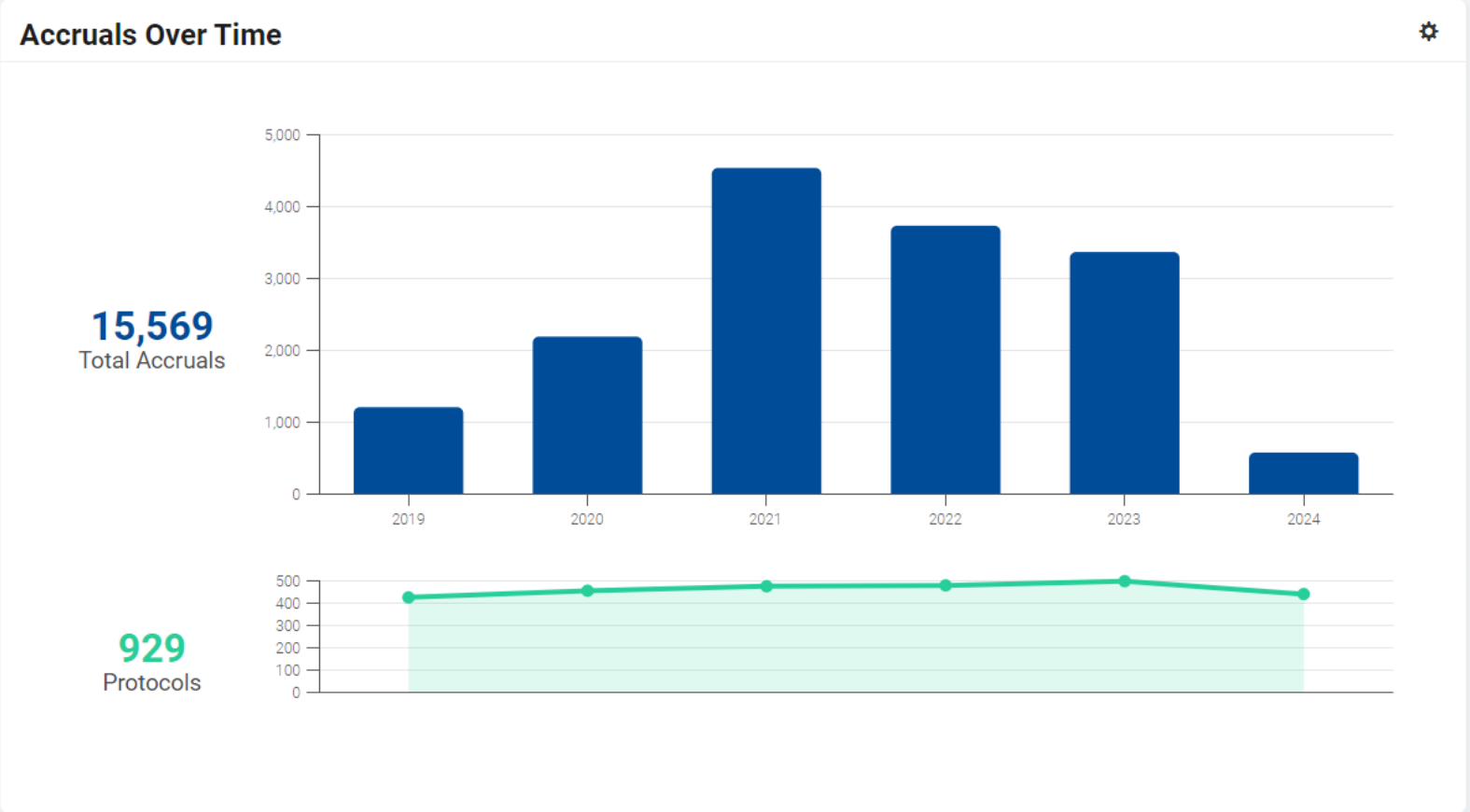
The OCR provides tools and services to help URMC faculty and staff with the administration of clinical trials. By streamlining the processes behind clinical research, we empower our clinical research teams to do more high-impact clinical trials that can advance clinical discovery and offer patients and community members more options and opportunities. We also make it easier for researchers to comply with clinical trial rules and regulations and produce successful outcomes.

