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ORIENTATION TO CLINICAL RESEARCH AT JOHNS HOPKINS FOR NEW RESEARCH TEAMS

November 18, 2022

Goals for this Webinar:

- Provide general description of main clinical research offices
  - IRB
  - Office of Research Administration
  - Office of Clinical Trials
  - Institute for Clinical and Translational Research
- Provide an overview of clinical research services
  - May be elective consultative functions, services only available through one group (CCDA and access to clinical data for research), and required administrative and compliance oversight
- Discuss some common clinical research protocols to demonstrate how the research offices work together

Johns Hopkins Clinical Research Environment

- One of the largest and most comprehensive clinical research environments
  - Child health, cancer, psychiatric and addictive disorders
  - Collaborators at BSPH, SOE, SON, Kennedy-Krieger Institute
  - Large health system including community hospitals and All Children's Hospital in Florida
- Span translational research pathway from basic science to implementation science
- Mix of sponsors from federal sources to PHARMA

Johns Hopkins Clinical Research Ecosystem

- Multiple training opportunities for faculty early research career awards
  - Individual Ks
  - ICTR KL2 (CTSA)
  - BIRCWH (Building Interdisciplinary Research Careers in Women's Health)
  - GTPCI (Graduate Training Program in Clinical Investigation
- Excellent Mentors
- Team Science Training

Johns Hopkins Clinical Research Ecosystem

- In response to an increasing complex environment (multicenter, data sharing, intellectual property, etc) Johns Hopkins support has had to respond

- Human Research Participant Protection Program
  - IRB Director – Megan Singleton
  - Vice Dean for Clinical Investigation – Gail Daumit
- Institute for Clinical and Translational Research - CTSA
  - Director – Daniel Ford
- Office of Clinical Trials
  - Director – Mark Sulkowski

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Institute for Clinical and Translational Research (ICTR)

Daniel Ford, MD, MPH
Director, ICTR

Dorothy Damron, MS
Administrative Director

Trial Innovation Unit (TIU)

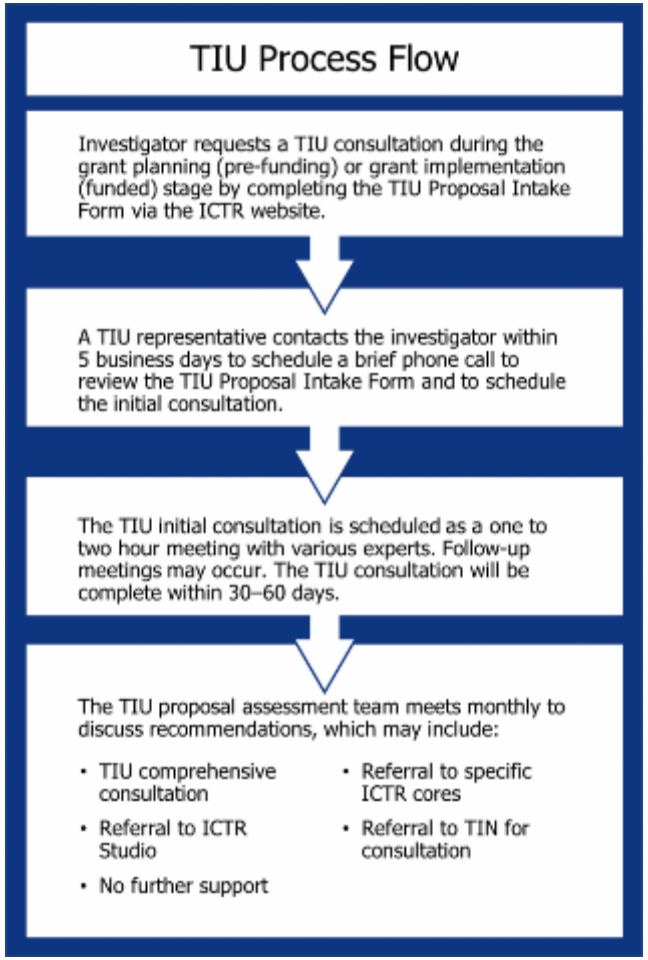
Dan Hanely, MD
Deputy Director ICTR
Division Director, BIOS, School of Medicine
TIU_INTAKE@jhu.edu

Trial Innovation Unit (TIU)

What We Do:

- The Trial Innovation Unit (TIU) is composed of two key organizational partners—the ICTR and BIOS, a JHU-based academic research organization.
- We work with trials funded by the NIH, commercial sponsors, or foundations. The TIU is committed to facilitating the development of investigative expertise.
- K-grant, T-grant, and other early career investigators are invited to participate in project evaluation, trial simulation, and planning activities. Biostatistical doctoral and postdoctoral candidates may participate in statistical analysis plan development and reporting. The TIU provides expert consultative support to investigators with small, local multi-center translational studies needing to:
    - Improve research study design, trial operations, and analysis plans.
    - Explore opportunities for single and multi-center trial innovation.
    - Improve diversity and community engagement in clinical trials.
    - Assess translational pathway and readiness for multi-center trials.
    - Provide strategic assistance with grant applications.
    - Develop and improve the overall stewardship, efficiency, accountability, and transparency of clinical trials.

How to work with us:



Trial Innovation Unit (TIU)

Tips and Trick to working with us:

- After the initial meeting, the TIU service provides an additional hour of free support for the research project to provide supporting material and/or further planning discussed during the initial meeting. The initial TIU 2 hour consult is free.
- If you need specific grant services, planning or additional support after the 2 hour consult, a broad spectrum of services are available through the TIU teams for a fee.

The Research Studio: A Master Class

Studio Director: Carol Kobrin, PhD

The ICTR Navigators: ICTRNavigators@jhmi.edu

Research Studio

What We Do:

Organize project specific consultations to assist with higher level research questions at all stages of developing a research program

- Creating Competitive Grants/Presubmission Grant Reviews
- Availability of Institutional Cores and/or Resources to Help Conduct Preclinical and Clinical Studies
- Project Feasibility Concerns

How to work with us:

Requests for a Studio consultation can be submitted via the ICTR Service Request Portal

Research Studio

Tips and Trick to working with us:

- Please allow between 4-8 weeks to organize a Studio
- Don’t request a consultation until you’ve identified specific questions to discuss with the Studio
- Remember that the Studio is a:
  - Multidisciplinary service center that brings investigators together with the experts and resources needed to address their questions
  - Disease agnostic but customized for each protocol or project
  - “One stop shop” where experts across diverse disciplines all meet together with the investigator in a single setting to provide coordinated assistance
  - Ongoing process that continues to work with the investigator and help make any necessary adjustments
  - Complimentary service

Community and Collaboration Core (CCC) Recruitment Innovation Unit (RIU) @ JH ICTR

CCC: Cyd Lacanienta, Assoc. Director, Stakeholder Engagement, clacani1@jh.edu

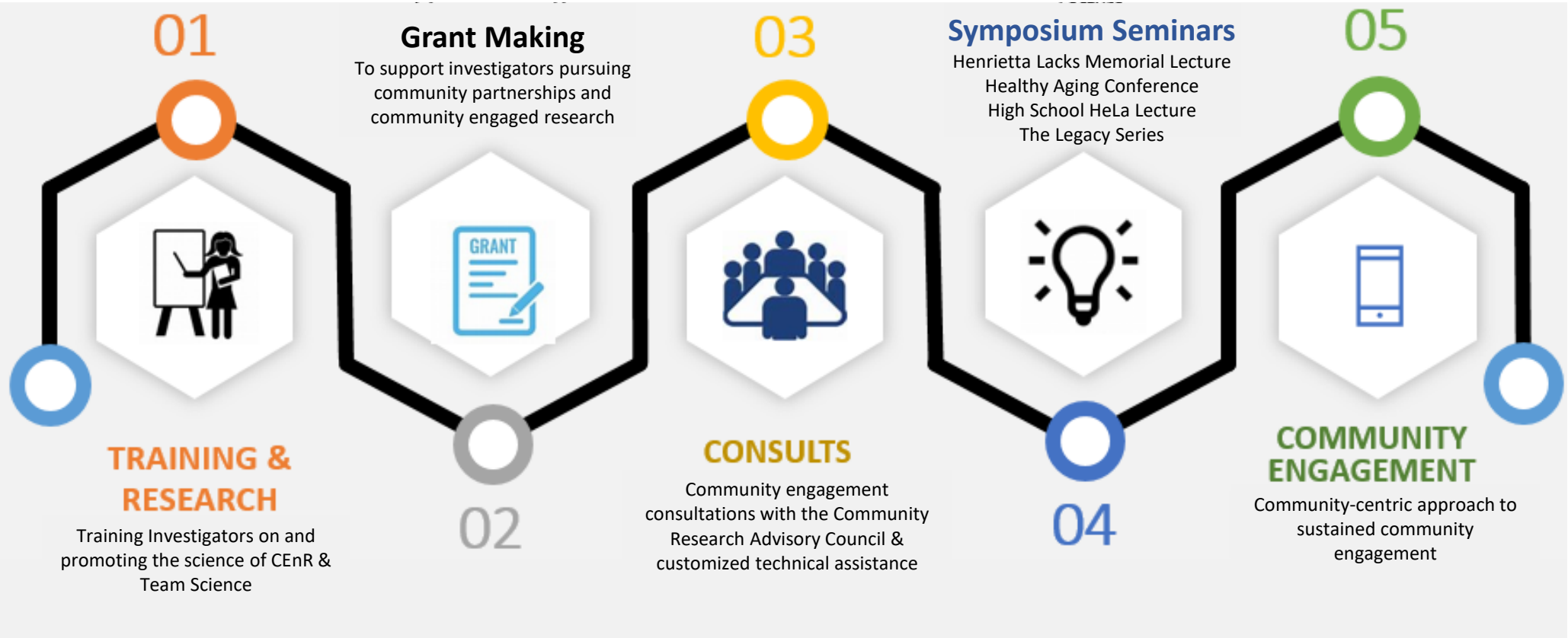
RIU: Cassie Lewis-Land, Program Administrator, clewis20@jhmi.edu

https://ictr.johnshopkins.edu/community-engagement/

https://ictr.johnshopkins.edu/service/recruitment/riu-consult/

Community and Collaboration Core (CCC)

