STATE AND LOCAL LAWS IN HUMAN SUBJECTS RESEARCH

POLICY
The University of Cincinnati IRB is committed to assuring that research approved by the IRB is conducted in accordance with state and local law, in addition to federal law. There are many sources of state and local law that may impact human subjects’ research, and these laws are subject to change. The IRB and its members should have ready access to legal counsel in order to obtain guidance on issues arising under state and local law. It is also vital that the IRB be kept aware of relevant changes in state and local law to ensure that human subjects receive the full protection of all laws enacted for their benefit. Such changes in state and local laws must be timely reported to the IRB in an easily digestible manner in order to achieve this goal.

APPLICABILITY
This policy applies to the Office of General Counsel and members of the IRB, including the IRB chairs and the institutional official for Human Subjects Research.

IMPLEMENTATION
The Office of General Counsel will task one of its attorneys to serve as counsel for the IRB. Counsel for the IRB will stay abreast of the relevant literature reporting developments in state and local law relating to human research subjects protection. Developments requiring the IRB’s immediate attention will be reported to the chairs and presented by counsel at the next meeting(s) of the IRB.

Each IRB member, including the IRB chair(s), will be provided with the name, telephone number, and email address of the attorney serving as counsel to the IRB. Additionally, the chairs will be provided with the name, telephone number, and email address of at least one other attorney who will be available to answer questions in the event that the designated attorney is unavailable. The attorney who receives the question will research the legal issues involved and provide an answer as soon as is practicable, but not later than next meeting of the board that posed the question.

Applicable Regulations, Documents:
45 CFR 46.116
45 CFR 46.402

Date Adopted November 2005  Signature signed copy on file