# Navigating the Requirements for Human Subjects Research: Tips and Resources when Working with the JHM IRB

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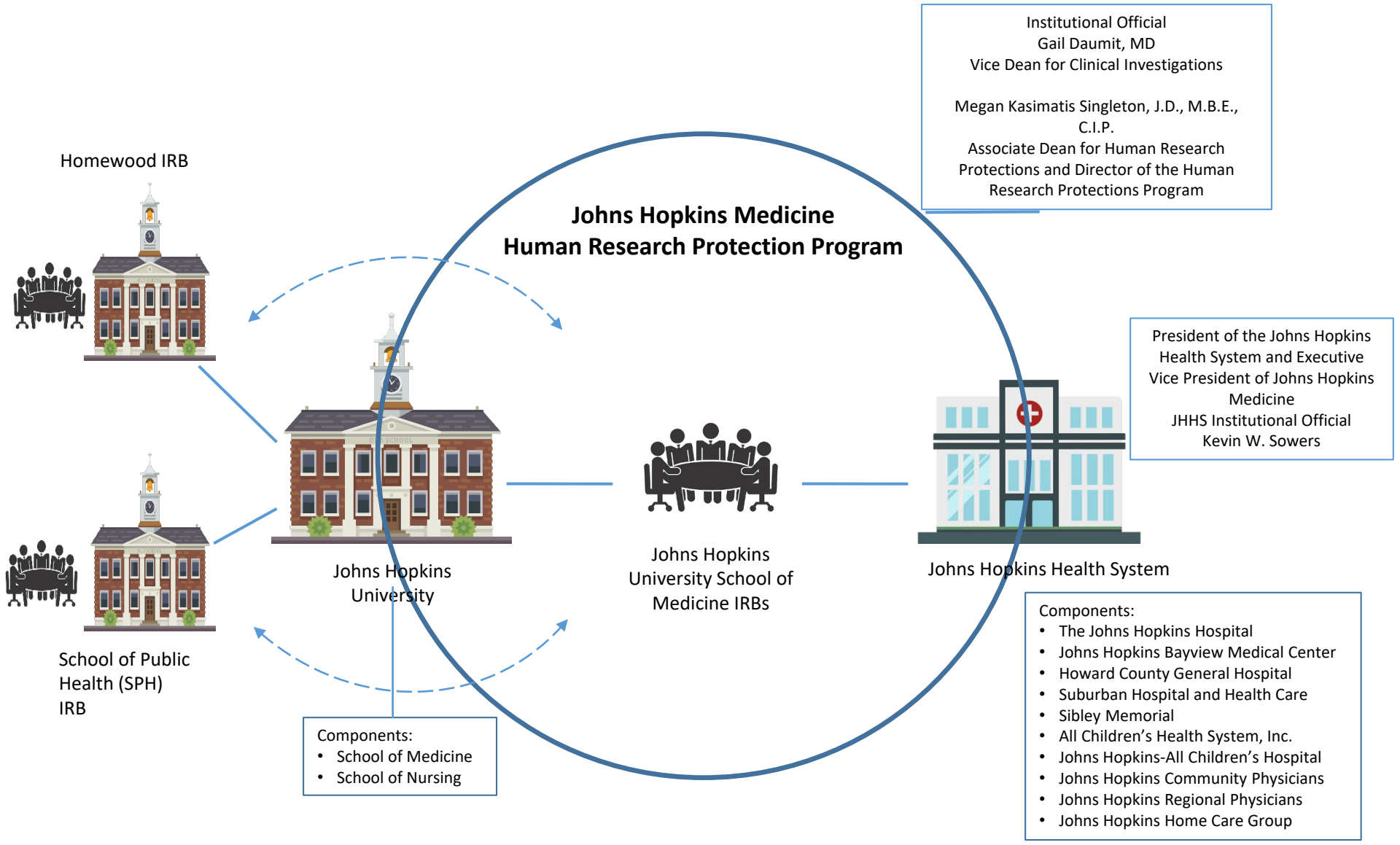
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Components:
• School of Medicine
• School of Nursing
Components:
• The Johns Hopkins Hospital
• Johns Hopkins Bayview Medical Center
• Howard County General Hospital
• Suburban Hospital and Health Care
• Sibley Memorial
• All Children's Health System, Inc.
• Johns Hopkins-All Children's Hospital
• Johns Hopkins Community Physicians
• Johns Hopkins Regional Physicians
• Johns Hopkins Home Care Group