What We Do:



Recruitment Innovation Unit (RIU)

What We Do:

Services	Brief Explanation of Services
Social Media Recruitment Service	RIU creates and launches the paid advertisements, monitors the campaign's progress, and reports the metrics
HOPE registry	Centralized recruitment of COVID research participants
MyChart Recruitment	Utilize Epic MyChart patient portal to send recruitment invitations
RIU Research Consultation	Providing research consultation service and providing help with creating recruitment plans that address challenges

HOPE is a community of over 17,000 people interested in participating in COVID-19 outpatient research

MyChart
Your health. Your knowledge. Your connection.
JOHNS HOPKINS MEDICINE

The MyChart Recruitment Service sends out research messaging invitations thru the patient portal

We also support teams with:
- customize consults for developing recruitment plans

-developing and managing social media campaigns

-designing print and digital recruitment materials

-supporting community engagement in research

Community and Collaboration Core (CCC) Recruitment Innovation Unit (RIU) @ JH ICTR

How to Work with Us:

- ICTR Service Request Portal: https://mrprcbcw.hosts.jhmi.edu/redcap/surveys/?s=A8FE8FT47W
- Trainings and grants in community-engaged research and team science: Sarah Stevens, Research Program Manager ssteve45@jhmi.edu
- Community engagement consults: Crystal Evans, Community Relations Coordinator cevans20@jhmi.edu
- Day at the Market Outreach: Barbara Bates-Hopkins, Community Relations Coordinator bhopkin1@jhu.edu
- Community engagement for COVID-19: Donald Young, Community Engagement Specialist dyoung49@jhu.edu
- RUI Contact: Cassie Lewis-Land clewis4@jhmi.edu

Community and Collaboration Core (CCC) Recruitment Innovation Unit (RIU) @ JH ICTR

Tips and Trick to working with us:

- Do tap into our team as you are designing your project and before you submit protocols to the IRB
- Do reach out to any of our core team members if you have questions.

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Research Collaborators

Path PCORNet – Daniel Ford, Harold Lehman, Megan Gauvey-Kern

Johns Hopkins Clinical Research Network – Adrian Dobs

CAPRES – Mark Sulkowski and Jackie Lobien

Research Collaborators

What We Do:

Help researchers collaborate with research teams Johns Hopkins community sites (CAPRES) local community health systems (JHCRN) or academic health systems (PCORNet)

PCORNet has EMR database across organizations ready for analysis

How to work with us:

Work with Jackie Lobien for CAPRES to determine if another JHHS site makes sense

Work with JHCRN leadership to present to JHCRN research committee – monthly Thursday 9 am

Work with Path to present to Front Door Committee

Johns Hopkins Clinical Research Network – Affiliate Sites

Research Collaborators

Tips and Trick to working with us:

- Need to start early (2 months before submission) to be respectful to collaborators and include budgetary support in any applications
- PCORNet can be utilized for studies not funded by PCORI
- ICTR can assist you with building patient partnerships

Capital Region Research (CAPRES)

Mark Sulkowski, MD
Professor of Medicine
Chief, Infectious Diseases Johns Hopkins Bayview
Senior Associate Dean for Clinical Trials and Capital Region Research

Jackie Lobien, BSN, CCRP-CP
Director, CAPRES

CAPRES

What We Do:

- The primary responsibility of CAPRES is to grow research at JHM community hospitals (Suburban, Sibley, HCGH) in both volume and impact. CAPRES assists the investigators at the academic centers in Baltimore in expanding their enrollment by including research opportunities at the local hospitals where the patient receives treatment

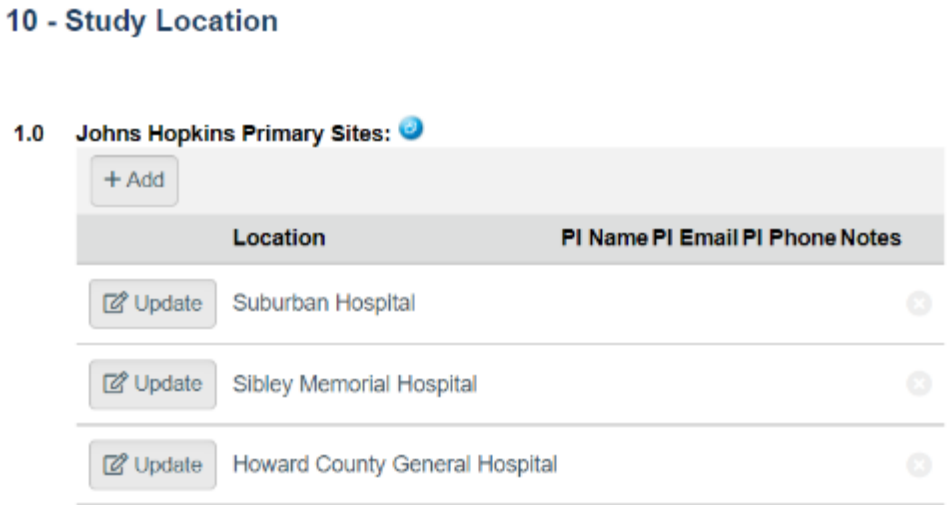
How to work with us:

- contact Jackie Lobien at JLobien1@jhmi.edu

CAPRES

Tips and Tricks to working with us:

- Consider including the community hospital sites (CAPRES) as early in the research process as possible (when writing a grant or signing a CDA for a sponsored study) as no sub-contracts are needed
- Sites can easily be added to one JHM IRB application in section 10



Clinical Research Units (CRUs)

Bayview: Suzanne Jan de Beur sjandebe@jhmi.edu
JHH (Blalock): Todd Brown tbrown27@jhmi.edu
PCRU: Robert Wood rwood@jhmi.edu

Clinical Research Units (CRUs)

What We Do:

- Provides dedicated, safe, clinically compliant space for research
- Access to well-trained and credentialed research personnel to perform study procedures
- Accommodates short to 24/7 multi-week research studies
- Offers specialized services
  - Drug administration, infusions
  - Frequent blood sampling for PK, PD etc
  - Blood and body fluid collection
  - DXA
  - Sleep studies
  - Cardiovascular studies
  - Exercise and body composition
- Train study teams
- Provides safety and compliance oversight of study teams
- Offers consultation from clinical research experts

How to work with us:

- Application: Brief web-based application

https://ictr.johnshopkins.edu/service/study-conduct/clinical-research-units/apply/

- Review process: streamlined, *administrative* review focused on capacity and feasibility
- Budgeting process in conjunction with full-time budget administrator based on charge master
- Timeline: two weeks after complete submission of application and budget

Clinical Research Units (CRUs)

Clinical Research Units (CRUs):

- Adult Outpatient CRUs
  - Blalock 3 (JHH)
  - 301 Building 4th floor (Bayview)
- Adult Inpatient/Domiciliary CRUs
  - Osler 5 (JHH)
  - 301 Building 4th floor(Bayview)
- Pediatric Outpatient/Inpatient CRU
  - Charlotte R. Bloomberg Building (JHH)
- COVID CRU
  - Bayview PODs

Cores:

- Research Nutrition Core
- Cardiovascular/Exercise Physiology Core
- Core Lab

Clinical Research Units (CRUs)

Tips and Tricks to working with us:

- Christine LaPonzina: Application claponz1@jhmi.edu
- Nicole Cooper: Budgeting Process ncooper2@jhmi.edu
- Virtual Tour:

https://ictr.johnshopkins.edu/service/study-conduct/clinical-research-units/locations/

- Charge Master:

https://ictr.johnshopkins.edu/programs_resources/programs-resources/clinical-research-units/

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Core for Clinical Research Data Acquisition (CCDA)

Bonnie Woods, Director of Clinical Research IT Services

Shipra Sachdeva, Manager, CCDA

CCDA

What We Do:

- Feasibility Counts for grant submission, IRB application
- Data extraction from Epic, PMAP, or other clinical systems
- Data de-identification
- Assistance using self-service cohort discovery tools (SlicerDicer, TriNetX, OMOP)
- Honest Broker services

How to work with us:

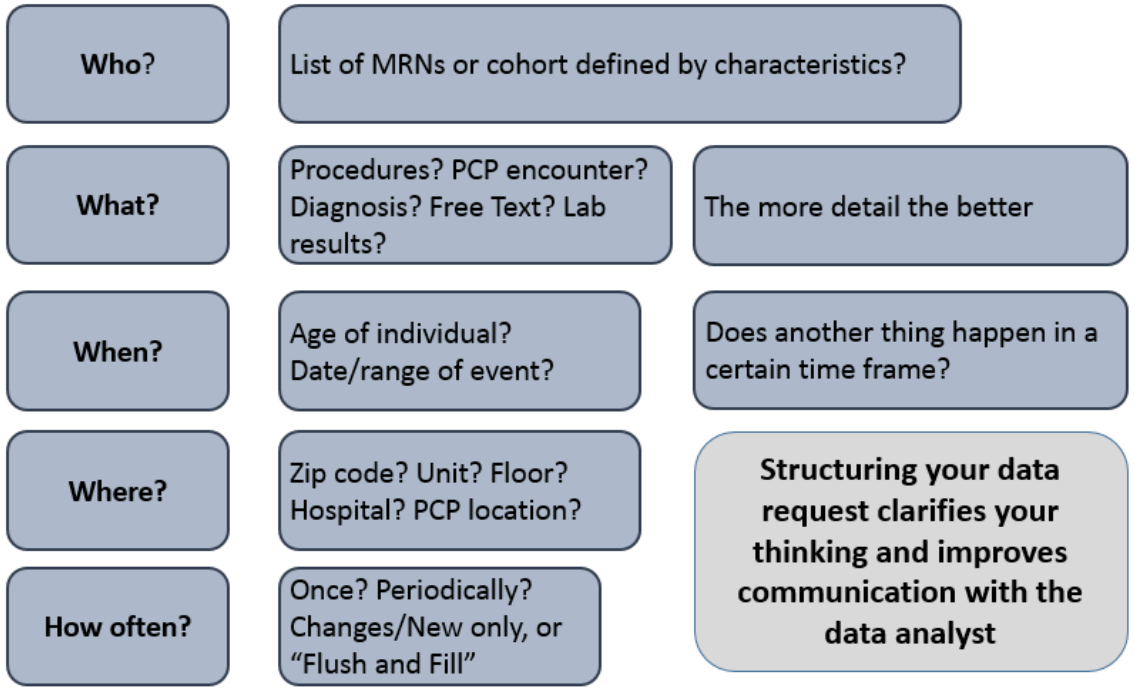
Make a Request

- We offer 2 hours of consultation service per project, covered by the ICTR ($118/hour after 2 hours)

