WELCOME

Data Managers Interest Group (DMIG)

May 11, 2023

JHU Clinical Research Investigator Resources - Session #4

Research Support and Ethics

We will being promptly at 11:00 am

JOHNS HOPKINS
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Welcome to the DMIG Session #4

Agenda:

Moderator: Stephanie Swords, MS, CCRP

Title: JHU Clinical Research Investigator Resources

- **Research Ethics Consultation Service (RECS)** – (Alan Regenberg, MBE)
- **Clinicaltrials.gov (ct-gov)** – (Oswald Tetteh, MD, MPH)
- **Research Coordinator Support Services (RCSS)** – (Tony Keyes, MBA)

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Research Ethics Consult Service

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of BIOETHICS

History

- Free Service, launched in 2005
- Initially - School of Public Health
- Expanded in 2008
- Holly Taylor and Nancy Kass

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Examples:

- Informed Consent Process
- Enrollment of Vulnerable Participants
- Risk/Benefit Assessment
- Study Design

RECS Team









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RECS Training

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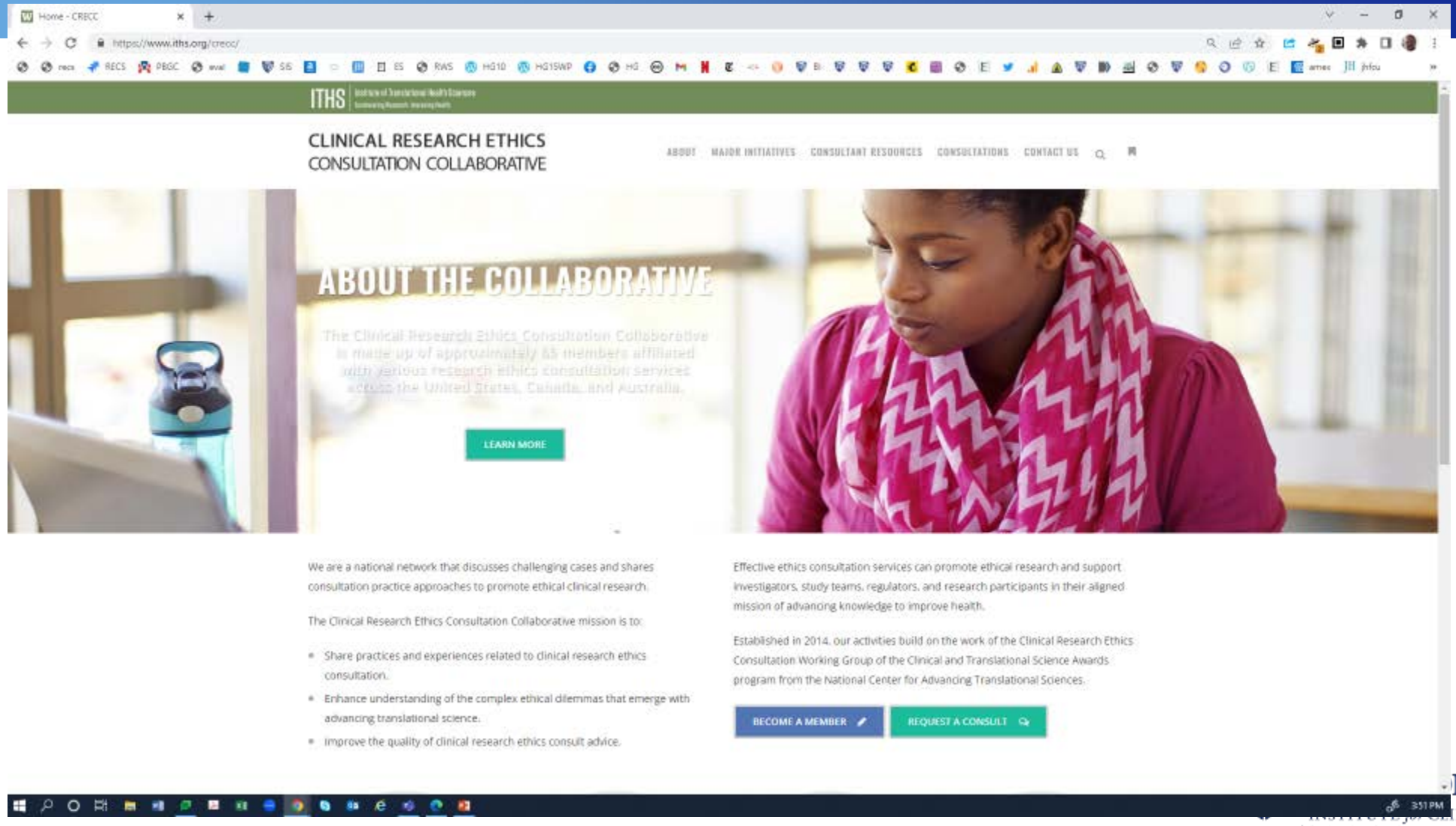

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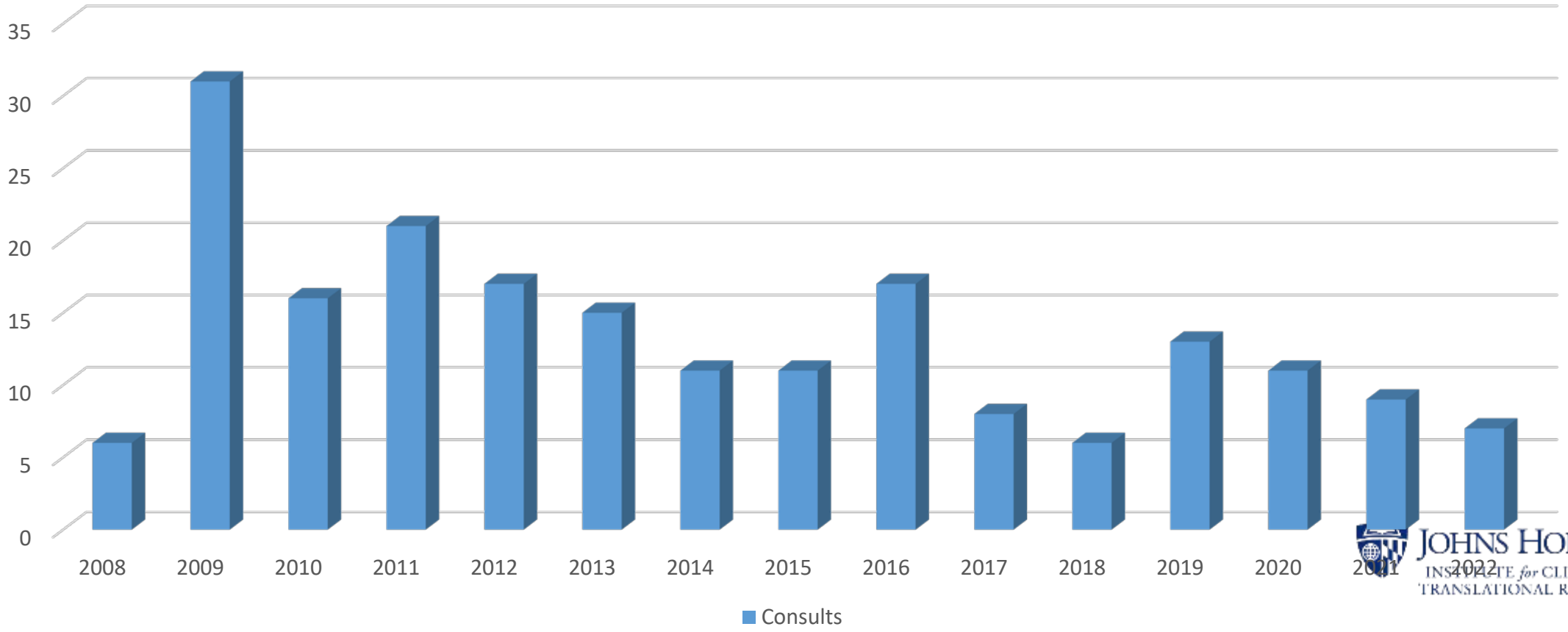
Number of Consult Requests Per Year

At Johns Hopkins (2008-22)



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CTS Clinical and Translational Science
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Clin Transl Sci. 2013 Feb; 6(1): 40–44
Published online 2012 Dec 6. doi: 10.1111/cts.12008

PMCID: PMC3573851
NIHMSID: NIHMS413799
PMID: 23399088

The Establishment of Research Ethics Consultation Services (RECS): An Emerging Research Resource

Jennifer B. McCormick, Ph.D., M.P.P.,[2,1] Richard R. Sharp, Ph.D.,[2] Abigale L. Ottenberg, M.A.,[3] Carson R. Reider, Ph.D.,[4] Holly A. Taylor, M.P.H., Ph.D.,[5] and Benjamin S. Wilfond, M.D.[6,7]

Demographic	2010 $n=35$ n/total (%)	2021 $n=43$ n/total (%)	p-value
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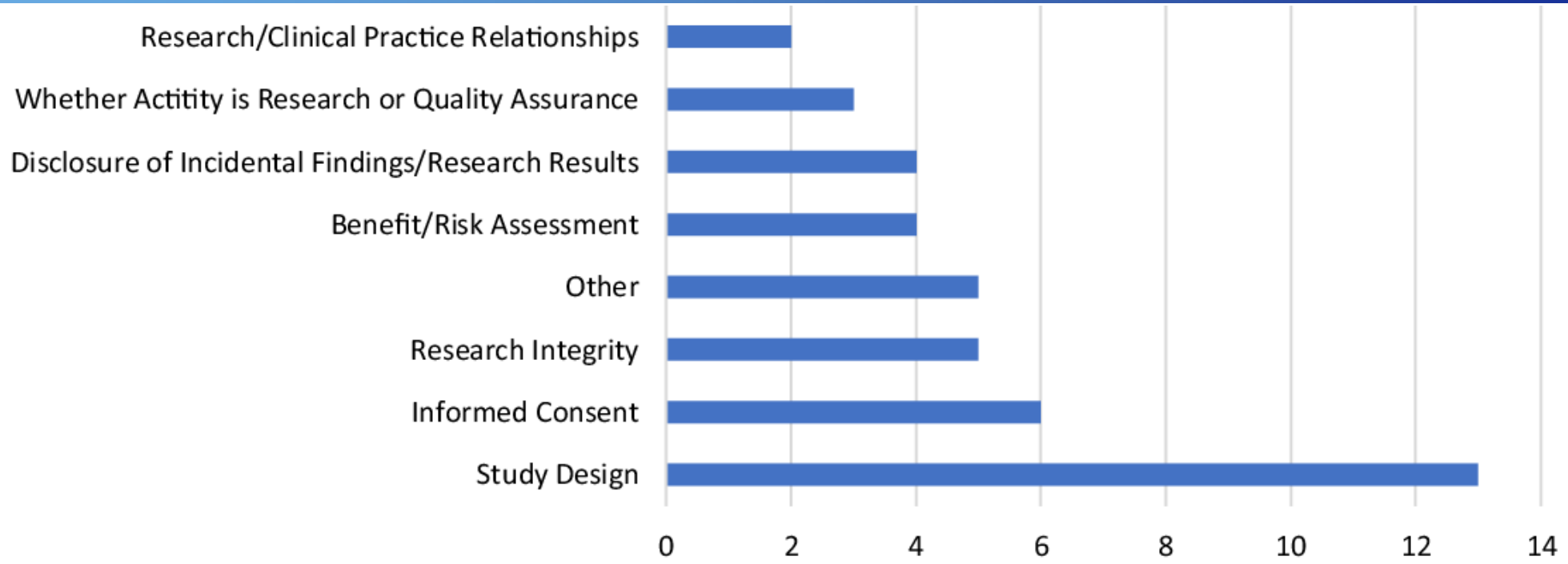
Most common ethical concerns:



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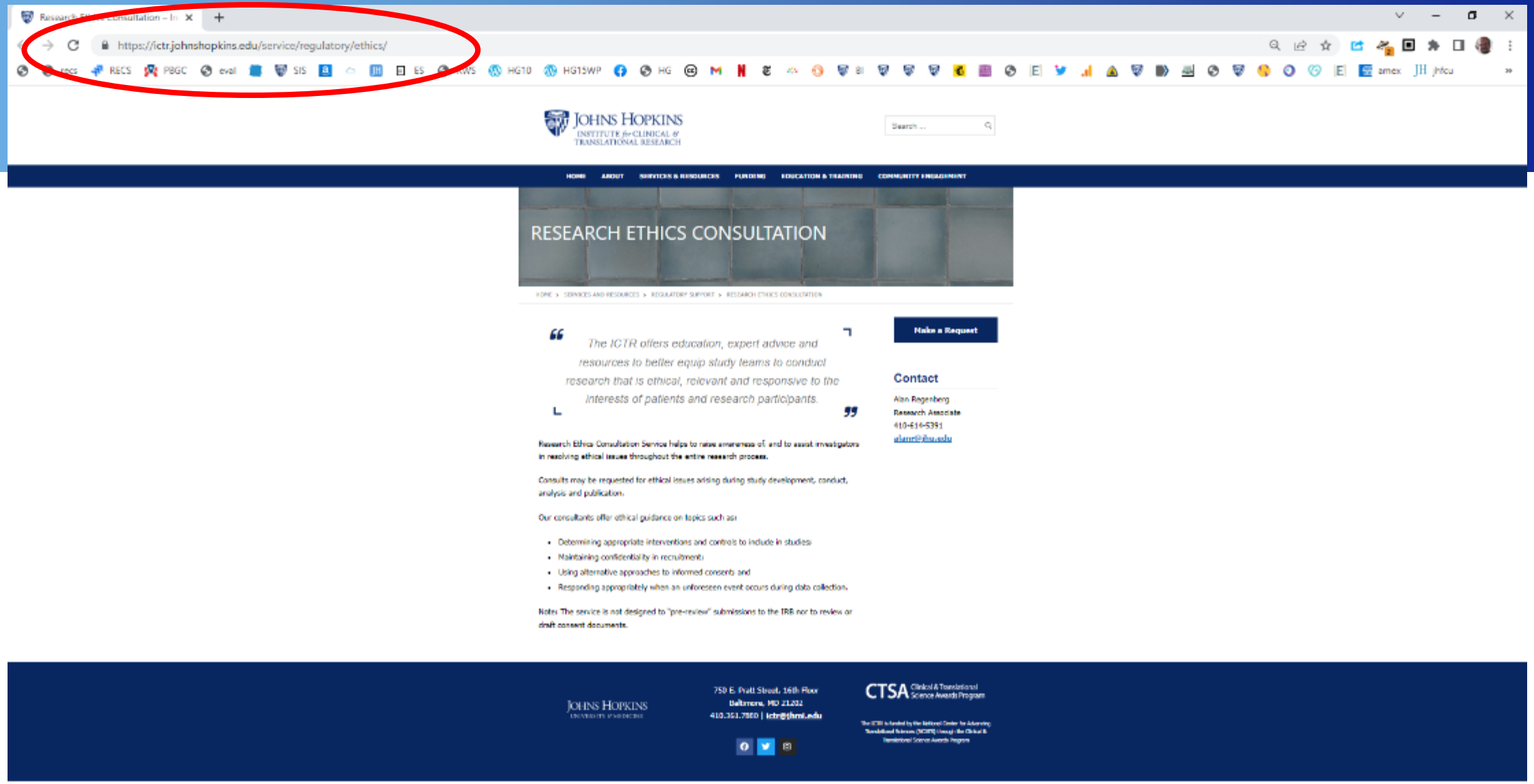

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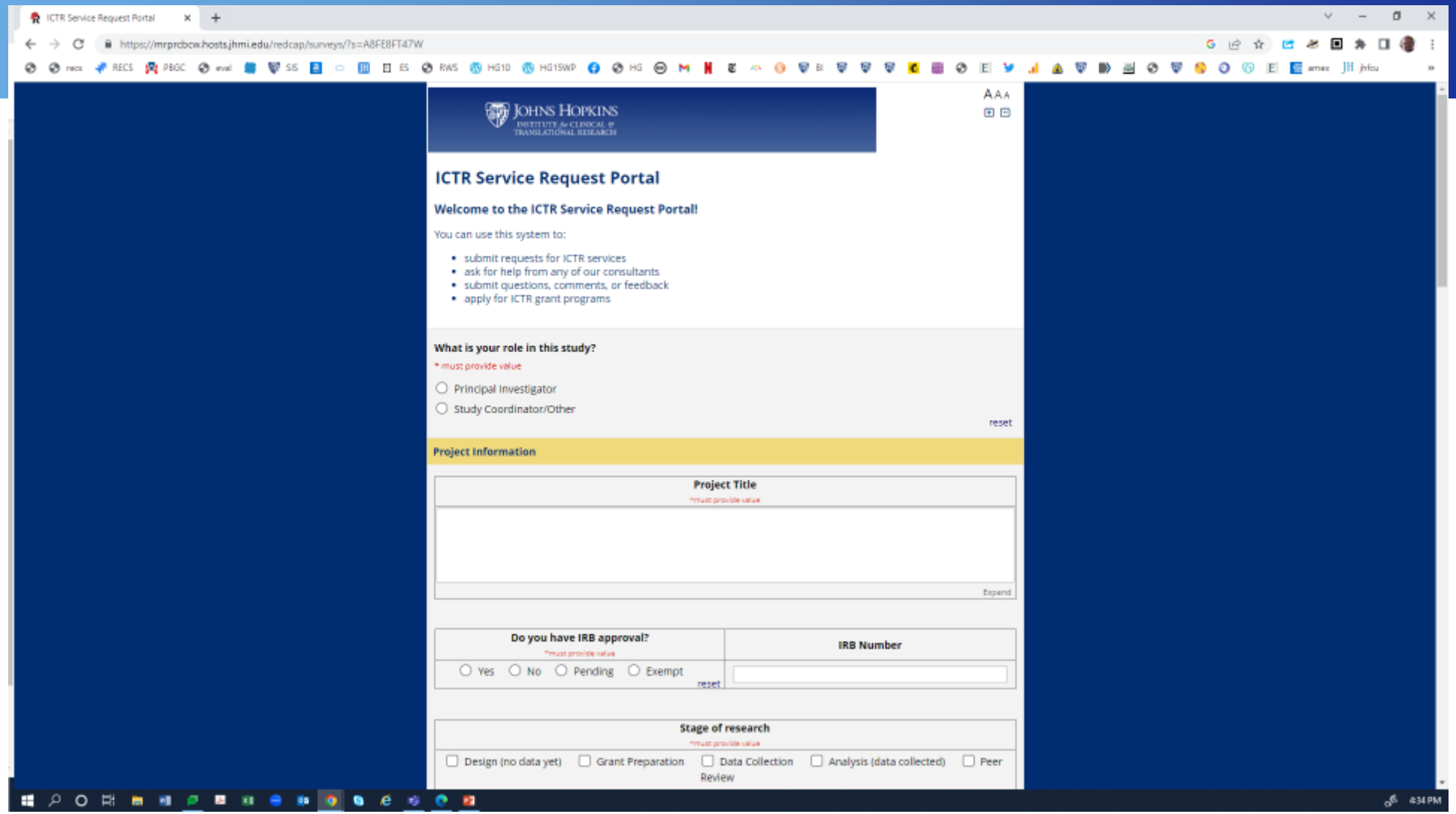