# JHM INSTITUTIONAL REVIEW BOARDS*

**IRB 1**
Chair - Howard Lederman, MD, PhD

**IRB 2**
Chair – Doug Smith, MD

**IRB 3**
Chair – Richard Moore, MD

**IRB 5**
Chair – Joseph Carrese, MD

**IRB 6**
Chair – Ken Cohen, MD

**IRB X**
Chair – Susan Bassett, PhD

**JH-ACH IRB**
Chair – Verena Jorgenson, MD

**Executive IRB**
Chair – Mary Catherine Beach, MD, MPH

**Current Active Protocol Volume ~12,000 protocols**

**Represents a 35% increase since 2015**

**Annually process ~2000 new protocols, ~17,000 further study actions**

Created to:

- Review incidents of non-compliance that cross multiple protocols
- Review incidents of non-compliance related to research conducted without IRB approval

*The JHM IRBs are all also constituted as HIPAA Privacy Boards and authorized to make required HIPAA determinations related to research

# ANCILLARY COMMITTEES

High Risk Review Committee

Data Trust Committee

Biospecimen Transfer Committee

Emergency Department Review

Institutional Biosafety Committee

Review of Research involving Employees or Students

Clinical Radiation Research Committee

JHH Nursing Review

Pharmacy and Therapeutics Committee

**Ancillary Review Committees**

Most ancillary reviews are pre-IRB review or concurrent with IRB review & required prior to IRB approval. See: Department & Ancillary Reviews (hopkinsmedicine.org)

# Serving as the Single IRB (sIRB) for Multisite Research

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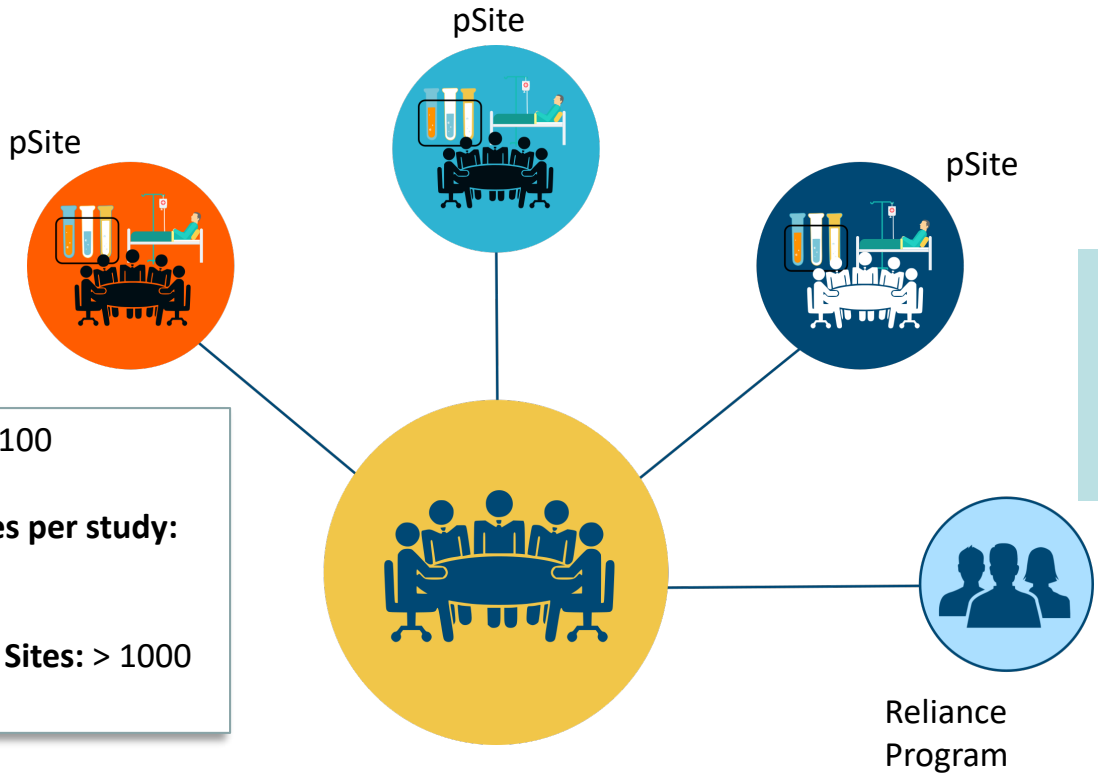
TRIAL INNOVATION NETWORK

sIRB Review is currently required for multisite non-exempt federally funded research