CCDA

Tips and Tricks to working with us:

- Structure your data request:



Consult with a biostatistics service on study design and/or statistical analysis phases:

- BEAD Core
- JHSPH Biostatistics Core

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OpenSpecimen

Bob Lange, Project Leader
rlangea@jhmi.edu
Hope Whitaker, IT Specialist
hwhitak1@jhmi.edu

OpenSpecimen

What We Do:

- OpenSpecimen is a biospecimen tracking, management and annotation tool with flexible workflows and user-friendly, robust query capability
- Epic patient lookup
- Data Trust's preferred biospecimen management system
- Interface with PMAP
- Our team provides support in configuring and using the tool to meet your biobanking needs

How to work with us:

- Contact us via the ICTR website
- Email us directly:
  - Bob Lange (rlangea@jhmi.edu)
  - Hope Whitaker (hwhitak1@jhmi.edu)

OpenSpecimen

Tips and Trick to working with us:

- There is an overview and documentation available at https://cscop.jhmi.edu/confluence/display/caTissue/OpenSpecimen+Tutorials
- Contact our team to discuss your biospecimen management needs or for a demo
- We are a fee-for-service program, but there is a free tier with no monthly charge; we do charge hourly for the work that we do regardless of tier

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REDCap: Research Electronic Data Capture

Scott Carey, Sr. Software Engineer – Lead REDCap Administrator (SOM/SON/JHH/JHBMC,KKI…)

Andre Hackman, Asst. Scientist – SPH Biostats Consulting Center (SPH)

REDCap

What it is:

- Secure web-based, IRB approved application for building and managing research data environments.
- Allows direct data entry (study staff) as well as online surveys (study participants)
- Accommodates multi-site studies
- Integrates w/ EPIC at multiple levels
- Many other features (too many to discuss today)

What We Do:

- Initial Consults
- REDCap Project Design Support
- Integration Support
- REDCap Technical Support

How to work with us:

redcap.jhu.edu

REDCap

Tips and Tricks to working with us:

- Familiarize yourself with REDCap BEFORE submitting to IRB
- Plan accordingly for the appropriate support tier:
  - **Bronze**:
    - No cost… no support
    - Intended for smaller, unfunded projects
    - Some advanced features not available
  - **Silver**:
    - Includes support
    - Includes all REDCap features
  - **Gold:**
    - Includes additional support
    - Very large studies

Consult with a biostatistics service on study design and/or statistical analysis phases:

- BEAD Core
- JHSPH Biostatistics Core

REDCap – Helpful Resources

REDCap Videos (learn more)

JH REDCap Project Tiers

REDCap at JHU

JH REDCap Training Central

Research Coordinator Support Service (RCSS)

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

Research Coordinator Support Service (RCSS)

What We Do:

- Formerly known as SCAMP, the ICTR Research Coordinator Support Service (RCSS) is a pool of trained coordinators able to handle a wide range of customizable responsibilities to best fit the needs of your research team
- Team of 15 Coordinators
- $60-$65/hour, all inclusive

How to work with us:

- Reach out to us early
- https://ictr.johnshopkins.edu/service/study-conduct/rcss/

Make a Request

RCSS

Tips and Trick to working with us:

- Reach out early (even at the grant writing, Pre-IRB stage)
- We can assist you with a variety of services
  - Consenting, regulatory, study management, research visits, data entry, etc.
- During the Work agreement phase we will outline
  - Specific duties, number of hours/week, duration of assignment, etc.
- Communication during assignments is essential as things change
- We assist investigators to rapidly onboard new research staff

JHU ClinicalTrials.gov Program

registerclinicaltrials@jhmi.edu

JHU ClinicalTrials.gov Program

What We Do:

- Create accounts
- Provide assistance with identifying trials that need to report results and/or register
- Provide alerts to keep trials up-to-date
- Review each submission
- Run compliance reports
- Protect Institutional reputation

How to work with us:

- registerclinicaltrials@jhmi.edu
- Reach out to us early

Anthony Keyes

Oswald Tetteh

Kimberly Hill

JHU ClinicalTrials.gov Program

Tips and Trick to working with us:

- We assist investigators and study teams in SOM, SON, SKCCC, JHSPH and ACH
  - ANYONE CAN REACH OUT TO US
- We will send periodic, time-sensitive e-mails to alert you to potential noncompliance
  - RESPOND IN TIME
- There is a learning curve to understanding the regulations
  - LET US HELP YOU
- Invite us to speak with your department

Johns Hopkins Office of Clinical Trials

Marian De Backer
Director, Office of Clinical Trials

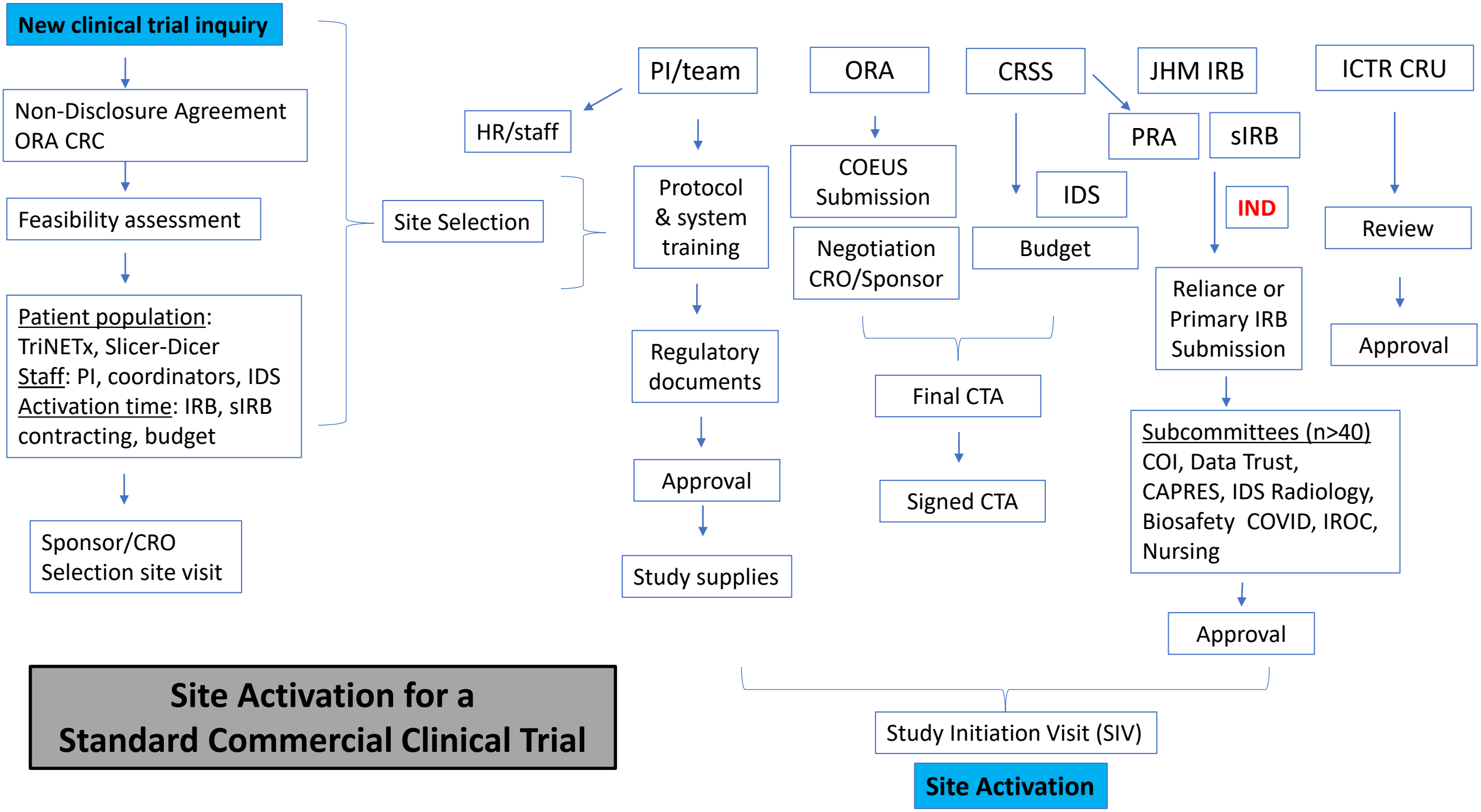
Mark Sulkowski, MD
Senior Associate Dean for Clinical Trials and Capital Research

