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

Scope
Mayo Clinic Human Research Protection Program

Purpose
The purpose of this policy is to provide guidance to investigators regarding communication with potential research subjects where verbal or written contact indicates a subject’s association with a specific medical diagnosis.

Policy
The investigator will 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 will ensure that the association of a diagnosis with a potential research subject is accurate, and that the subject is alive prior to attempting to contact the individual. Family members of a deceased person may not be contacted for the purpose of research without IRB approval.

The methods for identifying potential subjects with a specific diagnosis, for confirming the accuracy of the information, and for confirming that 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 Procedure(s)
N/A

Related Document(s)

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: (1) do no harm and (2) maximize possible benefits and minimize possible harms. (Belmont Report, 1978)

**References**
N/A

**Owner**
Pamela Kwon on behalf of Office for Human Research Protection

**Contact**
Angela Patterson

**Revision History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Synopsis of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 19, 2018</td>
<td>Updated to new template; no other changes due to AAHRPP accreditation cycle</td>
</tr>
<tr>
<td>March 15, 2017</td>
<td>Updated definition for Belmont Report as a minor revision.</td>
</tr>
<tr>
<td>2/18/2016</td>
<td>Scheduled Review; added Revision History</td>
</tr>
<tr>
<td>12/19/2012</td>
<td>HRPP Oversight Approval</td>
</tr>
</tbody>
</table>