Submit a Reliance Request

**Approved Studies:** Over 100

**Range of Approved pSites per study:** 2-60

**Total Number of Relying Sites:** > 1000

**In response to NIH Policy changes and changes to federal regulation requiring single IRB review for multisite research, JHM IRB has emerged as a major provider of sIRB review services among academic peers**

# How does the IRB review research?

- **Reviews are divided into categories**
  - **Administrative Determination** (not human subjects/not research/or both)
  - **Exempt** (minimal risk and meets defined category for exemption)
  - **Expedited** (minimal risk & meets expedited review criteria)
  - **Convened review** (greater than minimal risk or minimal risk but not in a defined expedited category)

# What should I do if I plan to conduct research with human subjects at Hopkins?

- Step 1: Is my project human subjects research?
- Step 2: What level of review is required and what must I submit to the IRB?

# Step 1: Is my Project Human Subjects Research? [Common Rule]

## Definition of Research

DHHS: defines **research** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

## Definition of Human Subject

DHHS: *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

# New Definitions Implemented with Revised Common Rule

- **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

- An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Definitions must be examined within 1 year and every 4 years after that- A bit of a moving target!

# When is IRB review NOT required?

- When the proposal does not meet the definition of **research or does not involve human subjects**.

- **Examples:**
  - Literature search
  - Collection of anecdotal stories for a brochure which may include health information
  - Case study using up to 3 individuals
  - Research using data from deceased individuals
  - Quality improvement initiative (it depends!)

# When is IRB review NOT required?

- **Quality Improvement (QI/QA):**
  - Data collection and analysis activities in the health 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)

# Program Evaluation

When the purpose of an activity is to assess the success of an *established* program in achieving its objectives and the information gained from the evaluation will be used to provide feedback to improve that program, the activity is not human subjects research (NHSR).

# Quality Improvement

- JHM IRB Policy on Quality Improvement

**Key Considerations:**

- What is the intent of your project?
- How will results be disseminated/used?
- Are you answering broad questions?
- What are the risks?
- Are you evaluating a new system, intervention or program?

Resources:

