

Policy Overview:

**Mass General Brigham Policy on
Limitations and Restrictions for Sharing Data under the
NIH Data Management and Sharing Policy**

- NIH has issued a [Data Management and Sharing Policy](#) (effective for due dates on/after January 25, 2023) to promote the sharing of scientific data. This Policy applies to all research that results in the generation of Scientific Data and is funded in whole or in part by NIH.
 - Under this policy, NIH recognizes that certain factors (legal, ethical, or technical) may limit the ability to preserve and share data.
 - Researchers must include a justification for the limiting or restricting of sharing Scientific Data in Section 5 of their NIH Data Management and Sharing Plan submitted with their NIH proposal ([Writing a Data Management & Sharing Plan | Data Sharing \(nih.gov\)](#)).
- **Mass General Brigham has developed its own policy with respect to limitations and restrictions on sharing data under the NIH policy.**
 - Requests for exception to these limitations and restrictions must be approved by the Mass General Brigham Joint Committee on NIH Sharing Requirements: **JOINTCOMMITTEE@mgb.org**
 - Exception Requests should be emailed to the address above at least 3 weeks prior to the proposal deadline to ensure sufficient time for committee review and include: draft DMS Plan and exception description and justification.

Researchers are responsible for compliance with the entire policy when developing and implementing their data management and sharing plan. The full policy is found at:

[MGB Policy on Limitations](#)

A summary of key policy points is available below.

Legal and Contractual Limitations and Restrictions for Sharing Data

Researchers may not share data from basic, animal, or human research if:

- The research or funding agreement governing the original source of your data does not allow sharing (MTA, DUA etc.)
- Any associated licensing agreements, laws, regulations, or policies (including MGB policies) do not allow sharing
- Any federal, state, local, or Tribal law, regulation, or policy prohibits disclosure or sharing

Technical Limitations and Restrictions to Sharing Data

Researchers may not share data from basic, animal, or human research if:

- De-identification of data is not feasible (e.g., large data sets requiring manual de-identification and the time/cost of doing so would require resources beyond the limits of the proposal timeline and budget)
- Digitizing data is not feasible

Sharing Human Data: Ethical and Legal Limitations and Restrictions

Any limitations or restrictions described in the Informed Consent Document/Process must be honored.

Includes use of Primary data or secondary data and whether a written or verbal consent process was use. Also includes the type of sharing (controlled access, uncontrolled/public, etc.), any described Data Use limitations and specific users (academic, industry etc.), use for specific condition/disease research, and any destruction dates.

Researchers may not share:

- Individual-level clinical/electronic medical record notes even if considered de-identified.
- Large number/high percentage of clinical data
- Data with small cell sizes or data that can be used to infer information about or inadvertently identify an individual
- Data that may be harmful or stigmatizing to an individual or to a particular group of people or a population.
- Any other individual-level “[sensitive](#)” data.
- Limited Data Sets unless consented
- Any data under GDPR (or other international privacy restrictions)

How to Share Human Data:

- Data must be anonymized or de-identified under HIPAA standards and requirements of federal human subjects regulations
- Data may only be shared in controlled access repositories/conditions
- EXCEPTION: Only data collected with explicit human research consent as approved by an IRB for sharing in public/open-access repositories may be shared in public/open access conditions.

Sharing Animal Data: Ethical and Legal Limitations and Restrictions

- Researchers must abide by all Mass General Brigham IACUC policies for limiting sharing of certain animal data and associated metadata.

Researchers may not share:

- IACUC Protocols
- Images or videos of procedures or animals under trauma, or identifiable animal images (unless excepted for sharing under IACUC policies)
- Individual Animal Medical Records (IAMRs), Rodent Record Cards (RRCs), or similar animal records
- Proprietary information
- Any information that could be used to identify individuals involved in the conduct of the research
- Any information that provides information about the specific location of animals
- Details around Category E studies