Our 4 primary areas of focus include:

- OnCore
- Feasibility
- Research Finance
- Participant Payments

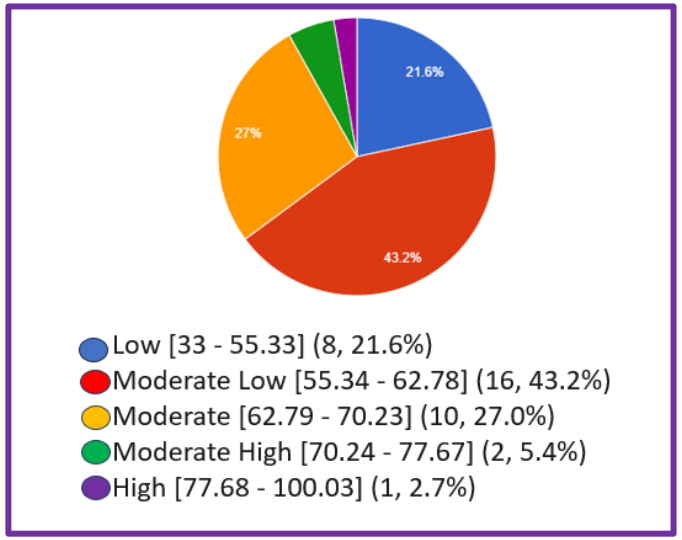
OnCore

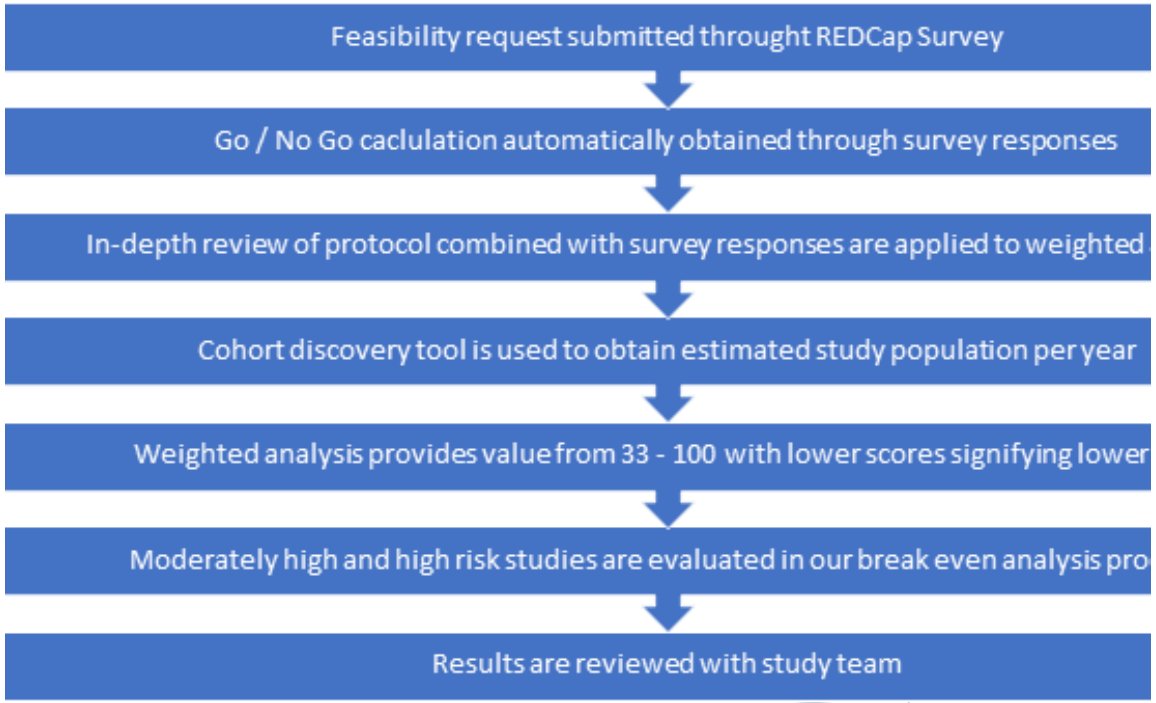
- Phase 1 was initiated in 2018 offering URMC researchers the option to use OnCore to support
- Phase 2 will be implemented over the next 18 months to roll out an institutional policy with tiered requirements for OnCore use



Feasibility

- Our team helps assess the feasibility of proposed clinical studies and develop meaningful metrics to help guide how URMC study teams manage clinical studies
  - Assist with completion of feasibility surveys
  - Tailored feasibility and breakeven analysis
  - Cohort discovery with TriNetX and Slicer-Dicer (Epic)
  - As of May 2023, feasibility analysis is performed on all studies using OCR pre-award finance services