OCT@jh.edu

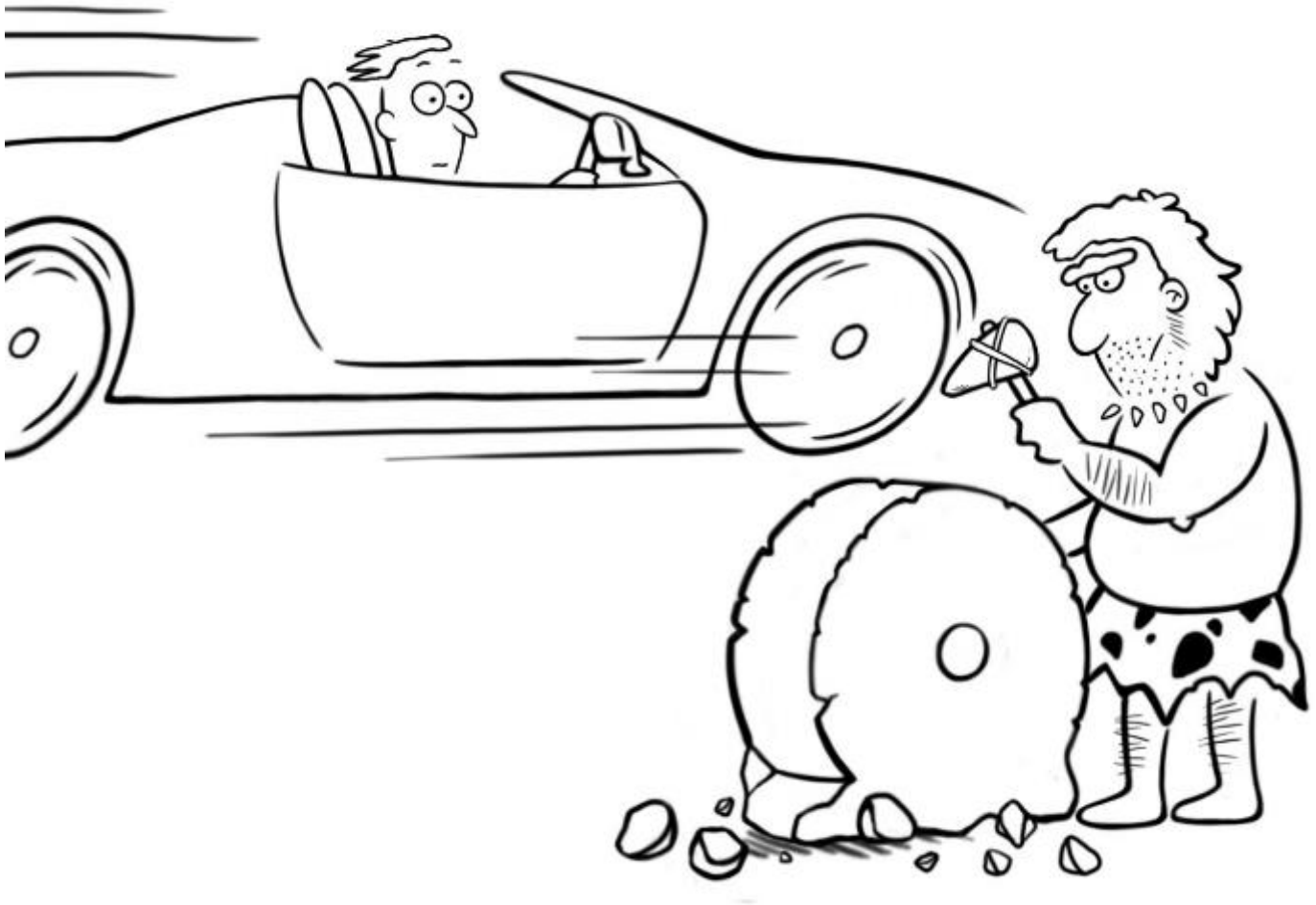
https://www.hopkinsmedicine.org/research/resources/offices-policies/office-clinical-trials/

The Office of Clinical Trials is focused on customer service

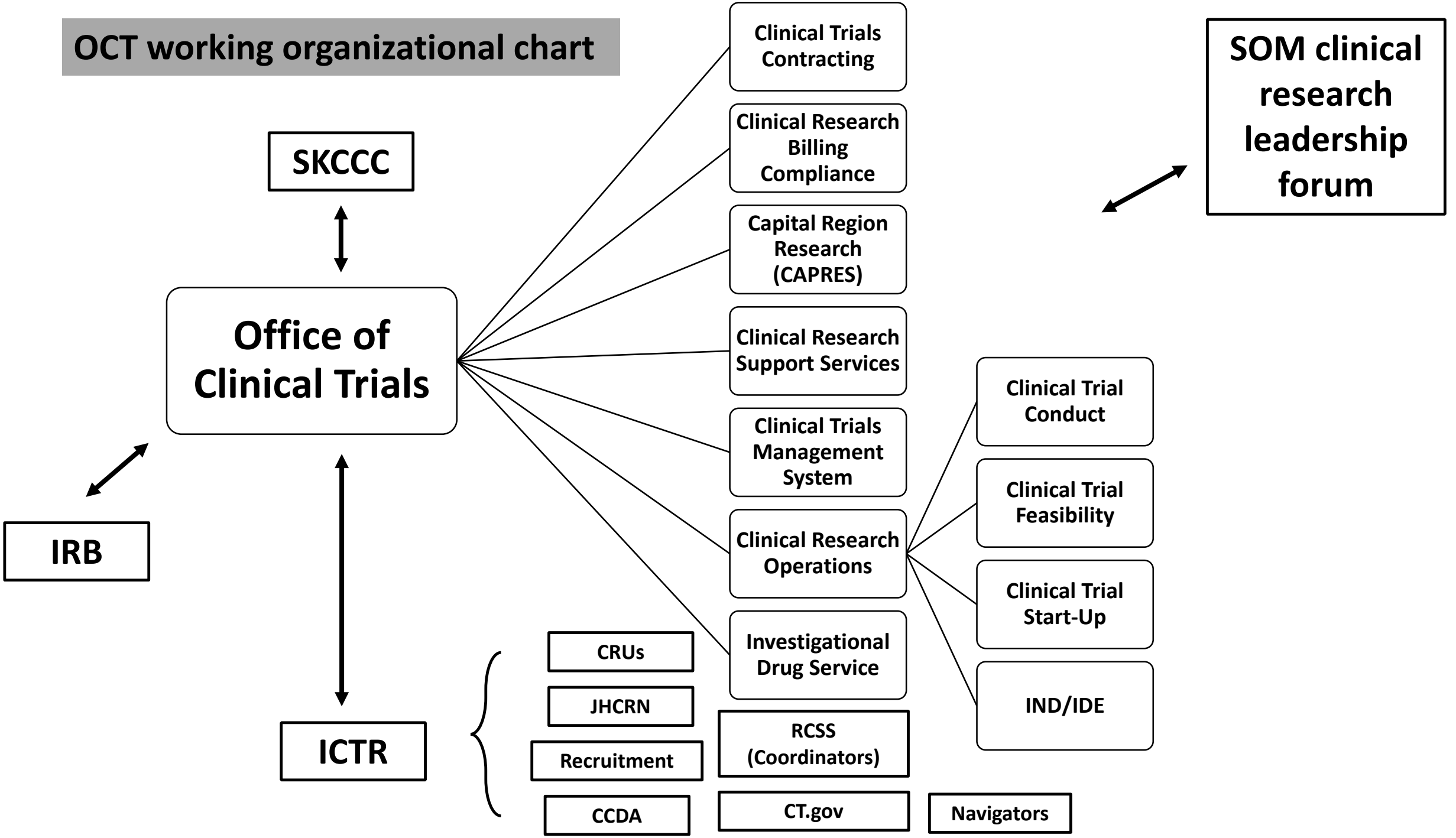
The OCT is the central administrative office dedicated to enabling the Johns Hopkins clinical investigators and research teams to push the boundaries of discovery. We aim to support, train, and facilitate investigators who conduct clinical research to improve health and manage disease


New clinical trial inquiry
Non-Disclosure Agreement
ORA CRC
Feasibility assessment
Patient population:
TriNETx, Slicer-Dicer
Staff: PI, coordinators, IDS
Activation time: IRB, sIRB
contracting, budget
Sponsor/CRO
Selection site visit
Site Selection
PI/team
HR/staff
Protocol
& system
training
Regulatory
documents
Approval
Study supplies
ORA
COEUS
Submission
Negotiation
CRO/Sponsor
Final CTA
Signed CTA
CRSS
IDS
Budget
JHM IRB
PRA
sIRB
IND
Reliance or
Primary IRB
Submission
Subcommittees (n>40)
COI, Data Trust,
CAPRES, IDS Radiology,
Biosafety COVID, IROC,
Nursing
Approval
ICTR CRU
Review
Approval
Study Initiation Visit (SIV)
Site Activation
Site Activation for a
Standard Commercial Clinical Trial

We strive to make clinical trials easier



OCT working organizational chart



OCT: New programs

https://www.hopkinsmedicine.org/research/resources/offices-policies/office-clinical-trials/

- IND/IDE regulatory program: Leader Eva Zimmerman
  - Registration of PI and protocol – before IRB and FDA submission
  - Consultation and service available
  - https://www.hopkinsmedicine.org/research/resources/offices-policies/office-clinical-trials/investigational-regulatory-program
- OnCore: Leader Sara Evans
  - Clinical Trials Management System
  - eReg Solution
- Clinical trial start-up service: Leader Marian De Backer
  - Team support/coordination from NDA to SIV to site activation
- Research at HCG, Suburban, Sibley (CAPRES): Leader Jackie Lobien

Investigational New Drug (IND) / Investigational Device Exemption (IDE) Regulatory Program

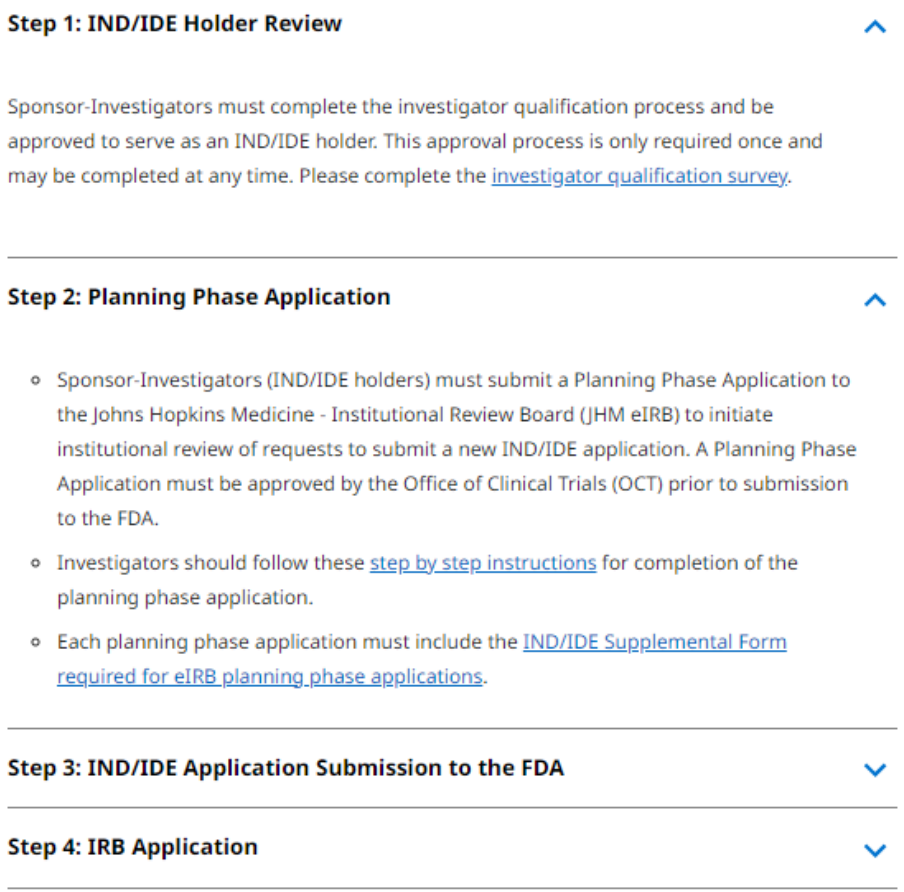
Eva Zimmerman, MCTM, CCRP, CIP, RAC | Director, IND/IDE Regulatory Program

