This decision tree helps clarify when to obtain Institutional Review Board (IRB) and/or Data Governance Committee (DGC) approval.

Decision Tree: IRB/DGC Protocol

Here is a step-by-step guide to determine the necessary approvals for your project.

Step 1: Determine the Purpose of Your Project

*The first step is to identify whether your project is for **Program Evaluation/Quality Improvement (QI)** or for **Research**.*

- **Program Evaluation/QI:**
    - Using data to analyze and improve courses and programs. The results are typically shared internally with relevant committees and stakeholders or presented at conferences to share innovations and improvements.
    - If it will be published **IRB approval will be needed - skip to Pathway B**. (Will likely be approved as exempt.)

- **Research:** A systematic investigation into a specific topic or problem that involves collecting, analyzing and interpreting information to discover new knowledge or use existing knowledge in a new way. **IRB and/or DGC approval will be needed - skip to Pathway B**.

Step 2: Follow the Appropriate Approval Pathway

Pathway A: For Program Evaluation/QI Projects

If your project's purpose is quality improvement, use the following criteria to determine the next steps:

- **Scenario 1: Using De-Identified & Aggregate Data You Directly Access**
    - This includes data like session and end-of-course evaluation reports that are routinely available to faculty and course directors.
    - **Approval Needed: None.** You may proceed with your analysis to improve your courses.
    - What data will be provided: all relevant students.

- **Scenario 2: Needing Additional De-Identified & Aggregate Data**
    - This applies when you need the Institutional Effectiveness and Assessment (IEA) office to share other de-identified data for your QI initiative.
    - **Approval Needed: None.** The IEA will share the necessary data.
    - What data will be provided: all relevant students.

- **Scenario 3: Needing Linked Data for Internal QI**
    - This is for projects requiring linked data to examine relationships between variables for internal improvement purposes. The data provided will not be personally identifiable.
    - **Approval Needed: DGC Approval Only.** The data provided for QI cannot be used for research purposes, as it includes data from individuals who have not consented to research.
    - What data will be provided: all relevant students.

Pathway B: For Research Projects

If your project's purpose is research, the type of data you plan to use will determine the required approvals.

- **Scenario 1: Using LongMed Data**
    - This involves using any data that meets the criteria of longMED for research activities, even data you might already have access to for work or QI purposes. The honest broker will provide only the data from students who have consented to be part of longMED.
        - longMED criteria: (1) data that would otherwise be collected or generated for the usual operations of the SOM and (2) takes a longitudinal/outcomes focused approach to the research question.
    - **Approval Needed: DGC Approval Only.** The IRB has already approved longMED for research, and you will be provided with the IRB reference number if you are approved by the DGC.
    - What data will be provided: data from relevant students who have consented to be part of longMED.

- **Scenario 2: Using Non-LongMed but HMSOM Data**
    - This applies when you are conducting a research study that does not meet the longMED criteria (e.g. collecting data not part of the usual operations of the SOM; a deep dive research study as opposed to a longitudinal question, etc). The data will be collected from/about members of the HMSOM community (students, faculty, or staff).
    - **Approval Needed: Both IRB and DGC Approval.** The IRB must provide approval (you may be able to obtain the exempt type of IRB approval). Once IRB approval is obtained, the PI should request DGC approval, providing the IRB approval information.
    - What data will be provided: data for relevant consented study participants.

- **Scenario 3: Using Non-LongMed and Non-HMSOM Data**
    - This includes any data collected from individuals or populations outside of the HMSOM community.
    - **Approval Needed: IRB Approval Only.** DGC approval is not required in this case.
    - What data will be provided: data for relevant consented study participants.

Important Overarching Requirement

- **Human Subjects Training Certificate:** Regardless of the approval pathway, all researchers and anyone seeking IRB approval must maintain a current human subjects training certification. Proof of this certification will be required by the DGC when it reviews any data request.

The Golden Rules

- **IRB:** When in doubt if your project is "research," do not decide yourself. Always contact the IRB office for a determination.
- **DGC:** If you use or plan to collect or use **any** School of Medicine data for **any** scholarly purpose (e.g., publication, presentation, grants, etc.), you **must** get DGC approval in advance of using or collecting the data – even if it is data you already have access to as part of your work responsibilities.
    - Note that the DGC reviews data requests quickly, and will not be a barrier to your work.