Quality Improvement (QI) Determination Worksheet

eForm Q

# Determining whether your Project is Research or QI

# Important Considerations regarding NHSR/QI Determinations

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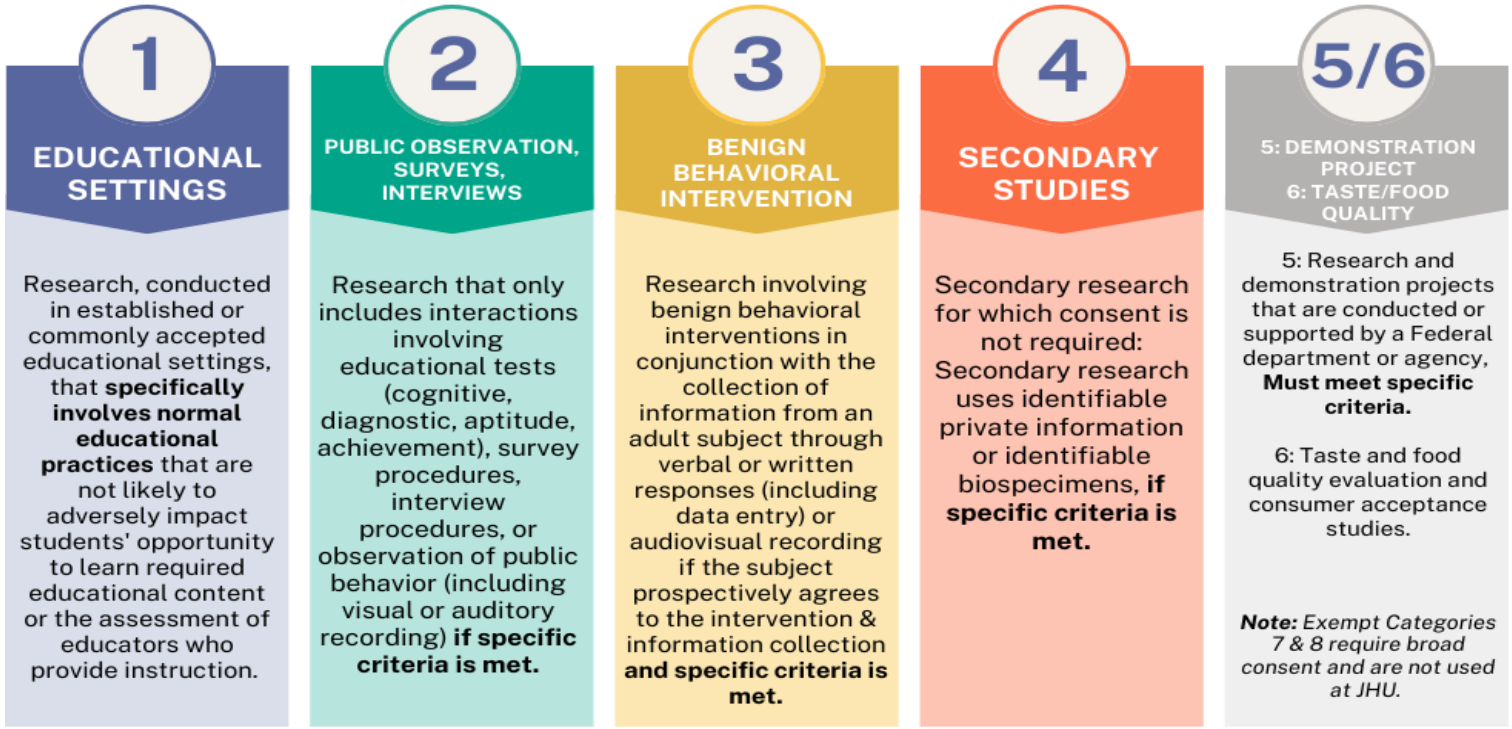
- Projects that start out as QI may become a research project
- Prospective consent enables future research use
- Failure to secure IRB approval for a research activity may result in inability to use data and a determination of noncompliance

# Upcoming IRB Office Hours Session

**Join us for JHM IRB's monthly Office Hours!** September's session will delve into the distinction between Quality Improvement (QI) and Research. Gain insights on determining the appropriate review type and receive submission tips. Session is on **September 20th at 2pm**. Our Exempt/Expedited Associate Director, Kristin MacNeal and our Exempt/Expedited Analyst, Tammy Bixby will lead this presentation and Dr. Elaine Stashinko will join the discussion. **Register Here or search "IRB Office Hours" in MyLearning.** Registration ends September 17th.

# Exempt Review Categories



# Categories of Research deemed to be minimal risk & eligible for initial Expedited Review:

**1: APPROVED DRUGS/DEVICES**

Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
a) drugs for which an investigational new drug application (IND) is not required
b) medical devices for which (i) an investigational device exemption application (IDE) is not required or (ii) the medical device is approved and used according to its approved indication

**2: BLOOD DRAW**

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
a) healthy, nonpregnant adults (</=100lbs) may not exceed 550ml in an 8wk. period & may not occur more than 2 times per wk. **or**
b) from other adults & children, the amount drawn may not exceed the lesser of 50ml or 3ml per kg in an 8wk period & collection may not occur more frequently than 2 times per week.

**3: PROSPECTIVE COLLECTION OF BIOLOGICAL SAMPLES**

Prospective collection of biological specimens for research purposes by **noninvasive** means.
Examples: hair/nail clippings, teeth from clinically indicated procedure, excreta including sweat, saliva, buccal/skin swabs

**4: NON-INVASIVE PROCEDURES**

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
Where medical devices are employed, they must be cleared/approved for marketing.

