Office of Research Administration & Corporate Legal Administration's

Data Use Agreement Memo

Version 1, July 2020

Data Use/Sharing/Transmission Guidance for Research at HMH

Given the prominent role HMH has played in the Covid 19 pandemic and the resulting volume of Covid 19 related data available to HMH researchers there has been an increase in requests to Legal supporting Research for agreements related to Data Sharing. Out of concern that many collaborators may be looking to exploit HMH Data for their own commercial purposes, the **HMH Board of Trustees has recently given direction that HMH will not allow exploitation of data that we provide other than in connection with the engagement that we are participating in and commercial exploitation of data will generally prohibited.** Recent retractions of publications have further raised concerns about the quality of data being shared. [1] Academic health institutions like HMH must manage the risk of data loss/corruption, inability to validate, privacy breach with the ethical and legal obligations to share and publish data. See 42 CFR parts 222, 431, 438 457 July 1, 2021 Interoperability and Patient Access Final Rule (CMS)

Legal has prepared this brief update regarding data sharing to assist researchers who are looking to engage in research with HMH data.

Research Data Sharing

Types of Engagements and Agreements

Data sharing in Research can present in the sharing of clinical data gathered in the performance of a clinical trial, minimal risk chart reviews, exchange of materials from a biorepository or lab, data sharing with a data bank or registry, and service agreements associated with the research being performed. These are some of the primary data sharing engagements seen in research in the academic health setting. Each data sharing engagement requires a data management plan (DMP) and some agreement that puts that DMP in writing and establishes the rights and obligations of the parties with respect to the data. Research collaborations involving HMH Data begin with the execution of a non-disclosure agreement (NDA) or confidentiality agreement (CDA) between the parties. The terms of the data sharing for clinical trial data will typically be included in the clinical trial agreement and associated ancillary agreements such as subsite and service agreements. Research that involves minimal risk chart reviews (a systemic collection of data from patient records in EPIC/EMR associated with specific research question) often only requires a data use agreement and a protocol to set the terms of the data sharing, unless a research collaboration with another entity creates a need for a collaborative research agreement or a service agreement is needed (CRO, biostatistician). Registries, data banks and

[1] https://www.biotechniques.com/coronavirus-news/opinion_covid-19-retractions-put-the-spotlight-on-bad-data/

consortiums are all collaborative research where data sharing terms and conditions can be found in the agreements governing the collaboration that typically include template data use agreements and their implementing letters. Engagements with entities who are not academic health centers that are bound by certain privacy obligations under HIPAA as "covered entities" may require the execution of the HMH Business Associates Agreement or even an IT Security Addendum (research software providers) in addition to the service agreement or PO.

Data Management Plan

Data Management Plans involve making decisions about data resources and potential products. A DMP describes data that will be acquired or produced during research: how the date will be managed, stored and how it will be handled and protected during and after a collaboration. A DMP should include:

- A description of the data to be collected or generated in the proposed project;
- Applicable data sharing standards and polices to be followed for generating and collecting and sharing the collected or generated data to ensure the quality of the data and ability to validate;
- Mechanisms for or limitations to providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, publication, intellectual property, or other rights). This section should include whether the access will be immediate or mediated by a consortium, biorepository or databank with established governance identified, and should address access to identifiable and de-identified data;
- Defined roles and responsibilities of the parties and team members;
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use;
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified. This section should address archiving and preservation of identifiable and de-identified data; and,
- A Budget that addresses data activities.

IRB Review and Conflicts Review

Like all clinical trials, data sharing via minimal chart reviews, data banks, biorepositories must be reviewed by an IRB and the Conflicts Committee to ensure that adequate human subject protection measures are in place and a conflict management plan, if necessary, to avoid the any impact bias or the appearance of bias might have on the research results. A minimal risk chart review (retrospective, prospective, or both) will be

reviewed by the IRB for a determination as to whether it is exempt from review or is entitled to an expedited review.

Exempt chart review studies include records and data already in existence before the review and the data must be de-identified with no possible way to go back to the records or re-link the data to the record at a later date. Expedited Chart Review Studies include a review of patient records either retrospective or prospective, or both, where it is necessary to collect identifying information or maintain a code or link to the data source.

Federal Regulations regarding exempt and expedited studies are:

