



Policy Number: IV.06

Mandatory Reporting in Human Subjects Research

Adopted: 11/05

Revised: 06/2014

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MANDATORY REPORTING IN HUMAN SUBJECTS RESEARCH

POLICY

Ohio law requires physicians and other health care providers to take specific actions and to submit specified reports when certain facts or conditions become known to them, even when such information is identified in the context of procedures involved in human subjects research. In any case in which it is reasonable to expect that a person subject to a reporting requirement under Ohio law will be required to make a report of a subject's condition or circumstances, due consideration shall be given by the IRB to ensuring that the informed consent document in use for that study reflects the possibility of such reporting. In order to carry out this policy, primary reviewers shall be requested, as a part of the IRB review checklist, to determine whether such a prospect exists.

DEFINITIONS

Person Subject to Reporting Requirements: Includes any physician, including a hospital intern or resident; dentist; podiatrist; registered nurse; licensed practical nurse; visiting nurse; other health care professional; licensed psychologist; licensed school psychologist; speech pathologist or audiologist.

Reportable Disease or Condition: AIDS (acquired immunodeficiency syndrome); Asiatic cholera; Yellow fever; Diphtheria; Typhus or Typhoid fever; and occupational diseases (including poisoning from lead, cadmium, phosphorus, arsenic brass, wood alcohol, mercury, anthrax or similar conditions).

Adult Abuse: The infliction upon an adult, 60 years of age or over of injury, unreasonable confinement, intimidation or cruel punishment with resulting physical harm or mental anguish. "abuse" also includes neglect or exploitation of any adult through the failure of a caretaker to provide necessary goods or services, or the use by an adult of that adult's resources for monetary or personal benefit.

Child Abuse: Any circumstance in which a person under 18 (or a person under 21 who is mentally retarded, developmentally disabled, or physically impaired) is the victim of sexual activity, or exhibits evidence of injury other than by accidental means, "child abuse" also



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includes neglect of a child through abandonment by a parent or a refusal by a parent to provide necessary goods or services.

PROCEDURE

1. Preliminary reviewers of all IRB submissions shall determine whether there is a reasonable likelihood that, during the course of the research, an investigator or other person subject to reporting requirements shall become aware of facts or conditions which give rise to a reporting obligation concerning a reportable disease or condition, adult abuse, or child abuse under applicable law. If such likelihood exists, then the reviewer(s) shall present such information as a part of their presentation of the research to the IRB.
2. The IRB shall ensure that in any case in which there is a reasonable likelihood that a subject's condition or circumstances will be the subject of a reporting requirement, that the informed consent process includes steps to ensure that the likelihood of such reporting is disclosed to the potential subject.
3. In any case in which the applicability of a reporting requirement is unclear, or in any case in which the law of a state other than Ohio may give rise to a reporting requirement, the IRB Chair or his/her designee shall refer the matter to the Office of General Counsel, who shall provide guidance to the IRB concerning such matters.

Applicable Regulations, Documents:

Ohio Revised Code § 3701.24
 Ohio Revised Code § 2151.031
 Ohio Revised Code § 5101.61
 Ohio Revised Code § 5123.61

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/2005	C.Fabby			
		6/2014	A Braggs-Brown	Revised to reflect changes in organizational structure

Date Adopted June 2014 **Signature signed copy on file**