USI Policy on Secondary Data

A. Definition of Secondary Data

Secondary data is defined as "data that has already been collected for either research or non-research purposes and has not been proposed to an institutional official or the IRB for review." USI's IRB has determined the following categories as secondary data:

- De-identified publicly available data (Exempt);
- De-identified non-publicly available data (Exempt);
- Publicly available data with private identifiable information ***or*** non-publicly available data with private identifiable information where researchers will not record individual identifiers (Exempt);
- Non-publicly available data containing private identifiable information (Expedited or Convened).

Because the information accessed in these forms of analysis varies, the USI IRB has instituted review procedures that reflect differences among data sources. USI Investigators conducting research involving secondary data sources are encouraged to review the qualifiers for each process (see section **C.**) in order to prepare the appropriate application form.

B. Secondary Data Policy Stated

Secondary data can be used in IRB protocols but is subject to the regulations in 45 CFR 46. All USI investigators must complete an IRB application and submit it electronically through IRBNet for review by the IRB committee. All questions can be directed to the USI Office of Sponsored Projects and Research Administration at rcr@usi.edu.

C. Policy Qualified

1. If research only involves the study of existing data, documents, records, pathological specimens, or diagnostic specimens, and if data is ***publicly available*** when collected, follow exempt review process using ***form A***.
2. If research only involves the study of existing data, documents, records, pathological specimens, or diagnostic specimens, that is ***not publicly available***, and is ***de-identified***, follow exempt review process using ***form A***.
3. If research only involves the study of existing data, documents, records, pathological specimens , or diagnostic specimens, that is ***not publicly available***, and if information will be recorded by the investigator in such a way that the subjects can be ***identified***, follow expedited or full board review process using ***form B***.
4. If research involves more than the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, follow appropriate review type for the data and for the type of additional research activities.
5. If research has previously been approved and requires a minor change within the one year period following approval, fill out modification ***form C***.
6. If research has not been previously approved and presents no more than minimal risk to human subjects, follow exempt review process using ***form A***.
7. If research has not been previously approved and presents more than minimal risk to human subjects, follow expedited or full board review process using ***form B***.
8. If research has not been previously approved, presents no more than minimal risk to participants, and identification of subjects could put them at risk of criminal or civil liability or be socially or economically damaging (with no measures to make these risks no more than minimal), follow expedited or full board review process using ***form B***.

Updated 2/20/2014