For more information or questions, email the IND/IDE Regulatory Program: IND_IDEprogram@jh.edu

Schedule a consultation

Investigational New Drug (IND) / Investigational Device Exemption (IDE) Regulatory Program

The Investigational New Drug (IND)/Investigational Device Exemption (IDE) Regulatory Program provides guidance to clinical investigators, sponsors, and sponsor-investigators regarding the process to secure institutional approval to serve in the role of sponsor-investigator and submit an application for an IND or IDE to the FDA in accordance with the institutional policy on Investigator-held INDs/IDEs.



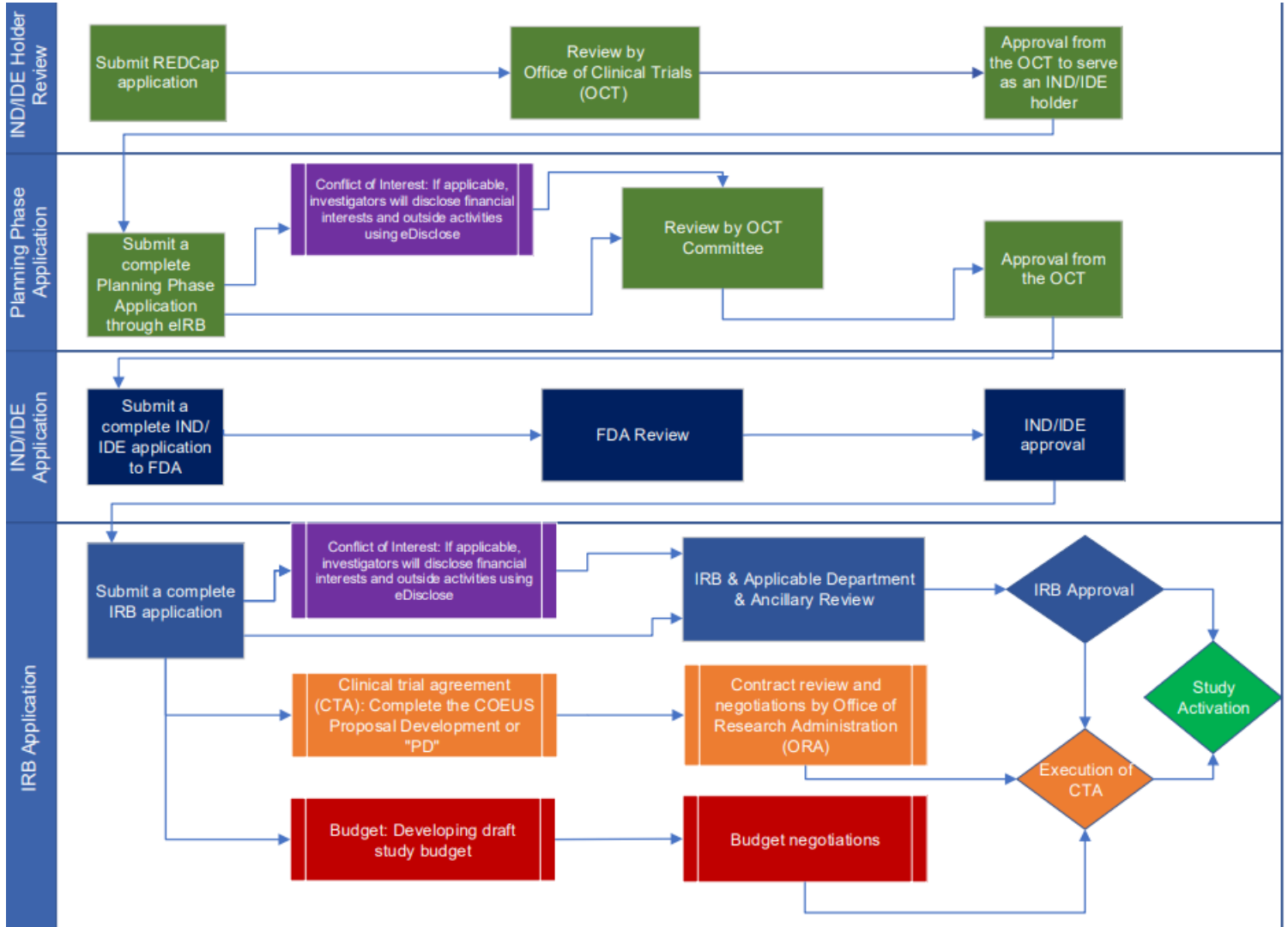
Investigational New Drug (IND) / Investigational Device Exemption (IDE) Regulatory Program

0-3 Calendar Days

30+ Calendar Days

35-45 Calendar Days

Variable



- ✓ Pro-active Sponsor-Investigator Qualification
- ✓ Early Engagement at the Planning Stage
- ✓ Collaborative Regulatory Application Preparation
- ✓ Continued Engagement

Clinical Research Contracting Office ("CRC")

https://ora.jhmi.edu/about-us/crc-crss-contact-information/

Mont Brownlee III, JD
Executive Director
fbrownl1@jhmi.edu

Clinical Research Contracting

What We Do:

CRC negotiates all clinical research agreements with commercial sponsors.

Not just Clinical Trial Agreements, but also Nondisclosure Agreements, Data Use Agreements, Material Transfer Agreements, etc.

How to work with us:

NDA's may be submitted by email.

Other agreements need to go through JHU's online submission system – your department staff can assist with this.

Clinical Research Contracting

Tips and Trick to working with us:

- Don’t wait! Contract reviews, budget negotiations, and IRB applications should all run in parallel; don’t finish one before starting the next.
- Good coordination between the study team and your department staff is important to making sure that your contract application is accurate and complete.
- And please make sure that the workscope included in the contract matches up with the protocol submitted to the IRB.

Office of Clinical Trials

Clinical Research Support Services (CRSS)

Clinical Research Billing Compliance (CRBC)

Karen Roz, Director rozka@jhmi.edu

CRSS@jhmi.edu

CLINIRESBILLING@exchange.johnshopkins.edu

Program Name

What We Do:

CRSS – develops Prospective Reimbursement Analysis (PRA) delineation of SOC vs. research; develops and negotiates commercial clinical trial budgets

CRBC – adjudicates patient care charges according to PRA

How to work with us:

PRA - can be initiated by IRB submission or contact central mailbox

Budget – message to central mailbox requesting assistance

Billing - contact central mailbox

Program Name

Tips and Trick to working with us:

- Please contact our central mailboxes which are monitored continuously, or Karen Roz directly

  CRSS@jhmi.edu
  Karen Roz, Director
  rozka@jhmi.edu

  CLINIRESBILLING@exchange.johnshopkins.edu
  Liza Rodriguez, Sr. Associate Director
  erodri13@jhmi.edu

- CRSS/CRBC has several training sessions that can be altered for investigators and delivered one on one.

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Office of Research Administration

Thomas Burns, JD, MBA Assistant Dean

Sharel Brown, MPhil, CRA Associate Director

https://ora.jhmi.edu/

Office of Research Administration

What We Do:

Grant proposal submissions

JIT, prior approval requests

Grant award review

SRA negotiation/signature

MTA, DUA, CDA

Clinical Trial Agreements

Subawards

How to work with us:

COEUS- all proposal/contract submissions

Department Assignments

SWiFT for Outgoing Subawards

ORA Website

Office of Research Administration

Tips and Trick to working with us:

- All proposals/contracts require a COEUS record. Make sure you are working with your Department Administration to route.
- Find your Department/Division ORA contacts
- Know the University's applicable F & A rates
- Submit applications within the 3 day deadline

Office of Human Subjects Research and the Institutional Review Board (IRB)

Kenneth Borst, JD
Associate Director of Operations
Email: kborst1@jhmi.edu
Phone: (443) 927-1458

IRBs at Johns Hopkins–

- First established in 1971
- Three separate IRBs
  - 1. School of Medicine
  - 2. School of Public Health
  - 3. Homewood
- Where to submit would be the PI's primary affiliation.

SOM IRBs meeting composition and frequency–

- 8 IRBs (1,2,3,5,6,X, EC and JHM ACH)
- Each IRB meets weekly except JHM ACH IRB and EC
- Emergency IRB
- IRBs meet for 2 hours; review 20 plus applications/week including:
  - New Applications
  - Change in Research
  - Continuing Review
  - Protocol Events
- Agendas are finalized 7 to 10 days prior to the meeting

The IRB Reviews –

- **Convened:** more than minimal risk and/or research involving vulnerable populations; full board review
- **Expedited:** must present no more than minimal risk as defined by FDA regulations; 1 reviewer
- **Exempt:** Includes some research done in educational settings, observations of public behavior, surveys, most chart reviews, use of publically available data, or taste and food quality evaluation. This category does not apply to FDA regulated research; this **exempt** from some federal regulations.
- **Not Human Subjects Research (NHSR)/ Quality Improvement (QI):** Research does not involve identifiable human subjects (NHSR). Data collection and analysis activities in the healing services area that are not intended for general scientific knowledge, but rather are used as a management tool to improve the provision of services to a specific health care population (QI/QA)

OHSR Staff–

- Pre-Team IRB Coordinator/Analyst - For questions regarding when an application will be scheduled for review, issues returned in a pre-review note and placement of documents in the application.
- Post Team IRB Coordinator/Analyst - For questions regarding the outcome of a study, requesting an extension to respond, stamped documents, questions about tabled issues or questions about your outcome letter.
- Consent Form Specialists - For questions about consent forms, the consenting process or types of consent please contact one of the consent form specialists.
- Compliance Associates - For questions about regulatory issues, compliance with federal, state and local policies, general compliance issues, protocol events or noncompliance.
- Reliance Team - For questions about requesting a reliance agreement, single IRBs for a multi-center study, or relying on a commercial IRB please contact the IRB Reliance Program.