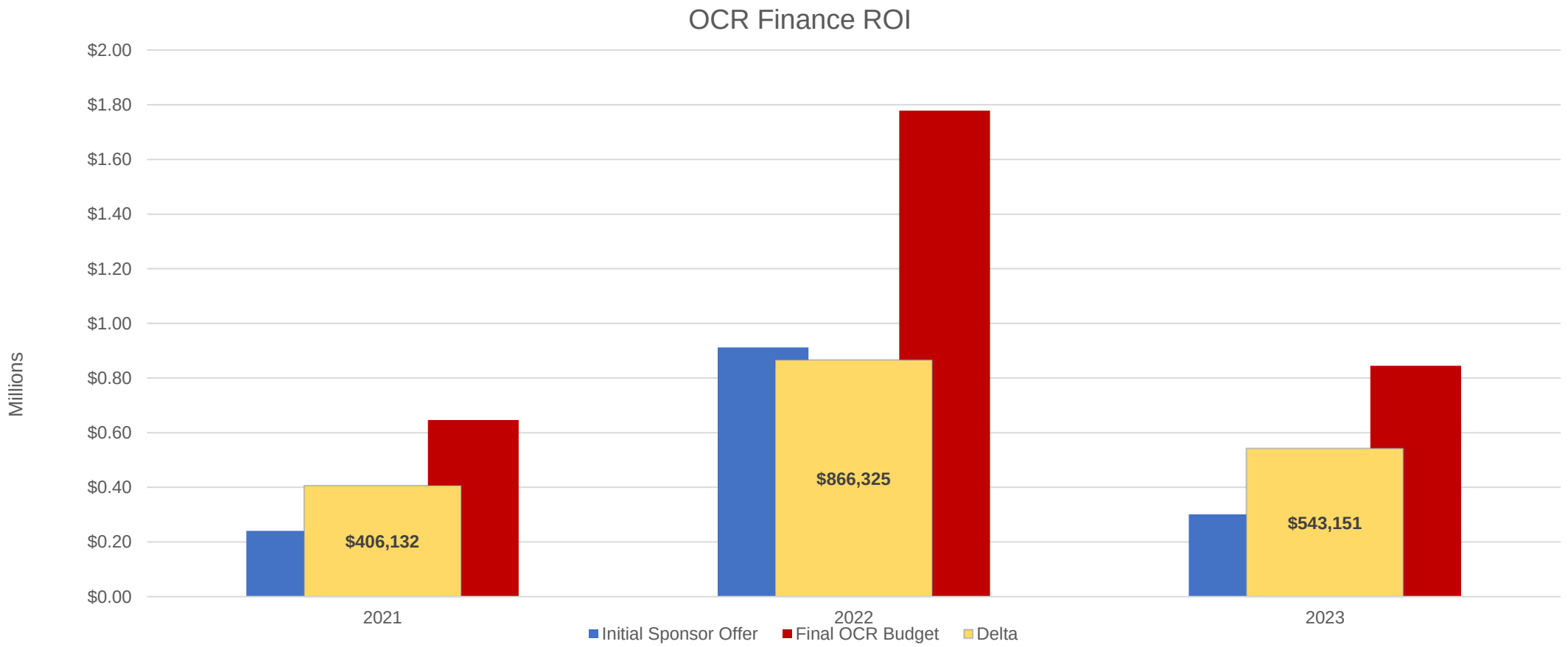


Research Finance

- Pre-Award Services: Medicaid/Medicare coverage, analyze the study cost and timeline, negotiate budgets with sponsors, and enter budget information into OnCore.
- Post-Award Services: Invoicing, revenue reconciliation, review of subject accounts, Participant Payments, and more.

Becky Dennis	Megan Wutzke	Erica Longbine
DER	NSY	PED
Nephrology	NEU	URO
ONC	OPH	PUL
OTO	AIR	ORT
SON	PSY	RAD
PHS	CAR	IDD
ANE	SUR	GEH
OBG		
SUR/Cancer Control		
NSC		

Research Finance



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Participant Payments

Participant Payments is a safe, secure automated system that helps immediately pay subjects after each clinical study visit.

Integrated with OnCore, Participant Payments eliminates manual and inefficient processes, so research teams can spend less time on administrative tasks and focus on patient care.

