

### Al and Data Trust Research Reviews

Prepared for the Office of Research Administration Office Hours Valerie Smothers, Director, Office of the Data Trust

May 8, 2025



# JHM AI and Data Trust Council

The AI and Data Trust governs the use and disclosure of JHM data and its responsible use in the implementation of AI. We are accountable to the office of JHM.

Mission: To bring together patient and health plan member-related data from across the health system to support our mission. 5/8/2025

### What we do (relevant to you)



- Create policy around the use of and access to JHM data, including use and access for research and use in AI
- Have processes to review
  different uses of JHM data

#### Stewardship



#### Compliant Sharing



#### **Responsible use**



### What is JHM Data?





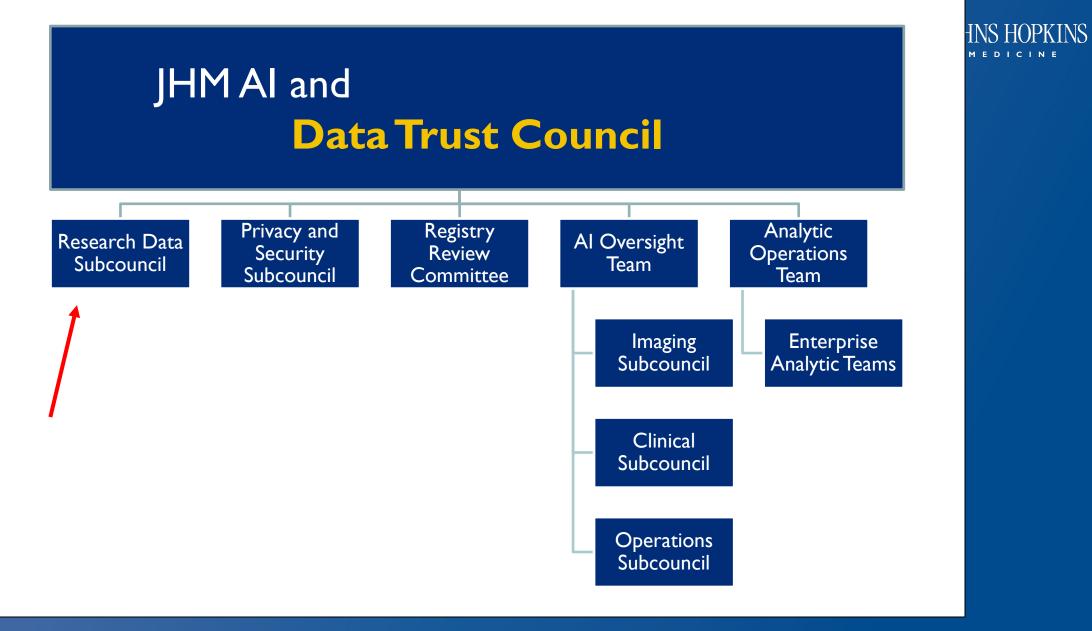
Patient or member-related data stored in our clinical enterprise systems.



• Billing, finance, health plan, and clinical administrative records or systems.



• Patient monitoring devices



# MEDICINE

# Principles of Responsible Artificial Intelligence JOHNS HOPKINS

- Created by taskforce of
  experts from across JHM
- Used to guide responsible Al implementation and an implementation plan of 44 taskforce recommendations





#### **Software Intake Process - SIP**



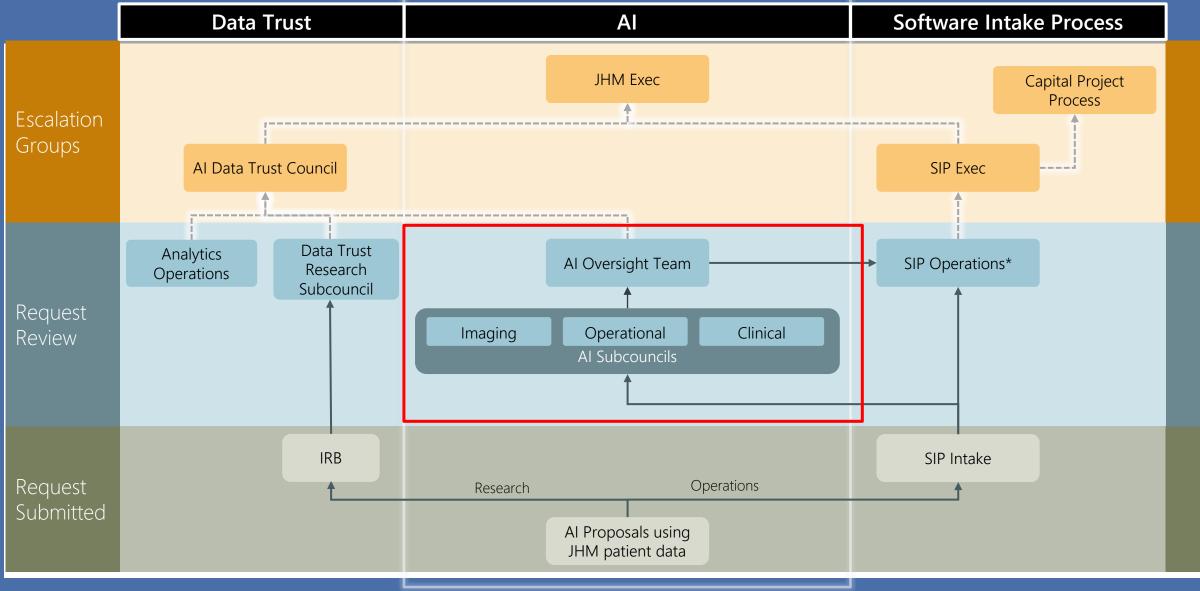
The Software Intake Process is a streamlined, single-entry point to collect and govern new technology requests.

