Release of Human Subject Identifiers for Research Policy

Scope

This document applies to the Mayo Clinic IRB and Mayo Clinic investigator(s) when releasing human subject identifiers for research purposes.

Purpose

This policy defines the limitations for the release of subject identifiers collected in research at Mayo Clinic.

Policy

Human subject identifiers may 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, 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 most often require the consent document to describe which subjects 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.

Related Procedure(s)

N/A

Related Document(s)

N/A

Definitions

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

Third Party: a person not employed by or under contract to provide services to a Mayo Clinic entity or an entity that is not an affiliate of Mayo Clinic.

References

N/A

Approved by

Pamela Kwon on behalf of the Office for Human Research Protections 9/27/2016

Owner

Pamela Kwon on behalf of the Office for Human Research Protections

Contact

Angela Patterson LaBaw

Revision History

Date	Synopsis of Change
September 27, 2016	Scheduled review. Moved content into the policy template. No other changes.