Reloadable Payment Card

- OCR will have cards on hand
- Only Name and DOB required
- Leave with payment in hand

Checking Account
(Direct Deposit / Paper Check)

- Participant enters in banking info
- Only Name, DOB and email required
- Payments received within 3 days

Managed by the CTSI Office of Clinical Research (OCR)
Email **Clinical_Research@URMC.Rochester.edu** for information

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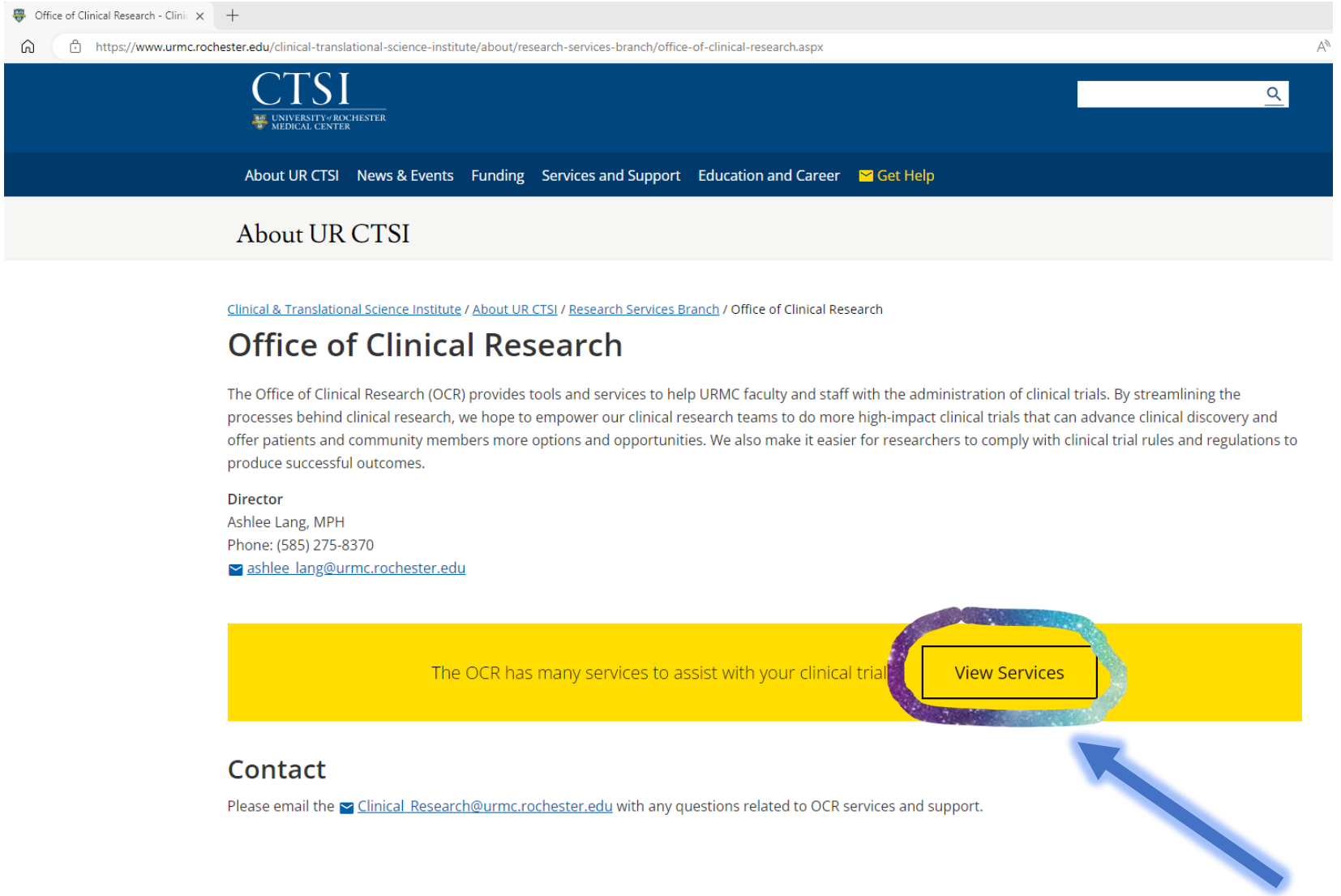
Participant Payments - Continued

Advarra Participant Payments is the preferred payment method for the University of Rochester for all participants enrolled in clinical trials except

- Non-resident aliens (NRA) who will need to have a separate Sprintax account set up through Accounts Payable
  - P2P-Study-Participant-Payment-Reference-Guide.docx (live.com)
- Minors under the age of 18 who cannot be paid through the system directly and instead will have payment applied to a Guardian, typically a parent;

How Do You Access OCR Services?

