ICTR

The Johns Hopkins Institute for Clinical and Translational Research

How Can the ICTR Help Research Teams?

August 15, 2024

Carol Kobrin, PhD
ICTR Research Studio Director
Manager Navigator Supported Services

Linda Post, RN, BSN, CCRP
Senior Research Navigator

Todd Nesson, MS, CHRC
ICTR Navigator

ICTR_Navigators@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

What is the goal of today's talk?

1. Give you the information that is needed to make the best use of the various services and resources offered by the ICTR to support research projects

2. The following topics will be discussed:
    a. Determining whether or not the ICTR can provide the required assistance
    b. Placing a request for ICTR services
    c. Finding out if any charges apply

3. Brief overview of commonly requested ICTR services (time permitting)
    a. This PowerPoint will be available to review all content that will not be discussed
    b. All slide titles shown in a yellow font are hyperlinks to the ICTR webpage describing that resource/service
    c. The naming convention used for the title is :
        Line 1: Resource/Service Category (see slides 6-8)
        Line 2: Name of the Resource/Service

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Introduction to the ICTR

1. The Johns Hopkins Institute for Clinical and Translational Research (ICTR) is one of more than 60 medical research institutions funded by the NIH Clinical and Translational Sciences Award (CTSA) program

2. All CTSA funded institutions work together as a national consortium to improve the way biomedical research is conducted across the United States.

3. Among the ways that **the ICTR contributes to this effort is by using its funding to help subsidize an array of resources and services** that research teams can take advantage of to work more efficiently and ultimately produce higher quality and impactful research

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

At what stage in a project can the ICTR be helpful?

Assistance can be provided any time it is needed, but for the best possible outcome **ICTR resources and services should be considered when a research study is being planned**

- Scientific/Clinical Justification:

  Avoid delays resulting from errors in designing and implementing a study

- Financial Justification

  Avoid limiting the scope of the support required because insufficient funding was included in the study budget

  Many services/resources offer a combination of **limited free services** and a fee-for-service for more comprehensive support

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

What services does the ICTR offer?
How are they requested?
Questions about services?

- All program and resource information can be found on the **ICTR website:**

  http://ictr.johnshopkins.edu/

- Most services are requested online via the **ICTR Service Request Portal:**

  https://mrprcbcw.hosts.jhmi.edu/redcap/surveys/?s=A8FE8FT47W

- For general questions or information about any ICTR or JHU research resource:
  1. Submit an ICTR Service Request for **General Help: '<u>Ask a Research Navigator</u>'**

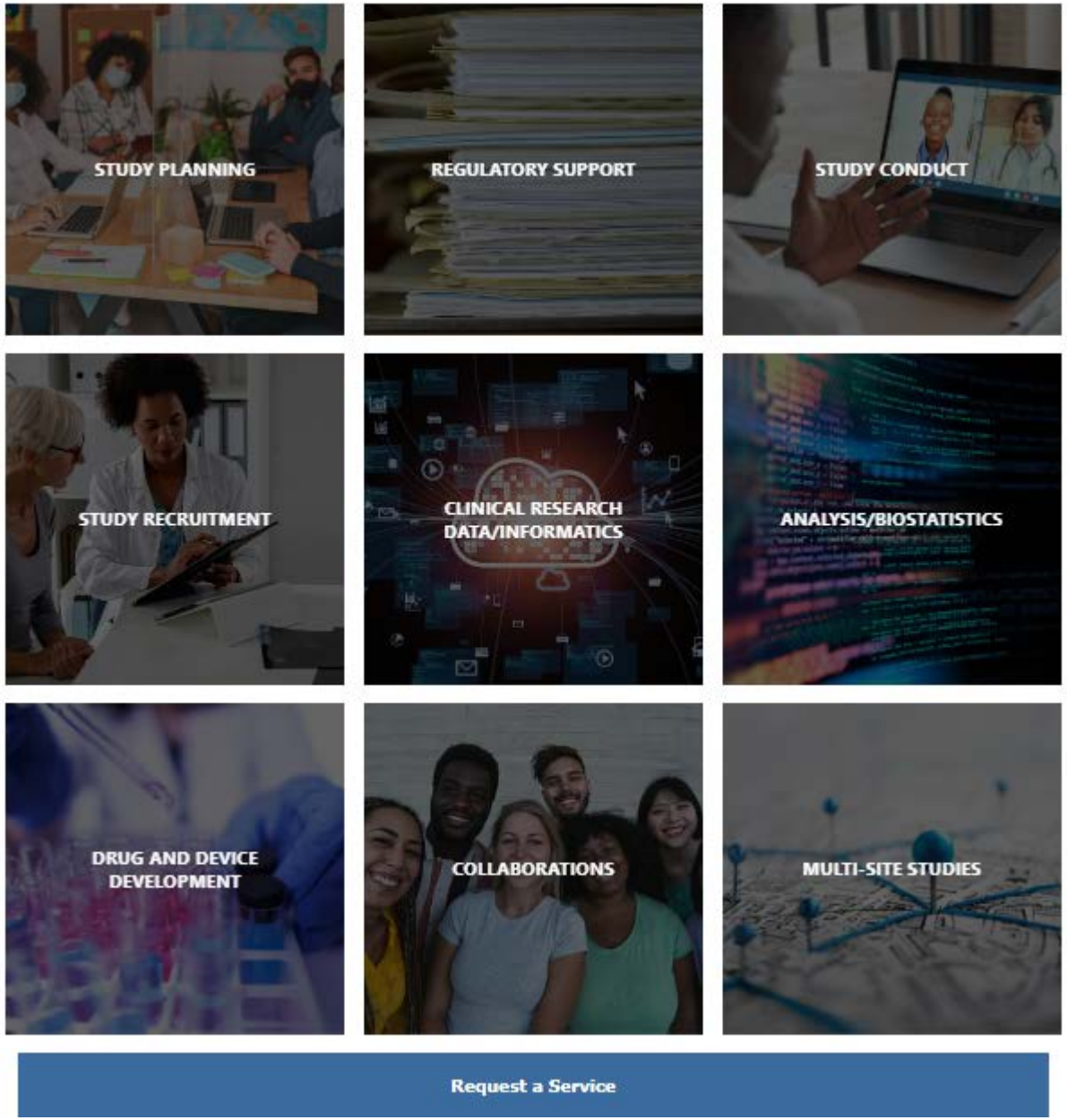
     or
  2. Email ICTR_Navigators@jhmi.edu