**5: SECONDARY STUDIES**

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

**6: RECORDINGS**

Collection of data from voice, video, digital, or image recordings made for research purposes

**7: FOCUS GROUPS, SURVEYS, INTERVIEWS**

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

# Potential IRB Determinations

- **Approve**
- **Approve with Administrative Changes**

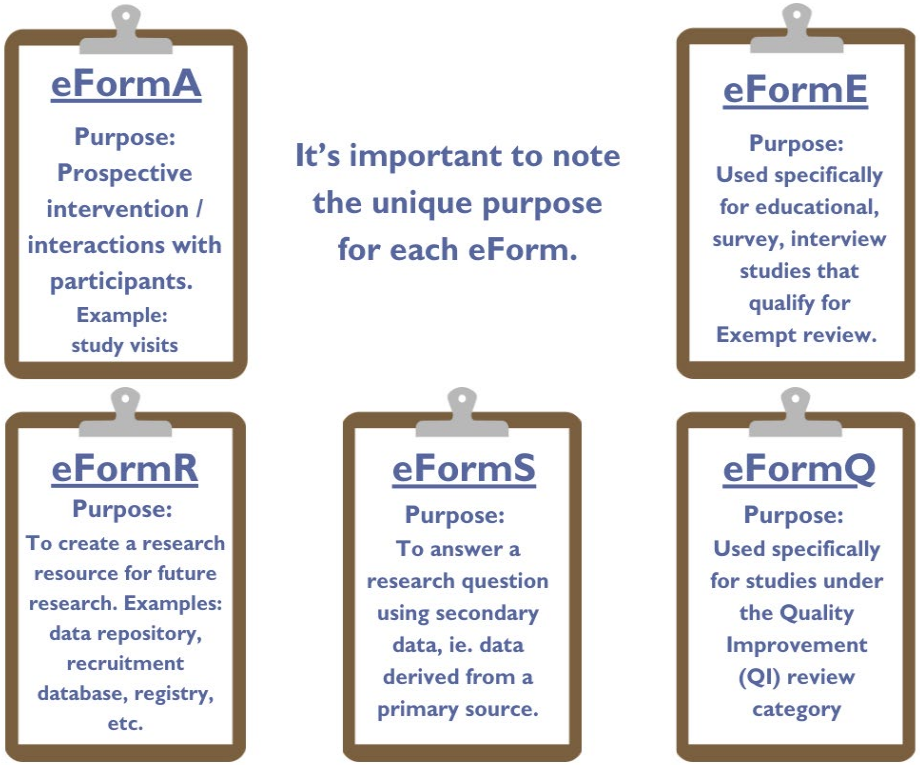
[minor administrative changes needed- expedited review of response]

- **Tabled**- Substantive changes/clarifications relevant to regulatory determinations- requires re-review by the convened IRB
- **Disapproval**- may appeal

