



# Rutgers Health Clinical Trials Office

**Translational Research Resources Workshop**

**10/25/2024**

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# Rutgers Health Clinical Trials Office

Enabled  
starting in  
2020  
through NJ  
ACTS



Focus on  
non-  
oncology  
clinical trials  
and studies  
with billing  
risk

Mission is to  
improve  
quality and  
efficiency of  
our clinical  
trials



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# Mission of the CTO

## Improve Efficiency

- Study Start-up processes
- Centralize/standardize key administrative functions (contract, budget, coverage analysis, etc.)
- Software solutions (OnCore)



## Improve Quality

- Mandatory feasibility Assessment
- Harmonization of processes
- Provide assistance with recruitment to assure targets are met
- Assure billing compliance



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# Services provided through the CTO for Rutgers Health studies with billable clinical procedures

## Mandatory

- **Feasibility assessment** (including use of Deep 6 AI Cohort Builder where available/appropriate)
- **CDA & Clinical trial agreement negotiation** (Industry trials only)
- **Budget review** (Industry trials only)
- **Medicare Coverage Analysis**
- **Study Build in OnCore**

## Optional

- Facilitation of **Partner Hospital** agreements/approvals (UH-Newark)
- **Budget negotiation** (Industry trials only)
- Post-Award Financial Management



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# Point of Clarification

- **Mandatory** aspects of CTO services (i.e. contract & budget negotiation/OnCore, etc.) apply to Rutgers Health non-oncology studies with **billable clinical procedures**
- However – CTO (and NJ ACTS) services & software systems are generally available to all Rutgers researchers as well as researchers from NJ ACTS-affiliated institutions



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# Technology Solutions managed by the CTO

- **OnCore** Clinical Trial Management System & **eReg** electronic binder system



- **Deep 6 AI Cohort Builder**



- **Greenphire's ClinCard**



- **FDA Part 11 Compliant DocuSign**



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# What is OnCore?



- Web-based clinical trial management system
- Mandatory part of workflow for any RH study with billable clinical procedures
- CTO team builds a profile for each new study
- Each participant will be enrolled in the system and associated with the study schedule of events
- Interfaces with Epic for the purposes of billing compliance



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# Deep6 AI Cohort Builder

DEEP 6 AI

- AI-based software tool designed for clinical trial feasibility and recruitment
- Searches structured & unstructured data in the EMR
- Live at all RWJBH locations
- Interface with UH-Newark's Epic is pending



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# Deep6 AI Cohort Builder



- **Prior to IRB submission:** No cost for a feasibility assessment (de-identified report provided)
- **Following IRB approval:** Used to generate a cohort of potentially eligible patients with names and hyperlink to relevant information in the patient's chart. Once built, can be continually refreshed. Incurs a cost of \$2500 (generally passed off to study sponsor)

See NJACTS/CTO website to request a report via Deep6

Home / Clinical Trials Office / DEEP6

CLINICAL TRIALS OFFICE

- Clinical Research Units
- ClinCard
- DEEP6**
- OnCore

### DEEP6

Deep6 AI Cohort Builder is an artificial intelligence tool available to RBHS researchers to assist in feasibility assessment as well as finding participants for clinical trials. Using artificial intelligence and EMR data sources, Deep6 AI Cohort Builder enables the Clinical Trials Office to help you find potential participants in minutes.

Request a Feasibility Assessment (prior to IRB submission)

Identify Potential Study Participants (with IRB approval)

Costs

[See How DEEP6 Works - Watch a Video Here](#)



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# ClinCard



- Electronic debit-card system for research subject payments or reimbursements
- Virtual cards/Lyft integration now available
- Fees incurred (for cards & each time a payment is authorized)
- <https://njacts.rbhs.rutgers.edu/clinical-trials-office/clincard/>



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# Additional Resources

CTO serves as a central point of contact for external sponsors of research wanting to place a clinical study at Rutgers



Database of Investigators and their areas of expertise



Social Media Recruitment Expertise



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<https://njacts.rbhs.rutgers.edu/clinical-trials-office/>



New Jersey Alliance for Clinical and Translational Science

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# Additional Recruitment Resources



Make a positive  
impact by  
volunteering for  
research

Join Now!

## What is ResearchMatch?

ResearchMatch is a nonprofit program funded by the National Institutes of Health (NIH). It helps to connect people interested in research studies with researchers from top medical centers across the U.S.

Get connected to research on many different health conditions - through ResearchMatch.

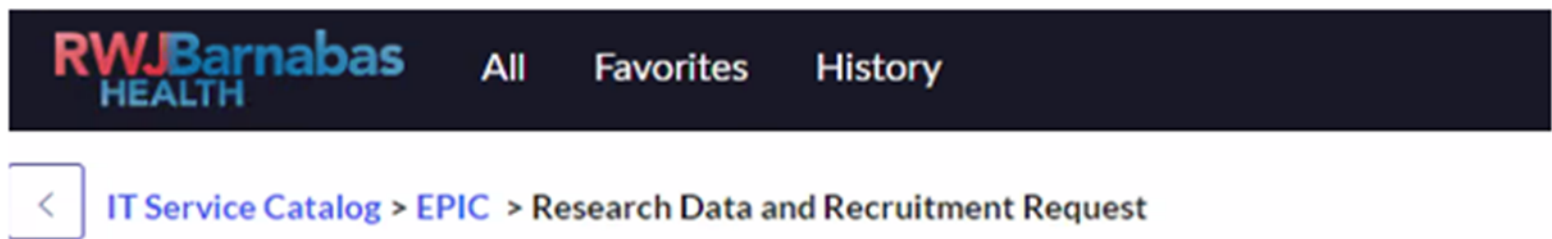


- <https://ritms.rutgers.edu/clinical-trials-resources/researchmatch/>

# RWJBH: Epic Slicer/Dicer & MyChart Recruitment messages

- IRB must approve proposed MyChart message
- “ServiceNow” request available within Epic

1. Navigate to [Research Data and Recruitment Request | RWJBarnabas Health, Inc. \(service-now.com\)](#) and fill out the request form.



# Thank you

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