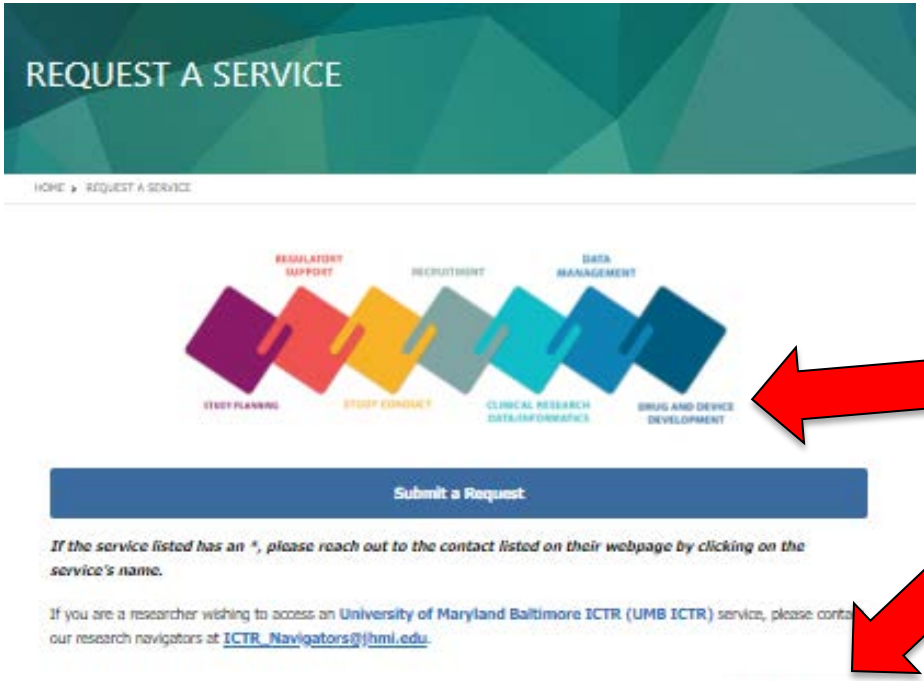
JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