- [Office of Clinical Research - Clinical Research - UR Clinical & Translational Science Institute - University of Rochester Medical Center]



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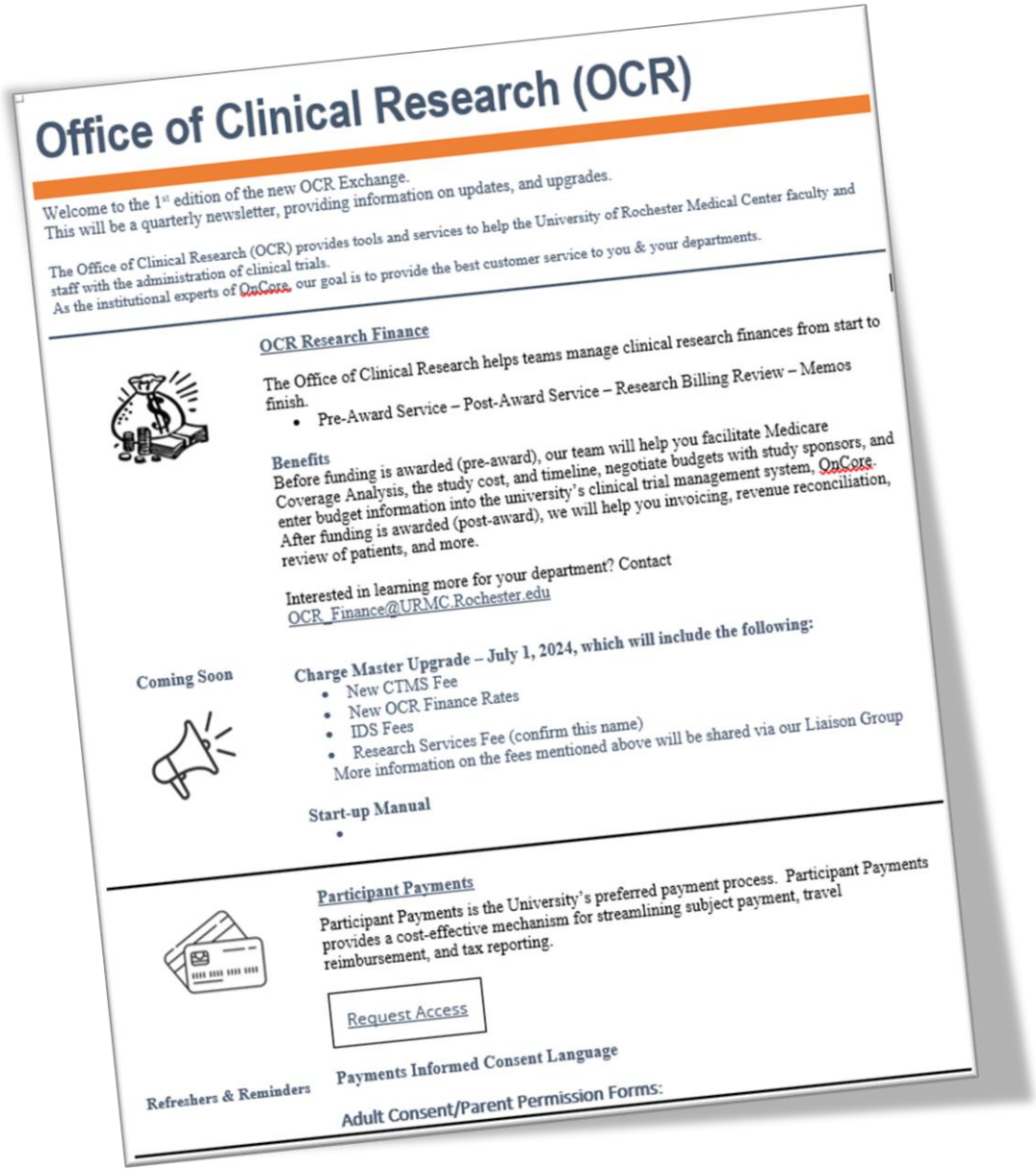
Communications

The OCR Exchange

- Quarterly Email Newsletter
  - News
  - Updates
  - Refreshers / Reminders
  - Coming Up Next …



Office of Clinical Research (OCR)

Welcome to the 1st edition of the new OCR Exchange.
This will be a quarterly newsletter, providing information on updates, and upgrades.

