Hackensack Meridian *Health*

CONTRACTS RESEARCH WORKFLOW

Below is the official workflow for Contracts Research for reference when submitting Clinical Trial Agreements, Amendments, Data Use Agreements, and any other agreements required to conduct the research within the Hackensack Meridian Health network.

All research agreements must be reviewed by the Research Contracts Office prior to study start-up/initiation. The Research Contracts Office must also be notified of study amendments and/or any clinical trial closures. Study teams on behalf of the Investigators are asked to provide the applicable documents listed for review.

Please note that reviews will not commence until full startup packet is received.

Please send the required information below to Contracts' general inbox at ContractsResearch@hmhn.org and make sure to include the appropriate budget team and copy Sergio Garcia on all contract emails. For HUMC/JSUMC studies please include Sergio Garcia, Shelly Chin and Elizabeth Stichling. For HUMC pediatrics please include Evette Payton Toledo and Sergio Garcia For any JTCC-Oncology studies, please copy Tzipora Kuba. For any oncology Studies outside of JTCC copy Sergio Garcia, Shelly Chin and Elizabeth Stichling

In the body of the email, please also provide the following information:

Sponsor:
Protocol # (Oncore & eResearch):
Principal Investigator:
Clinical Research Coordinator:
Expected Enrollment:

Also, task lists within OnCore need to be released prior to submitting any requests to the Contracts Research Office. Should you require any assistance with Oncore, please contact Kathrena Aljallad.

For Initial Contracts Request (CTAs/Work Orders), please include the following:

- Contract Checklist
- Clinical Trial Agreement/Work Order Research Agreement
- Budget
- Finalized Protocol
- ICF
- Sponsor Contact information
- Name of PI
- Name of lead coordinator
- Expected enrollment number
- Release Oncore Task List for CTA or Work Order

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For Amendments, please include the following:

- Clinical Trial/Amendment Agreement
- Budget (if applicable)
- Finalized Protocol
- ICF
- Sponsor Contact info
- Release Oncore Task List for Amendment

If the project involves data exchange that will merit a Data Use Agreement, we kindly ask that you send the following:

- Finalized protocol that addresses a clear Data Management Plan and how data will be stored
- Completed HMH Data Use - DUA Request Intake Form *(attached in this email for your storing for future reference)*
- Sponsor Contact information
- Name of PI
- Name of lead coordinator
- Release Oncore Task List for DUA

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Hackensack Meridian Health Research Contracts FAQs

What Types of Contracts does the Office of Research Administration Research Contracts Office negotiate?

Research Contract Team with the assistance of Legal Counsel negotiates industry sponsored agreements: clinical trials agreements, work orders, Data Use Agreements, confidentiality disclosure agreements, master agreements, and subcontracts for clinical trial agreements.

Do Hackensack Meridian Health Investigators sign Research Contracts as a party to the agreement?

No. As employees of Hackensack Meridian Health conducting research within his/her role as an employee, investigators do not sign Research contracts as a party.

If Hackensack Meridian Health principal investigators do not sign Research Contracts as parties, what do they sign as?

The Principal Investigator will sign as “Read and Acknowledged”.

If the Principal Investigator is not available to sign a negotiated Research Contract, Can someone else sign on his/her behalf?

No. The Hackensack Meridian Health principal investigator (PI) must sign the contract. No one else in the PI's department can sign the contract in his or her place.

Why can’t I just sign the Contract?

Only certain individuals have the legal authority to bind Hackensack Meridian Health to obligations with a 3rd party. If the contract is not signed by one of these individuals, the contract will have no binding effect.

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Data Use Agreement (DUA) Frequently Asked Questions (FAQs)

Why sign a DUA?

DUAs address important issues such as limitations on use of the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. The understanding established by the DUA can help avoid later issues and will ensure the appropriate use of data for a specific research project, protecting both the provider and the recipient.

Establishing a Data Use Agreement Achieves the Following:

- Protects the investment and reputation of both the investigator and the University
- Access to important data makes an investigator more competitive in publications and grants; sharing of this data helps to foster collaboration with other leading scientists
- Ensures that the investigator and University receive academic credit for their work
- Appropriate acknowledgement of the data's source in academic publications and presentations can be addressed in the DUA, although any determination of appropriate designation must be based on actual contribution of the research and cannot be agreed upon in a DUA.
- Prevents the inappropriate use of intellectual property or protected or confidential information that could cause harm to research subjects, the investigator or the University
- Helps to shelter the investigator and University from any liability or loss arising from a recipient's use of University data
- Assures that the recipients are using the data in accordance with applicable law
- Contractually obligates the recipient to use the data only for the purpose described in the DUA
- Where data may be subject to HIPAA, ensures that appropriate restrictions on use are maintained

Who signs DUAs?

Office of Research Administration's Contract office is authorized to enter into research agreements, including DUAs, on behalf of Hackensack Meridian Health. Researchers are not authorized to negotiate or sign agreements on behalf of HMH. When a researcher signs such an agreement on behalf of the HMH, the researcher could be subjected to legal and financial risks. It is important for the researcher to read the terms of the DUA before forwarding it to the Research Contract Office for signature. The Research Contract Office assumes that a researcher who submits a DUA has read it and agrees to conform to those terms, whether or not the researcher's signature is required on the DUA itself. Research Contract Office will confer with Research Legal Counsel and IRB or other pertinent compliance offices as required in the evaluation of DUAs.

What are examples of data that might be exchanged under a DUA?

- Records from government agencies or corporation
- Human Research Subject Data
- A De-identified or Limited Data Set of Protected Health Information (PHI)
- Genetic sequences
- Models
- Proprietary or valuable information or material that does not fit the profile of a tangible physical material

What is De-identified Data Set?

The HIPAA Privacy Rule (45 CFR, Parts 160 and 164(A) and (E)) specifies that patient data can be to de-identified by removing 18 elements that could be used to identify an individual or an individual's relatives, employers, or household members; these elements are enumerated in the Privacy Rule. Investigators also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, the following identifiers must be removed:

1. Names
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Census Bureau, a) the geographical unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people or b) the initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. Facsimile numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plates
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including fingerprints and voiceprints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

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What are Limited Data Sets?

Data sets that include dates of service or entire ZIP codes are considered limited data sets. As defined by HIPAA, limited data sets are data sets stripped of certain direct identifiers that are specified in the Privacy Rule. They are not de-identified information under the Privacy Rule.

A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1. Names
2. Postal address information, other than town or city, State, and zip code
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license plate numbers
11. Vehicle identifiers and serial numbers
12. Device identifiers and serial numbers
13. Web URLs
14. Internet Protocol (IP) address numbers
15. Biometric identifiers, including fingerprints and voiceprints
16. Full-face photographic images and any comparable images

Limited data sets may include the following: city, state and zip codes; all elements of dates; and unique codes or identifiers not listed as direct identifiers

When do I need a DUA?

For Human Subject Data

A. Disclosure of data for research purposes and
B. Individual authorization for disclosure to this recipient is not/has not been obtained (from human subject, as through use of a subject-signed informed consent authorization) and
C. Disclosure is permitted under an IRB-approved protocol (for human subject research) or
D. The researcher is disclosing or receiving a "De-identified or Limited Data Set of Protected Health Information (PHI)", as defined under HIPAA.

For Non-Clinical Data

A. When no other form of contract concerning the data transfer exists between the provider and the recipient and
B. When the data is not in the public domain, and the disclosing party wishes to limit the further use or distribution of the data in some way, and
C. The recipient intends to use the data for research purposes

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