Process–

- Pre-meeting
  - Initial submission
  - Ancillary reviews (pre/concurrent/post)
  - Assignment
  - 48 hours pre-review
  - Scheduled for an agenda
- Post-meeting
  - Meeting date
  - Minutes finalized
  - Outcomes letters processed

IRB Communication–

- OHSR is fully remote
  - MS Teams
  - Signature line
  - Request a consult: link
  - IRB Help Desk email: jhmeirb@jhmi.edu
  - IRB Help Desk phone 410-502-2092
  - Ancillary Committees: **Department & Ancillary Reviews - Hopkins Medicine**

Institutional Compliance Training Requirements

- SOM affiliates must provide evidence of Human Subjects Research-Biomedical Research Training, Conflict of Interest & Commitment and Researchers compliance training. These courses are now included in our Initial IRB Compliance Training Bundle. Clinical Research Billing Orientation is required for PIs and study team members who obtain consent on human subjects research studies.

- Any course that is also administered on the CITI website should be should be registered through myLearning. Otherwise once completed, your training will not automatically update.

- SOM affiliates are required to recertify Human Subjects Research Training every 3 years. PIs register for Principal Investigator Human Subject Recertification. Non-PIs register for Study Team Member Human Subject Recertification.
- School of Public Health and Homewood affiliates are required to provide evidence of their institutional Basic Human Subject Research compliance training and are required to recertify their HSR training every 5 years.

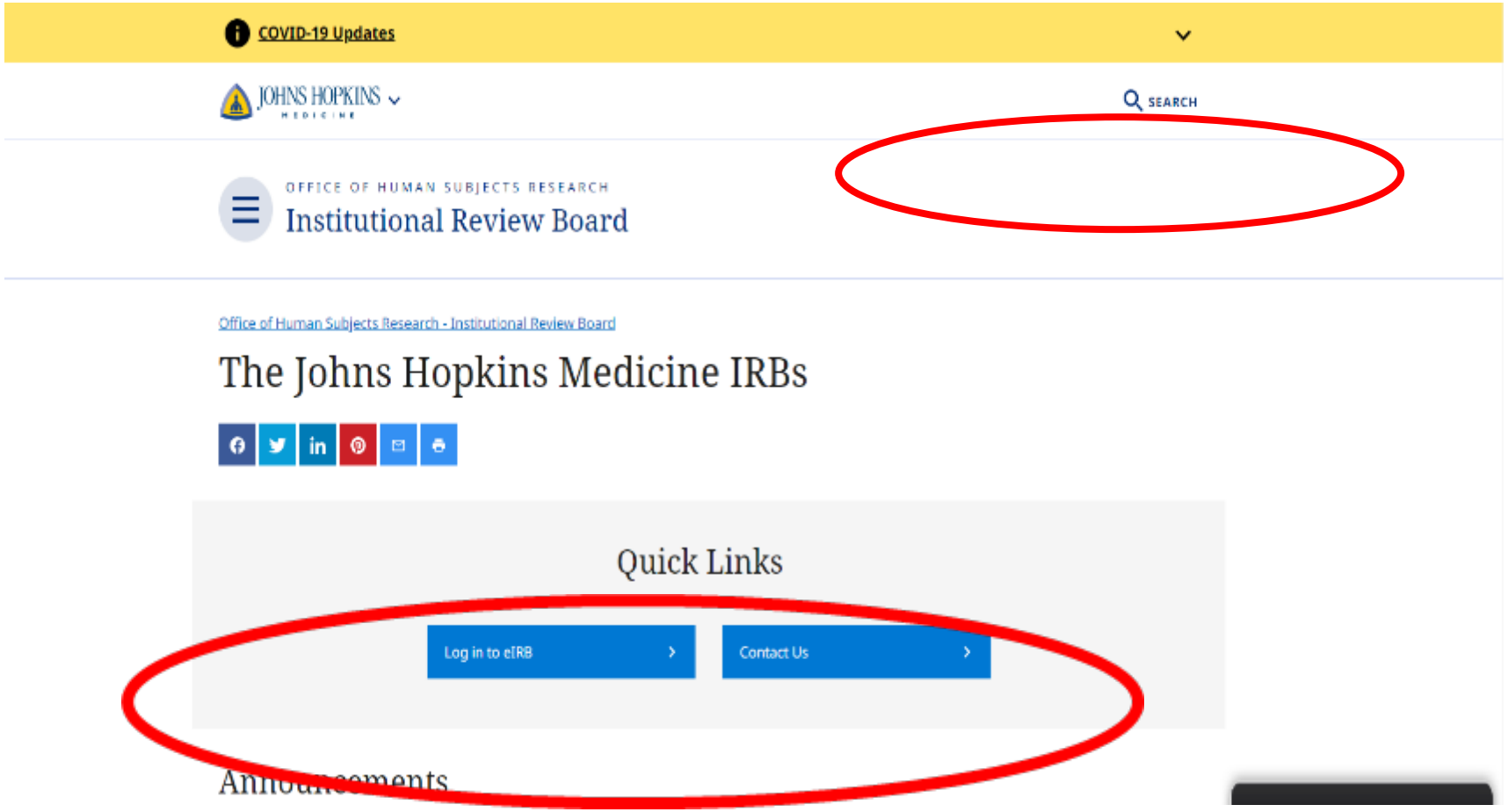
REWards training

The Research Ethics Workshops About Responsibilities and Duties of Scientists (REWards) program is designed to address key concepts in human subjects protection in specific research communities. REWards combines lectures and small group discussions to provide practical information on the ethical issues involved in research protocol development and implementation.

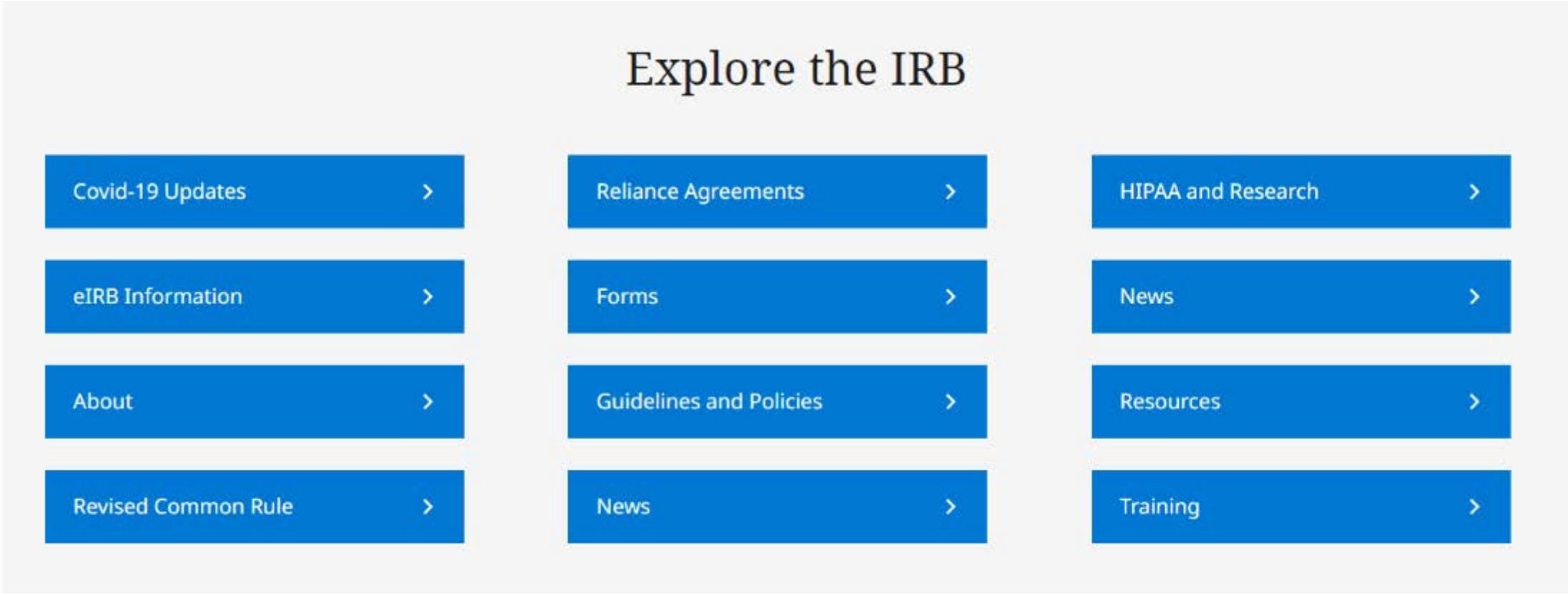
- **Who needs it?**

- New Principal Investigators must complete their requirement to attend REWards within one year from the date of their first eIRB protocol submission as a PI. **PIs must attend 2 workshops to fulfill their training requirement.**
- If the PI does not complete REWards within 1 year from the date of their first eIRB submission, they will not be able to submit new applications or changes in research until the requirement has been met. For eIRB applications that are determined to be not human subjects research (NHSR) REWards training is recommended, but not required.

IRB Website http://www.hopkinsmedicine.org/institutional_review_board



The different tabs provide further information on those IRB topics



Useful Resources

- FAQ Page:

https://www.hopkinsmedicine.org/institutional_review_board/about/faqs.html

- IRB Membership: Each committee is listed with the date of the meeting and roster.

https://www.hopkinsmedicine.org/institutional_review_board/about/irbs/index.html

- Forms Page: Includes are protocol templates, consent form templates, recruitment, reliance and other forms that may be useful.

https://www.hopkinsmedicine.org/institutional_review_board/forms/

- Reliance Agreement Page: Provides information on reliance agreements and how to start the process.

https://www.hopkinsmedicine.org/institutional_review_board/about/agreements/index.html

- Department and Ancillary Review Page: Lists the different reviews that can occur. These reviews can occur pre, concurrent or post IRB review. Also includes the reviewers name and contact information.