The Office of Clinical Research (OCR) provides tools and services to help the University of Rochester Medical Center faculty and staff with the administration of clinical trials.
As the institutional experts of OnCore, our goal is to provide the best customer service to you & your departments.

OCR Research Finance

The Office of Clinical Research helps teams manage clinical research finances from start to finish.

- Pre-Award Service – Post-Award Service – Research Billing Review – Memos

Benefits
Before funding is awarded (pre-award), our team will help you facilitate Medicare Coverage Analysis, the study cost, and timeline, negotiate budgets with study sponsors, and enter budget information into the university's clinical trial management system, OnCore.
After funding is awarded (post-award), we will help you invoicing, revenue reconciliation, review of patients, and more.

Interested in learning more for your department? Contact
OCR_Finance@URMC.Rochester.edu

Coming Soon

Charge Master Upgrade – July 1, 2024, which will include the following:

- New CTMS Fee
- New OCR Finance Rates
- IDS Fees
- Research Services Fee (confirm this name)

More information on the fees mentioned above will be shared via our Liaison Group

Start-up Manual

Participant Payments

Participant Payments is the University's preferred payment process. Participant Payments provides a cost-effective mechanism for streamlining subject payment, travel reimbursement, and tax reporting.

Request Access

Refreshers & Reminders

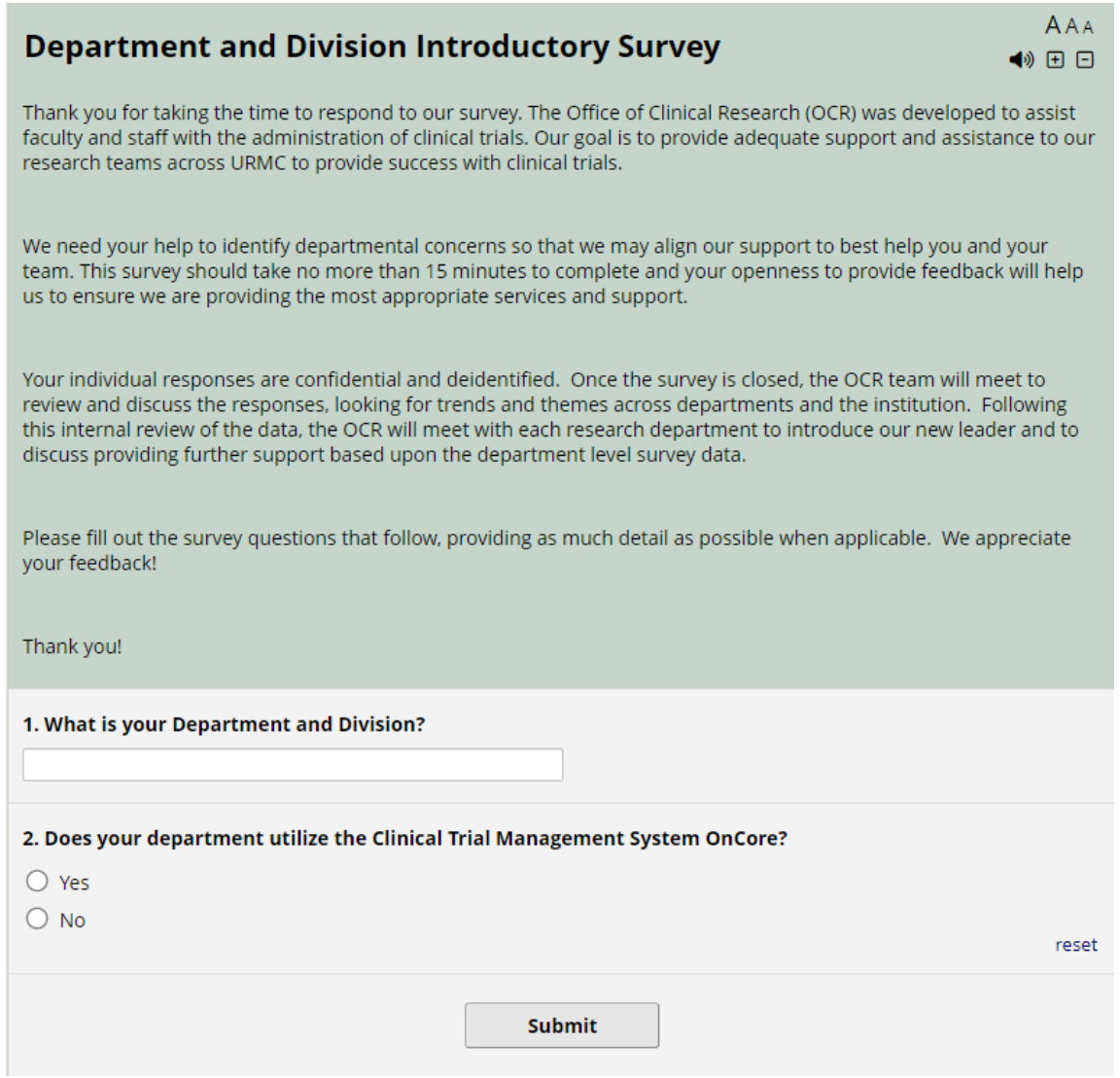
Payments Informed Consent Language

Adult Consent/Parent Permission Forms:

Communications

Introductory Survey

- Survey sent to all OnCore users and all Research Liaisons News (April 12th – March 12th)
  - 115 responses
- Next Steps:
  - Review data by Institution/URMC as a whole and by department/division for themes and trends
  - Set up meetings with each department/division to discuss the responses and establish path forward for full OnCore Usage



Department and Division Introductory Survey

AAA

Thank you for taking the time to respond to our survey. The Office of Clinical Research (OCR) was developed to assist faculty and staff with the administration of clinical trials. Our goal is to provide adequate support and assistance to our research teams across URMC to provide success with clinical trials.

