Mount Sinai

Icahn School of Medicine at Mount Sinai
Mount Sinai Beth Israel
Mount Sinai Brooklyn
The Mount Sinai Hospital
Mount Sinai Queens
New York Eye and Ear Infirmary
of Mount Sinai
Mount Sinai St. Luke's
Mount Sinai West

Program for the Protection of Human Subjects
Institutional Review Boards
Mount Sinai Health System
One Gustave L. Levy Place, Box 1081
New York, NY 10029-6574
T 212-824-8200
F 212-876-6789
irb@mssm.edu
icahn.mssm.edu/ppbs

APPROVAL

February 4, 2025

BRETT ANDERSON
(212) 241-4565
brett.anderson@mssm.edu

Dear BRETT ANDERSON:

On 2/4/2025 an Institutional Review Board of the Mount Sinai School of Medicine, in accordance with Mount Sinai's Federal Wide Assurances (FWA#00005656, FWA#00005651) to the Department of Health and Human Services approved the following human subject research from 2/4/2025 to 2/3/2026 inclusive:

Type of Review:	Initial Study
Project Title:	Health Outcomes and Expenditures for Children using All Payer Claims Data (APCD)
Investigator:	BRETT ANDERSON
Project Information:	STUDY-24-01346 Funding Source: Name: Icahn School of Medicine at Mount Sinai
MSHS System Sites:	Mount Sinai Medical Center
IND, IDE, or HDE:	None
Documents Reviewed:	• 503r, Category: IRB Protocol; • APCD IRB_SOP_1_8_2025.docx, Category: Other; • Colorado Data Dictionary , Category: Other; • HIPAA_waiver_authorization_APCDdraft[25].pdf, Category: Other; • HIPAAWizardForIRBSubmissions_H_2024-11-22_1503.pdf, Category: HIPAA Wizard; • HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process.docx, Category: Other; • HuronRUTHAncillaryOfficesSurve_2024-11-18_2355.pdf, Category: Ancillary Review Form; • MA APCD Data variables, Category: Other;

• The IRB approved this research under expedited review procedure category(ies) (5) Data, documents, records, or specimens

• The request for a waiver of informed consent was approved for the specified procedures described in the protocol.

The PHI for which access and use has been granted for this project [which are the minimum necessary] include the following

Identifiers:

Name

Street address, city, county, zip code

Date of Birth

All elements of date (admission date, discharge date, service date, etc)

Date of death

Health plan beneficiary numbers

Billing Provider ID

Health Information:

Inpatient and outpatient visits

Diagnostic testing

Procedures and surgeries

Medication usage

Access to care (e.g., distance to healthcare facilities)

Healthcare provider characteristics

Resource utilization patterns (e.g., frequency of visits, intensity of care)

Insurance coverage type

Mortality

Morbidities (e.g., hospital readmissions, complications)

• The request for a waiver of HIPAA authorization was approved. The PHI for which access and use has been granted for this project [which are the minimum necessary] include the following:

Identifiers:

Name
Street address, city, county, zip code
Date of Birth
All elements of date (admission date, discharge date, service date, etc)
Date of death
Health plan beneficiary numbers
Billing Provider ID

Health Information:

Inpatient and outpatient visits
Diagnostic testing
Procedures and surgeries
Medication usage
Access to care (e.g., distance to healthcare facilities)
Healthcare provider characteristics
Resource utilization patterns (e.g., frequency of visits, intensity of care)
Insurance coverage type
Mortality
Morbidities (e.g., hospital readmissions, complications)

IRB approval requires that this research is conducted in full compliance with the requirements indicated in the PPHS/IRB Investigator Manual. Additionally, all required local committee approvals at each research affiliate site must be obtained prior to study initiation.

It is imperative to recognize that IRB approval does not constitute or imply institutional support for the conduct of this research. Further, IRB approval from Mount Sinai is provided with the understanding that the investigator and research team will strictly adhere to all laws and regulations governing research in the localities where the project is to be conducted.

To access stamped consent forms, log into RUTH, search for your project in the IRB, Active tab, and click the Documents tab in the study workspace.

As a courtesy reminder, in order to request continuing IRB approval or study closure, you are required to submit a Continuing/Final Review Progress Report and required

attachments at least six weeks prior to your project's expiration date. If IRB continuing review approval is not granted before the expiration date of 2/3/2026, IRB approval of this research expires on that date. There is no grace period beyond one year from the last approval date. It is your responsibility to submit your research protocol for continuing review.

If your project qualified for an extended expedited expiration, and was given an approval period of more than one year, please note that the elimination of annual continuing reviews does not remove the responsibility of the PI/Research Team to monitor the ongoing conduct of the research. The rules as they apply to reporting new information, requesting modifications to the protocol or consent and making final reports have not changed. CITI refresher training for research staff must still be completed every three years, and financial conflicts of interest must be managed by the FCOI committee independent of the project approval period. In addition, any other changes by the PPHS, ISMMS, or federal or state regulations that affect projects, e.g. consent language changes or new policy, must still be implemented during the three-year period.

For questions, please contact the IRB staff member working on the project or the PPHS at 212-824-8200.