Options for viewing and requesting services from the ICTR website

<u>Screen</u> when Option 1 is selected

Click on a tile to see the types of services offered in that category



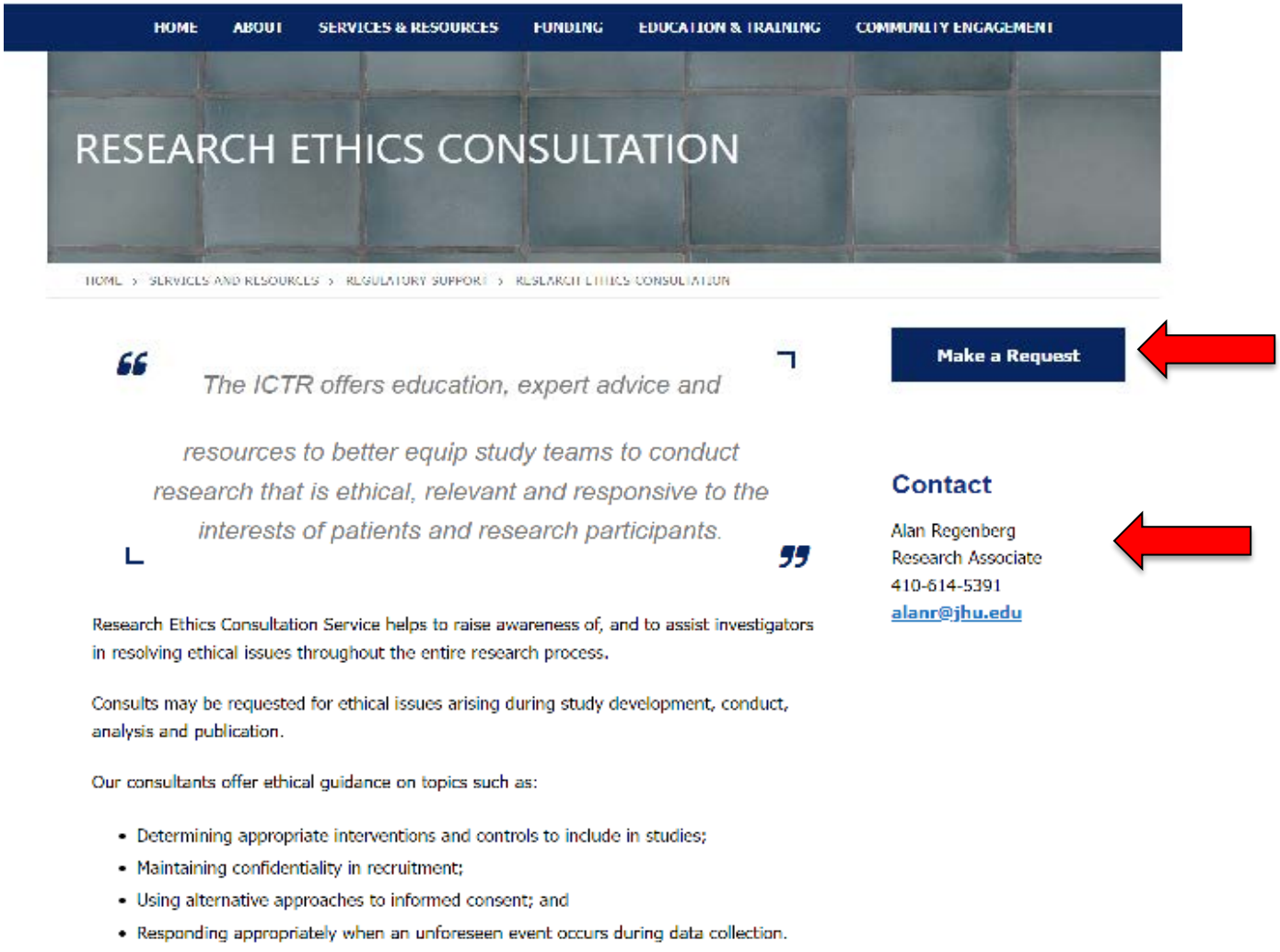


Screen when Option 2 is selected

To see the types of services offered in each category:

1. Click on the tile
   Or
2. Enter the category in the "Search" box

Screen after specific service is selected under Option 1,2 or 3



JOHNS HOPKINS
INSTITUTE for CLINICAL & TRANSLATIONAL RESEARCH

ICTR Service Request Portal

Welcome to the ICTR Service Request Portal!

You can use this system to:

- submit requests for ICTR services
- ask for help from any of our consultants
- submit questions, comments, or feedback
- apply for ICTR grant programs

Screen after :
“Make a Request”,
“Submit a Request” ,
“Request a Service” or
“Request”
button is selected

What is your role in this study?

* must provide value

- ○ Principal Investigator
- ◉ Study Coordinator/Other

reset

Your Contact Information

First Name *must provide value	Last Name *must provide value

Email Address *must provide value

Begin an ICTR Service Request

Select the service or services you would like to use. If you need more information about a particular program, just hover over the "Details" next to the program name.

We'll ask you some questions, give you the opportunity to upload some supporting documents, and then pass your request on to our experts. You'll receive an email acknowledgement of your submission right away.

General Help: Ask a Research Navigator

- [ ] I have a general research question not covered by the options below. Please put me in touch with an ICTR Navigator.

Analysis/Biostatistics

- [ ] Biostatistics Consulting - Details

Community Engagement/Recruitment

- [ ] Community Engagement Consulting Service - Details
- [ ] Recruitment Innovation Unit (RIU) Consulting Service - Details
- [ ] Integrating Special Populations (ISP) - Details

Clinical Research Data/Informatics

- [x] Core for Clinical Research Data Acquisition (CCDA) Consulting Service - Details
  - ( ) Consult for IRB submission (feasibility counts, specification documents, or general consult) - Details
  - ( ) Data extraction for IRB-approved studies (Epic, PMAP, Casemix Datamart) - Details
  - ( ) Patient list download from SlicerDicer or TriNetX for IRB-approved studies - Details
  - ( ) New TriNetX account - Details
  - ( ) OMOP ATLAS - Cohort Discovery - Details

reset

- [ ] Clinical Research Management System (CRMS) - Details
- [ ] OpenSpecimen - Biobank management application - Details
- [ ] Program to Accelerate Clinical Research in Epic (PACE) - Details

ICTR

Analysis/Biostatistics

Biostatistics and Study Design Program

1. Consultants in the Johns Hopkins Biostatistics Center can assist with:
   a. Biostatistical Services
      - Research study design/protocol development(including sample size justification, randomization, sampling, development of statistical analysis plans)
      - Manuscript and report preparation,
   b. Data Management Services
      - Programming and developing analyzable datasets from EPIC
      - Preparing data for analysis and reporting
      - REDCap support

2. *Free services provided for JH faculty, staff, pre-MD, and post docs include:*
   a. Up to 5 hours of initial support per project, for those engaged in faculty-led research.
   b. 30 minute online consultations on a "first come, first serve" basis for quick problems/questions

3. Logistic and administrative questions about this resource, including current pricing for services can be directed to:
   - Erica Tunstall
     etunsta2@jhu.edu

4. General study design/grant application/biostatistics methods inquiries may be directed to:
   - Gayane Yenokyan, MD, MHS, PhD
     gyenoky1@jhu.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR Johns Hopkins Center for Innovative Medicine(CIM) Biostatistics, Epidemiology and Data Management (BEAD) Core