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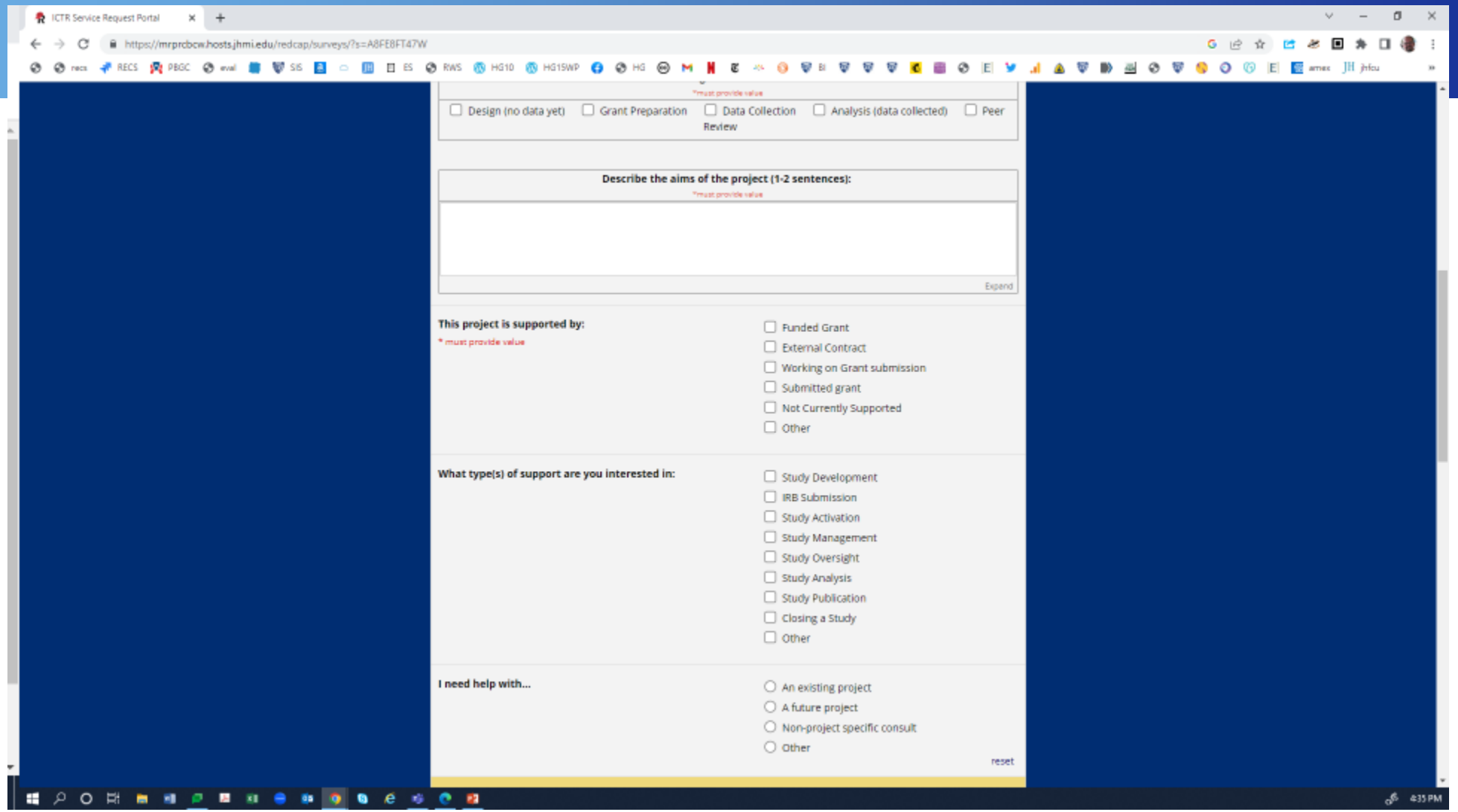

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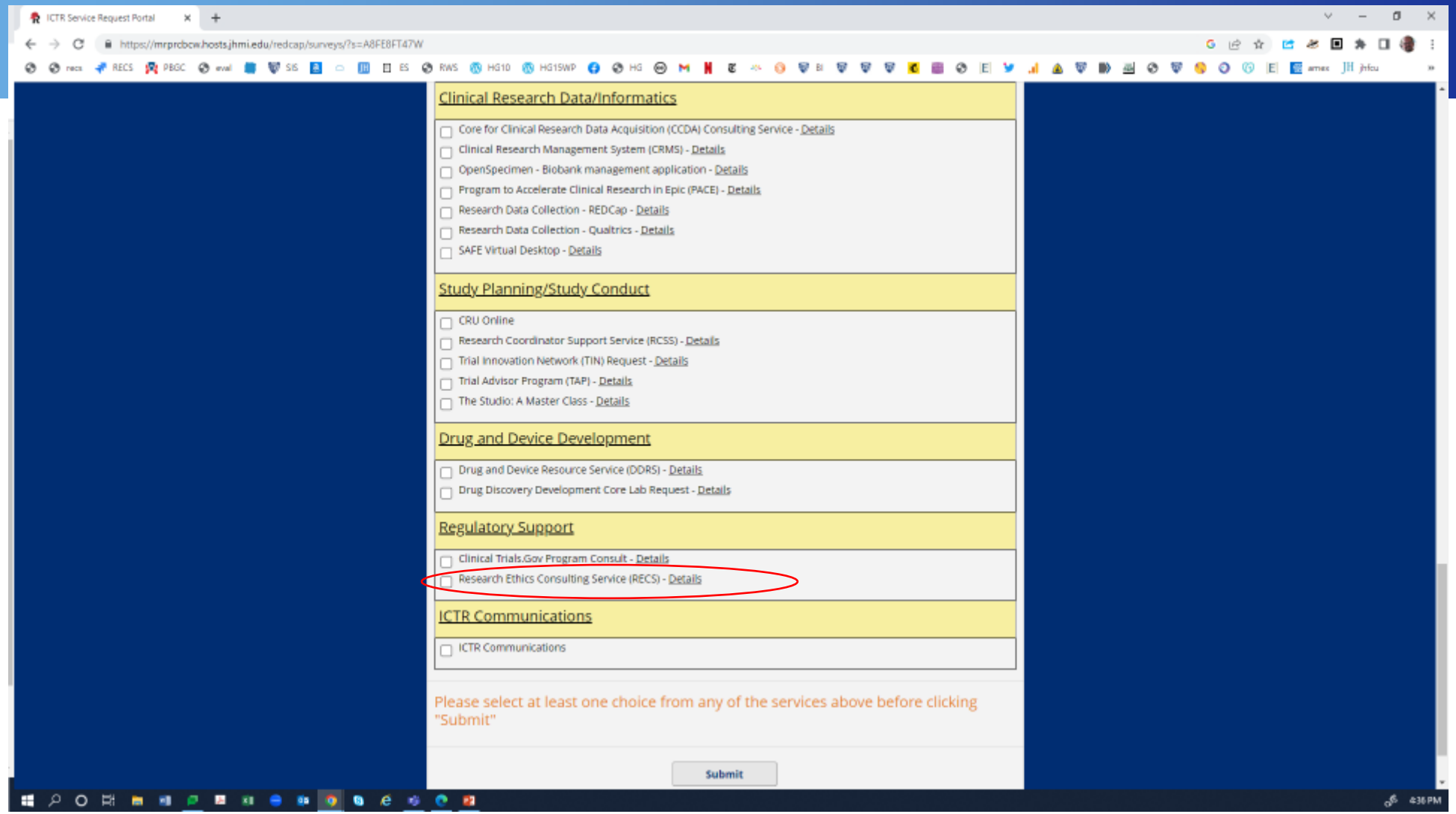

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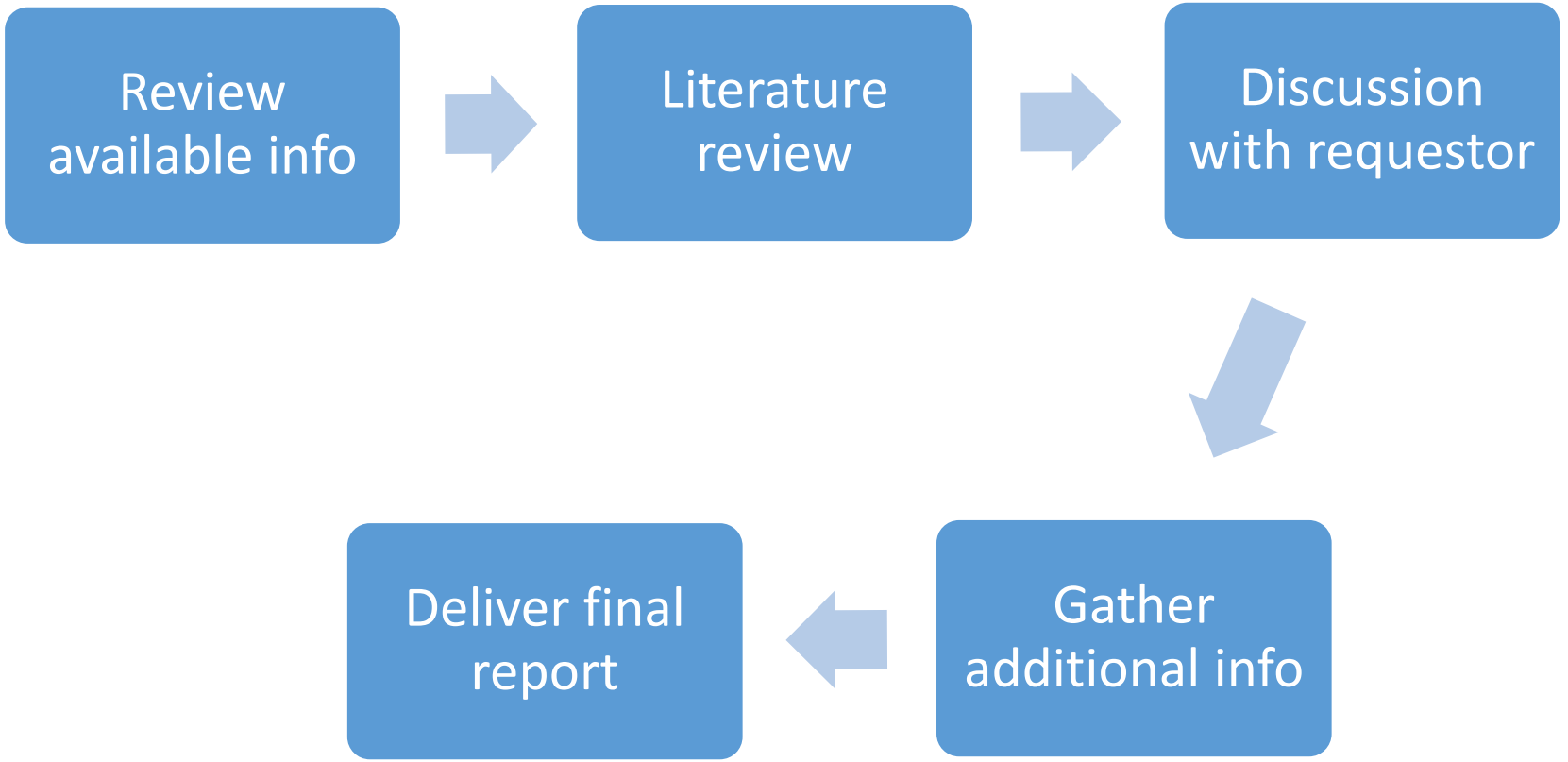
Consultation Process:



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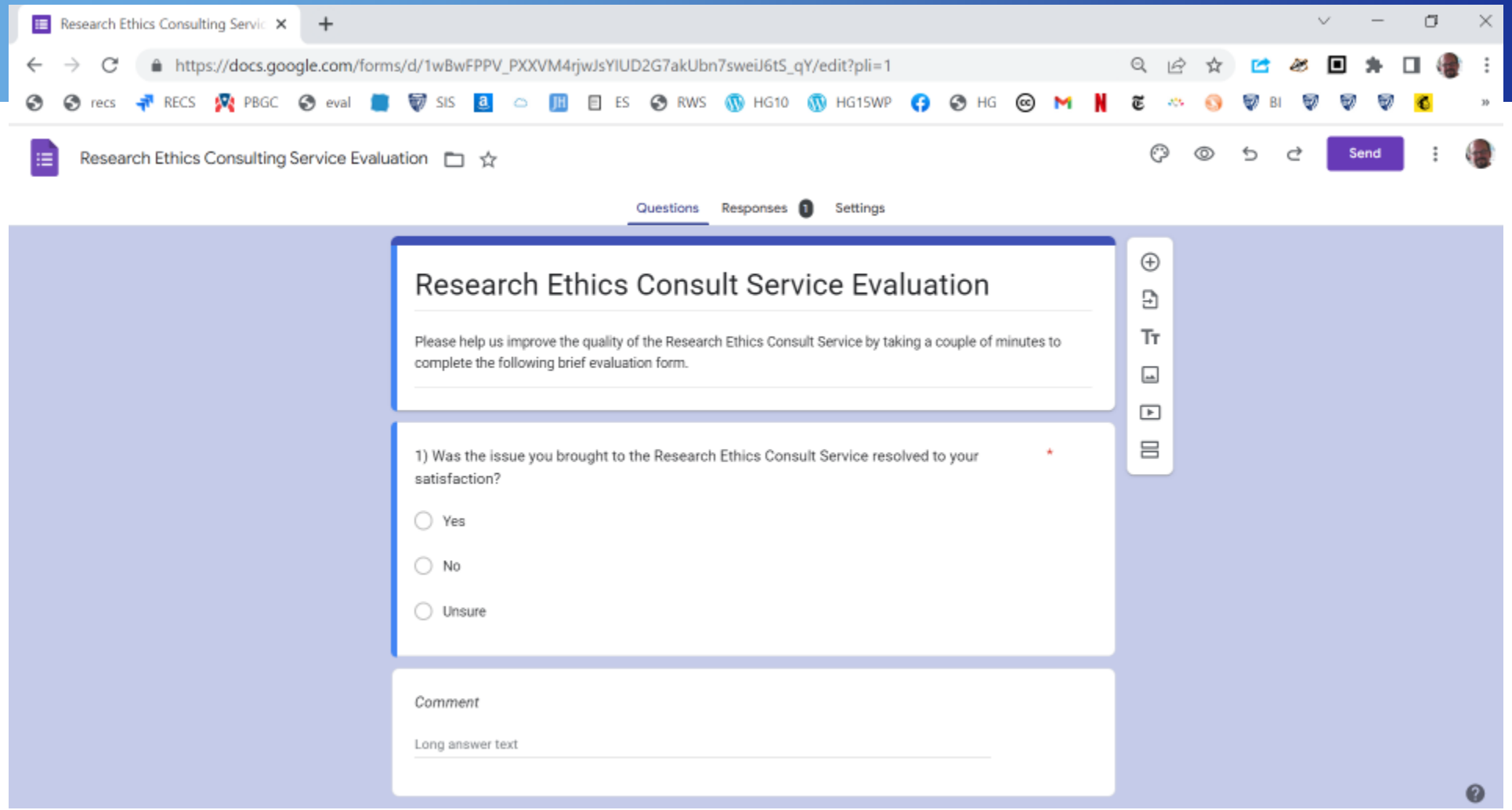

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Case:
Sham Surgery

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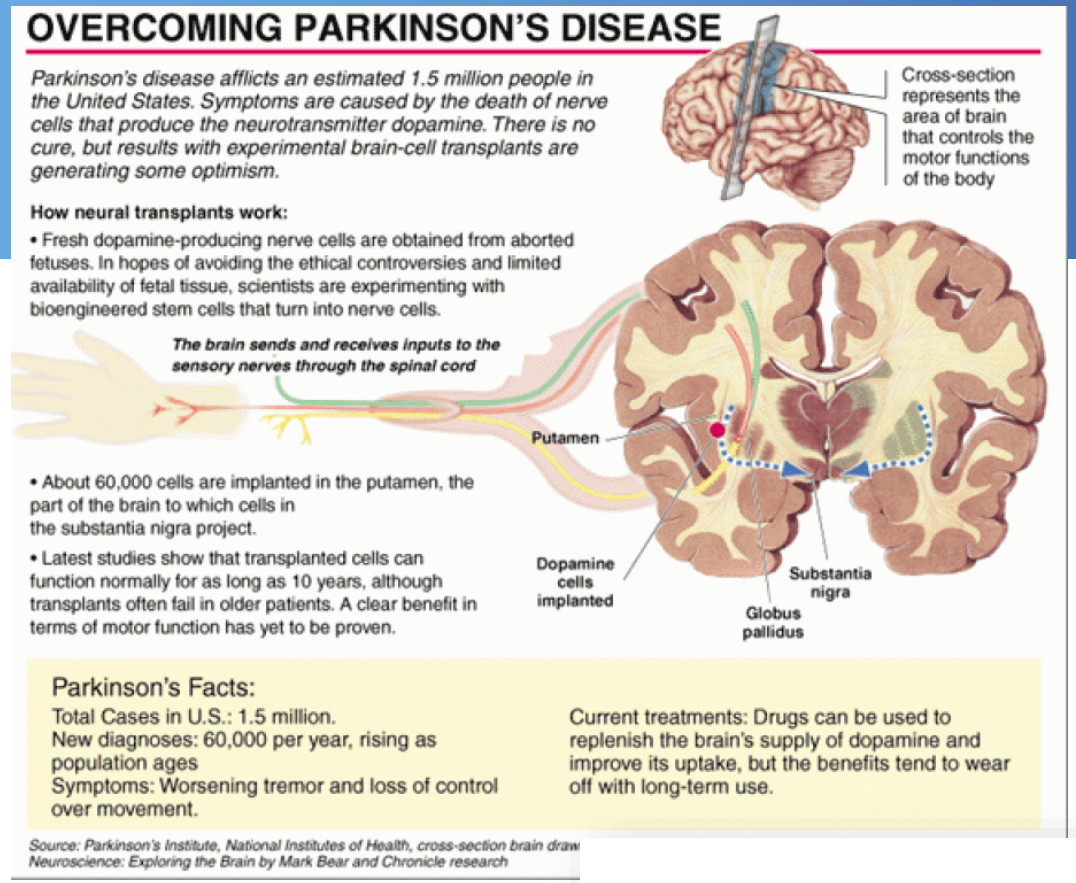

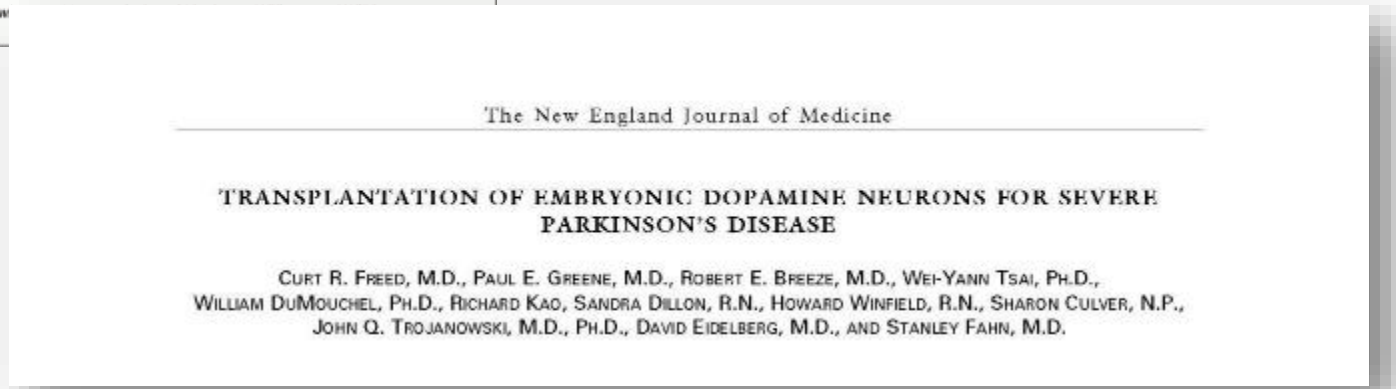

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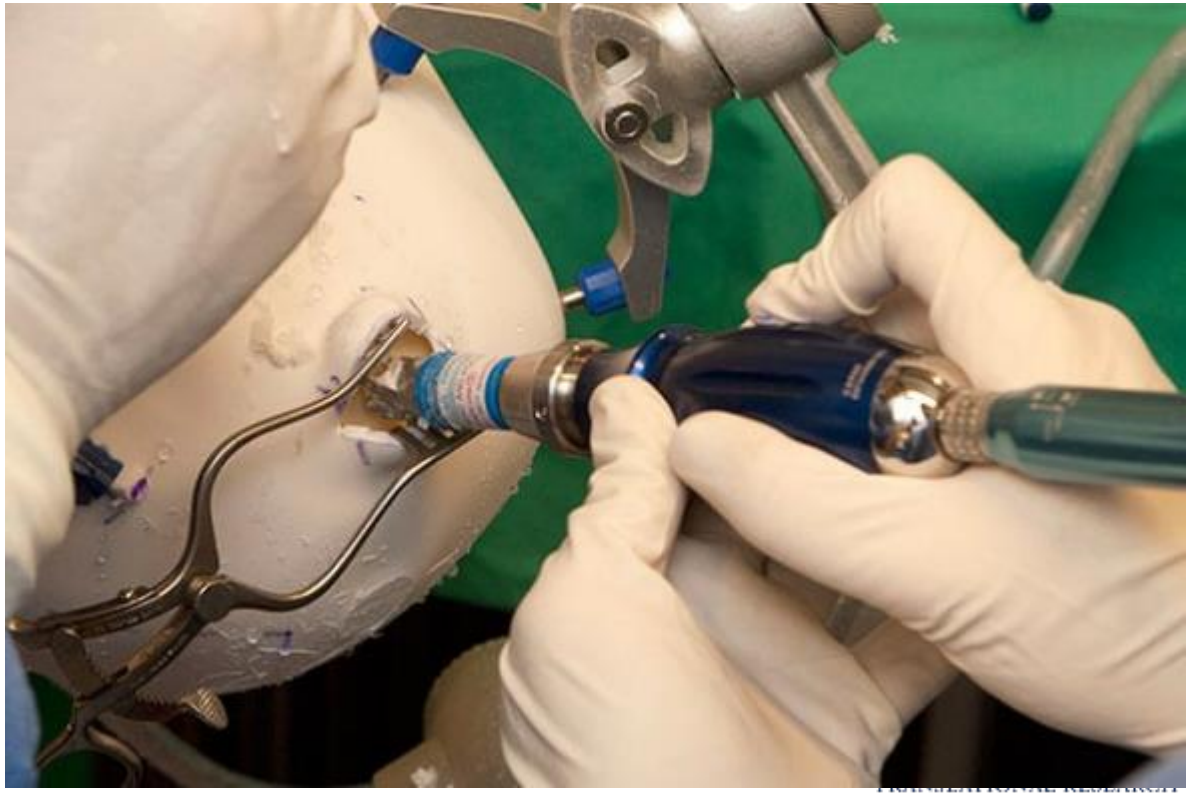

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Research Ethics Consult Service

Thank you!