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/dept_prereview.html

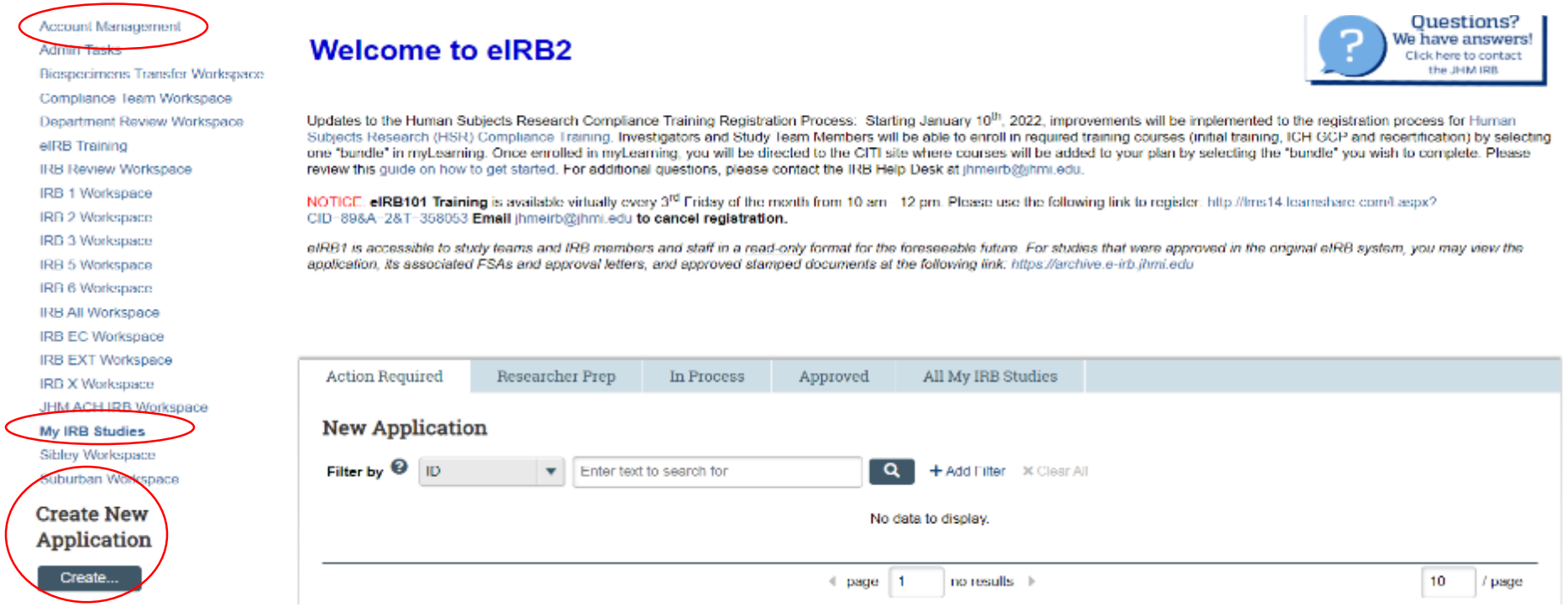
Investigator Home Page

- Left Navigation Bar
  - Account Management (*Non-JHED Users Only)*
  - My IRB Studies
  - Create New Application
- Welcome Message

  -Link to Archive eIRB website

  - User alerts

  -Important research community eIRB updates and announcements

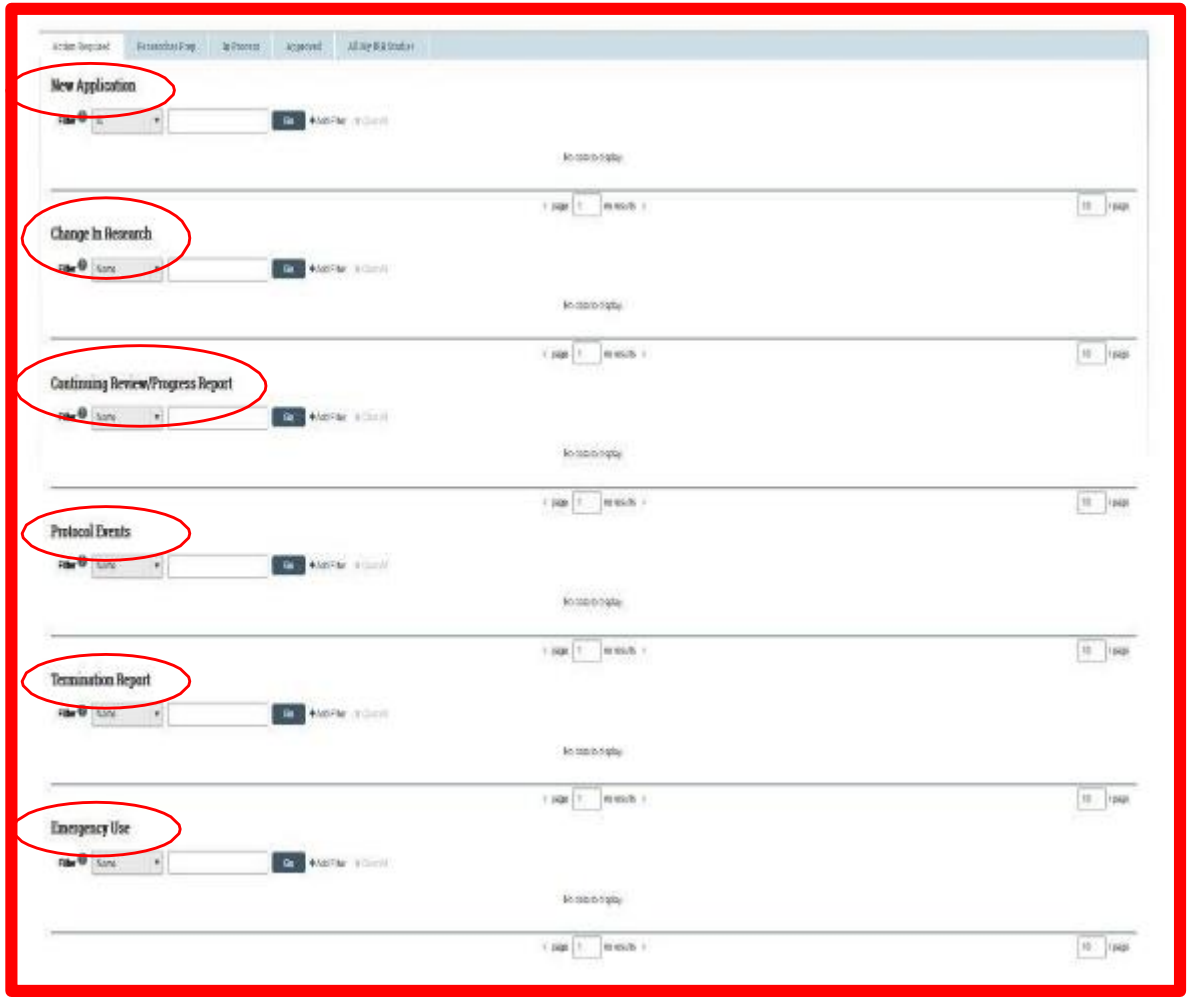


Investigator Workspace

- Studies List
  - Studies are listed by project type

Studies List

- Your studiesare listed by type.
  - New Application
  - Change in Research
  - Continuing Review/Progress Report
  - Protocol Event
  - Termination Report
  - Emergency Use
- Click the study name to open the study workspace.



Investigator Tabs

Action Required (*default tab*)

- Studies that have been returned for PI response

Researcher Prep

- Studies that have never been submitted

In Process

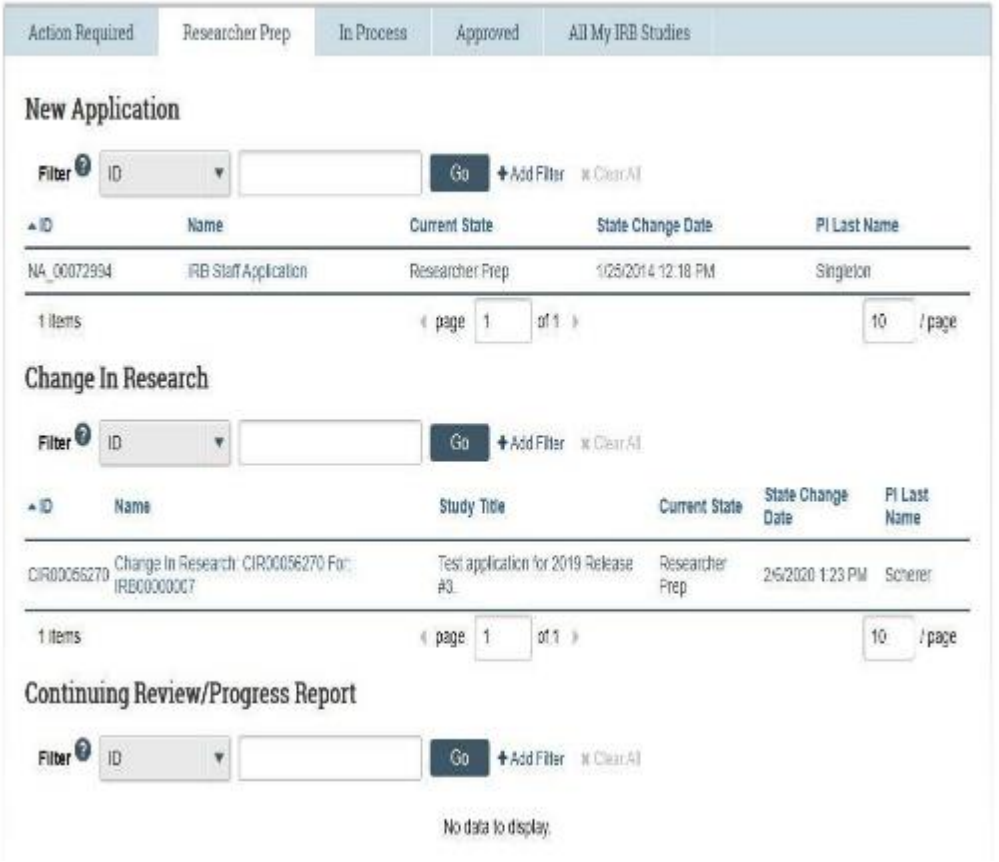
- Studies awaiting Pre-IRB or IRB review