1. Services include:
   - Biostatistical Methods
   - Epidemiological Methods
   - Academic Submissions
   - Data Management
   - Patient Reported Outcomes
   - Qualitative Methods

2. *Twenty hours plus twenty grant hours plus twenty hours for each post-doctoral trainee (Fellows and Residents) are provided at no charge each fiscal year to the following full-time Hopkins faculty:*
   - *Faculty members and their post-doctoral trainees from the Departments of (1) Medicine, (2) Pediatrics, (3) Gynecology/Obstetrics, (4) Anesthesiology & Critical Care Medicine, (5) Dermatology & (6) any SKCCC/SOM faculty member conducting patient reported outcomes (PROs) work.*
   - *Post-doctoral trainees (Fellows and Residents) must be accompanied by their primary faculty mentor to the first consult and must stay engaged in the work to completion.*

3. Services may be requested by completing the online **BEAD Core Intake Form**: https://mrprcbcw.hosts.jhmi.edu/redcap/surveys/?s=XWF4AXX3JPACP9R9

4. Questions about this resource, including current pricing for services can be directed by email to: BEADCore@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Clinical Research Data/Informatics

Core for Clinical Research Data Acquisition (CCDA)

1. Assists researchers with accessing clinical data for research purposes
2. Services provided include:
   - Preliminary, anonymous data for feasibility, grant applications and statistical population sample-size estimates
   - IRB-approved case-finding for study enrollment (mailings, phone solicitation), chart review, and cohort/case-control studies
   - Natural Language Processing –Text mining and information extraction methods to identify disease, medications, symptoms, and signs from clinical text, as well as artificial intelligence techniques for sentiment analysis, opinion mining, measuring cognitive ability, and exploring social determinants of health.
   - Research data extracts
   - Data de-identification services to conform to **HIPAA Privacy standards**
   - Honest Broker services
   - Assistance using Epic's SlicerDicer and TriNetX self-service tools

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

Clinical Research Data/Informatics

Core for Clinical Research Data Acquisition (CCDA)(contd.)

3. Current Cost: $130/Hour for new Projects

- *The first 2 hours of guidance and feasibility review for new projects are free*
- *Ongoing maintenance of established periodic extracts is factored into the cost*
- *Additional requests outside the scope of the initial project will be charged at the agreed upon hourly rates*

4. Data Sources
   - Epic
   - CaseMix/Data Mart
   - EPR2020
   - Sunrise Clinical Manager

5. Questions about this resource including current pricing for services can be directed to: Shipra Sachdeva, IT Manager
   Shipra.Sachdeva@jhu.edu

ICTR

Clinical Research Data/Informatics

Epic for Research

The following functionalities are currently available from the Epic Medical Record System:

1. An indication in the patient banner that a patient is on a research study and information about their studies.
2. Ability to link an encounter to a study.
3. Ability to associate an order with a study
4. Research order sets.
5. Research notes, which can be created by the study coordinator
6. Use of existing MyChart Questionnaires to collect patient reported outcomes
7. SlicerDicer for generating patient counts
8. Epic reports to support research
9. Scanned research consent forms in the Media tab
10. Questions about using Epic to support clinical research can be directed to:

Matthew Courtemanche, Epic Project Manager
matthew@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Clinical Research Data/Informatics

Program to Accelerate Clinical Research Using Epic (PACE)

1. *A fee based service* that can design and build customized Epic content to optimize a study's data collection and workflow.
   - To ensure a successful application of any customized Epic build, all PACE requests are subject to a formal review process
   - PACE's Fee Menu can be found here

2. Potential applications that can be supported by PACE include:
   - Collection of patient-reported outcomes via questionnaires in MyChart or on tablet in waiting room.
   - Discrete Data collection via Flowsheet or SmartForm
   - Data/Phenotype Visualization via Report or Synopsis View
   - Alerts to assist with clinical care and tracking of study patients
   - Multi-Provider Schedule visualizations/columns to sort and identify study patients

3. Questions about using PACE may be directed to:
   - Thomas Grader-Beck, MD, Epic Clinical Lead (PACE)
     tgb@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Clinical Research Data/Informatics

Feasibility Counts

1. **SlicerDicer**:
   a. Permits investigators with access to Epic to obtain rough patient counts without IRB approval.
      - Accessed by typing “SlicerDicer” into the Epic search bar
      - IRB approval is needed prior to using these data for recruitment. to conduct research or publish.

   b. Limitations
      - Not all data in Epic are available for searching in SlicerDicer (most notably text data)
      - Patient data collected outside of the Johns Hopkins Epic system will not be available in SlicerDicer with the exception of some historical lab and encounter data.

2. **TriNetX**
   a. Self-service web-based data exploration tool, which helps researchers define a patient cohort using inclusion and exclusion criteria and to explore cohort attributes.
      - IRB approval required for patient level data
      - Training required for access

   b. Relative to SlicerDicer:
      - Populated with data from Epic which have been cleaned, curated and more fully mapped to codes like LOINC to improve data quality and analysis
      - Has advanced analytic tools

3. **Accrual to Clinical Trials**
   - Real-time platform allowing for online exploration and validation of feasibility for clinical studies across the NCATS Clinical and Translational Science Award (CTSA) consortium,

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Clinical Research Data/Informatics

REDCap

1. REDCap is a HIPAA compliant and secure web application for building and managing online surveys and databases

2. Both surveys and databases can be built:
   - By an online method from a web browser using the "*Online Designer*"
   - By an offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap
   - By a combination of the online and offline methods

3. Features:
   - Automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R)
   - A built-in project calendar
   - A scheduling module
   - Ad hoc reporting tools
   - Advanced features, such as branching logic, file uploading, and calculated fields.