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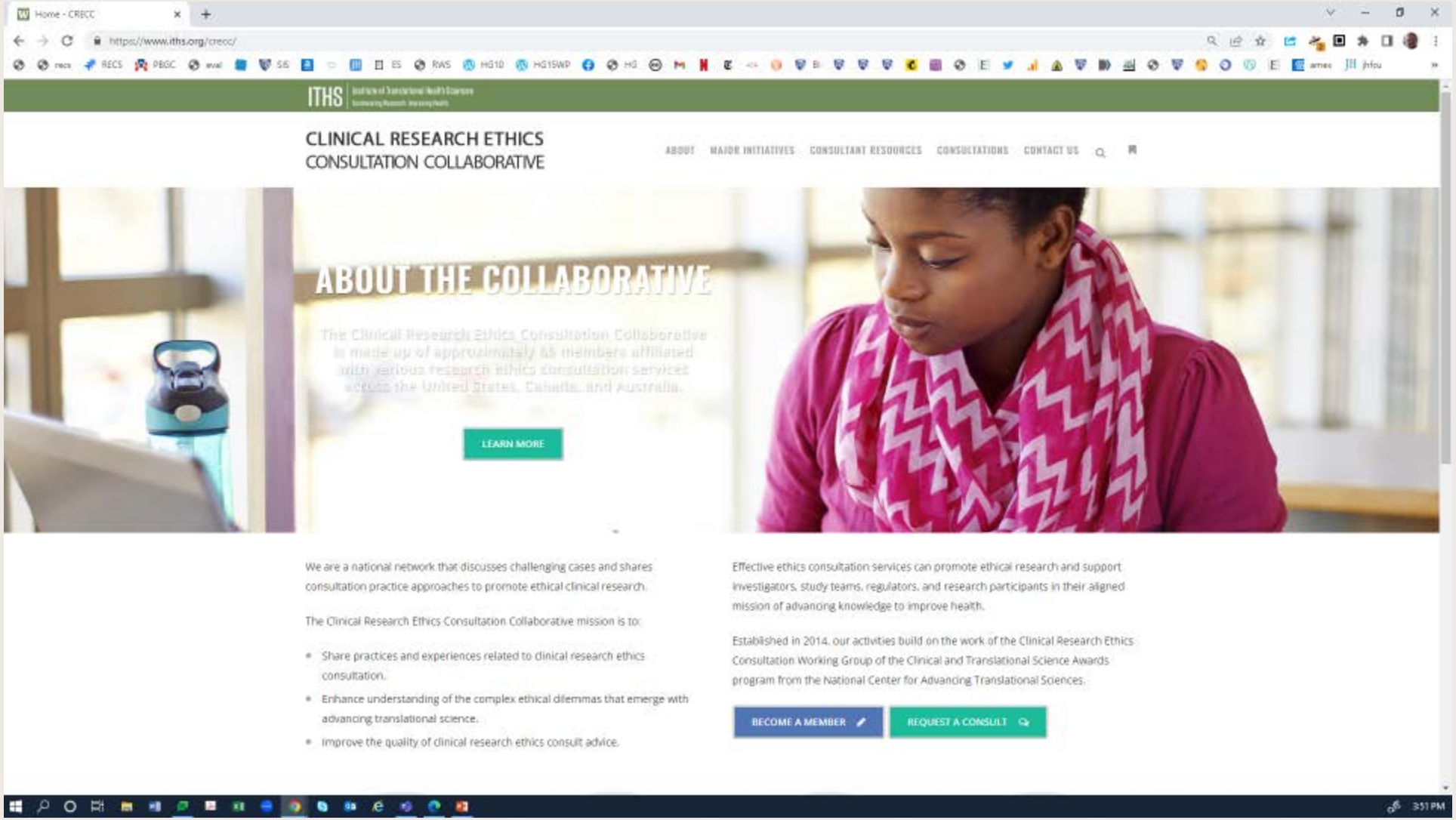
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We are a national network that discusses challenging cases and shares consultation practice approaches to promote ethical clinical research.
The Clinical Research Ethics Consultation Collaborative mission is to:
Share practices and experiences related to clinical research ethics consultation.
Enhance understanding of the complex ethical dilemmas that emerge with advancing translational science.
Improve the quality of clinical research ethics consult advice.
Effective ethics consultation services can promote ethical research and support investigators, study teams, regulators, and research participants in their aligned mission of advancing knowledge to improve health.
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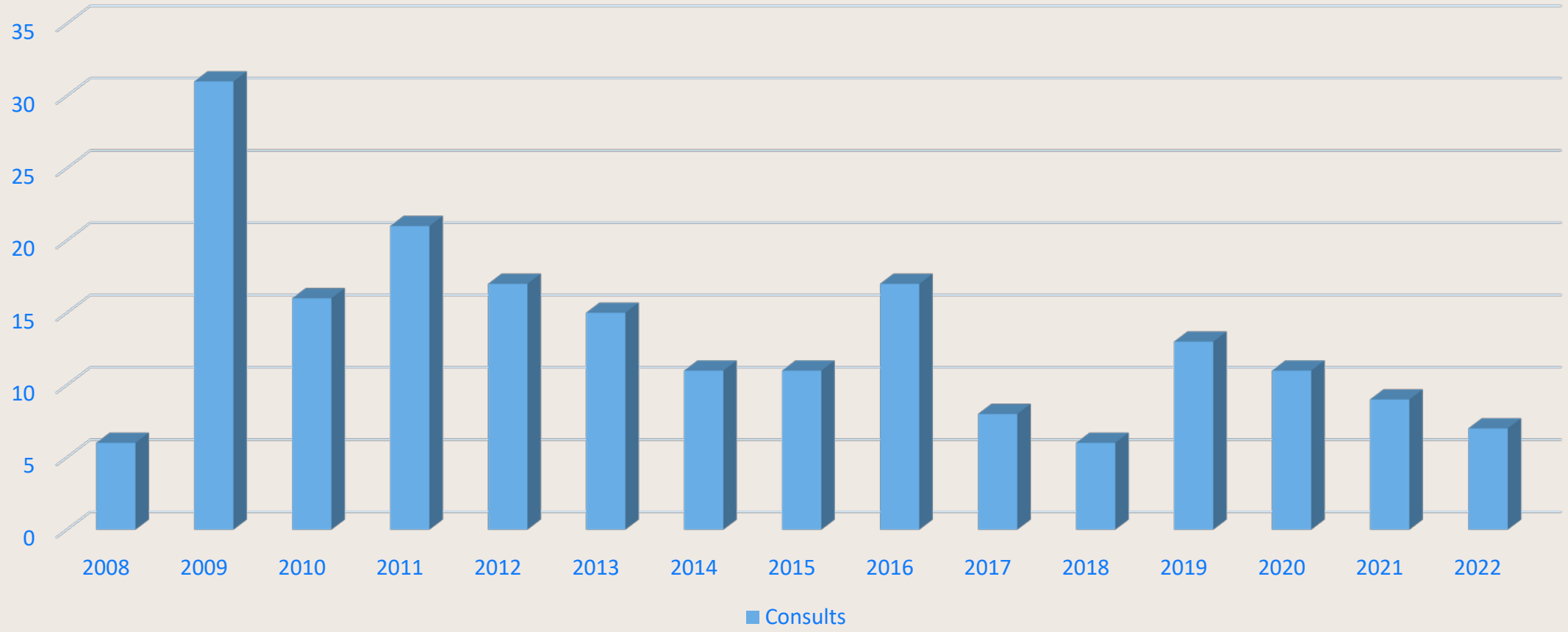

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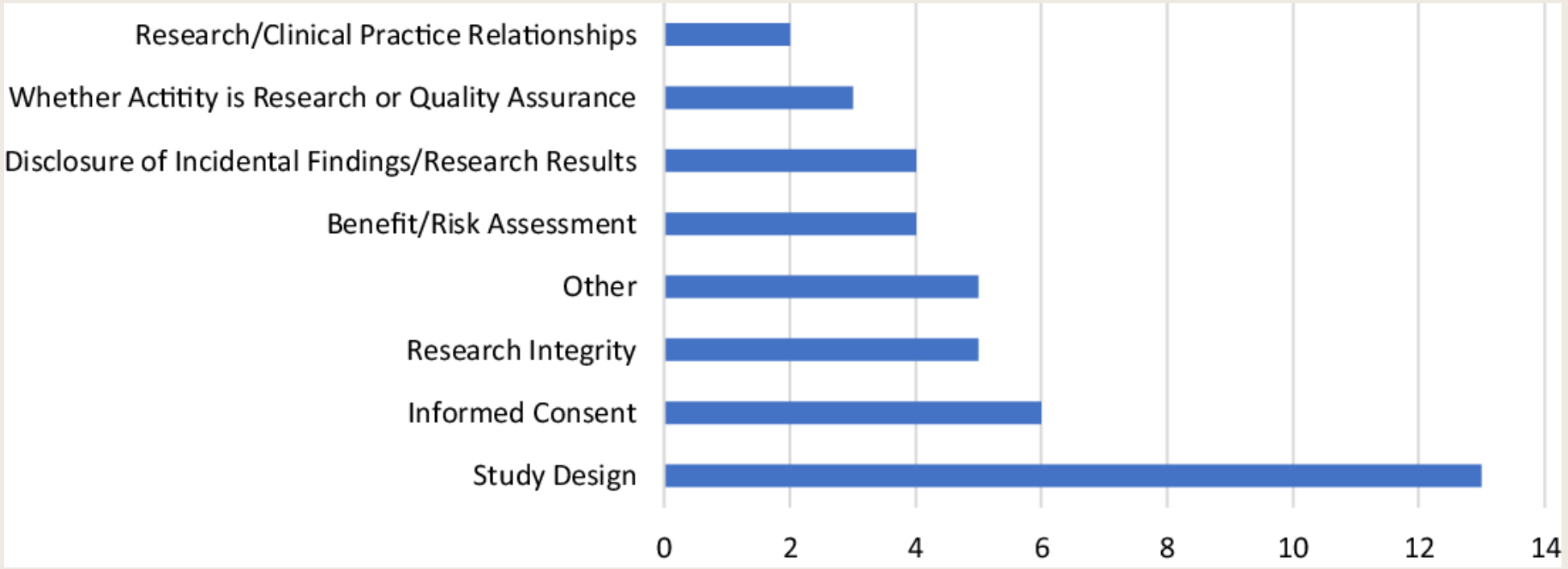

