Release of Human Subject Identifiers for Research Policy

Scope

Applies to the Mayo Clinic Institutional Review Board (IRB) and Mayo Clinic investigator(s) when releasing human subject identifiers including Protected Health Information (PHI) to third party for research purposes.

Purpose

To define the limitations for the release of subject identifiers collected in research at Mayo Clinic.

Policy

- Human subject identifiers must not be released to a third party in the course of human subject research, except with the approval of the Mayo Clinic IRB and the consent and authorization of the research subject.
- Human subject identifiers that will be shared with a third party must be described in the research protocol, IRB electronic (IRBe) application, and in the written informed consent document.
- For human subject research studies in which the third party is a commercial entity or an affiliate of the commercial entity, the legal contract must include provisions for:
    - Maintaining the privacy and confidentiality of the human subject identifiers.
    - Destroying the human subject identifiers when they are no longer necessary to accomplish the stated purpose.
    - Prohibiting the sharing of human subject identifiers with another third party without approval of the Mayo Clinic IRB and
    - Prohibiting the use of human subject identifiers for marketing, solicitation, or other commercial purposes.

Investigator Responsibilities

The Investigator will:

- Provide a description of the human subject identifiers that will be released to third parties in the research protocol, IRBe application, and the written informed consent document.
    - Mayo Clinic IRB will require the consent document to describe which subject identifiers are required to be released as stated in the protocol document.
- Withhold the human subject identifiers until the Mayo Clinic IRB has reviewed and approved the release.
- Obtain and document the informed consent and authorization of the research subject as required by the IRB.
- Ensure the legal contract includes the policy provisions listed above.

IRB Responsibilities

The IRB will:

- Determine whether the human subject identifiers may be released for research purposes as appropriate for the proposed research activity.
- Review the consent document to assure it contains the same information in the research protocol and IRBe application which will be necessary to convey to the potential research subject.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

N/A

Definitions

Human Subject Identifiers: Any word, number, symbol, or combination of words, numbers or symbols that can be used by a third party to uniquely identify an individual, such as Name, Social Security number, address or patient registration number that is provided for use in a research protocol.

Mayo Clinic: Mayo Clinic refers to Mayo Clinic in Arizona, Florida, and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Third Party: An individual not employed by Mayo Clinic or an entity that is not an affiliate of Mayo Clinic, but performs an activity or function on behalf of Mayo Clinic. This definition includes business associates, which are third party vendor relationships that involve access to Protected Health Information (PHI) or the creation or collection of PHI for Mayo Clinic.

References

N/A

Owner

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Contact

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Revision History

Date	Synopsis of Change
05/03/2021	Scheduled review. Transferred to new template; updated Owner and Contact.
August 21, 2018	Scheduled review, no changes at this time due to AAHRPP Accreditation Cycle. Removed 'Approved by' section - no longer on template. Corrected Angie's last name.
09/22/2017	Minor revision. Updated the following definitions per Glossary review: Human Subject Identifier; Mayo Clinic; and Third Party.
09/27/2016	Scheduled review. Moved content into the policy template. No other changes.

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