OHSU Policy

1. The OHSU IRBs and its designees may require CoCs for studies involving sensitive information. Investigators are expected to plan for this requirement when conducting studies involving sensitive information.

2. When a CoC is required, the IRB will approve a study contingent upon the issuance of a CoC by the NIH. Once the CoC is issued and documentation of such is submitted to the IRB, final approval will be granted.

3. Projects not eligible for a Certificate are:
   a. Projects that are not research;
   b. Projects that do not collect personally identifiable information;
   c. Projects that are not reviewed and approved by an IRB; and
   d. Projects collecting information that, if disclosed, would not significantly harm or damage the subject.

4. For foreign studies, if the data obtained from a study done outside the U.S. are maintained within the U.S., a researcher may obtain a CoC. If the data are only maintained in a foreign country, a CoC’s legal protections are not effective.

5. OHSU researchers are expected to comply with State and Local requirements to report communicable diseases, and also to meet other requirements, such as reporting suspected child and elder abuse. Any researcher desiring not to comply with reporting requirements must justify the request to IRB and obtain IRB approval of the non-disclosure plan. Requests must be based on the welfare and rights of the subjects.

Effective: 3/20/2008