We need your help to identify departmental concerns so that we may align our support to best help you and your team. This survey should take no more than 15 minutes to complete and your openness to provide feedback will help us to ensure we are providing the most appropriate services and support.

Your individual responses are confidential and deidentified. Once the survey is closed, the OCR team will meet to review and discuss the responses, looking for trends and themes across departments and the institution. Following this internal review of the data, the OCR will meet with each research department to introduce our new leader and to discuss providing further support based upon the department level survey data.

Please fill out the survey questions that follow, providing as much detail as possible when applicable. We appreciate your feedback!

Thank you!

1. What is your Department and Division?

2. Does your department utilize the Clinical Trial Management System OnCore?

Yes

No

reset

Submit

OCR Working Groups

Start Up Manual Working Group	Start Up Manual complete and published
Charge Master Working Group	Scheduled to begin in May 2024
Amendment Working Group	Scheduled to begin in September 2024
Feasibility Working Group	Next meeting scheduled July 2024

Start Up Manual

Resources

The OCR maintains a set of resources related to key aspects of clinical trials that departments involved in clinical trials can utilize. URMC research coordinators, administrators, and faculty can access and download tip sheets, memos, directions, and other important documentation to help them with various stages and aspects of clinical trials.

URMC Clinical Research Study Start-Up Manual

The purpose of the URMC Clinical Research Study Start-Up Manual is to review best practices concerning Study Start-Up within the University of Rochester (UR) and is to be used as an overall guideline for individuals within Study Teams to use as applicable.

Download the URMC Clinical Research Study Start-Up Manual

Shared Information

Please note you must access these resources through Box.