ICTR

Clinical Research Data/Informatics
REDCap (contd.)

4. Available to Investigators and staff at JHU (JHU, JHH, JHBMC, KKI, SOM,SON, SPH)
   - Accounts/Projects requested via the green or blue (SPH only) link at http://redcap.jhu.edu

5. *Use is free for investigators whose project does not exceed between 5,000 (QI projects, Registries) and 20,000 (Clinical Research) data points and/or 30 MB of storage ("Bronze" Service Plan)*
   - *The complete fee and service structure is available at: https://redcap.jhu.edu/main/REDCapTiers.pdf*

6. Additional information and assistance is available at: http://redcap.jhu.edu

7. Video tutorials showing REDCap in action and an overview of its features, are available at: https://projectredcap.org/resources/videos /

8. Questions about this resource may be directed to:
   - Scott Carey, Sr. Software Engineer
     scarey@jhmi.edu
     redcap@jhu.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Clinical Research Data/Informatics

Qualtrics Surveys

1. The Qualtrics platform is available to create research surveys containing sensitive data (i.e. PHI)

2. Additional capabilities include:
   - Sharing survey design and results with colleagues
   - Institutional research and assessment
   - Experimental design
   - Academic survey outreach
   - Alumni outreach
   - Event registration
   - Student and faculty elections
   - Course and professor evaluation
   - Tests and quizzes

3. *Use is free* but requires an account obtained through the school or department that you are affiliated with

   DO NOT CREATE A FREE TRIAL ACCOUNT ON THE PUBLIC QUALTRICS WEBSITE.

   - Work done in a free trial account will not be accessible under the Johns Hopkins Qualtrics license
   - Active free trial accounts can delay your ability to obtain an account under the Johns Hopkins Qualtrics license

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Clinical Research Data/Informatics

Qualtrics Surveys (contd.)

4. School of Medicine faculty, students and staff can request Qualtrics accounts at: https://ictrweb.johnshopkins.edu/ictr/?QualtricsAccount

5. Questions about this resource may be directed to :
   Richard Zhu , Sr. Software Engineer
   zhu@jhu.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Clinical Research Data/Informatics

Secure Analytic Framework Environment (SAFE) DESKTOP

1. A virtual desktop that provides a secure environment to share and analyze PHI and PII with colleagues within Johns Hopkins.[a]
2. Installed with Microsoft Word and Excel, SAS, Stata, R, R Studio, and Python. Other software can be installed for investigators willing to cover the licensing fees.
3. *There is no cost for the "basic" SAFE, which includes use of the virtual desktop, 100 GB of storage space, and the licensing for SAS and Stata.*
   - *Storage space can be expanded at a monthly cost of $3.00/100 GB*
4. Access to SAFE may be requested by submitting a SAFE Desktop Request Form to JH IT Services who manage this resource OR via the ICTR Service Request Portal.
5. Questions about SAFE may be directed to:
   - Research Information Technology at Johns Hopkins University **RITServices@jh.edu**

[a] JHU Research IT. should be consulted for appropriate options for sharing data with collaborators outside of Johns Hopkins

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Analysis/Biostatistics

Best Practices for Research Data Management

1. Developed by the ICTR Data Managers Working Group to promote purposeful, structured, compliant, and secure data management.

2. *Free access* to topics which include:
   i. Data Quality
   ii. Data Management Planning [a]
   iii. Compliance
   iv. Data Sharing
   v. Security
   vi. Backup and Archiving

3. Guidance intended for:
   i. Principal Investigators
   ii. Study Coordinators
   iii. Data Managers
   iv. Data Analysts
   v. Biostatisticians

[a] **JHU Data Services** (The Data Services Unit at the Johns Hopkins University Sheridan Libraries)
Offers assistance and resources with creating data management and sharing plans that are compliant with NIH's Data Management and Sharing (DMS) Policy (effective January 25, 2023)
Please email dataservices@jhu.edu
with any questions or for additional information about their services

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Study Conduct

Clinical Research Units (CRUs)

1. Provides a safe and efficient way to perform clinical and translational research across the Johns Hopkins medical campuses

2. Are available for investigators needing outpatient, domiciliary overnight, inpatient, adult, pediatric, and neurological services.

3. Through protocol review, investigator mentoring, and a trained nursing staff, protocols performed in the CRUs are planned, vetted, monitored and performed under a similar safety standard to clinical care.

4. Questions about this resource may be directed to:

   Christine LaPonzina, CRU Program Administrator

   CRUs@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Study Conduct

Clinical Research Units-Locations

1. **Bayview Adult Outpatient and Overnight Clinical Research Unit** *(301 Building, Mason Lord Dr. Suite 4100, 4th Fl.)*
   a. The outpatient wing has exam rooms, an infusion lab, -80 freezer, sample processing and a pharmacy.
   b. The overnight wing has 8 rooms with each having its own bathroom and shower.