Approved

- Studies that have been approved

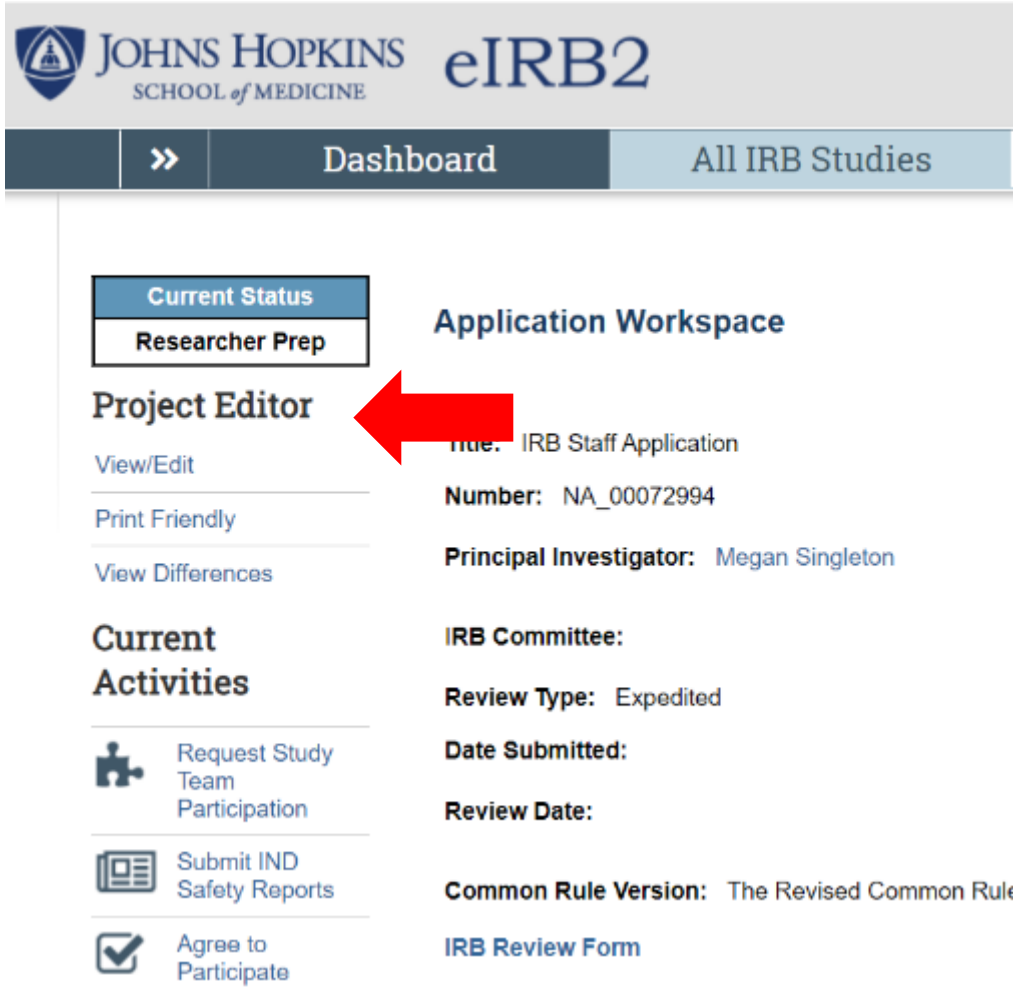
All My IRB Studies

- All approved, disapproved, expired, terminated, or withdrawn studies with which you are associated.



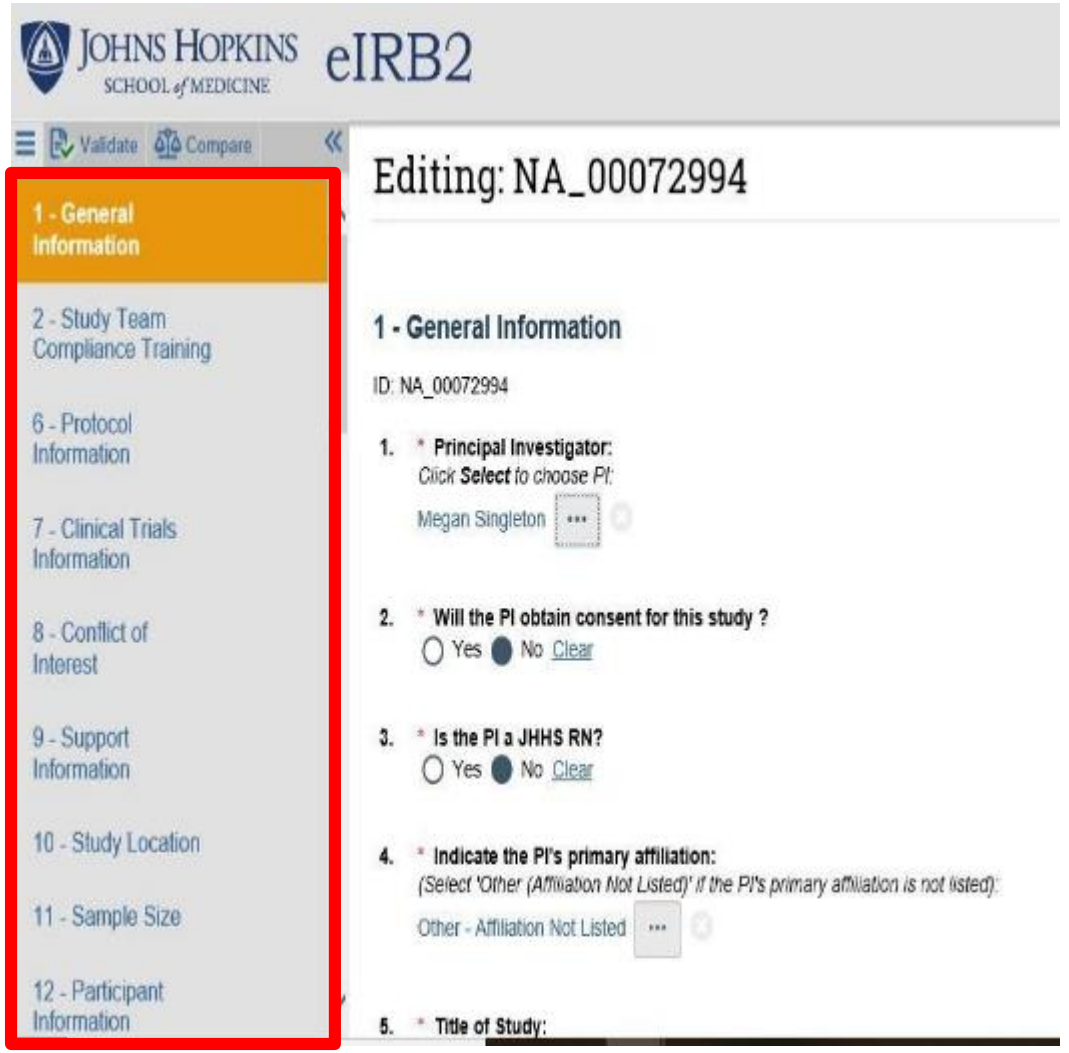
Application Workspace

- The **View** function is how you access the application
- The **Print Friendly** function is similar to the *View* function which allows you to access the application and view in a continuous scroll.
- **View Differences** function will show any changes made to the application since the last submission.



Navigation Panel

- Navigation Panel appears on left side of application.
- The Navigation Panel shows eIRB application sections on the left side and is available on all actions (new, change in research, continuing review, etc.).
- Each available application section will appear on the left navigation panel allowing you to jump to a specific section in the application.



Transferring Human Biospecimens –

- Human biospecimens obtained for clinical and/or research purposes at any Johns Hopkins Medicine (JHM) facility are the property of the applicable JHM entity under whose authority the samples were collected. Any transfer of human biospecimens must meet the institution's policy and procedural requirements. ADMIN015: Transferring Human Biospecimens to Outside Organizations
- The JHM Human Biospecimens Transfer Committee ("Committee") is responsible for the review of transfer requests.
- There are supporting documents that must accompany the human biospecimen transfer request. Please see: **Transferring Human Biospecimens to Outside Organizations - Hopkins Medicine**

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Practice Protocols

Clinical Research Registry – No Funding

- Consult research studio or Trial Innovation Unit (TIU) to develop research hypotheses
- Consult with CCDA about access to clinical data
- Consult RedCap about setting up research data collection
- Consult with CRAC to get consult from community on priorities and design – recruitment and return of results
- Consult with OpenSpecimen for IT support for biospecimen colleciton
- Submit application to IRB (with Data Trust Council review)

NIH/PCORI application for single site clinical trial

- Consult with Trial Innovation Unit
- Consult with Biostatistics Center
- Consult with Community Research Engagement
- Consult with Recruitment Innovation Center
- Consult with Clinical Research Units
- Consult with Research Coordinator Support Office
- Consult with clinicaltrials.gov office
- Work with Clinical Research Support Services (Budget for Clinical Services) in OCT
- Submit application through ORA
- Submit protocol to IRB

Multicenter commercially sponsored trial - application to be a clinical site

- Consult with OCT about feasibility
- Work with OCT for PRA/budget/contract
- Consult with Research Coordinator Support Service
- Consult with Recruitment Innovation Center
- Submit application to the IRB

NIH/PCORI Application for Multisite Clinical Trial

- Consult with Trial Innovation Unit
- Consider collaborators through PaTH PCORNet and JHCRN
- Consult with Biostatistics Center
- Consult with IRB about single IRB arrangements
- Consult with Community Research Engagement and Recruitment Program
- Work with OCT for PRA/budget (and possibly IND/IDE)
- Submit application through ORA
- Submit protocol to IRB

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QUESTIONS?