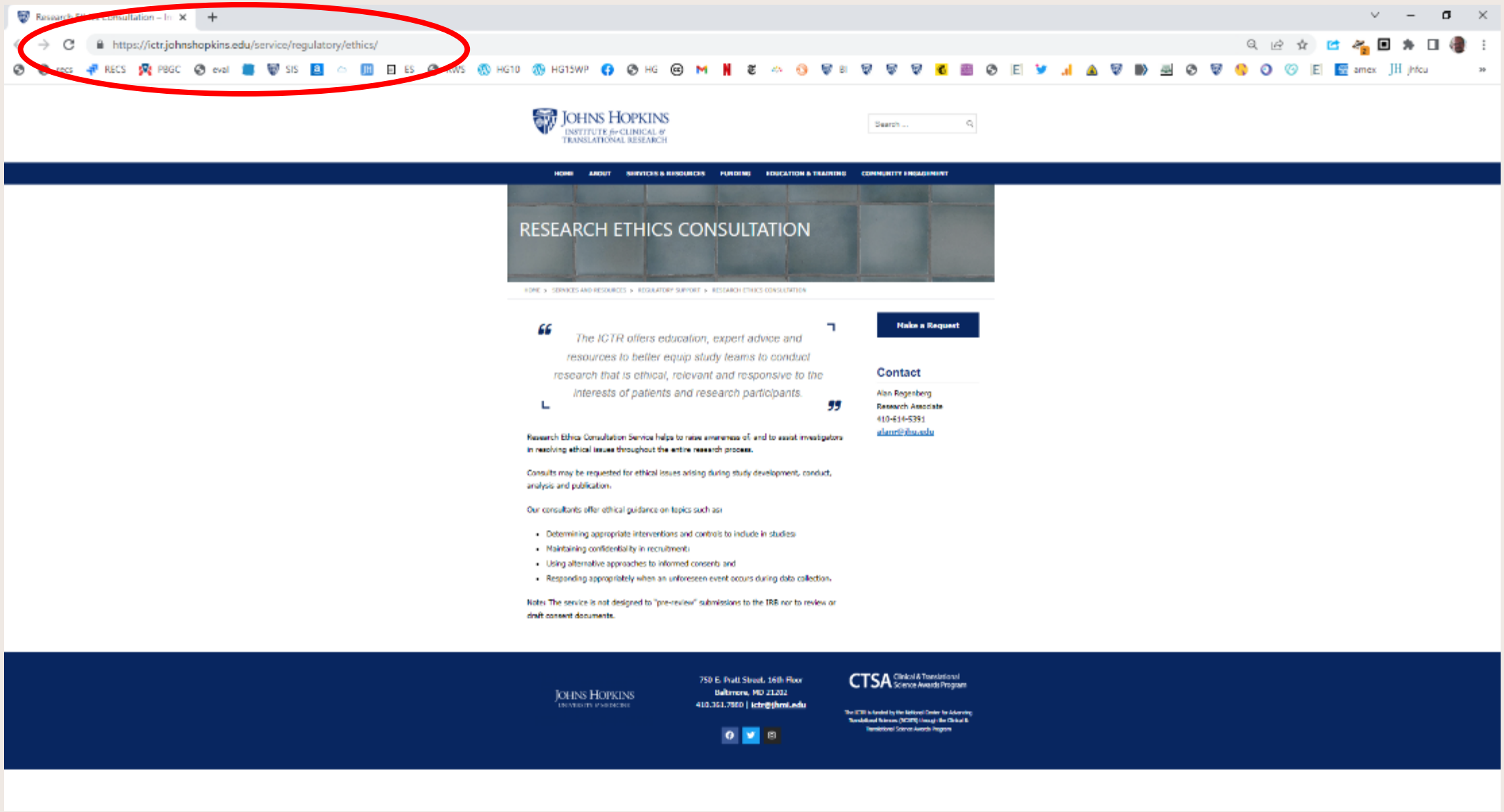
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"The ICTR offers education, expert advice and resources to better equip study teams to conduct research that is ethical, relevant and responsive to the interests of patients and research participants."
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Our consultants offer ethical guidance on topics such as:
Determining appropriate interventions and controls to include in studies
Maintaining confidentiality in recruitment
Using alternative approaches to informed consents and
Responding appropriately when an unforeseen event occurs during data collection.
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Make a Request
Contact
Alan Regenberg
Research Associate
410-614-5391
alanr@jhu.edu
JOHNS HOPKINS
750 E. Pratt Street, 16th Floor
Baltimore, MD 21202
410.361.7800 | ictr@jhmi.edu
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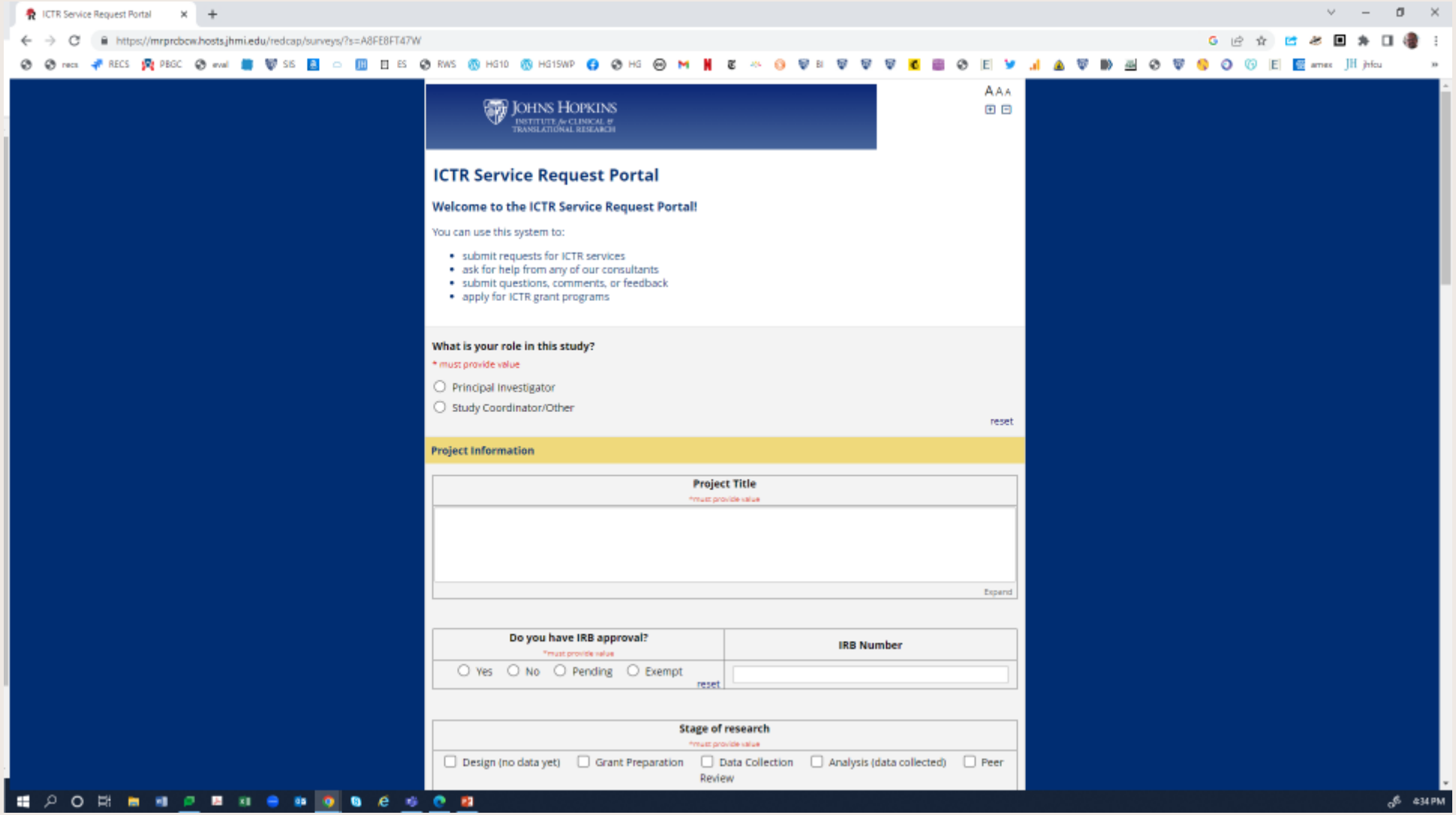
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* must provide value
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reset
Project Information
Project Title
*must provide value
Expand
Do you have IRB approval?
*must provide value
Yes
No
Pending
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IRB Number
Stage of research
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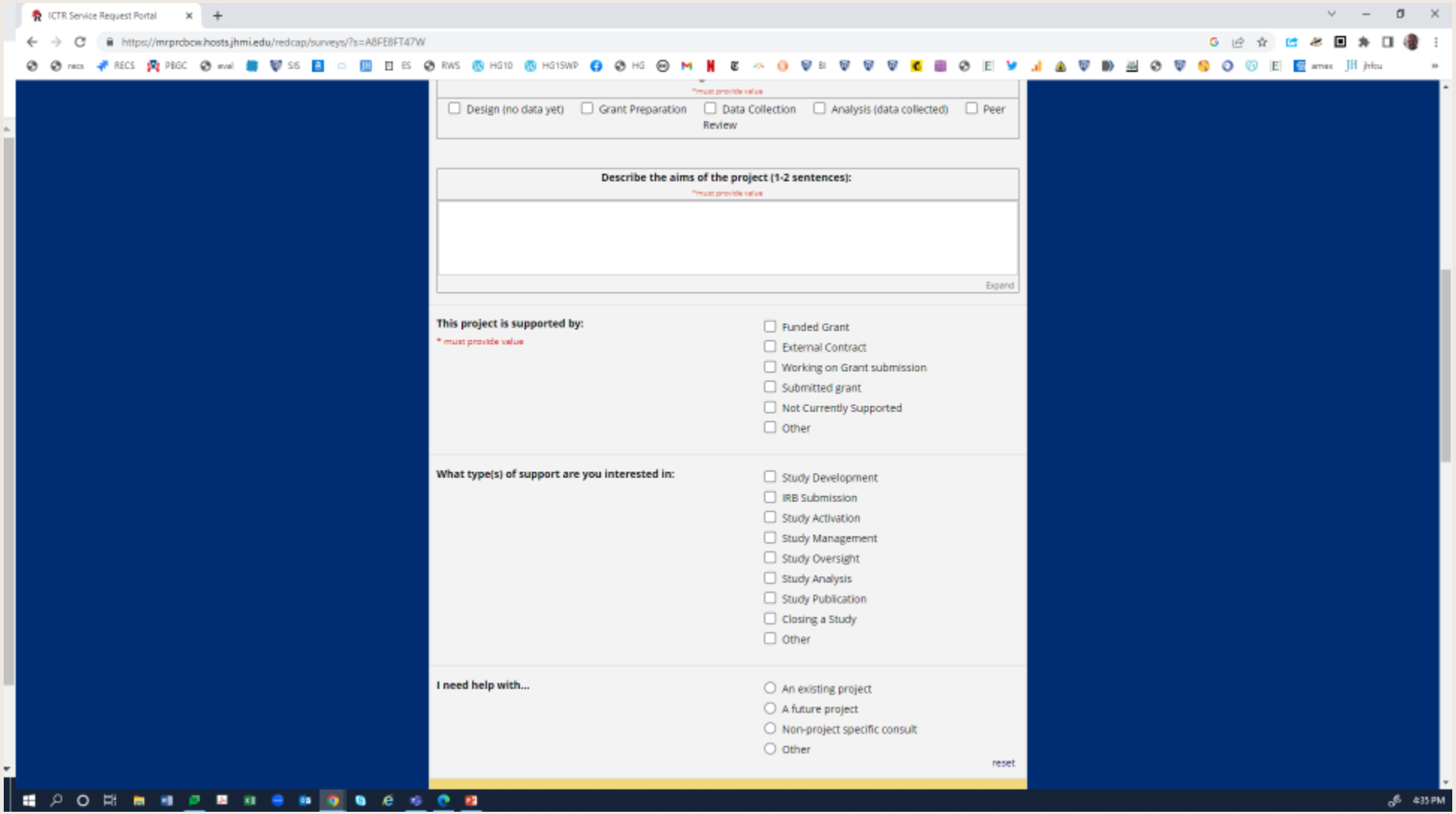
Design (no data yet)
Grant Preparation
Data Collection
Analysis (data collected)
Peer Review
4:34 PM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Design (no data yet)
Grant Preparation
Data Collection
Analysis (data collected)
Peer Review
Describe the aims of the project (1-2 sentences):
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Expand
This project is supported by:
* must provide value
Funded Grant
External Contract
Working on Grant submission
Submitted grant
Not Currently Supported
Other
What type(s) of support are you interested in:
Study Development
IRB Submission
Study Activation
Study Management
Study Oversight
Study Analysis
Study Publication
Closing a Study
Other
I need help with...
An existing project
A future project
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Other
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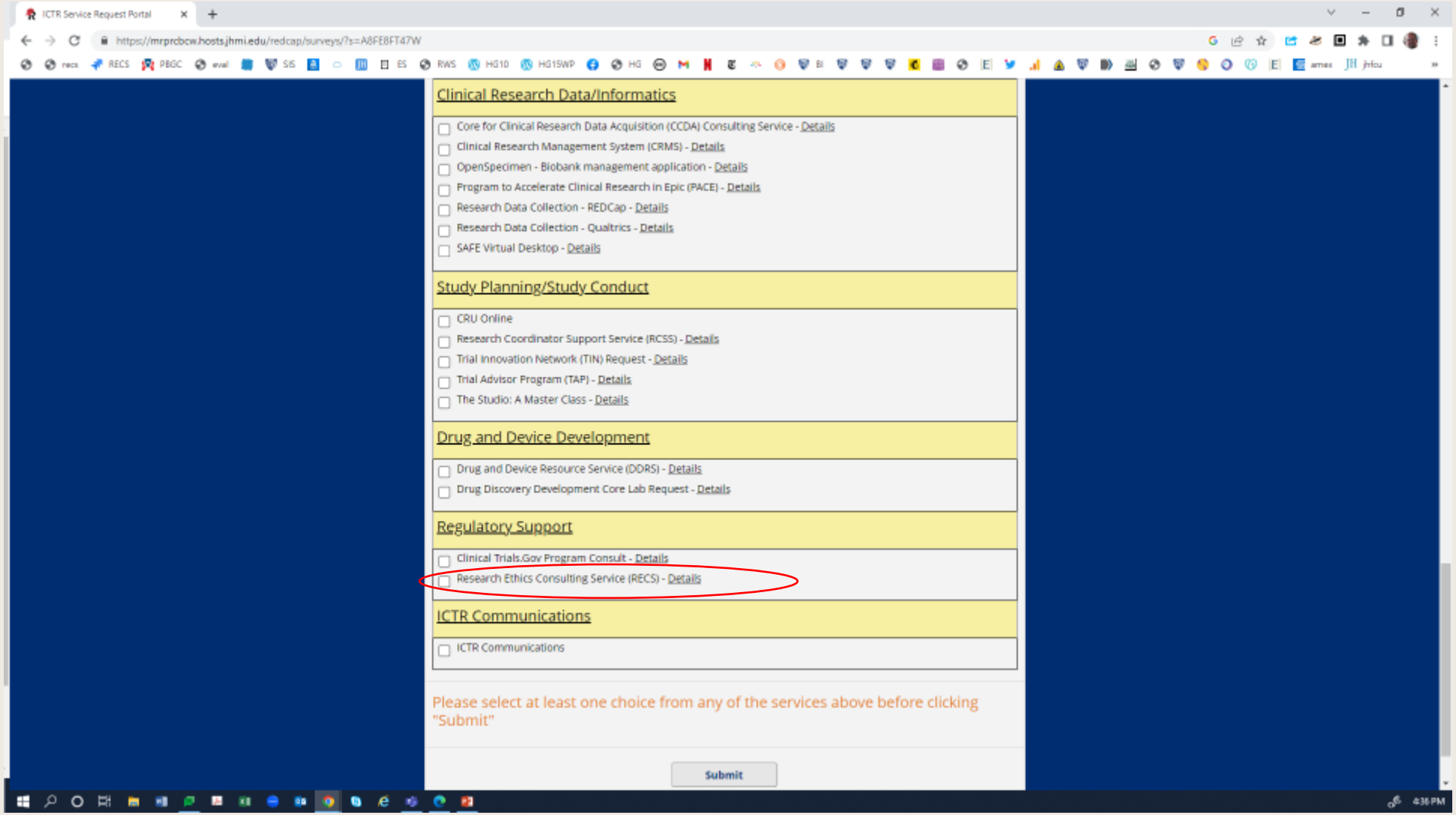
4:35 PM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Clinical Research Data/Informatics
Core for Clinical Research Data Acquisition (CCDA) Consulting Service - Details
Clinical Research Management System (CRMS) - Details
OpenSpecimen - Biobank management application - Details
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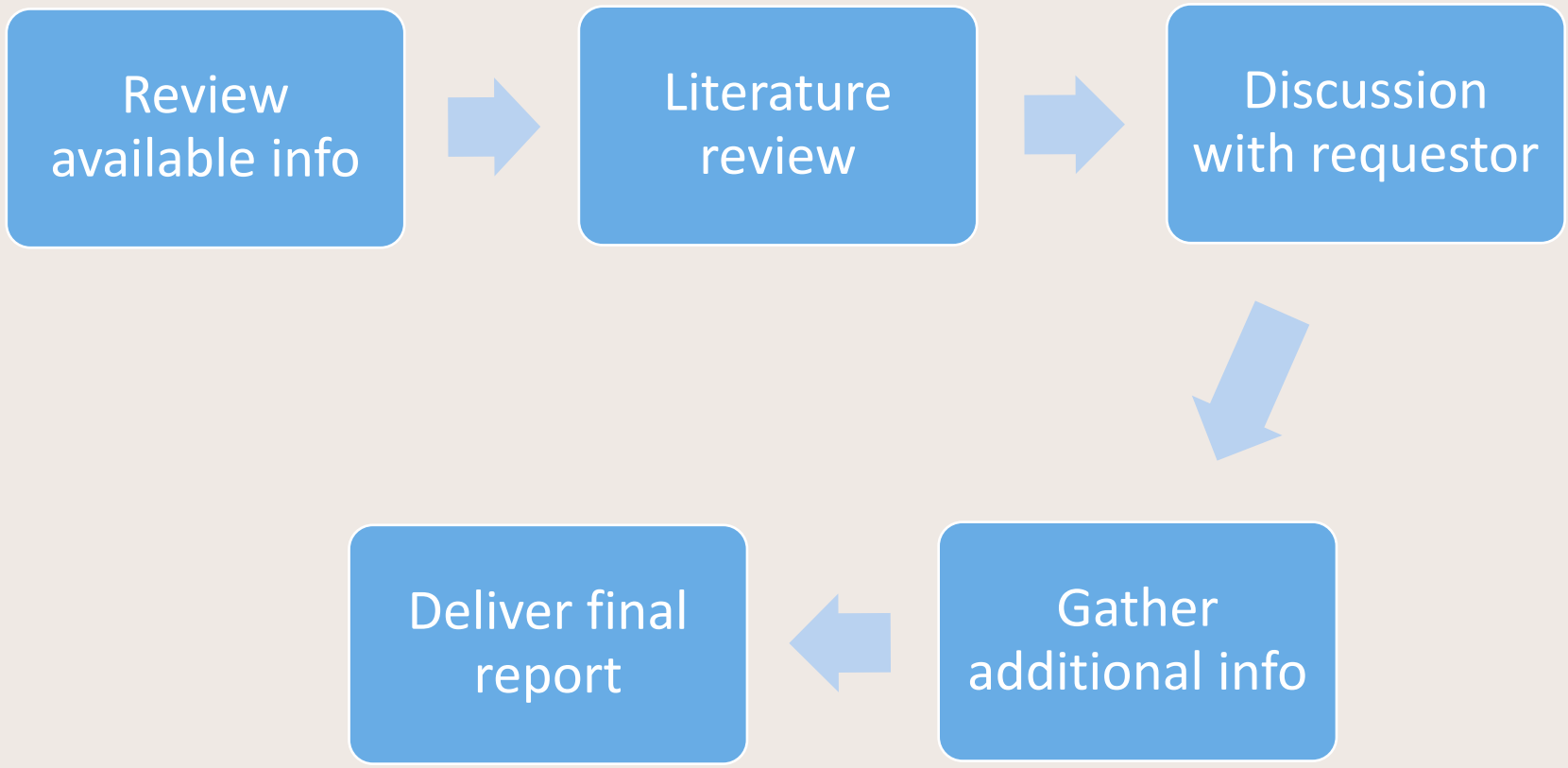
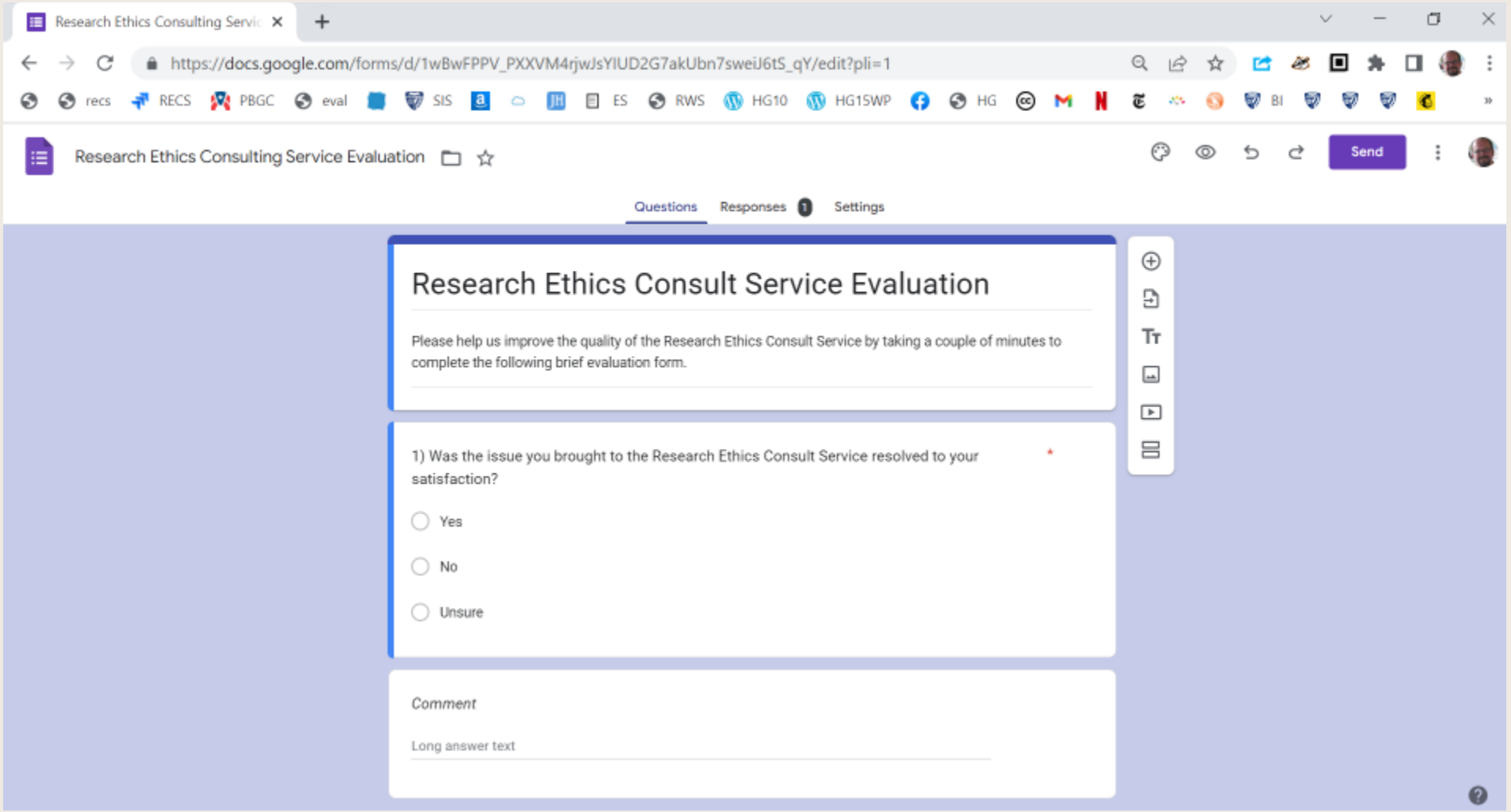
Consultation Process:

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1) Was the issue you brought to the Research Ethics Consult Service resolved to your satisfaction? *
Yes
No
Unsure
Comment
Long answer text

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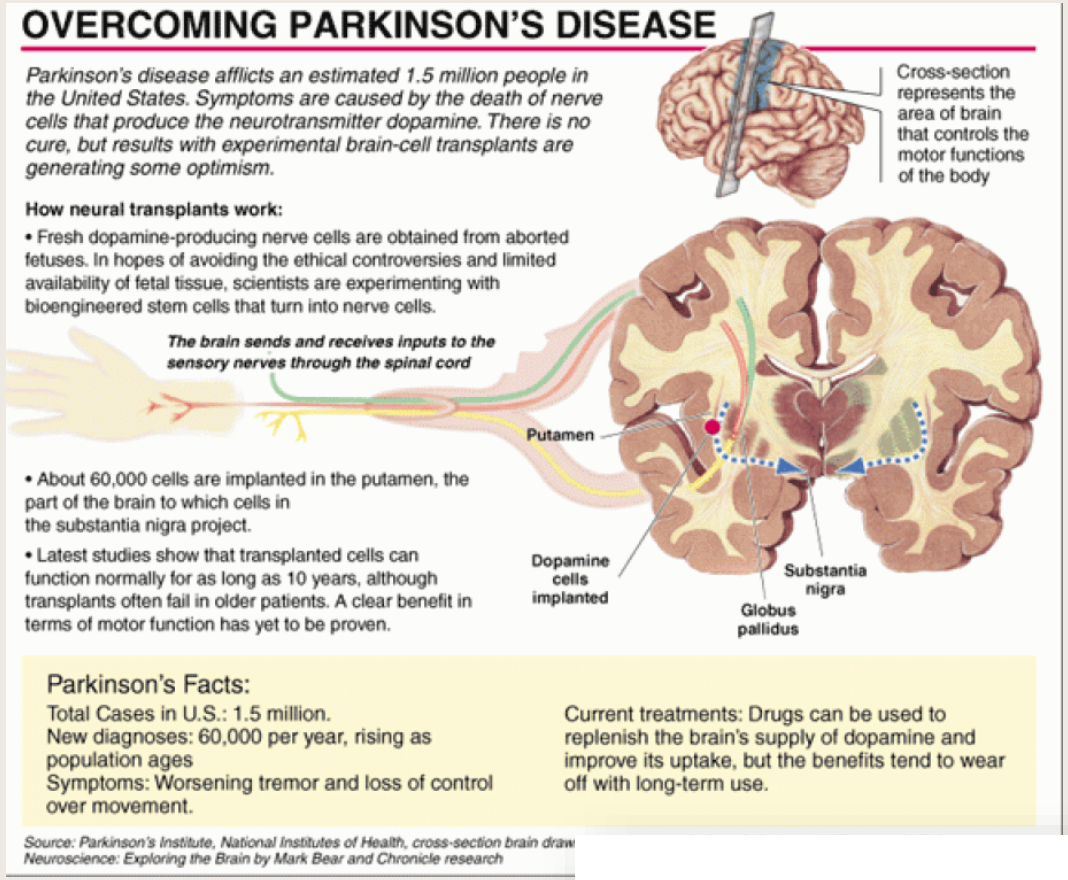

