HPI·MS

Hasso Plattner Institute
for Digital Health
at Mount Sinai

HPI·MS Research Project SOP

Standard operating procedure for HPI·MS personnel that needs access to Mount Sinai/HPI·MS resources (e.g. data, technical environments, etc.) to carry out research projects

HPI Hasso Plattner Institut
Digital Engineering · Universität Potsdam

Mount Sinai

Introduction:

This document explains how to register a new research project and how to add new people to registered research projects.

A Brief Explanation of the Mount Sinai Institutional Review Board (IRB)

At Mount Sinai, every study that involves human subjects (including data from patients) needs to be submitted to the IRB (the Mount Sinai ethics board) and approved by the IRB prior to study launch. These submissions are called "study protocols" and include comprehensive information about the scope of the research, design of the study, and research team. Oftentimes, our team at HPI·MS includes a Data Use Agreement (DUA) in our protocol submissions in order to cover research team members who cannot be officially added to our Mount Sinai study roster (this is due to technical reasons beyond our control. This includes HPI students who are not a part of Mount Sinai). Each member of the research team is also required to have previously completed a set of CITI training modules (this training is part of the HPI·MS onboarding process, see also HPI·MS Onboarding SOP).

Sometimes, our study protocols encompass numerous research endeavors within them. That means that one protocol can cover multiple projects. For instance, a broad "data science" protocol with a list of covered research themes, inclusive of a large team of researchers, could cover multiple projects within it. Our machine learning / data science protocol is an example of this, with some master's projects and master's theses, and other projects led by HPI·MS faculty, covered under one protocol. In this instance, each master's thesis and project are considered separate, individual "projects" under the same protocol. It is required that each study team confirms / ensures that their projects are covered by an approved IRB protocol prior to starting the research. This includes confirming that all team members are covered under the approved IRB protocol and have completed their required Mount Sinai CITI training / appropriate DUAs.

Contact:

If you have questions related to this document, please contact:

- HPI·MS Managing Director Silke Mühlstedt (silke.muehlstedt@hpi.de or Tel.: +49 331 5509-168)

In case you have questions regarding regulatory issues or you are not sure of the steps to start a new project, please contact:

- Clinical Operations Director Micol Zweig (micol.zweig@mssm.edu) (Potsdam-based requests)
- Research Program Manager Eddye Golden (eddye.golden@mssm.edu) (NY-based requests)

For IT-related questions or in case of technical problems, please contact:

- Associate IT Director Manbir Singh (manbir.singh@mssm.edu)

Steps to register a current or new project:

1. One person from the project team (e.g. project lead or other project researcher) submits project details on the Project Submission Form
    - All new & existing projects must be logged in this Project Submission Form
    - All projects require an HPI·MS faculty advisor
    - The primary contact for each project is required to submit a brief update every two weeks (they will receive a regular email request for this)
    - PRO TIP: The IRB number can be provided to you by your faculty advisor
    - PRO TIP: The project can be submitted to the Smartsheet *before or after* IRB approval. If you submit the project at the start of project development (before submitting to the IRB), just be sure to send us an update post-approval with your official IRB #.
2. One person from the project team places project-related IT requests (e.g. new data environment) via the IT Ticketing System
3. Research Program Manager and/or IT Director review new submission(s)
4. IT Director provides data access to new project team (if data is currently required) and informs personnel via email
    a. Data access is dependent on the protocol description and IT request that was placed
    b. Additional discussion with PI of the project might be needed to ensure proper technical requirements are met
    c. We will alert anyone who has not completed all necessary trainings/documentation prior to giving data access

What to do when you want to add a new person to a registered project:

1. Designated contact person or project lead (as defined in Project Submission Form) emails the Operations Director, IT Director, and Regulatory Manager with the project title and full name, Sinai email, Sinai ID, and role of the new person. No need to wait for reply.
2. Submit request for the person to access a VM or a dataset via the IT Ticketing System

What to do when a project ends, or a person leaves a project:

1. When data no longer needs to be accessed, please inform the IT Director via the IT Ticketing System, who will remove team/personnel access.
    - If one person from your project no longer needs data or is leaving the project, but the project is not ending, please inform the IT Director.
2. Please inform the IT Director and Research Program Manager of the tentative date when your project is ending.
    - If the project is completely over, please note this in your biweekly update request
3. If you are continuing your research project, including data access, but you do not need all of the resources we have set up for you, please inform the IT Director.

Notes on students:

PLEASE CONSULT YOUR SUPERVISOR/MENTOR IF YOU HAVE ANY QUESTIONS RELATED TO YOUR SPECIFIC PROJECT

New student information will be provided to HPI·MS Operations team 1.5 months prior to the start of the semester.

Students may only use data for reasons that were submitted via the project tracker and IT requests and approved by the operations team.