Creating an Effective and Compliant Research Data Request Process

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Background

- Academic health systems have a number of care team members who work across the continuum to support the tripartite mission of teaching, research and patient care.
- These shifting roles mean that individuals may often be accessing data for operational purposes **or** research.
- While clinical data is well regulated by national policies, research often falls into a gray area.

Objectives

- To Provide steps that can be taken to create a data request process which ensures high quality, reliable data for research purposes while ensuring compliance both regarding the study and patient rights.

Methods
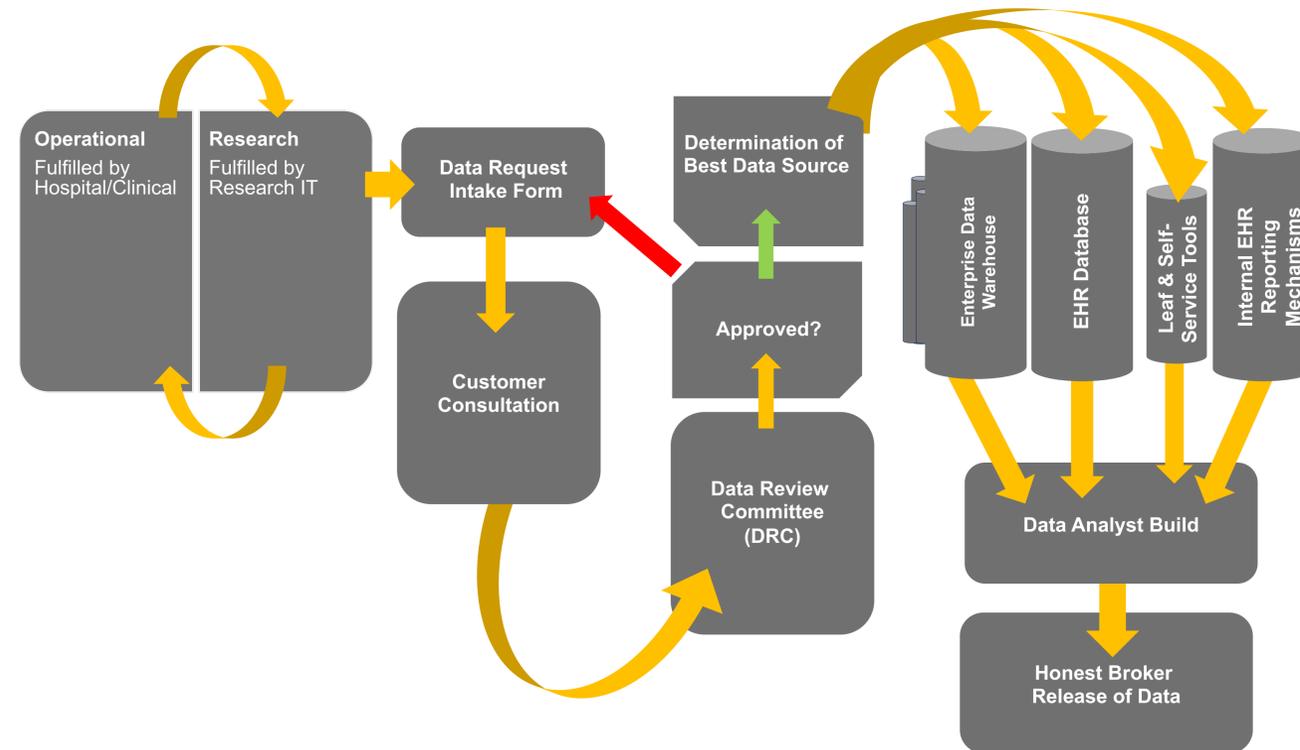
Discussion

The UW research data request model has been successful in keeping operational costs for the workflow low—even recovering funds through the service line—but more importantly it has increased both investigator satisfaction and confidence that the data is appropriate, and of research quality without compromising compliance.

Critical Components

Intake

- **Centralized Intake Portal**
  - Keeps workflow streamlined
  - Provides documentation on which requests were entered when
  - Provides documentation on who submitted the requests
- **Standardized Intake Forms within the portal**
  - Ensures consistent information
  - Allows for required information to be submitted upfront
 - Allows for basic understanding of project up front
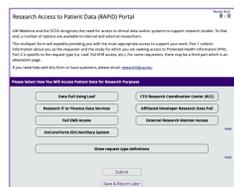
- **Knowledgeable Consultation Staff**
  - Clarifies any ambiguity in the request
  - Sets Expectations and determines priority
  - Establishes relationship with requesters

Governance

- **Data Access Review Committee**
  - Multi disciplined group notified by automated system when request is ready for review
  - Reviews the intake request and the notes from the consultation staff and compares it to the IRB approved study protocol and any other documentation or approvals
  - Reponses from the committee are logged electronically and based on the committee majority the determination regarding the request is emailed to the requester and assigned consultation staff
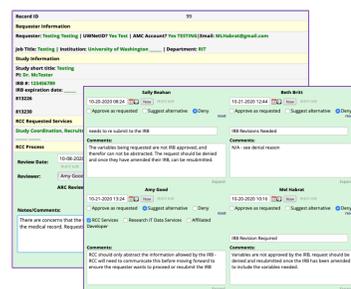
Data Pull & secure Transfer

- **Data Analyst Pull**
  - Once approved by the Data Access Review Committee, the request information provided to the data analyst by the consultation staff if they are not filling both roles.
  - The appropriate data source(s) is/are determined and the request is fulfilled adhering to any conditions of the Data Access Review Committee (if any)
- **Data Transfer to Requester**
  - Data is released to the requester through a secure mechanism such as SFTP, Networked Drive, or a report released into the live EHR environment

Compliance & Auditing

- **Accounting of Disclosure**
  - Each patient whose information is released for research purposes should be logged with institutional compliance with a minimum of the following information: MRN, Name, Date of Release, Person the data was released to, Method of release, Data elements released
- **Auditing**
  - If requesters have the ability to pull data themselves through Leaf or other self-service tools or a live report in the EHR, auditing processes and policies should be put into place to review what data is pulled and by whom to ensure the requests were first reviewed and approved through governance