

Serious and Continuing Non-Compliance

OHSU Policy

I. POLICY

- A.** All members of the OHSU community engaged in Human Subjects Research are expected to comply with federal regulations pertaining to research and OHSU IRB requirements and determinations.
- B.** Any member of the OHSU community who is or becomes aware of information related to non-compliance with federal regulations pertaining to research or OHSU IRB requirements or determinations should report that information to the OHSU IRB. Special protections are in place to protect the identity of a whistleblower.
- C.** Any serious or continuing non-compliance with federal regulations affecting human subjects research or the requirements or policies of the OHSU IRB must be promptly reported to the OHSU IRB, appropriate institutional officials, the sponsor, if any, and appropriate federal agencies.
- D.** The OHSU IRB is responsible for making the final determination as to whether serious or continuing non-compliance has occurred.
- E.** The OHSU Office of Research Integrity (ORIO) is responsible for handling suspicions, allegations or detected non-compliance at OHSU. When non-compliance is alleged, further information will be obtained by the ORIO to determine whether the allegation is true.
- F.** The OHSU IRB has the authority to suspend or terminate approval of human subject research that is not being conducted in accordance with the OHSU IRB's requirements or that have been associated with unexpected serious harm to subjects.
- G.** When unapproved research is discovered, the OHSU IRB will act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the investigator's fitness to conduct human subject research.

Effective: 4/21/2008