The Christ Hospital IRB **Number:** 1.13
Submitted By: Erica Jones **Effective Date:** 02/09
Reviewed By: Matt Shuler, JD and Steve Roberts, MD **Revised/Reviewed Date:** 02/25
Approved By: Steve Roberts, MD

STANDARD OPERATING PROCEDURE

Mandatory Reporting in Human Subjects Research

POLICY

Ohio law requires physicians and other healthcare 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 research participant's condition or circumstances, due consideration shall be given by the IRB to ensure that the informed consent document in use for that study reflects the possibility of such reporting. In order to carry out this policy, the IRB Chair (or designee) and/or Primary (scientific) Reviewer shall be requested, as part of the IRB Reviewer Checklist in Mentor IRB, to determine whether such a prospect exists.

Persons Subject to Reporting Requirements

Health care providers subject to reporting requirements include, but not limited to, hospitals, medical clinics and offices, special care facilities, medical laboratories, physicians, pharmacists, dentists, physician assistants, registered and licensed practical nurses, laboratory technicians, emergency medical service organization personnel, and ambulance service organization personnel.

Reportable Diseases or Conditions

- Asiatic cholera
- Yellow Fever
- Diphtheria
- Typhus or Typhoid Fever
- AIDS (illness designated as acquired immunodeficiency syndrome) or AIDS-related condition
- HIV (human immunodeficiency virus identified as the causative agent of AIDS)
- Other contagious or infectious diseases, illnesses, health conditions, or unusual infectious agents or biological toxins posing a risk of human fatality or disability

(Ref: Ohio Revised Code §3701.23, §3701.24

Adult Abuse

When a healthcare provider believes that an adult is being abused, neglected, or exploited, or is in a condition which is the result of abuse, neglect or exploitation, such belief must be immediately reported to the county department of job and family services.
(Ref: Ohio Revised Code 2919.25, 2151.421, 2921.22, 5101.60, 3113.31)

PROCEDURE

1. The IRB Chair designates an IRB member to be Primary Scientific Reviewer for each new protocol. As part of their review, the reviewer determines 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. Such facts or conditions may include issues concerning a reportable disease or condition, or adult abuse under Ohio law. If such likelihood exists, then the Chair or Primary Reviewer shall present the relevant information to the IRB during the review of the research at the convened IRB meeting.

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, 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 Office shall refer the matter to the Risk Management Office, where legal counsel will be provided to guide the IRB concerning such matters.