

Recruitment Methods Involving Identification of Potential Research Participants From Medical Records Indicating a Specific Medical Diagnosis Policy

Scope

Applies to Principal Investigators (PIs), their designees, and Study Coordinators (SCs) when recruiting participants for Research studies from medical records indicating a specific medical diagnosis.

Purpose

To provide instructions to investigators for communication with potential research subjects where verbal or written contract indicates a subject's association with a specific medical diagnosis.

Policy

- The investigator must ensure that potential subjects and their families are protected from undue psychological distress or harm, in accordance with the ethical principles specified in [The Belmont Report](#).
- The investigator must ensure that the association of a diagnosis with a potential research subject is accurate, the potential subject has received prior notification of the diagnosis, and that the subject is alive before attempting to contact the individual. Family members of a deceased person may not be contacted for the purpose of research without Institutional Review Board's (IRB) approval.
- The methods for identifying potential subjects with a specific diagnosis, for confirming the accuracy of the information, and for confirming if the individual is alive must be specified in the protocol.
- The methods for identifying potential deceased subjects with a specific diagnosis for the purpose of contacting family members must include methods for confirming the association of the individual with the diagnosis and that the potential participant is deceased.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

N/A

Definitions

Belmont Report: Report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research identifying the basic ethical principles underlying the conduct of research involving human subjects, that is, respect for persons, beneficence, and justice.

Beneficence: Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. Two general rules have been formulated as expressions of beneficent actions:

- do no harm and
- maximize possible benefits and minimize possible harms. (Belmont Report, 1978)

References

[The Belmont Report](#)

Owner

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Contact

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Revision History

Date	Synopsis of Change
04/28/2021	Scheduled review. Transferred to standardized template; updated owner and contact; and included notification of potential subject is aware of diagnosis before contacting for research purposes.
01/19 2018	Updated to new template; no other changes due to AAHRPP accreditation cycle
03/15/ 2017	Updated definition for Belmont Report as a minor revision.
02/18/2016	Scheduled Review; added Revision History

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