2. **East Baltimore Pediatric Inpatient and Outpatient Clinical Research Unit (PCRU)** *(Charlotte R. Bloomberg Children's Center, 9th Fl.)*
   a. Consists of a 7-bed inpatient unit and 8-room outpatient clinic
   b. Includes , a multi-purpose procedure room, pediatric phlebotomy laboratory, spirometry, metabolic formula room, and pediatric sleep lab.
   c. Pediatric-oriented nursing support and child life services are also provided.

3. **East Baltimore Adult Outpatient Clinical Research Unit** *(Blalock 3)*
   a. Full-time clinic support staff includes two registered research nurses, a phlebotomist and technicians.
   b. Includes 11 full-service exam rooms, a phlebotomy room, sample processing lab, -80 degree freezer, an infusion center, and a DEXA scanner.
   c. Offers assistance with limited clinical skills training for non-clinical research staff, tutorials on creating research order sets and other study-related paperwork for investigators.

4. **East Baltimore Adult Inpatient Clinical Research Unit** *(Nelson 5)*
   a. Provides scheduled access to as many as 21 inpatient research beds on a intermediate care unit floor that has a 1:3 nurse/patient ratio.

5. **West Baltimore Prohealth Community Based Clinical Research Unit** (1849 Gwynn Oak Avenue, Baltimore)
   a. Community-based clinical research unit with an exceptional record of enrolling and retaining a diverse cadre of study participants.
   b. Consists of ~15,000 sq ft of space, including offices (private, semi-private), exam rooms, phlebotomy station, procedure room, meeting rooms, staff lounge, and metabolic kitchen
   c. Includes four -70 freezers, refrigerated centrifuges, and computer services maintained by Hopkins, including WiFi

ICTR

Study Conduct

Clinical Research Units-Locations(contd.)

7. Johns Hopkins (Florida) All Children's Outpatient Clinical Research Unit
    a. Services include drawing blood, performing infusions, procuring biorepository samples and monitoring patients taking study medications.

8. Scattersite Research Nursing Services for the East Baltimore Campus
    a. ICTR CRU staff will travel to provide services such as phlebotomy, IV placement, blood processing, or vital signs, for adult research participants in the afternoon

ICTR

Study Conduct/
Clinical Research Unit Laboratory Core

1. Housed in the Asthma and Allergy Center at the Bayview Medical Campus, the CRU core lab conducts different assays of clinical chemical endpoints and biomarkers to support pre-clinical and clinical research protocols.

2. Provides:
   a. A high volume of specialized laboratory services supporting clinical studies performed at the Johns Hopkins Bayview campus and the Johns Hopkins Hospital
   b. Consultative services in addition to sample processing, storage, and analysis

3. Supports study protocols by providing investigators with facilities, technical experience, and training for non-routine blood, saliva, cerebrospinal fluid, and urine biochemical analyses

4. *A list of available assays and costs is available at the ICTR website:* https://ictr.johnshopkins.edu/wp-content/uploads/FY25-ICTR-Bayview-Core-Lab-Charge-Master.pdf

iLab: ***https://johnshopkins.ilab-int.agilent.com.***

Questions about this resource may be directed to:

Neal Fedarko, PhD, Director
(410) 550-2632
ndarko@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Study Conduct/ Clinical Research Unit Application and Fees

1. **CRU Application Process**
   Use of all Clinical Research Units and associated services requires an application through the **CRU online system**, and CRU review and approval, which is a separate process from the JHM/JHSPH IRB approval.

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

2. ***Charges for CRU Services***
   All investigator-initiated and industry sponsored trials are subject to the following fee schedule: https://ictr.johnshopkins.edu/wp-content/uploads/FY25-ICTR-Clinical-Research-Units-Charge-Master.pdf

Contact:
Christine LaPonzina
claponz1@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Study Conduct/
Research Coordinator Support Service (RCSS)

1. *Fee for service program* that maintains a pool of trained research coordinators who can be hired on a part-time basis to handle a wide range of customizable responsibilities to best fit the needs of your research team.

2. Prior to starting any work assignments, RCSS coordinators complete the following minimal training:
   a. Human Subjects Research protections
   b. eIRB
   c. OnCore
   d. Epic
   e. DOT/IATA
   f. Clinical Skills (vitals, ECGs, phlebotomy)
   g. CPR

3. RCSS assistance can include but isn't limited to :
   a. eForm and informed consent creation/modification
   b. eIRB applications
   c. Participant screening and recruitment
   d. Consenting
   e. Running study visits
   f. Data entry and resolving queries
   g. Completing /Creating source documents and case report forms
   h. Sample collection, processing and shipping

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

Study Conduct/
Research Coordinator Support Service (RCSS)

4. The RCSS **Research Personnel Onboarding Program** is designed to rapidly onboard inexperienced clinical research personnel
   a. A customized 6-8 weeks training plan is developed that meets both the studies' and new hire's needs.
   b. Trainees receive 1:1 support during the process, which consists of self-paced assignments and training courses (both Instructor-Led and online).