#### The Software Intake Process (SIP): Requesting a New Software-Based Solution

#### Submit a Request

Are you looking to purchase or implement a software-based solution for a Johns Hopkins Medicine entity or department – including The Johns Hopkins Health System Corporation, affiliated hospitals, joint ventures, and the Johns Hopkins University School of Medicine? Will your software be implemented enterprise-wide? If so, review the types of requests that should go & should not go through SIP below. If you have questions about whether or not the technology you would like to bring onboard is appropriate for this process, please contact <u>sip@lists.johnshopkins.edu</u>.

### **Integrated Governance Structure**

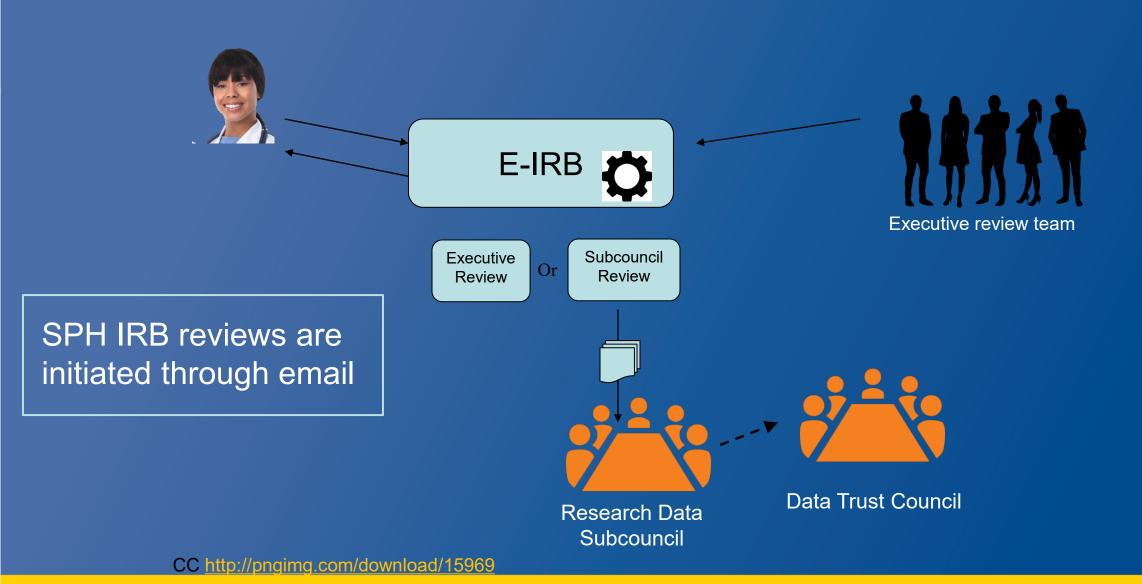


SIP should be initiated when there is software integration with a clinical system, when the software is intended for enterprise-wide use, or upon request of the study team to review the software

#### **Data Trust Review Process**



9



### **Different levels of review for research**



Executive Committee Review

Research Data Subcouncil Review

#### AI and Data Trust Council Review

Handles ~90% of reviews 6 reviewers Meets weekly (Mondays 8:30-9:30)

Required for projects proposing:

- To send over 500 records with PHI greater than a limited dataset to a third party without patient consent of data sharing
- If tier C and 10,000 records or more. If Tier C is determined solely by access to large numbers of records and access to PHI, submission for full subcouncil review will be at the discretion of the Executive Committee.
- Anything referred by the Executive Committee
- Data collaborations (first considered by Subcouncil)
- Anything referred by subcouncil
- May refer to JHM Leadership

## **Triggers for Data Trust Review**



- >499 records shared with a 3<sup>rd</sup> party, except for NIH/FDA req'd sharing
- Live data feed from enterprise clinical system
- Protected Health Information (PHI) collection via an app
- Creation of a Research Data Registry, (see <u>GEN001</u>)
- Risk Tier of C
- Referred by the IRB, CCDA, ORA, or data steward

## **ORA/JHURA** referrals



- We look for a Fibi, MyRap, SWiFT, or JAWS number in section 36, q2 of SOM e-IRB
- If you don't list one, we will ask for one.
- Pending isn't sufficient.
- If the level of identification of the data changes, we will ask the study team to inform ORA/JHURA.





- Respond to Data Trust comments in eIRB
- Contact <u>datatrust@jhmi.edu</u> if protocol is pre-Jan 2019
- Get the FAQs!
- See the <u>Research Data Subcouncil</u> page Make the data lifecycle clear: collection, storage, analysis, sharing

### **Teams and Office Hours**



- Short videos on relevant topics.
- Opportunity for ad hoc Q&A

#### Data Trust Research Data Subcouncil Videos

Friday, May 5, 2023 4:53 PM

#### **Office Hours**

2025

3/20/25 Introduction to Globus for Data Transfers

2/20/25 Availability of Johns Hopkins Health Plan Data for Research

1/16/2025 Using New Software for Research: SIP Review

#### 2024

12/12/24 Vivli Demographic Anonymization

10/17/2024 DISCOVERY HPC High Performance Computing cluster and the SAFER virtual desktop

9/19/2024 Data Provenance and Research Integrity Considerations

6/20/24 Using Large Language Models in Research

Third Thursday 8:30 to 9:30 AM. Join the Data Trust Research Data Subcouncil MS



### More information



Data Trust (sharepoint.com)

datatrust@jhmi.edu