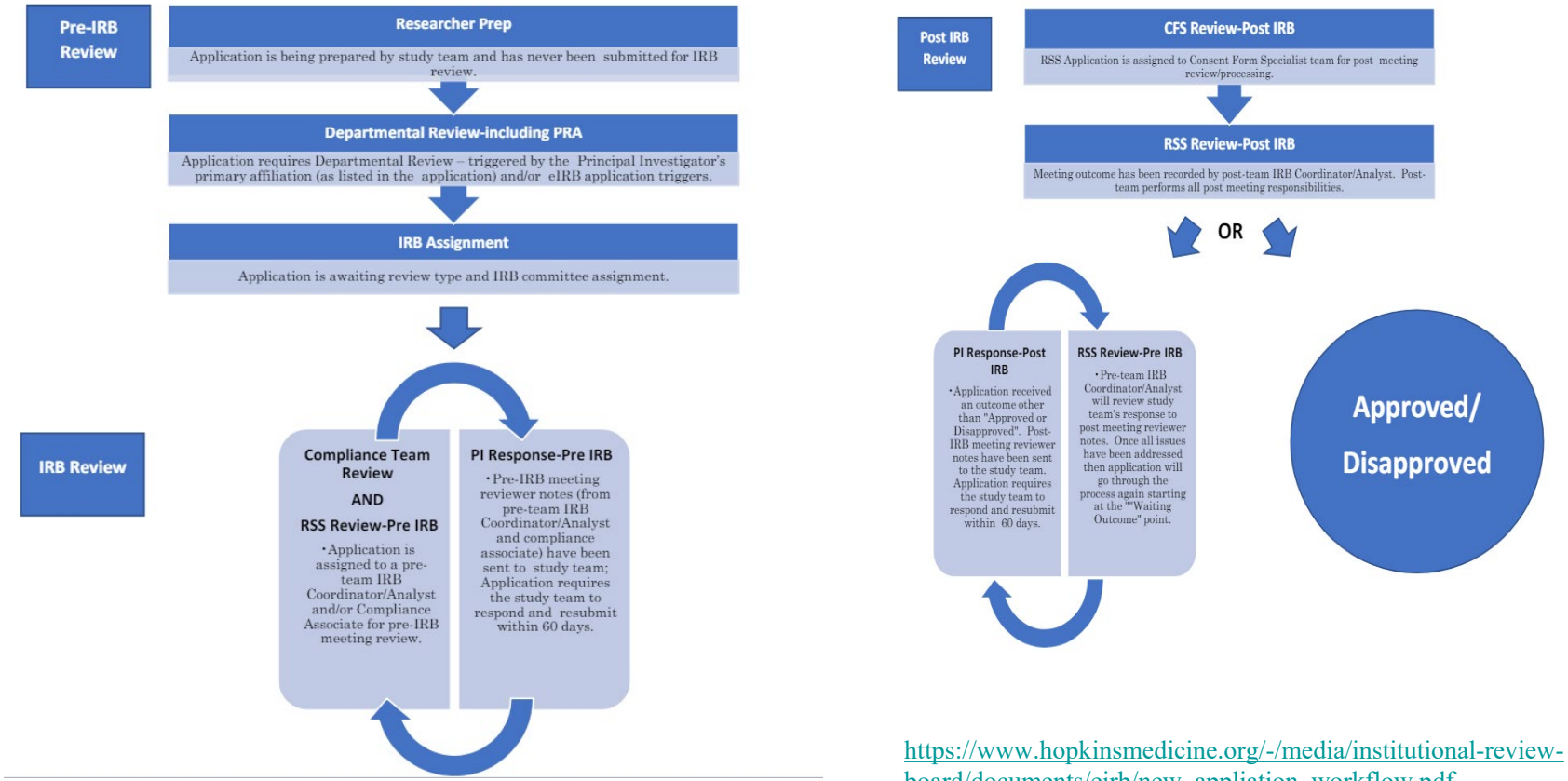
# Which protocol template should you use?

To access the most current versions of the JHM IRB eForms: Click Here

For IRB Quick Tips and Instructional Videos Visit: https://www.hopkinsmedicine.org/institutional-review-board/about/eirb

