

Mission Statement

To provide exemplary clinical care to all patients with MASH/MASLD through standardization of clinical protocols and innovative clinical/translational studies and to elucidate molecular, cellular, immunological pathogenic mechanisms and predictors of disease progression and regression.

Rationale

Metabolic dysfunction-associated steatohepatitis (MASH) is emerging as the predominant liver disease and lead indication for liver transplant because of rising obesity and diabetes.

Mount Sinai is uniquely positioned to develop models for patient identification, predictive modeling for risk stratification, and enrollment of a highly diverse pediatric and adult population into registries and biobanking through multidisciplinary partnerships with colleagues in BiOME, primary care, obesity medicine, cardiology, and endocrinology. These resources will be leveraged to partner with industry and NIH to support a highly funded research program.

MASH Center of Excellence Team*

- | | | |
|--|---|--|
| Alejandra Paredes-Marin Vikram Sivakumar | Meena B. Bansal Scott L. Friedman | Asher Leviton Hsini Chou Michele Cohen |
| Doug Dieterich Alyson Harty Bishuang Cai Scott Friedman Bachir Taouli Sara Lewis Jamie Chu John Bucuvalas Tae Hoon Lee Ritu Agarwal Jim Crismale Tom Schiano | Andrea Branch Augusto Villanueva Girish Nadkarni Tatyana Kushner Xiaotao Zhang Isabel Fiel | |

*MASH Center of Excellence funded by the Department of Medicine

MASH-Related Grants Awarded in 2022-2023

Meena B. Bansal

- A. Addressing Diagnostic Challenges for Non-Alcoholic Steatohepatitis (NASH)
- B. Outcome Study of Adults using TPE/SHG Imaging and Histological Evaluation of Retrospective NAFLD Biopsies Obtained from Mount Sinai Hospital
- C. Generating Evidence to Assess the Optimal Application of NASHnext™ within Real-World Workflows
- D. Real World Use of ELF to evaluate MASH

Scott Friedman

- A. Therapeutic antibodies for treating liver fibrosis
- B. Efficacy of EVT0185 in FAT-NASH model

Bishuang Cai

- A. Disturbed Crosstalk between Cholesterol Homeostasis and Inflammation Resolution in NASH
- B. Novel cellular crosstalk in NASH

Andrea Branch

- A. NAFLD/Fibrosis Screening Tools for Multi-ethnic Populations: Focus on Non-Hispanic Black and Mexican American Persons in the United States
- B. Evidence of Toxicant-associated Fatty Liver Disease in WTC Responders

Shuang Wang

- A. Hepatic stellate cell plasticity and maladaptive fibrogenic memory in chronic liver disease

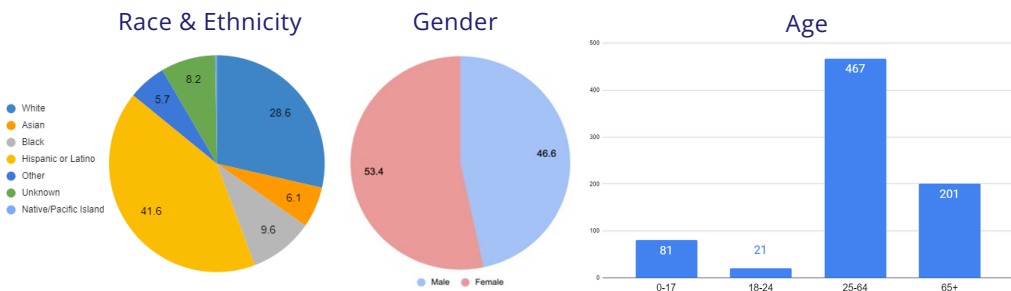
Clinical Trials Open to Enrollment

| Sponsor | Protocol | Principal Investigator | Indication | CCO Number | IRB Number | Phase |
|--------------------------|-----------------------|------------------------|------------|------------|------------|--------------------|
| Madrigal Pharmaceuticals | MGL-3198-18 | Bansal | NASH | 21-1245 | 21-01150 | Open to Enrollment |
| Inventiva | 337HNAS20011 (NATIV3) | Villanueva | NASH F2-F3 | 22-0760 | 22-00635 | Open to Enrollment |
| NIH | Lisinopril | Villanueva | NAFLD | 19-2796 | 21-00477 | Open to Enrollment |
| Perspectrum Diagnostics | IIP137 | Dieterich | NASH | 19-2841 | 19-01371 | Open to Enrollment |
| Madrigal Pharmaceuticals | MGL-3198-19 | Bansal | NASH F4 | 22-1910 | 22-01535 | Open to Enrollment |
| Novo Nordisk | NN9931-4553 | Bansal | NASH F2-F3 | 21-2134 | 21-01801 | Open to Enrollment |

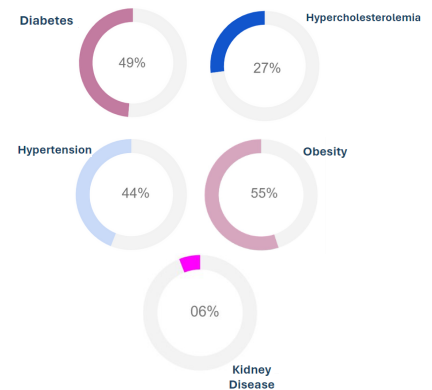
Please contact tanjina.razaque@mssm.edu for more information

MASH Longitudinal Registry and Biobank (N=770)

Cohort Distribution



Comorbidities



Liver Biopsy Results with MASH (n =105)

| Grade (Inflammation) | Stage (Fibrosis) |
|----------------------|------------------|
| Grade 0 | F0/1 |
| Grade 1 | F2 |
| Grade 2 | F3 |
| Grade 3 | F4 |

Fibrosis Stages Based on FibroScan