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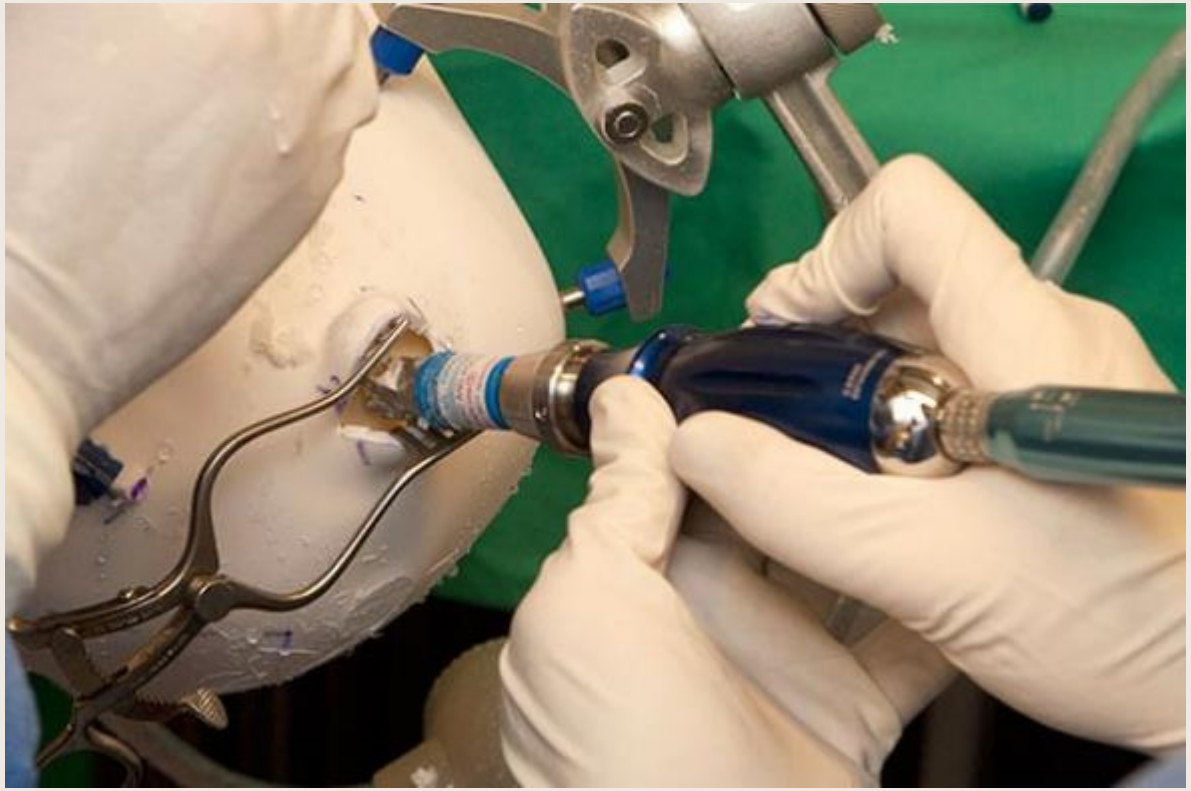

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Research Ethics
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Thank you!

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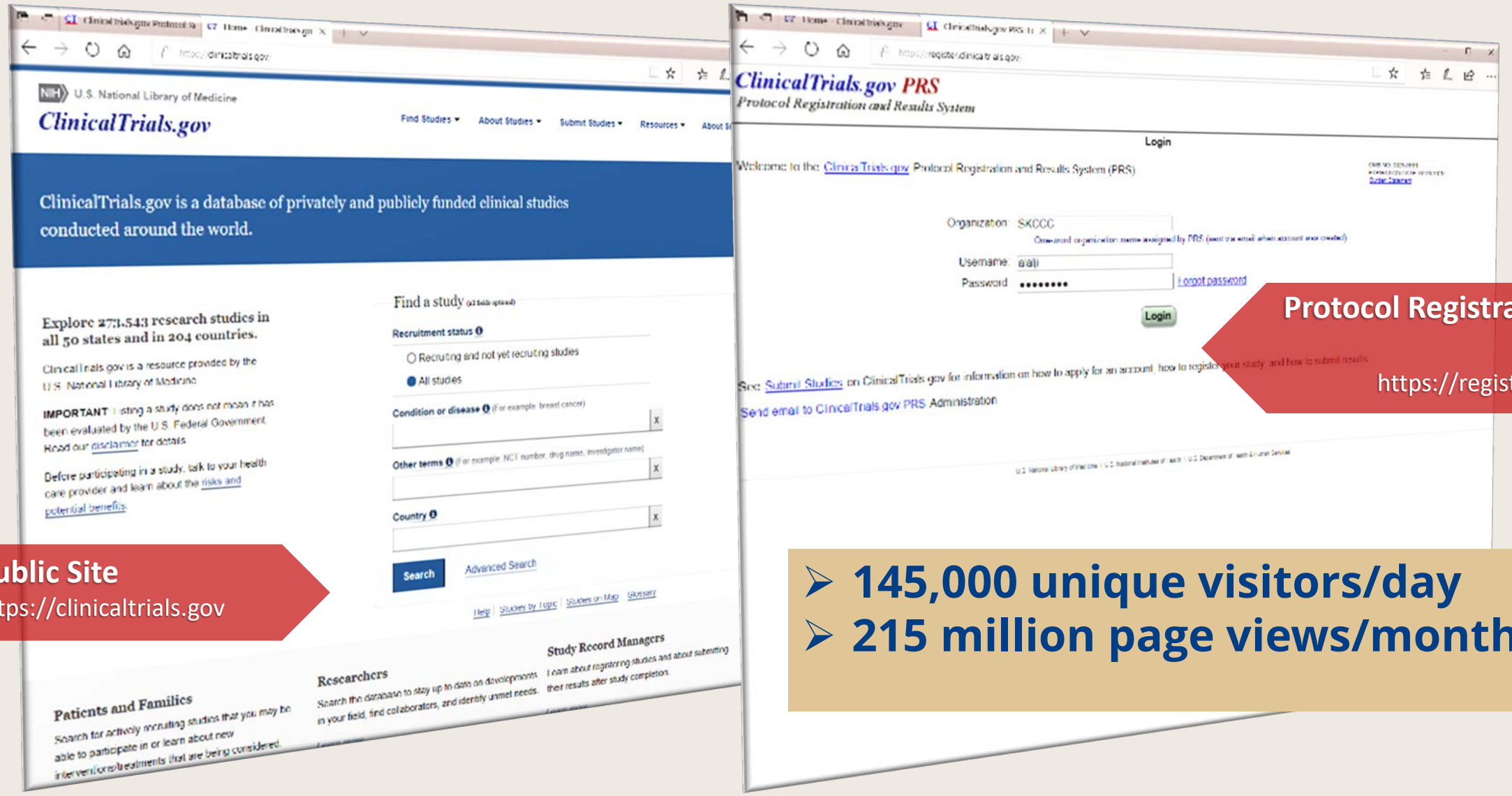
ClinicalTrials.gov and The JHU ClinicalTrials.gov Program: An overview

Presented by: Oswald Tetteh, Clinical Research Compliance Specialist



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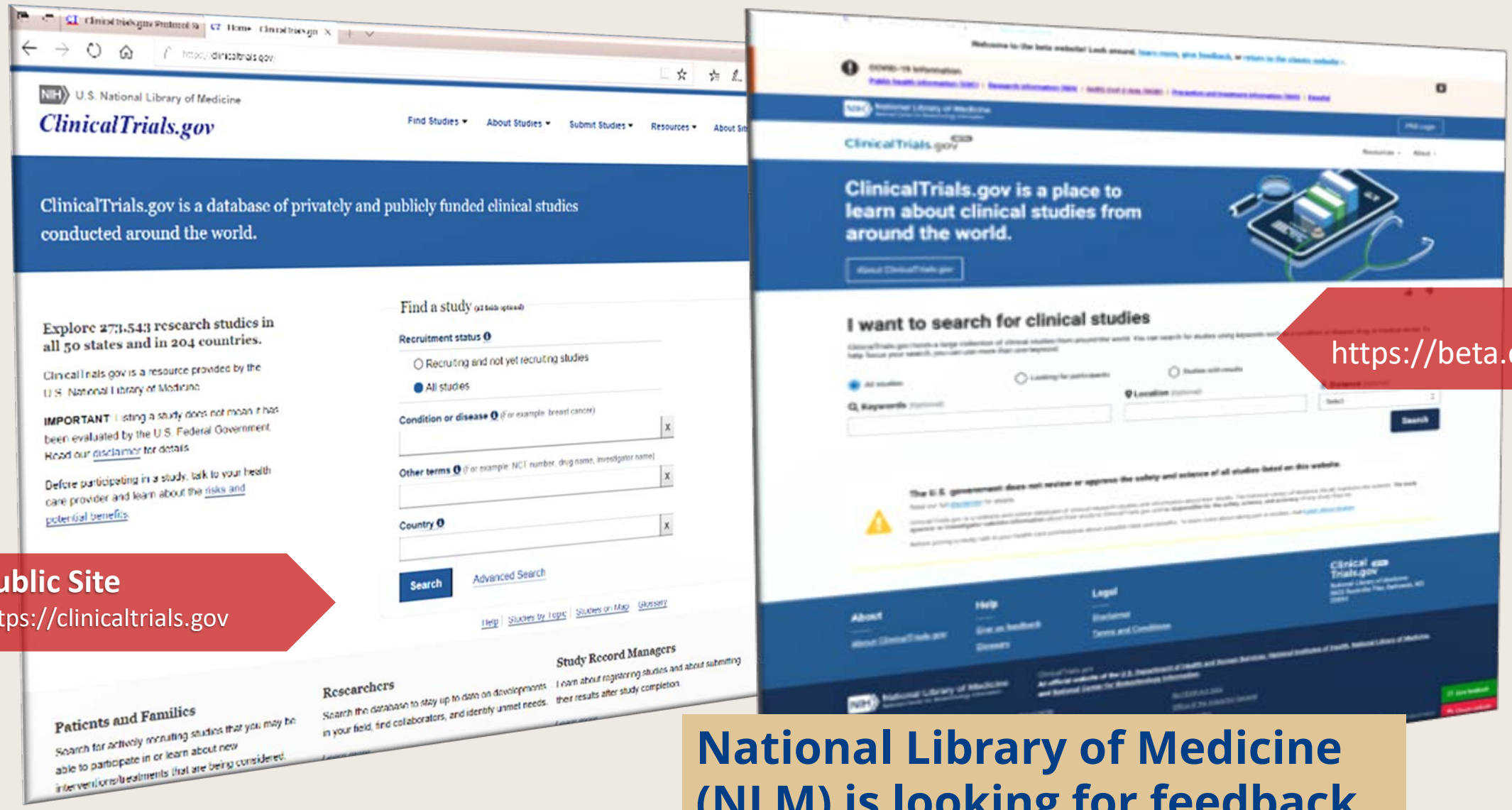

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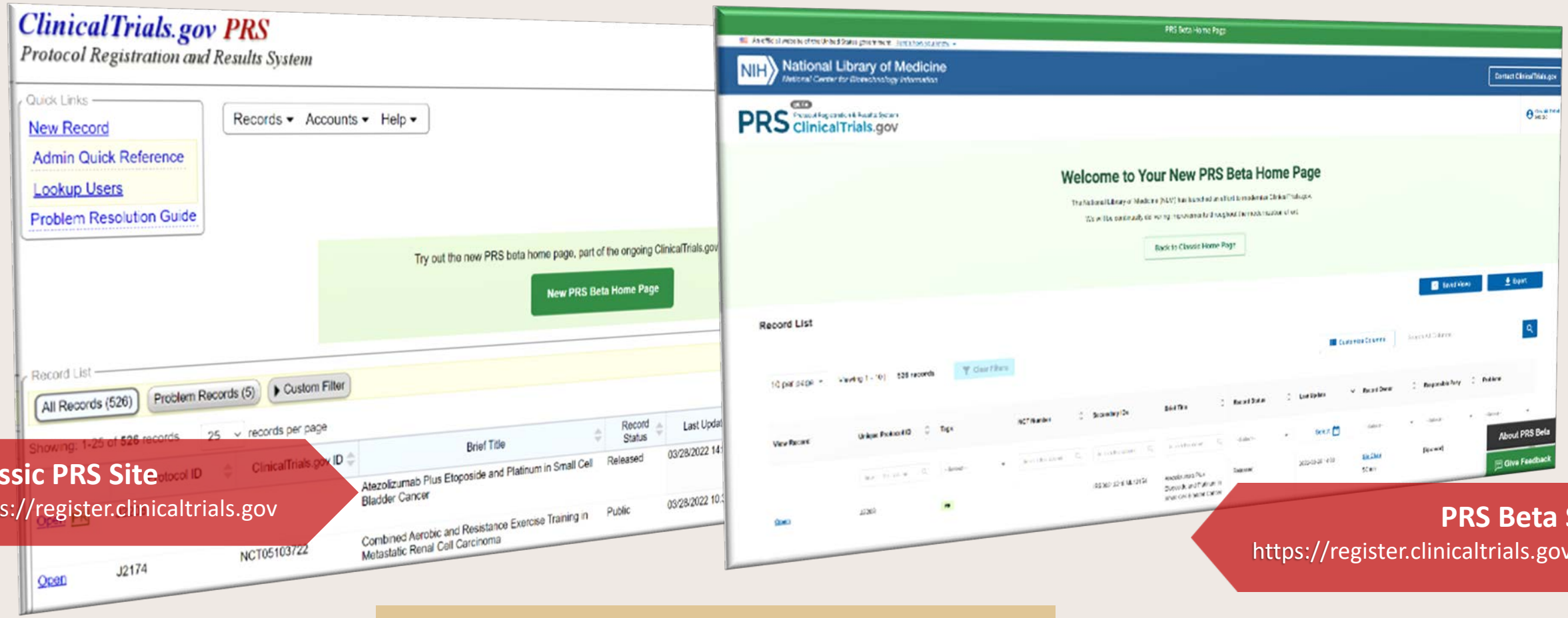

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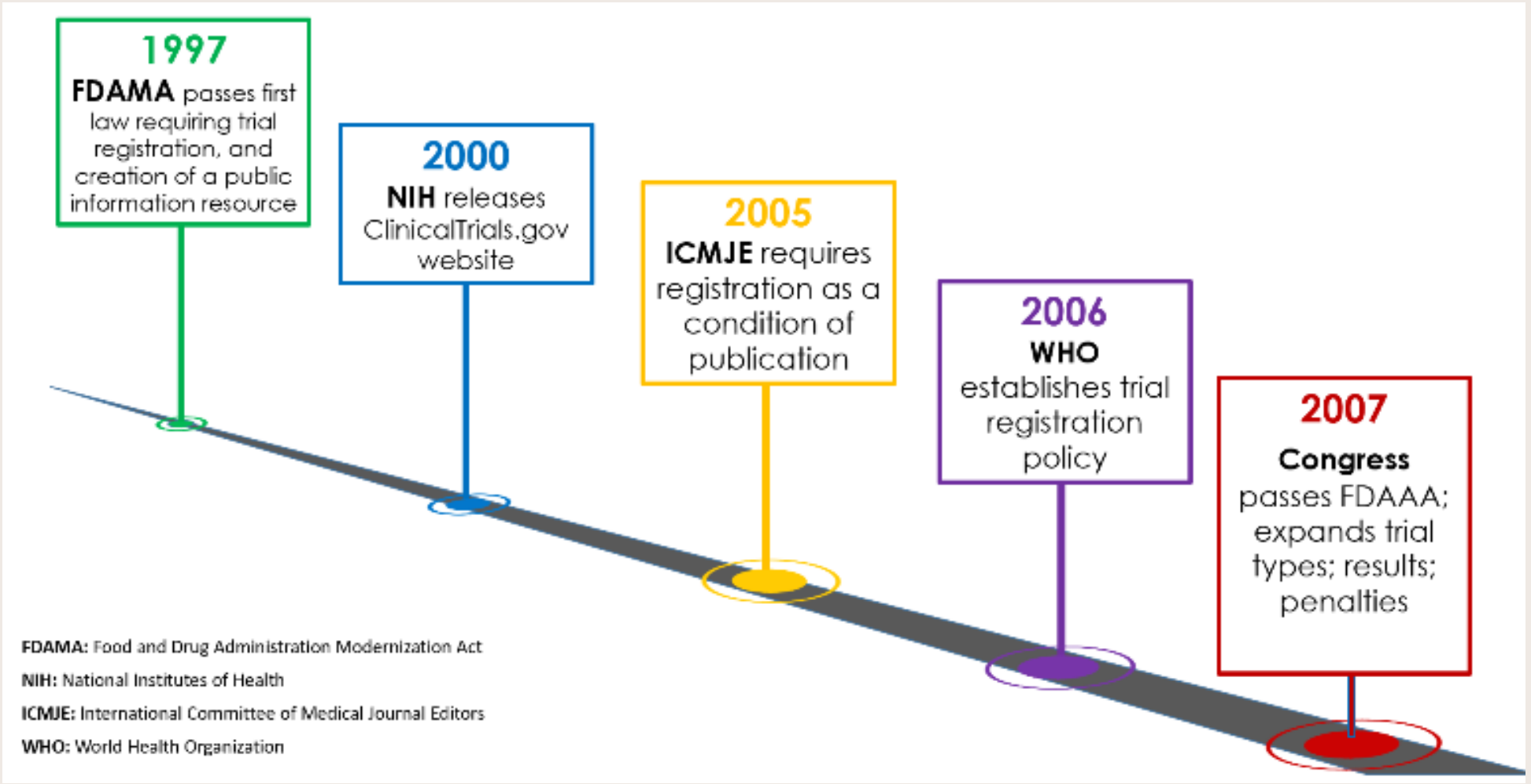
1997
FDAMA passes first law requiring trial registration, and creation of a public information resource
2000
NIH releases ClinicalTrials.gov website
2005
ICMJE requires registration as a condition of publication
2006
WHO establishes trial registration policy
2007
Congress passes FDAAA; expands trial types; results; penalties
FDAMA: Food and Drug Administration Modernization Act
NIH: National Institutes of Health
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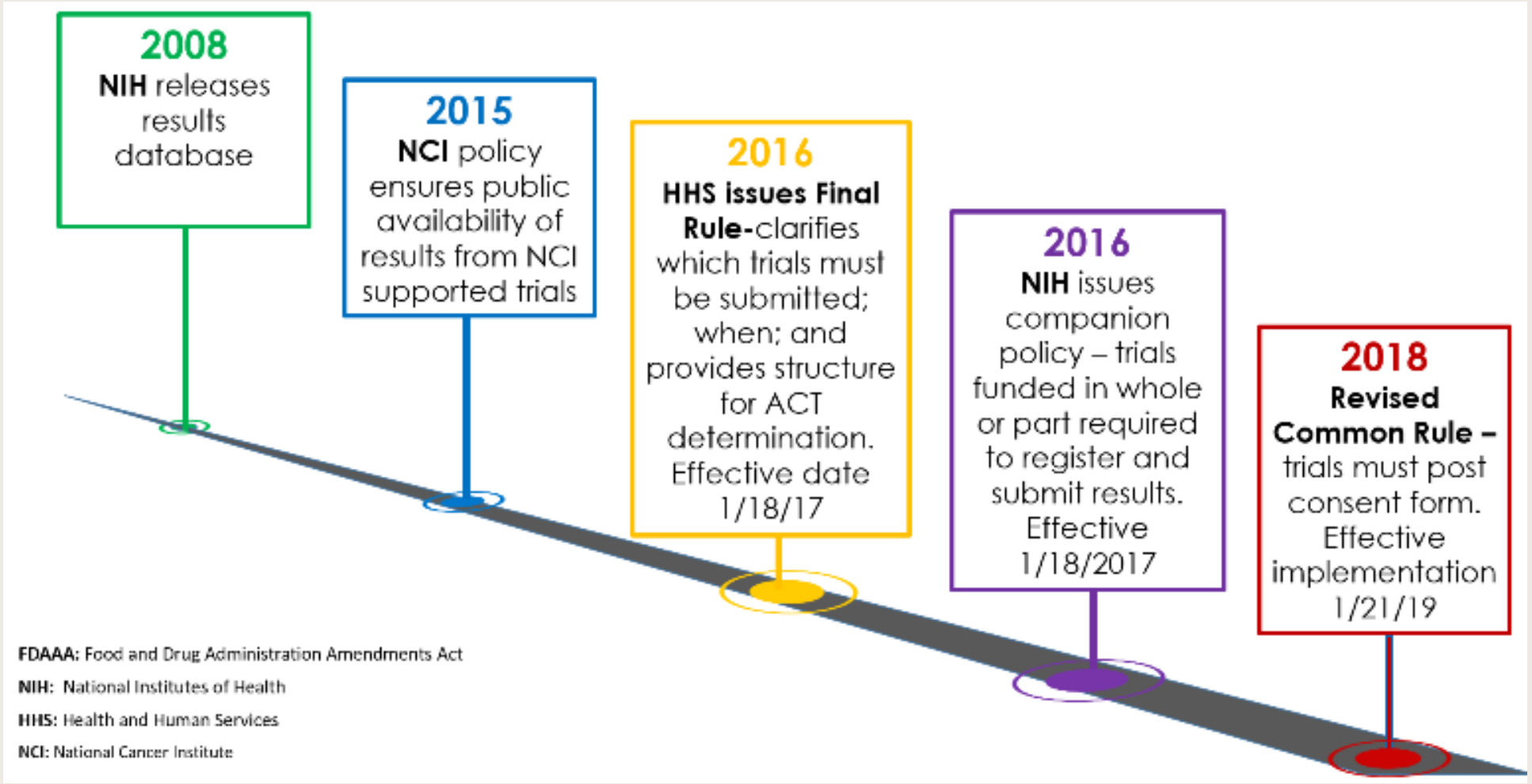
2008
NIH releases results database
2015
NCI policy ensures public availability of results from NCI supported trials
2016
HHS issues Final Rule-clarifies which trials must be submitted; when; and provides structure for ACT determination. Effective date 1/18/17
2016
NIH issues companion policy – trials funded in whole or part required to register and submit results. Effective 1/18/2017
2018
Revised Common Rule – trials must post consent form. Effective implementation 1/21/19
FDAAA: Food and Drug Administration Amendments Act
NIH: National Institutes of Health
HHS: Health and Human Services
NCI: National Cancer Institute