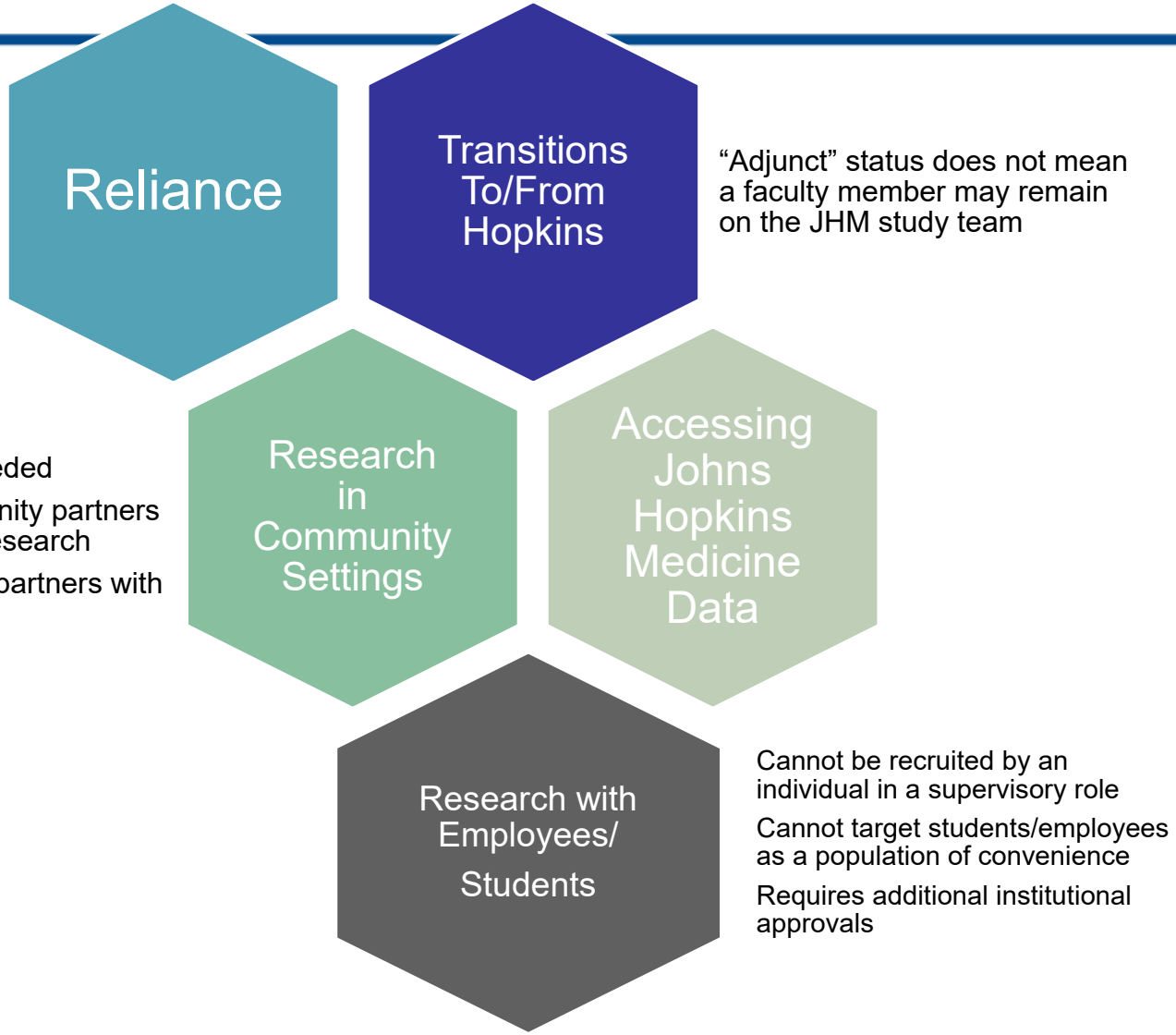


# Application Review Work Flow




https://www.hopkinsmedicine.org/-/media/institutional-review-board/documents/eirb/new_appliation_workflow.pdf

# Common Areas of Confusion




"Adjunct" status does not mean a faculty member may remain on the JHM study team

Common Issues:

-Permissions Needed

-Whether community partners are engaged in research

-How to address partners with multiple roles

Cannot be recruited by an individual in a supervisory role

Cannot target students/employees as a population of convenience

Requires additional institutional approvals

# Resources:
## Arriving and Departing Faculty

- Departing faculty with ongoing research:
  - ORA/JHMI departing faculty checklist
  - Chair Review of Data Sharing with Departing Faculty
  - Research faculty resignation checklist

  process-for-departing-faculty-requesting-data

- Arriving faculty with ongoing research:
  - *Request consult with JH reliance team using this link

# Resources:
## Engagement and Reliance

- Determining engagement:
  - Third party engagement
  - Request consult with JHM IRB compliance team using this link

- Reliance:
  - Single IRB and Reliance Agreements

# Resources:

## Research with patients, employees, and students

- Accessing JHM patient data for research
  - Access to patient data for research
  - HIPAA JHM covered entity
- Research with employees and students (and/or their data)
  - Guidance and policies for research with employees and students

# How do I connect with the IRB?

- For eIRB Technical Assistance and Training Questions contact the eIRB Help Desk: jhmeirb@jhmi.edu
- The Office of Human Subjects Research is a fully remote office. OHSR team members may be reached via MS Team phone lines or MS Chat- See Contact List
- Training Opportunities
  - IRB Office Hours: Features a new topic each month
  - IRB Basics and eIRB 101
  - GCP
  - OHSR Compliance Monitoring Program Webinar Series

**Sessions Qualify for PI recertification “in person” training requirement. Register in My Learning by searching for course title

# JHM IRB Request a Consult Service

Need help navigating the IRB review process?
Use the QR code or visit the IRB website: https://www.hopkinsmedicine.org/institutional-review-board/about/contact to request a consult and be matched with IRB staff who will address your needs.

**Sample topics we can help with:**

- Protocol planning
- Determining IRB review type & forms
- IRB regulations and policies
- Recruitment & consent
- Responding to IRB review


**Consult requests will receive a response within 24 hours – please reach out!**