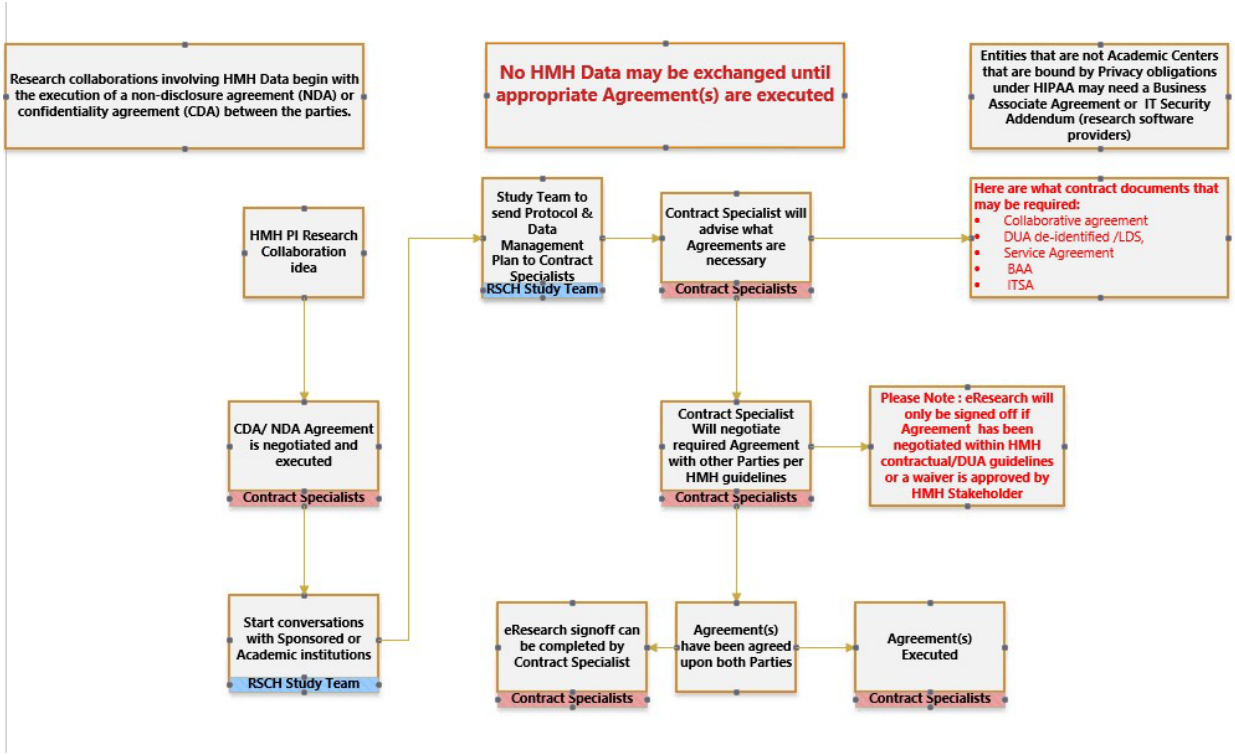
45 CFR 46.101 Exempt Studies-Retrospective and no identifiers collected so no possible way to re-link the data at a later date.

45 CFR 46.110 and 21 CFR 56.110 Expedited Studies-retrospective or prospective study where it is necessary to collect identifying information or maintain a code or link to the data source.

HMH Policies pertaining to Data Sharing

There is guidance in the ***Data Handling Policy for HMH*** which is also available on PolicyStat**.** The policy requires that all data sharing must be via encrypted format with an agreement in place approved by the CIO or assignee. The policy continues that it is Legal' s responsibility to provide non-disclosure agreements and other agreements that establish the terms for data sharing as approved by the CIO or designee.

Flow Diagram:



Legal Review and Drafting of Agreements

Upon submission of a protocol including data sharing in *eResearch* the matter will be assigned to a Contract Specialist in Research who will work with you and Legal to prepare the necessary agreements to establish the terms and conditions of the research and data sharing. Helpful Guidance as to when a Data sharing agreement is required can be found in the chart on The Federal Demonstration Partnership website in the section pertaining to Data Transfers http://thefdp.org/default/assets/File/Documents/dtua_guidance_chart.pdf **Data sharing agreements are always study specific. Blanket data sharing agreements do not exist between organizations.** At HMH, there are institutional contract guidelines and essential terms in each data use agreement. There are template agreements to expedite the process.

Essential Data Use Terms

- Data should not be used by the recipient except as authorized under the agreement for the specific engagement, or as required by law, and ensure that any agents, subcontractors agree and are bound by the restrictions of the agreement.

- here should be no-re-identification of data or contact of patients if a Limited Data Set or de- identified data is being exchanged.
- The ownership of source data (medical records) remains with HMH. A plan for ownership and use of research data must be in place.
- The recipient will report any misuse or unauthorized disclosure as soon as known.
- The "sale" and marketing or other commercialization of any HMH data (identifiable or deidentified) is prohibited. The only funds exchanged should be related to the fair market value of the cost of the transfer, use, and storage of data.
- Recipient must agree to recognize the contribution of the "Provider" HMH as the source of the data in all written, visual, or oral public disclosures concerning Recipient's research using Data.

Tips and best practices:

1) If data-related issues are already addressed in clinical trial agreements, time and resources can be saved when putting together the DUA. The HMH clinical trial template agreements include many data use and ownership terms up front.

2) Ensure as much time as possible to allow for interpretation and possible reaction to legal wording in the agreements. Set your DUAs up early in the life of the project.

5) Clarify specific data elements needed for the analysis up front.

6) Keep the following documents in the project files at each site:

• Fully signed DUA.

• Signed Data Release Checklist (or similar documentation required by your site)

• Documentation of content of the data sent/received (e.g., SAS proc contents report).

• Cover letter or email documenting data transfer