**Medication Safety Research Network of Indiana (Rx-SafeNet)**

**Policy for Conducting Research with Human Subjects**

## IRB Review Requirements

All research projects conducted within Rx-SafeNet must receive approval by the Indiana University (IU) Institutional Review Board and any other necessary IRB prior to commencement of the project, unless sole approval by another IRB is allowed per existing IU policies or discussion with IU IRB leadership. For projects involving IU, Notre Dame or Purdue University faculty and Network Site Coordinators, pharmacists and pharmacy technicians, the IU IRB will be the only required IRB review (if all research personnel have signed the Non-Affiliated Investigator Agreement; see below for more details), unless in the case of any pharmacies that are required to report to another IRB.

For projects submitted by external principal investigators (e.g., faculty from another University), IRB approval must be received both from the IU IRB and the principal investigator's primary IRB, unless sole approval by the external principal investigator's IRB is allowed per existing IU policies or discussion with IU IRB leadership.

All projects to be reviewed by the IU IRB should be developed with the assistance of the Program Manager. The Program Manager will be the primary contact person for the IU IRB and will be responsible for ensuring the study is conducted in accordance with IRB policies.

## Educational Requirements

Before engaging in any research efforts, all personnel collaborating on Rx-SafeNet projects must complete the online CITI training for working with human subjects. The specific online course that is required is dependent on an individual's role in the research. Guidance is available on the IU IRB webpage http://researchcompliance.iu.edu/hso/index.html

Once the CITI modules have been completed, all investigators and other research personnel should forward their completion reports to the Program Manager, who will assist pharmacy sites in ensuring all personnel are appropriately trained.

## Non-Affiliated Investigator Agreement

Before engaging in research efforts other than those categorized as "exempt", all individuals from institutions external to IU (both those designated as "key" and "non-key" personnel) are required to sign the Non-Affiliated Investigator Agreement. This agreement indicates that non-IU investigators have completed the appropriate human subjects protection training and agree to conduct research in a manner compliant with IRB policies. Questions about this agreement should be addressed to the Program Manager.