- ✓ Commitment to research participants (including recruitment)
- ✓ Scientific validity/transparency
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Agencies* https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

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Entity	Registration	Results Reporting	Penalties
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Department of Defense (DoD)	Prior to enrollment. Prior to release of funding.	Study-specific	• Withholding or recovery of award funds

Recent Enforcement and Monitoring

Responsible Party/Submitter	NCT Number	Notice of Noncompliance	Response Letter (if any)	Civil Money Penalty Amount (if any)
Ocugen	NCT03785340	4/15/2022	08/01/2022	
Petrikovets, Andrey M.D.	NCT03052816	8/31/2021	12/20/2021	
Accuitis Inc.	NCT03064438	7/26/2021	05/26/2022	
Acceleron Pharma, Inc.	NCT01727336	4/27/2021	12/13/2021	

https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions#:~:text=FDA%20has%20the%20authority%20to,or%20misleading%20clinical%20trial%20information

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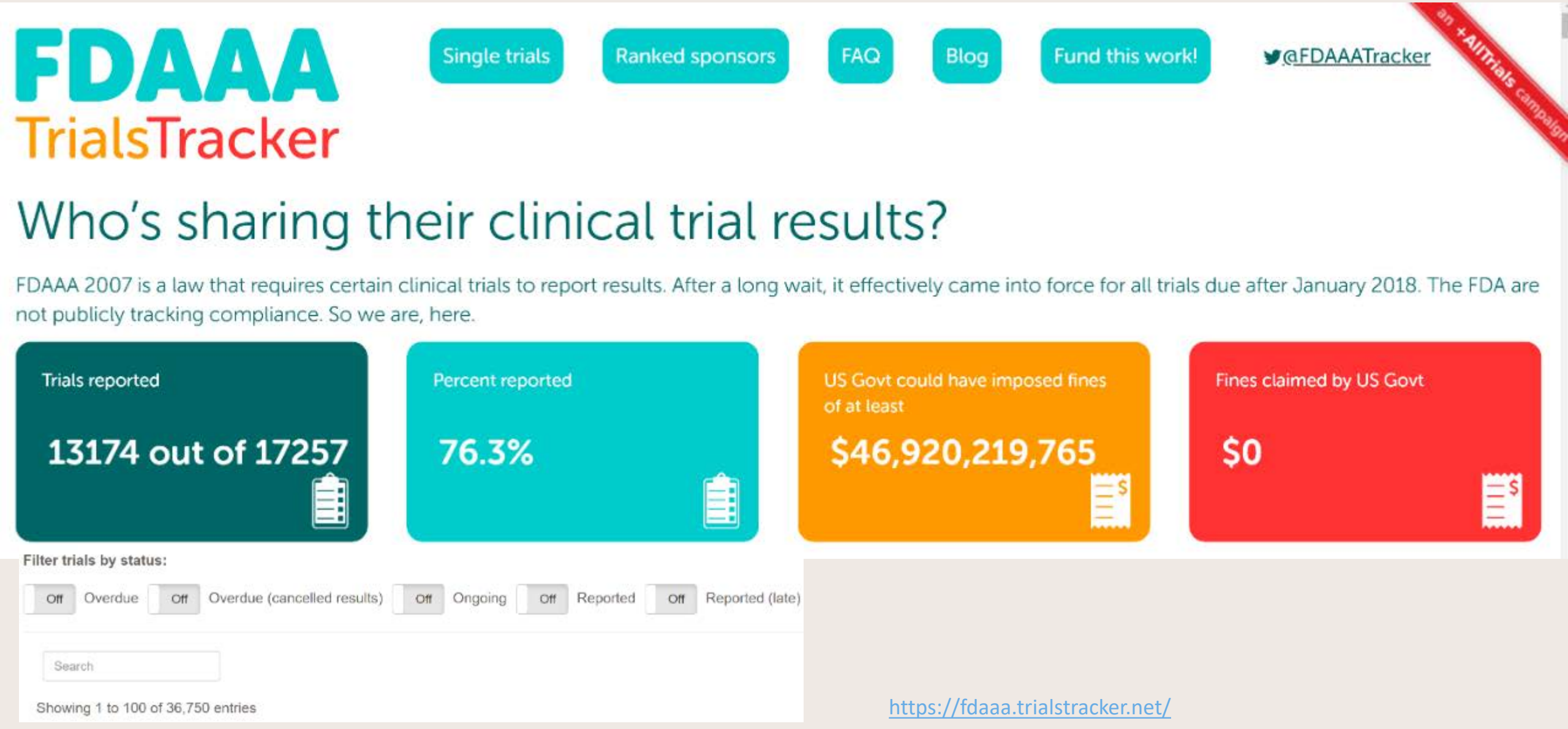
https://www.uaem.org/freedom_of_information_act

Congress demands that FDA and NIH sanction sponsors that fail to report clinical trial results

FDA is petitioned to boost enforcement of trial sponsors that fail to register studies or report results

NIH waste far over $100 million in medical research funding every year – new study

https://www.transparimed.org/single-post/fdaaa-pallone
https://www.statnews.com/pharmalot/2023/02/27/fda-petition-clinical-trials-transparency-nih/
https://www.transparimed.org/single-post/nih-research-waste



https://fdaaa.trialstracker.net/

Our Program

JHU ClinicalTrials.gov Program

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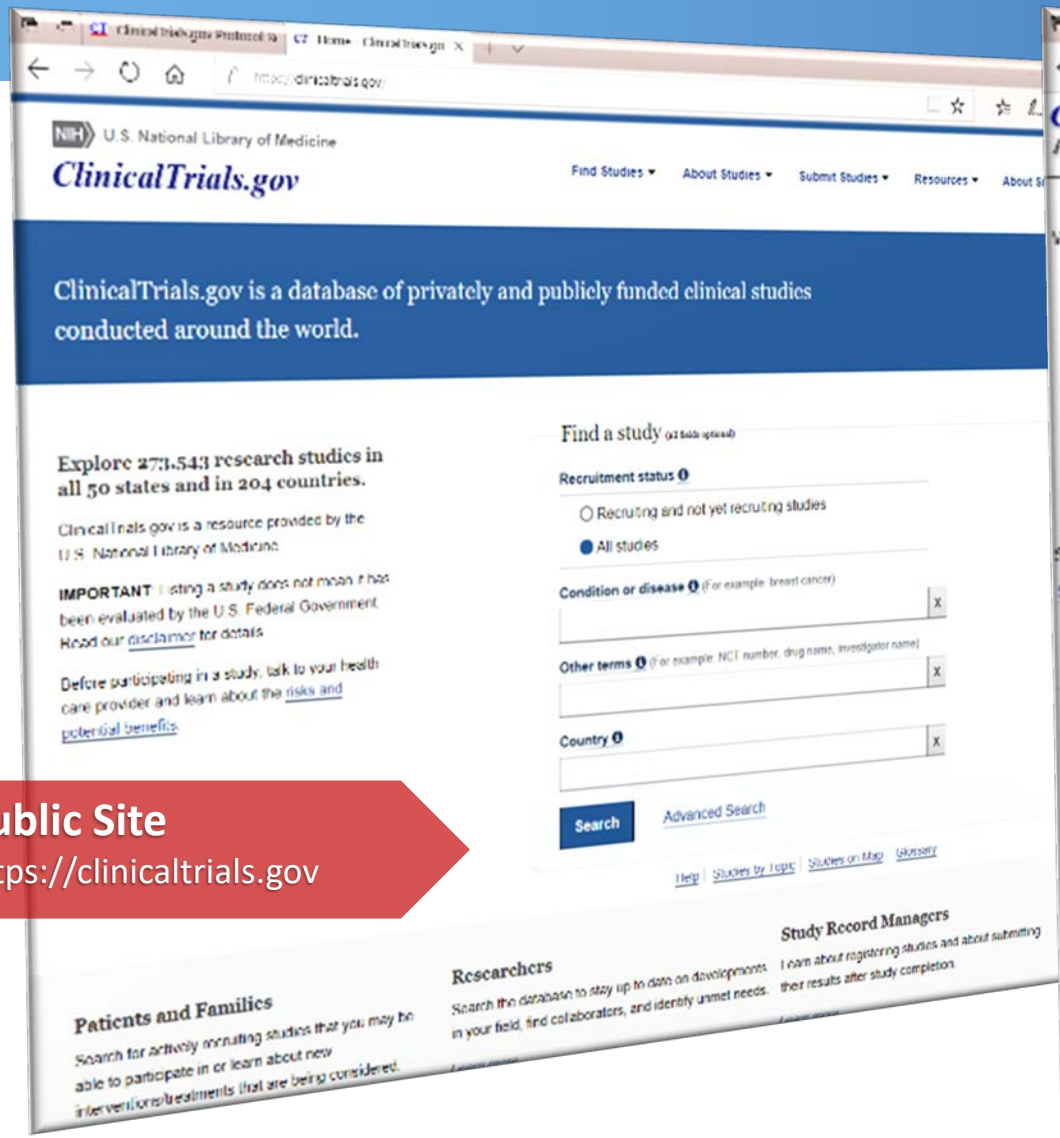
ClinicalTrials.gov



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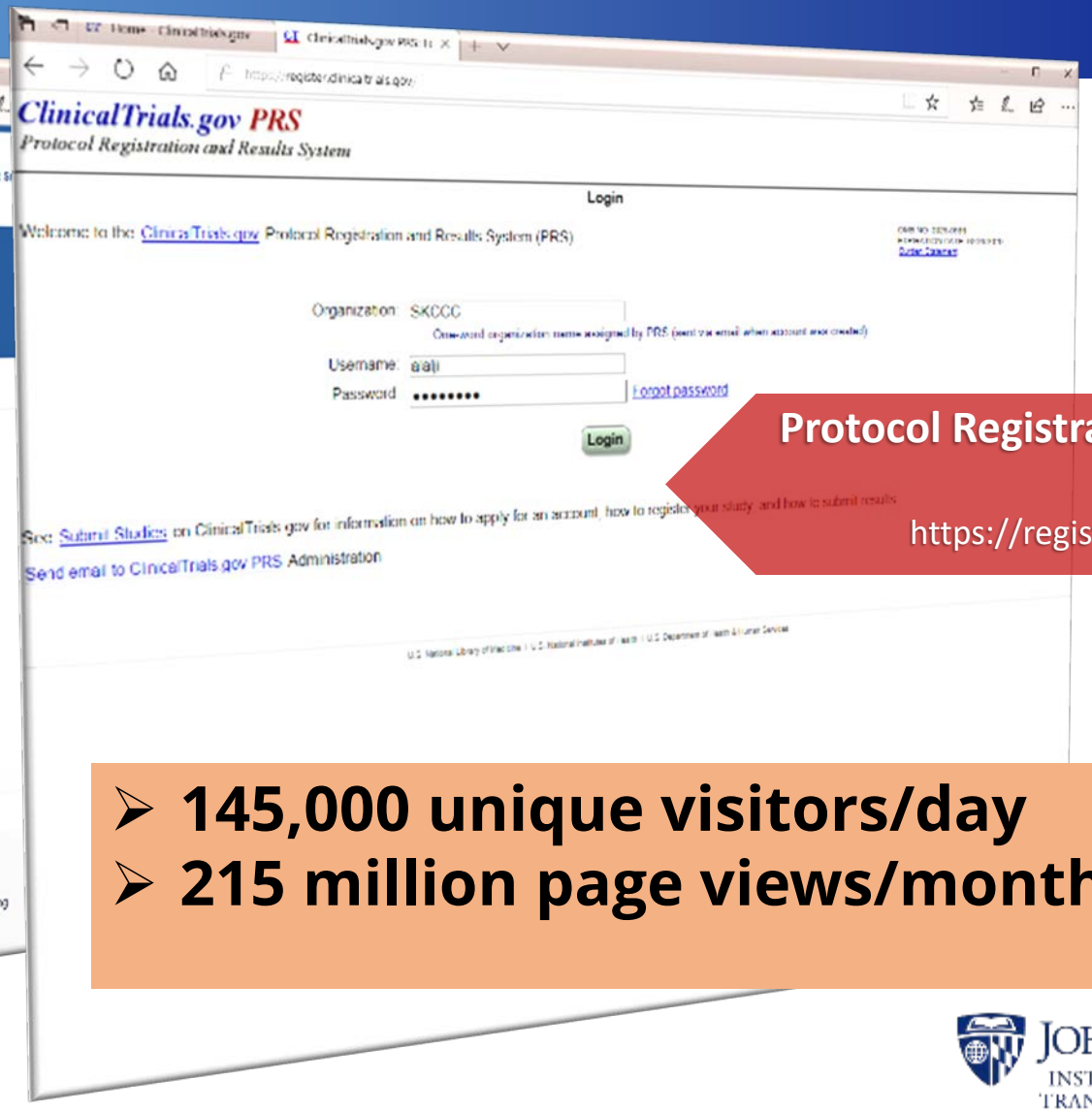

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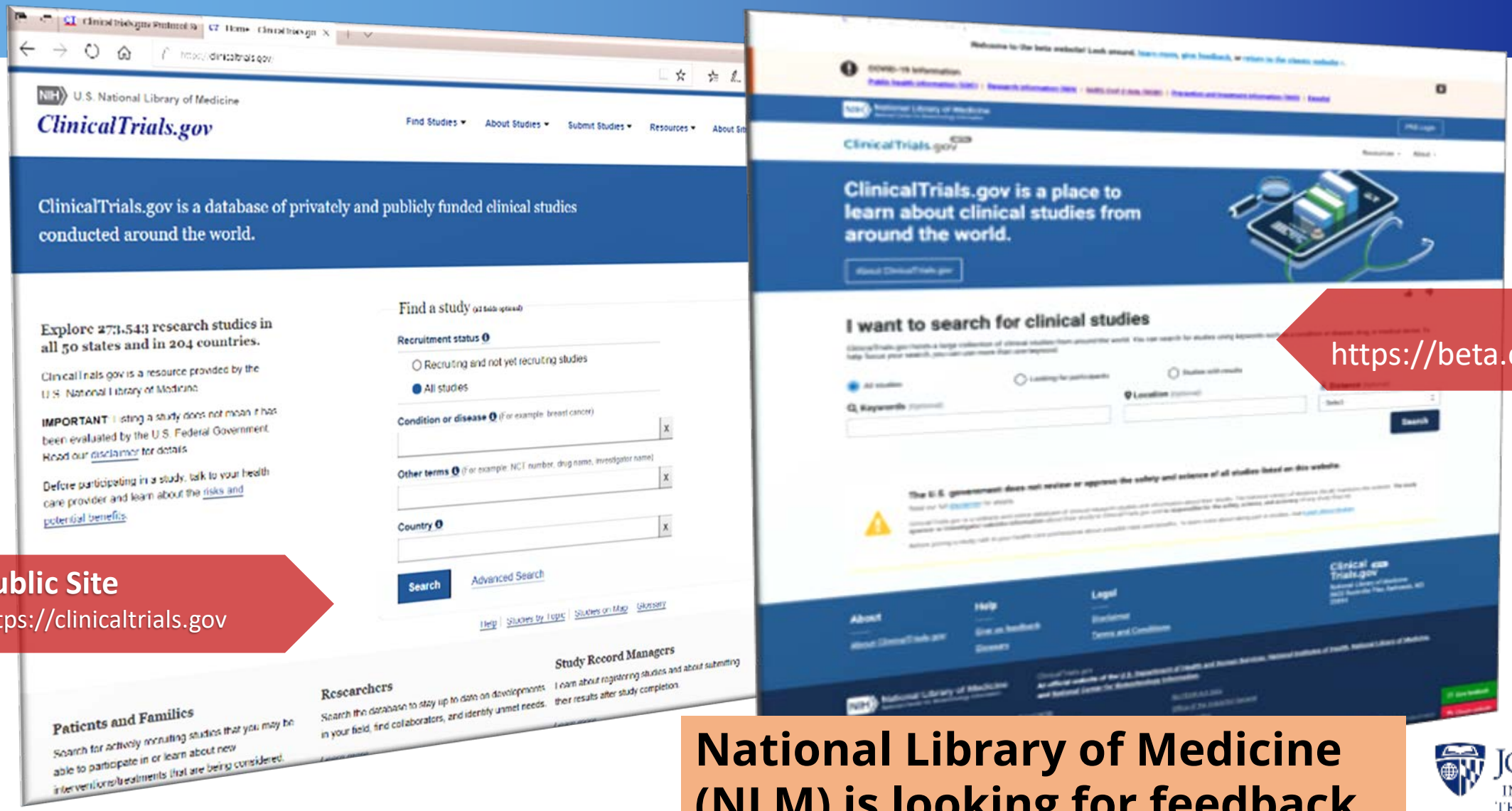