Questions about these resources and pricing for services may be directed to:

Tony Keyes, Assistant Director
akeyes1@jhmi.edu

Mais Hamdawi, MD, Sr. Research Program Manager
malhamd2@jh.edu

ICTR

ICTR Recruitment Resources/ Recruitment Innovation Unit (RIU)

1. The RIU is designed to facilitate the recruitment and retention of study participants into research activities throughout the Johns Hopkins Medical Institutions
2. Assists with training, consultations and a toolkit of evidence-based, field-tested recruitment practices, developed in collaboration with experts in information technology, ethics, and patient and community-engagement.
3. Provides recruitment support in the following areas:
   - EPIC & MyChart
   - Social Media Recruitment Service
   - Comprehensive Recruitment Consults
   - Recruitment Materials Design Service

Questions may be directed to:

Cassie Lewis-Land, MS,
CCRP Program Administrator
clewis4@jhmi.edu

Foujan Moghimi MSPH,
Research Program Coordinator
fmoghim2@jh.edu

Tosin Tomiwa, MPA,
Research Data Manager
otomiwa1@jhu.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Community Engagement/C-RAC

1. Offers consultations to study teams to help identify issues and concerns from the community perspective.
2. Feedback can be provided to research teams prior to conducting a study as well as guidance on how to disseminate their findings back to the community.
3. The **Community Research Advisory Council (C-RAC)** leads efforts to promote trust, understanding, and involvement in the Greater Baltimore Region in research activities and community priorities.

Contact:
Crystal Evans, MS, Community Relations Coordinator
cevans20@jh.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Study Conduct/ The Studio: A Master Class

1. Provides a *free* consultative process to help investigators improve the quality and impact of their translational research by:
   - Creating competitive grants by offering pre-submission grant reviews or guidance for restructuring resubmissions
   - Identifying institutional cores and/or resources to conduct preclinical and clinical studies
   - Addressing project feasibility concerns
   - Advising on managing internal and external regulatory compliance issues
2. The Studio is :
   - A **multidisciplinary service center** that brings investigators together with the experts and resources needed to address their higher level research questions at all stages in the project lifecycle
   - **Disease agnostic** but customized for each protocol or project
   - A **"one stop shop"** where experts across diverse disciplines all meet together with the investigator in a single setting to provide coordinated assistance
   - An **ongoing process** that continues to work with the investigator and help make any necessary adjustments

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Study Conduct/ The Studio: A Master Class (contd.)

3. Projects requesting Studio support are first subjected to an ICTR internal review to confirm the suitability of this resource to address an investigator's questions
4. Two formats for a Studio consultation are offered:
   - A 60-90 minute meeting between the investigator and a customized panel of faculty consultants, whose members are specifically selected to accommodate the unique needs of the presented project
   - A 60 minute meeting between the investigator and the ICTR Navigators to exhaustively identify the availability of ICTR and institutional resources that can support the unique requirements of the presented project.
5. Studio consultants are active researchers who are recognized authorities in their respective fields as well as the faculty directors of the various ICTR and institutional resources
6. Requests for a Studio consultation may be submitted via the **ICTR Service Request Portal**

Questions about the Studio resource may be directed to:

Carol Kobrin, PhD
ckobrin1@jhmi.edu or ICTR_Navigators@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Drug and Device Development/ **Drug and Device Resource Service**

1. For studies using investigational biologics, drugs, and devices, project specific support is provided to:
   a. Better understand the issues governing whether or not an IND/IDE may be needed
   b. Create the content for FDA submissions which include but aren't limited to:
      - IND Exemption Requests
      - Meeting Requests (i.e. Pre-IND/IDE)
      - IND /IDE Application Filings [a]
      - IND/IDE Submissions (Annual Reports, Amendments)
      - Compassionate Use INDs /IDEs (including emergency use)
      - Drug and Biologic Manufacturing Questions

2. *The first 5 hours of support are available at no charge with additional services provided at a rate of $72/hour*

Questions about this resource may be directed to:

Carol Kobrin, PhD
ckobrin1@jhmi.edu or ICTR_Navigators@jhmi.edu

[a] Institutional policy requires that prior to submitting an investigator sponsored IND or IDE application to the FDA, the intended regulatory sponsor must:

I. Complete a "one time" investigator qualification process and be approved to serve as an IND/IDE holder
II. Submit a Planning Phase Application to the Johns Hopkins Medicine - Institutional Review Board (JHM eIRB) to initiate institutional review and ultimately obtain approval to submit each new IND/IDE application

Information for obtaining either of these approvals, as well as any questions about the process should be directed to the JH SOM Office of Clinical Trials IND/IDE Regulatory Program.

ICTR

Regulatory Support/ ClinicalTrials.gov Program

1. Assists with the registration and reporting of clinical trials to maintain compliance with federal regulations (FDAAA, NIH, Center for Medicare and Medicaid Services), as well as requirements of the International Committee of Medical Journal Editors (ICMJE) and/or other major research funders and international organizations.

2. Services offered include:
   a. Clarifying the ethical, scientific and legal reasons for clinical trials registration & reporting
   b. Identifying which trials are required to be registered and the corresponding timelines
   c. Improving the process by sharing tips, tricks and helpful content
   d. Providing up-to-date information on institutional and federal policies
   e. Direct effort upon request (billable/hr.)

Questions about this resource should be directed as follows:

JohnsHopkinsU (SOM, SON), Oncology (SKCCC), JHBSPH, and All Children's Hospital contact: registerclinicaltrials@jhmi.edu

Kennedy Krieger Institute contact: Eun Sol Jung at: JungES@kennedykrieger.org

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

Thank you!