Access OCR Shared Information

Study Participants

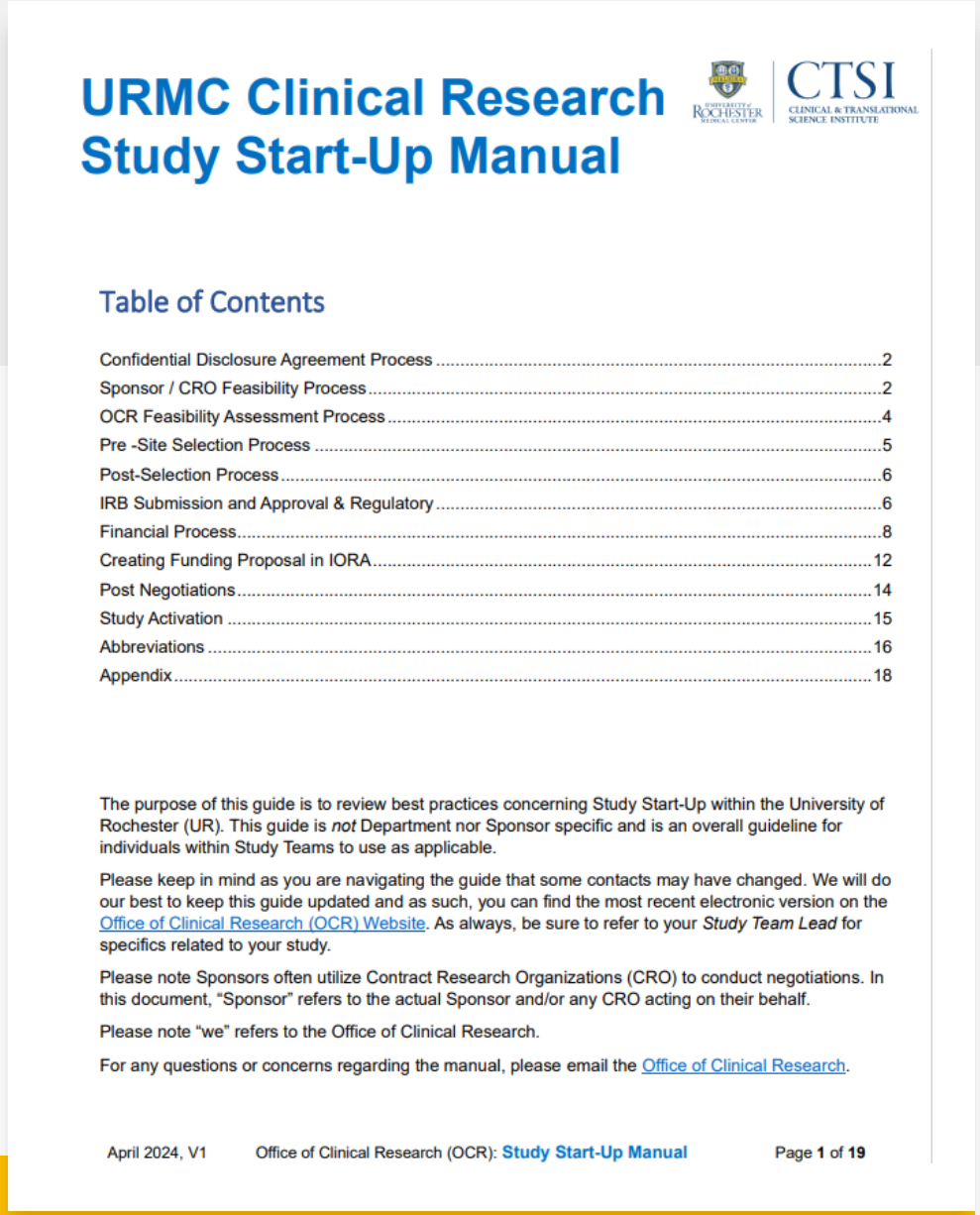
Potential study participants can learn more about health research and clinical trials at URMC.

Visit UR Health Research

Office for Human Subject Protection

The Office for Human Subject Protection (OHSP) supports the administration of the University of Rochester's Human Research Protection Program.

Visit OHSP



URMC Clinical Research Study Start-Up Manual

Table of Contents

The purpose of this guide is to review best practices concerning Study Start-Up within the University of Rochester (UR). This guide is *not* Department nor Sponsor specific and is an overall guideline for individuals within Study Teams to use as applicable.

Please keep in mind as you are navigating the guide that some contacts may have changed. We will do our best to keep this guide updated and as such, you can find the most recent electronic version on the Office of Clinical Research (OCR) Website. As always, be sure to refer to your *Study Team Lead* for specifics related to your study.

Please note Sponsors often utilize Contract Research Organizations (CRO) to conduct negotiations. In this document, "Sponsor" refers to the actual Sponsor and/or any CRO acting on their behalf.

Please note "we" refers to the Office of Clinical Research.

For any questions or concerns regarding the manual, please email the Office of Clinical Research.

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The Next 6 Months

- Update OnCore Demographic (SOGI) Mapping from eRecord
- eReg implementation
- Workday integration update
- OnCore Task Lists
- OnCore Notifications
- Charge Master Updates
- Amendment Manual
- OnCore Training Offerings Diversification
- Departmental Meetings

Thank you!

Office of Clinical Research:
clinical_research@urmc.rochester.edu