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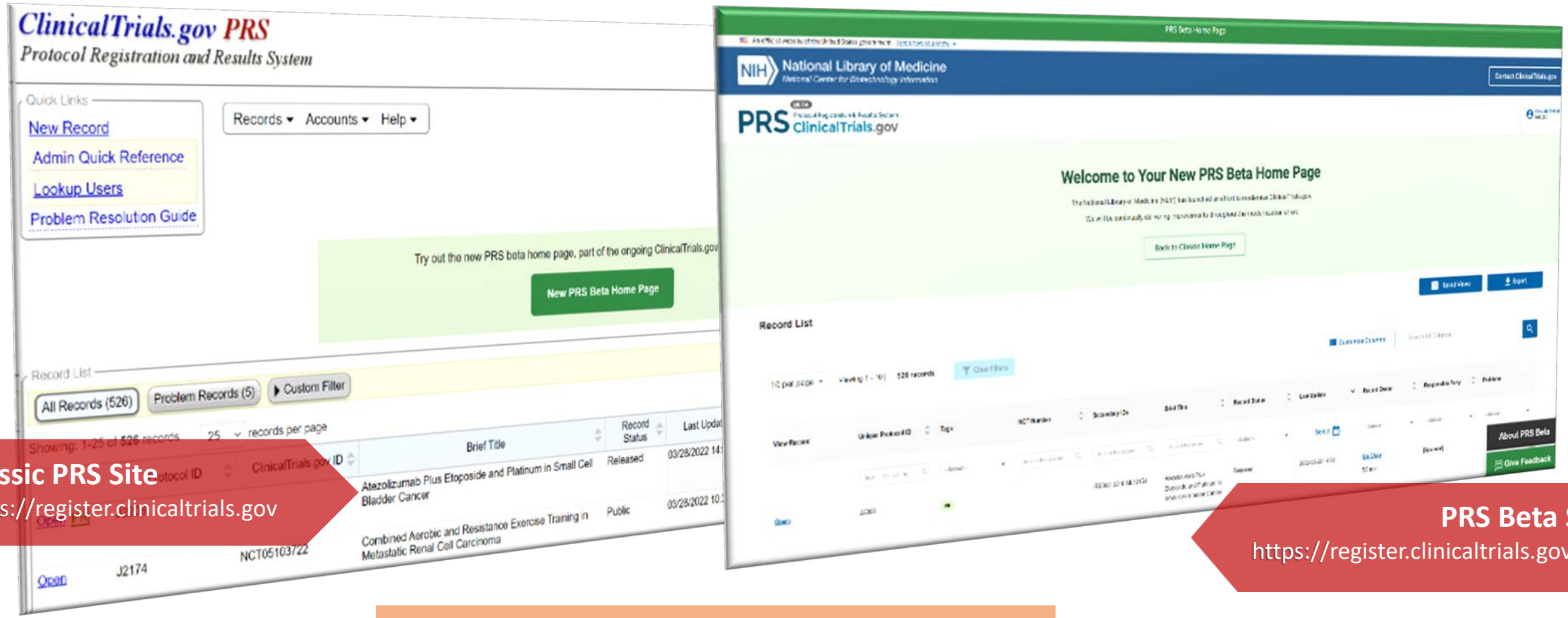
ClinicalTrials.gov - PRS



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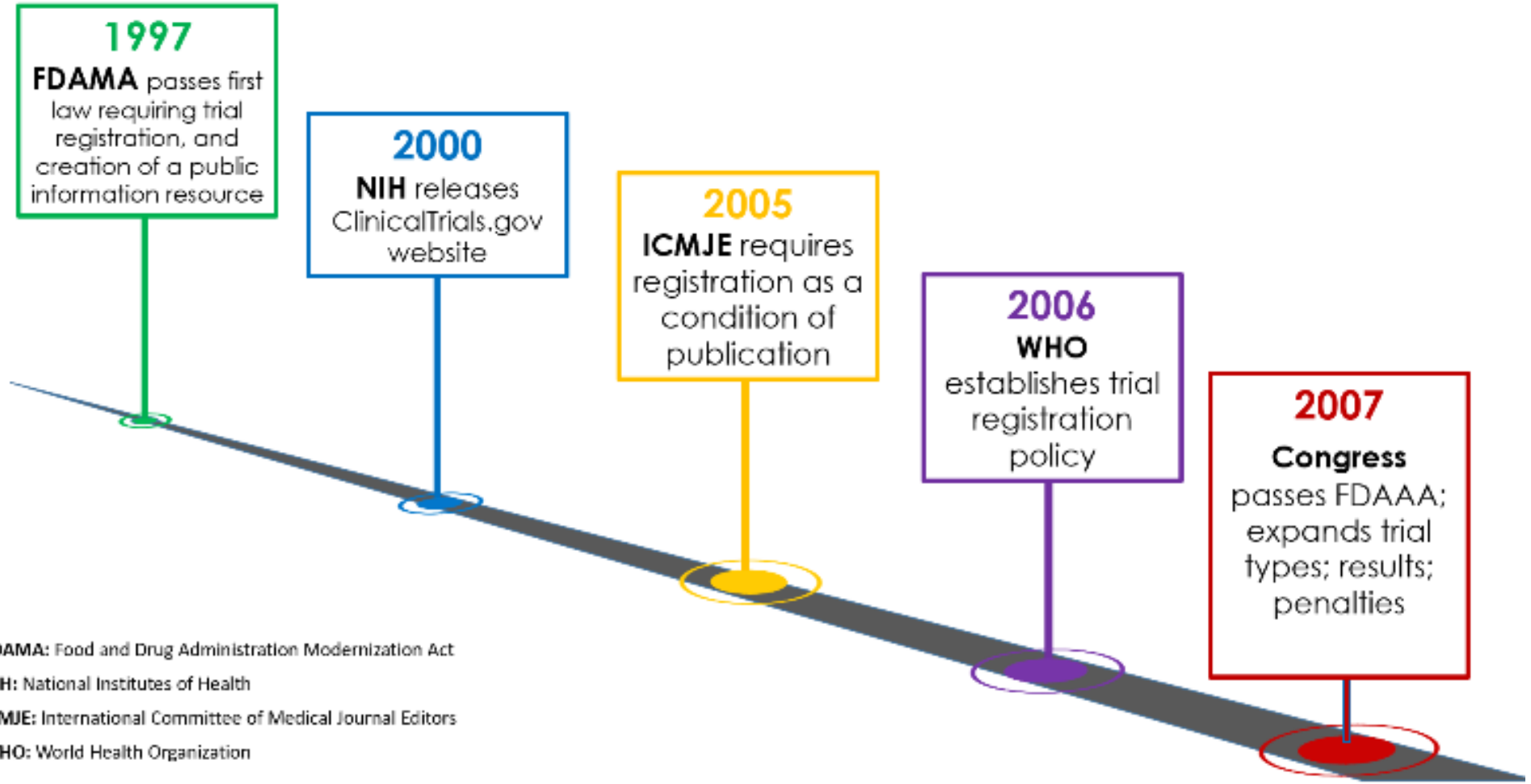

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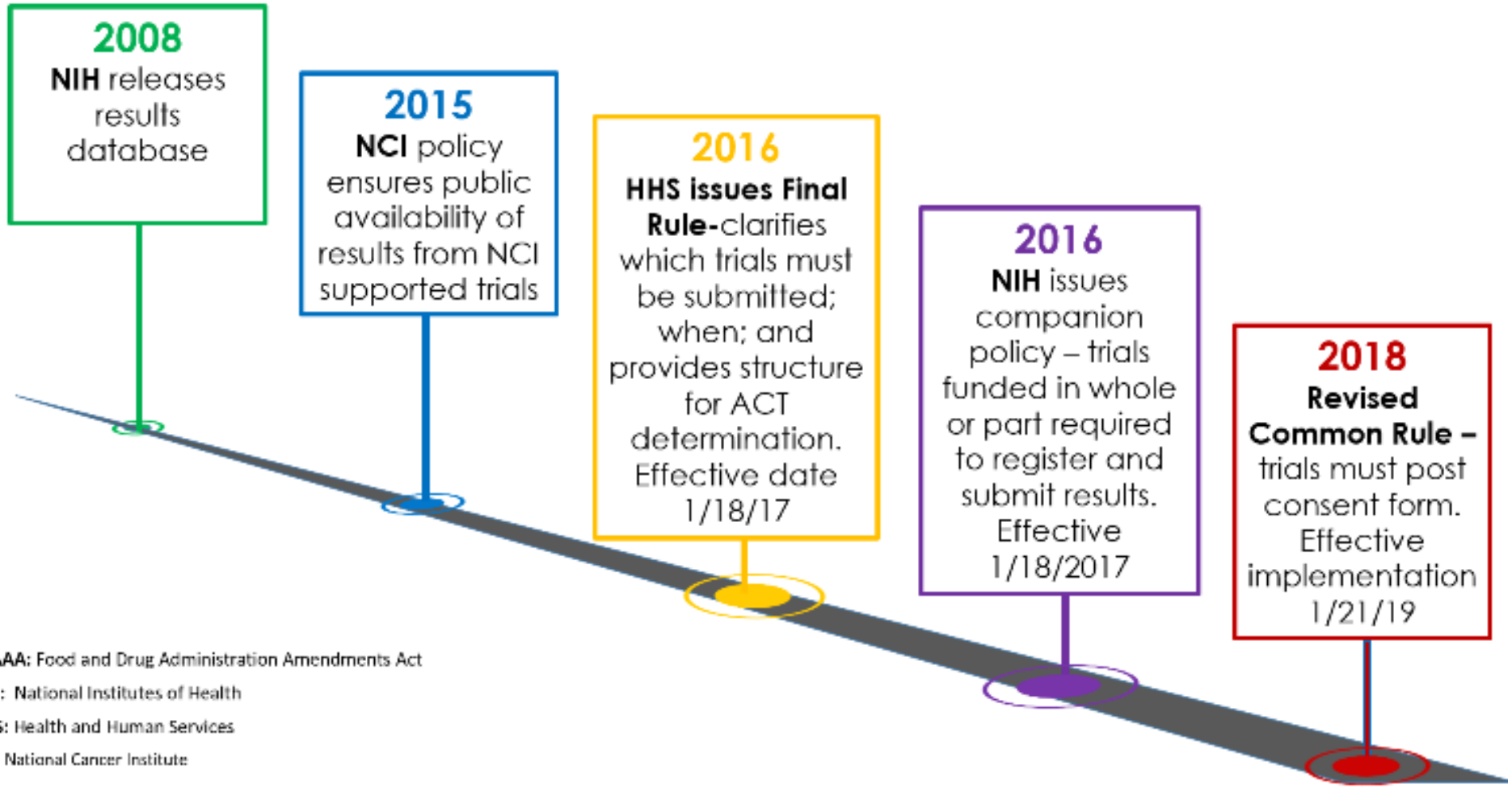

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Why is this necessary?

- ✓ Commitment to research participants (including recruitment)
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What needs to be registered?

- Any research study meeting the definition of a clinical trial
  - International Committee for Medical Journal Editors (ICMJE)
  - Food and Drug Administration Amendments Act (FDAAA)
  - National Institutes of Health (NIH)

- Any research study with funding from an agency that requires registration

Uploading the Consent Form

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Recent Enforcement and Monitoring

FDAAA 801 Violations

- Notice is sent to the Responsible Party
- **Pre-Notice Letters** are **not** identified as an FDAAA 801 Violation and **not** identified in ClinicalTrials.gov
- **Notice of Noncompliance** Letters are identified as an FDAAA 801 Violation in ClinicalTrials.gov

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2023 Articles

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https://www.transparimed.org/single-post/fdaaa-pallone
https://www.statnews.com/pharmalot/2023/02/27/fda-petition-clinical-trials-transparency-nih/
https://www.transparimed.org/single-post/nih-research-waste

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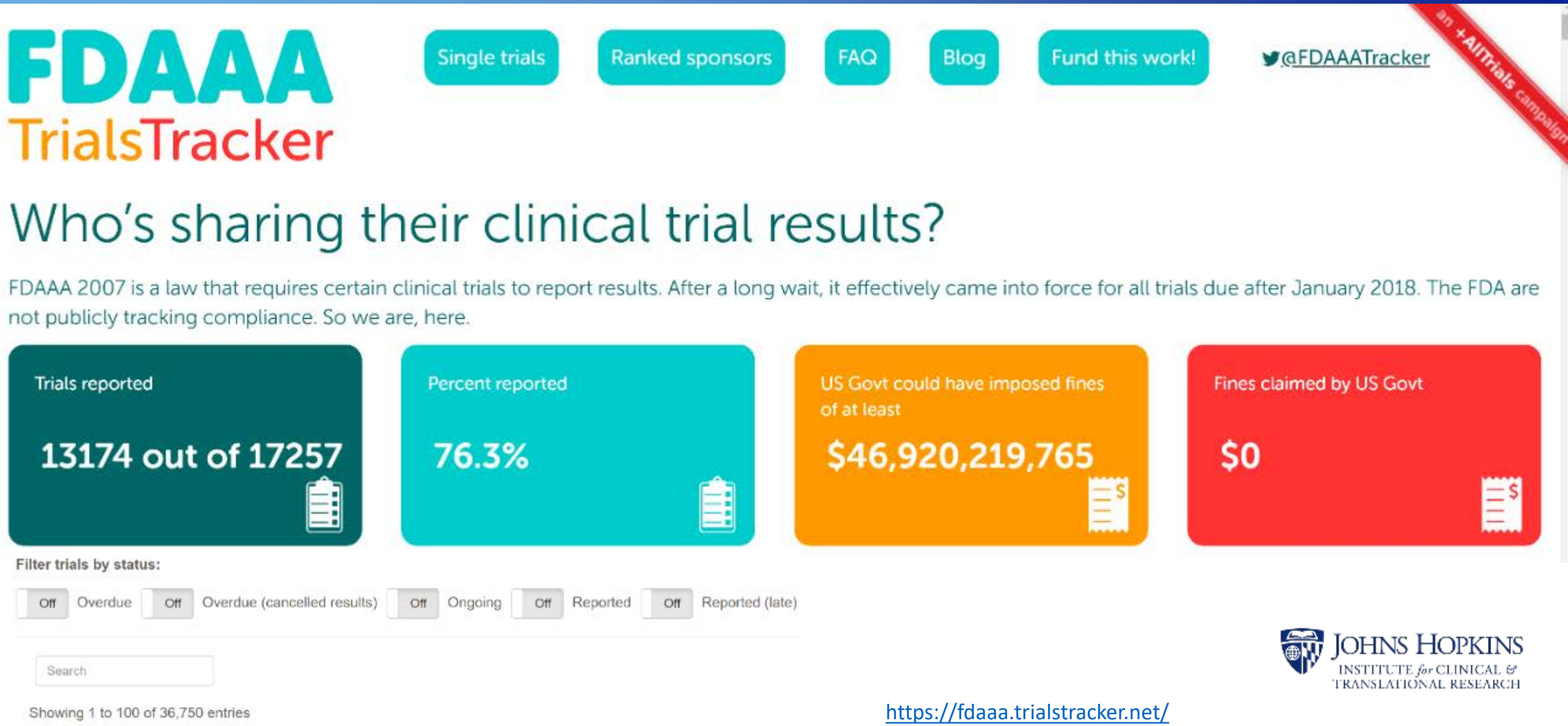
Watchful Eyes – FDAAA TrialsTracker



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Our Program

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JHU ClinicalTrials.gov Program

For the PI/Study team, assistance with…

—**Registration**

- Account creation and maintenance
- Initial registration
- PRS reviewer comments (15 calendar days)
- Update reminders (required every 12 months regardless of changes)
- Changes to PI/Study team (including when a PI leaves)

JHU ClinicalTrials.gov Program

Results Reporting

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DMIG: May 11, 2023

Research Coordinator Support Service (RCSS)

The ICTR Research Coordinator Support Service (RCSS) is a pool of research coordinators that are available for hire on a part-time basis by Johns Hopkins researchers.

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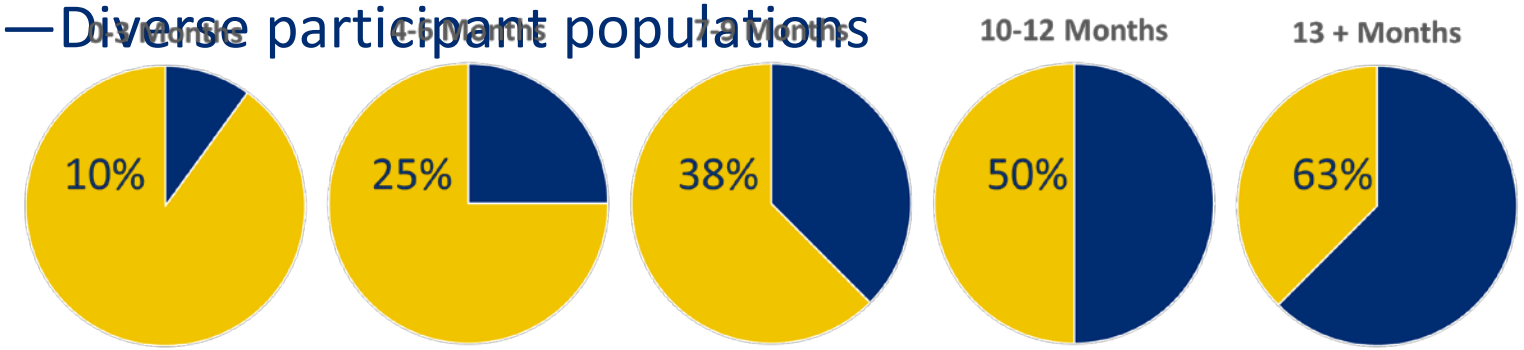
Overview of Program/Core

- SCAMP was established in 2012
  - —Provide coordinator training to trainees with no clinical research training
- RCSS was established in 2014
  - —Provide services to investigators who needed part-time research support
- SCAMP was been re-branded as the Coordinator Apprentice Program (CAP) in November 2020

SCAMP: Study Coordinator Apprenticeship and Mentoring Program
RCSS: Research Coordinator Support Service
CAP: Coordinator Apprentice Program

Rapid Onboarding → Early Assignments

- Tracking tool for completion of required courses and the time/course
  - —Nearly 150 hours of onboarding
- Multiple short-term work assignments of escalating responsibilities
  - —Drugs, devices, behavioral
  - —Sponsored, federally-funded, investigator-initiated
  - —Study status (beginning, middle, end)
  - —Mixture of disease states
  - —Diverse participant populations



(e.g., at 4-6 months, the apprentice will aim for 25%, 10 billable hours per 40 hour work week)

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What's in it for them?