Questions?

ICTR_Navigators@jhmi.edu

Survey code for today's presentation

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Study Conduct/
Trial Advisor Program (TAP)

1. The **Trial Advisor Program** 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.

2. *Initial 2 hour consult is free after which a broad spectrum of services are available for a fee*

3. Requests for TAP assistance are submitted via the **ICTR Service Request Portal**

Questions about this service may be directed to TAP Staff at:
TAPTeam@jhu.edu.

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Multi-Site Studies/ Trial Innovation Network (TIN)

1. The **Trial Innovation Network (TIN)** is a collaborative initiative within NIH/NCATS' CTSA Program to:
   - Accelerate the translation of novel interventions into life-saving therapies by helping investigators execute **multicenter trials** better, faster, and more cost-efficiently
   - Function as a national laboratory to study, **understand and innovate the process of conducting clinical trial**s
   - A more detailed discussion about the TIN can be found at: https://trialinnovationnetwork.org/

2. Investigators can submit a protocol to the TIN for either a consultation or a request for assistance from a specific resource
   a. Potential issues that can be discussed during an initial consultation
      - Study Design
      - Study Budgets
      - Projected Timelines
      - Recruitment
      - Study Feasibility
      - Efficacy-to-Effectiveness (E2E) Trial Design

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Trial Innovation Network (TIN)

(contd.)

b. Potential resources available for protocol assistance
   - Standard Agreements
   - Single IRB Support
   - Recruitment and Retention Plan
   - Recruitment Feasibility Assessment
   - Recruitment Materials
   - Community Engagement Studio
   - EHR-Based Cohort Assessment
   - Innovations in Clinical Effectiveness Trial Design

c. A more detailed discussion about all TIN services offered and the application process for assistance can be found **here.**

d. The initial step in applying for this support is submission of a brief intake form **via ICTR Service Request Portal** to the **Hub Liaison** point of contact

Questions about this resource may be directed to:

Liz Martinez, RN, BSN, CCRC, Hub Liaison Team Navigator
Liz@jhmi.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Regulatory Support\ Research Ethics Consultation Service

1. 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.

2. Ethical guidance offered on topics such as:
   a. Determining appropriate interventions and controls to include in studies
   b. Maintaining confidentiality in recruitment
   c. Using alternative approaches to informed consent
   d. Responding appropriately when an unforeseen event occurs during data collection.

3. **Questions may be directed to:**

Alan Regenberg, Research Associate
alanr@jhu.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

Study Conduct

Research Nutrition

Services performed *for a fee* include:

- In-depth nutrition assessments
- Diet intake analysis for both macro- and micro-nutrients
- Nutrition counseling
- Anthropometric and body composition measurements
- Energy assessment
- Design and preparation of protocol-specific meals.

Contact:

Susan Oh, MS, MPH, Director
susanoh@jhu.edu

ICTR

Study Conduct/ Centro Sol

1. Promotes equity in health and opportunity for the Latinx community by advancing clinical innovations, diversity in research, education access and exposure, as well as advocacy in active collaboration with the Johns Hopkins Institutions and a diverse group of partner organizations who share these goals

2. Faculty are members of the Johns Hopkins University School of Medicine.

3. *Fee for service* research consultation available include: material review, study planning, participant recruitment planning, and study staff recruitment planning.

4. Research consultation service requests are submitted to : https://www.jhcentrosol.org/research-and-policy-research

5. For more information, please go to: https://www.jhcentrosol.org/research-and-policy-research

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Education and Training/ Science of Clinical Investigation (SOCI)

The **Science of Clinical Investigation (SOCI) Training Program** is designed to prepare clinicians and other biological scientists to participate in multidisciplinary clinical research. Courses are offered on-site and online.

The SOCI program contains both onsite and online courses including:

- Database Design and Implementation in Clinical Research
- Ethical and Regulatory Issues in Clinical Research
- Design of Clinical Studies
- Quantitative Analysis of Clinical Data
- Outcomes and Effectiveness Research
- Quality Improvement and Knowledge Translation

Courses are designed for:

- Clinicians and scientists engaged in clinical research
- IRB and other clinical research review committee members and staff
- Those aspiring to careers in clinical research
- Individuals both here at Johns Hopkins and abroad interested in clinical research

Contact:
Cristina Denardo, Academic Program Manager
JHSPH.gtpci@jhu.edu

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH

ICTR

Education and Training/

Introduction to Clinical Research Summer Course

The annual 5-day "**Introduction to Clinical Research**" summer course provides an introduction to clinical research methods, emphasizing epidemiological & biostatistical methods.

The objectives of this course are to help students:

1. Define a research question
2. Describe the steps involved in conducting clinical research
3. Review and evaluate the main study designs used in clinical research: case-control, cohort, clinical trials, cross-sectional, meta-analyses
4. Explain the basis of statistical analyses of clinical research studies
5. Describe the methodological basis of diagnostic and prognostic testing
6. Prepare and review a research project

Contact:
Visit the Johns Hopkins Bloomberg School of Public Health course catalog Course Number: PH.390.750 for more information.

Note that **enrollment maximum is 45 students** and **course historically fills within 24 hours.**

JOHNS HOPKINS
INSTITUTE for CLINICAL and TRANSLATIONAL RESEARCH