- Opportunity
- Shadowing experienced Coordinators
- 1:1 Mentoring
- Expansive access to training
- Scrubs and a personalized lab coat
- SoCRA membership and test fee
- Free parking

SOCRA
FOR CLINICAL RESEARCH EXCELLENCE

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Current Staff

Role	Number of Staff
Director	1
Sr. Supervisor	1
Sr. Coordinators	1
RCSS Coordinators	5
Year 2 Apprentices	1
Year 1 Apprentices	7
Total	**16**

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SCOPE of Work

- Connection request
  - —1:1 meeting

    -AND/OR-
  - —REDCap survey
- Assign a Coordinator/ Coordinators
  - —Based on work assignment
  - —Ongoing Senior level support

What coordinator responsibilities do you need support with? (Check all that apply)

- ☐ Feasibility
- ☐ Regulatory support (e.g., IRB applications, binders)
- ☐ Pre-Screening/Screening
- ☐ CRMS/Epic
- ☐ Scheduling/Consenting participants
- ☐ Conducting study visits
- ☐ REDCap
- ☐ Data entry and mangement
- ☐ Study close out
- ☐ Other, please specify

SCOPE of Work

- Scheduling
  - —Prefer fixed times
  - —Can be flexible
- Location
  - —Multiple available
  - —Usually the study covers parking with vouchers or reimbursement

What is the weekly work schedule needed? (Check all that apply)	☐ Flexible ☐ Mondays ☐ Tuesdays ☐ Wednesdays ☐ Thursdays ☐ Fridays ☐ Weekends (typically not available) ☐ Unsure
Study location?	☐ East Baltimore, Please specify location(s) ☐ Bayview, Please specify location(s) ☐ Greenspring, Please specify location(s) ☐ Home visits ☐ Remote (no study locations) ☐ Other, please specify

SCOPE of Work

- Regular meetings with PI
  - —Follow up
  - —Feedback
- Invoicing
  - —Wed-based hours tracking Tool (Clockify)
  - —Detailed description of each day
- Survey at end of work assignment (coming soon!)

Onboarding Program

- Research Staff/Coordinators Onboarding program
  - —For PIs hiring research staff with minimal research experience.
  - —1:1 meeting with PI/Department
    - Trainee's background
    - Studies' need
    - Training Catalogue
  - —2 hrs. per week/6-8 weeks
    - RCSS may continue with "Ongoing support" (Optional)

RCSS Training Catalogue sample

☐ **Required Trainings:** (The box includes the following minimal required courses to conduct research)

☐ Johns Hopkins School of Medicine Training (*for New hires*)	☐ School of Medicine New Employee Orientation ☐ School of Medicine Annual Required Training ☐ Opioid Awareness ☐ Preventing and Addressing Harassment and Sexual Misconduct.	2-3 hrs. 2-3 hrs. 1 hr. 1-2 hrs.
☐ Johns Hopkins Institutional Review Boards (IRB) Requirement	☐ Human Subject Research - Biomedical Research (HSR) - (CITI) ☐ Researchers - (CITI) *(Prev.=Health Privacy Issue)* ☐ Conflict of Interest and Commitment (COI) ☐ Responsible Conduct of Research (RCR) ☐ Clinical Research Billing Orientation (CRBO)	10 hrs. for bundle same bundle same Bundle 7 hrs. 1 hr.
☐ NIH/Institution Requirement	☐ Good Clinical Practice (GCP) and ICH - (CITI)	15-17 hrs.
☐ Fit testing	☐ JH - Safety Respiratory Protection Training (Pre-requisite)	1 hr.

Impacts

- CAP has trained 51* coordinators since 2012
  - —**81%** (39/48) are still in research
  - —**58%** (28/48) are still at JHU
- Investigators have turned to RCSS
  - —To take on projects they would normally have to turn down
  - —To support research teams that have lost staff members
  - —To supplement their own staffing/knowledge gaps
  - —To grow research portfolios

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*Percentages reported based on 48 we are still in contact with, as 3 are lost to follow-up

Priorities

I. Growing research professionals
   - —Hire the right candidates
   - —Rapid onboarding
   - —Early, study-specific assignments
   - —Ecosystem where Apprentices become mentors

II. Supporting researchers at JHU …and beyond
   - —Assist onboarding their staff
   - —Expand our coordinator onboarding pilot program
   - —Contribute to the national discussion with other CTSAs
   - —Other Universities considering similar programs
   - —Poster presented at ACTS 2023 in DC (04/18/23)

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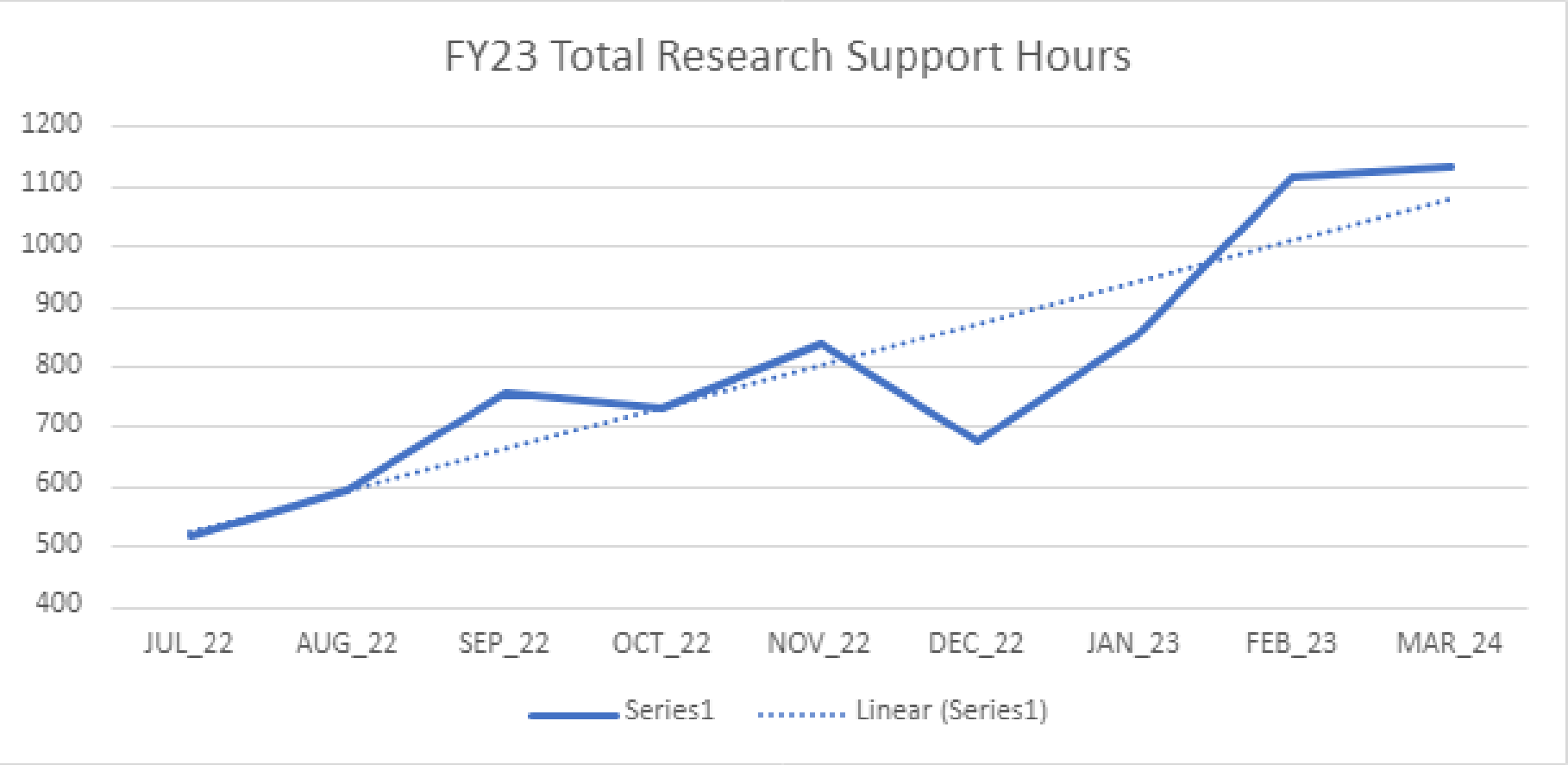
Supporting Research at JHU

- Over 7,200 research support hours in the last 9 months (800/month)



$60/hr. - Apprentices, Coordinators

$65/hr. - Regulatory Specialists, Sr. Coordinators Onboarding

Johns Hopkins Institute for Clinical & Translational Research

How to Connect with us

- https://ictr.johnshopkins.edu/service/study-conduct/rcss/

HOME › SERVICES AND RESOURCES › STUDY CONDUCT › RESEARCH COORDINATOR SUPPORT SERVICE (RCSS)

The ICTR Research Coordinator Support Service (RCSS) is a pool of research coordinators that are available for hire on a part-time basis by Johns Hopkins researchers.

Make a Request

Contact

Tony Keyes
Program Administrator
akeyes1@jhmi.edu

About Us

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Questions?

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- akeyes1@jhmi.edu

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DMIG: May 11, 2023

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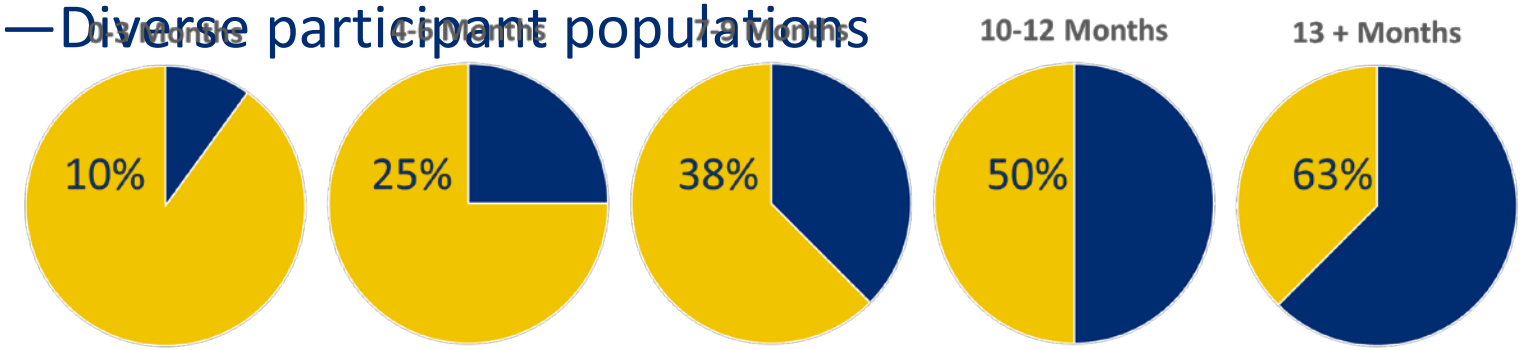
Overview of Program/Core

- SCAMP was established in 2012
  - —Provide coordinator training to trainees with no clinical research training
- RCSS was established in 2014
  - —Provide services to investigators who needed part-time research support
- SCAMP was been re-branded as the Coordinator Apprentice Program (CAP) in November 2020

SCAMP: Study Coordinator Apprenticeship and Mentoring Program
RCSS: Research Coordinator Support Service
CAP: Coordinator Apprentice Program

Rapid Onboarding → Early Assignments

- Tracking tool for completion of required courses and the time/course
  - —Nearly 150 hours of onboarding
- Multiple short-term work assignments of escalating responsibilities
  - —Drugs, devices, behavioral
  - —Sponsored, federally-funded, investigator-initiated
  - —Study status (beginning, middle, end)
  - —Mixture of disease states
  - —Diverse participant populations



(e.g., at 4-6 months, the apprentice will aim for 25%, 10 billable hours per 40 hour work week)

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What's in it for them?

- Opportunity
- Shadowing experienced Coordinators
- 1:1 Mentoring
- Expansive access to training
- Scrubs and a personalized lab coat
- SoCRA membership and test fee
- Free parking

SOCRA
FOR CLINICAL RESEARCH EXCELLENCE

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Current Staff

Role	Number of Staff
Director	1
Sr. Supervisor	1
Sr. Coordinators	1
RCSS Coordinators	5
Year 2 Apprentices	1
Year 1 Apprentices	7
Total	**16**

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SCOPE of Work

- Connection request
  - —1:1 meeting

    -AND/OR-
  - —REDCap survey
- Assign a Coordinator/ Coordinators
  - —Based on work assignment
  - —Ongoing Senior level support

What coordinator responsibilities do you need support with? (Check all that apply)

- ☐ Feasibility
- ☐ Regulatory support (e.g., IRB applications, binders)
- ☐ Pre-Screening/Screening
- ☐ CRMS/Epic
- ☐ Scheduling/Consenting participants
- ☐ Conducting study visits
- ☐ REDCap
- ☐ Data entry and mangement
- ☐ Study close out
- ☐ Other, please specify

SCOPE of Work

- Scheduling
  - —Prefer fixed times
  - —Can be flexible
- Location
  - —Multiple available
  - —Usually the study covers parking with vouchers or reimbursement

What is the weekly work schedule needed? (Check all that apply)	☐ Flexible ☐ Mondays ☐ Tuesdays ☐ Wednesdays ☐ Thursdays ☐ Fridays ☐ Weekends (typically not available) ☐ Unsure
Study location?	☐ East Baltimore, Please specify location(s) ☐ Bayview, Please specify location(s) ☐ Greenspring, Please specify location(s) ☐ Home visits ☐ Remote (no study locations) ☐ Other, please specify

SCOPE of Work

- Regular meetings with PI
  - —Follow up
  - —Feedback
- Invoicing
  - —Wed-based hours tracking Tool (Clockify)
  - —Detailed description of each day
- Survey at end of work assignment (coming soon!)

Onboarding Program

- Research Staff/Coordinators Onboarding program
  - —For PIs hiring research staff with minimal research experience.
  - —1:1 meeting with PI/Department
    - Trainee's background
    - Studies' need
    - Training Catalogue
  - —2 hrs. per week/6-8 weeks
    - RCSS may continue with "Ongoing support" (Optional)

RCSS Training Catalogue sample

☐ **Required Trainings:** (The box includes the following minimal required courses to conduct research)

☐ Johns Hopkins School of Medicine Training (*for New hires*)	☐ School of Medicine New Employee Orientation ☐ School of Medicine Annual Required Training ☐ Opioid Awareness ☐ Preventing and Addressing Harassment and Sexual Misconduct.	2-3 hrs. 2-3 hrs. 1 hr. 1-2 hrs.
☐ Johns Hopkins Institutional Review Boards (IRB) Requirement	☐ Human Subject Research - Biomedical Research (HSR) - (CITI) ☐ Researchers - (CITI) *(Prev.=Health Privacy Issue)* ☐ Conflict of Interest and Commitment (COI) ☐ Responsible Conduct of Research (RCR) ☐ Clinical Research Billing Orientation (CRBO)	10 hrs. for bundle same bundle same Bundle 7 hrs. 1 hr.
☐ NIH/Institution Requirement	☐ Good Clinical Practice (GCP) and ICH - (CITI)	15-17 hrs.
☐ Fit testing	☐ JH - Safety Respiratory Protection Training (Pre-requisite)	1 hr.

Impacts

- CAP has trained 51* coordinators since 2012
  - —**81%** (39/48) are still in research
  - —**58%** (28/48) are still at JHU
- Investigators have turned to RCSS
  - —To take on projects they would normally have to turn down
  - —To support research teams that have lost staff members
  - —To supplement their own staffing/knowledge gaps
  - —To grow research portfolios

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*Percentages reported based on 48 we are still in contact with, as 3 are lost to follow-up

Priorities

I. Growing research professionals
   - —Hire the right candidates
   - —Rapid onboarding
   - —Early, study-specific assignments
   - —Ecosystem where Apprentices become mentors

II. Supporting researchers at JHU …and beyond
   - —Assist onboarding their staff
   - —Expand our coordinator onboarding pilot program
   - —Contribute to the national discussion with other CTSAs
   - —Other Universities considering similar programs
   - —Poster presented at ACTS 2023 in DC (04/18/23)

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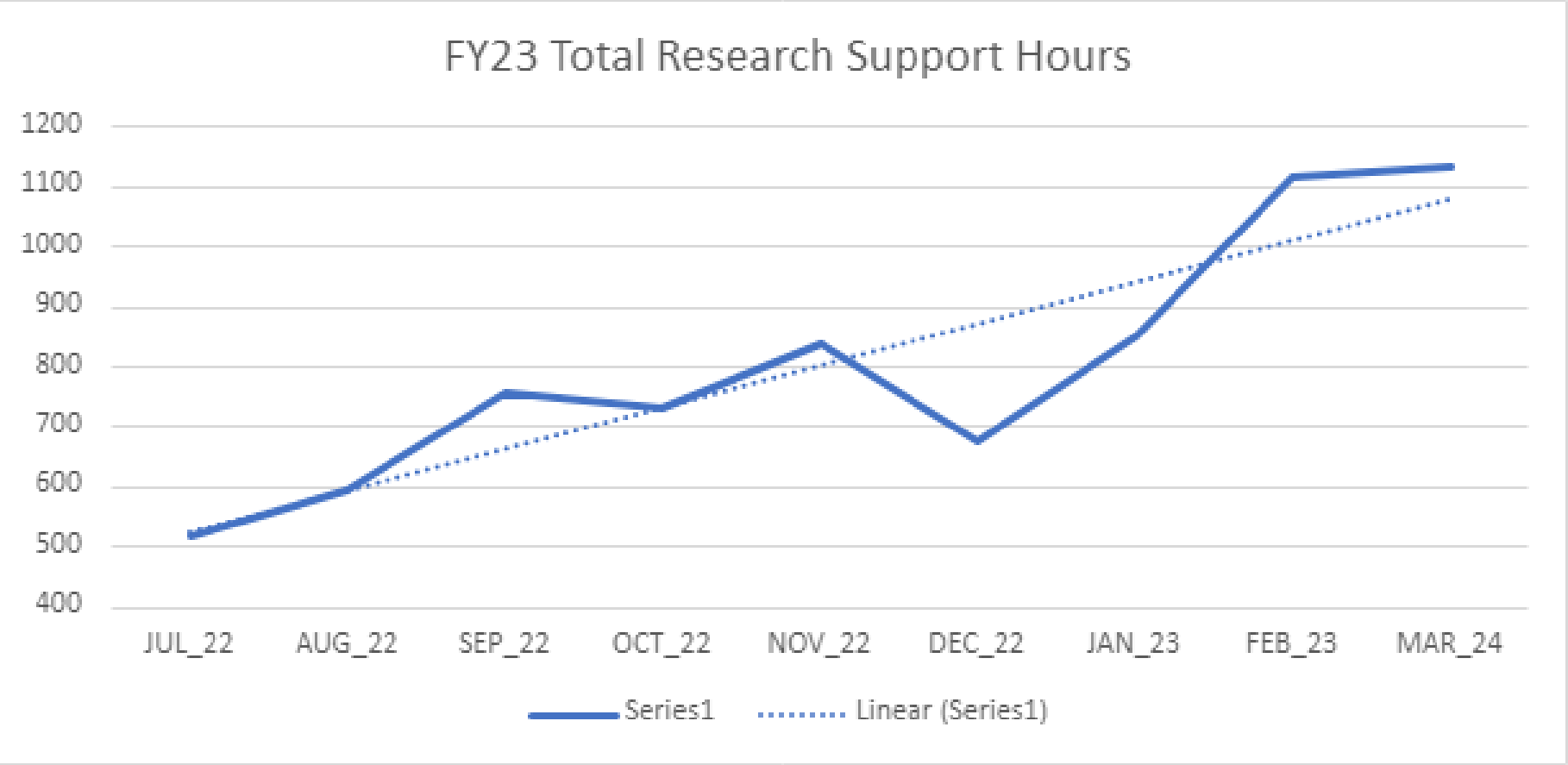

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