MEMORANDUM

DATE: October 12, 2010

TO: Investigators and Sponsors

FROM: Human Research Protection Office

RE: Reporting Requirements for IND Safety Reports

Washington University in St. Louis (WUSTL) complies with the federal regulations at 21 CFR 312.32(c) which state:

The sponsor shall notify FDA and all participating investigators in a written IND safety report of:

(A) Any adverse experience associated with the use of the drug that is both serious and unexpected; or

(B) Any finding from tests in laboratory animals that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity, or carcinogenicity.

NOTE: 21 CFR 312.32(c)(ii) states “In each written IND safety report, the sponsor shall identify all safety reports previously filed with the IND concerning a similar adverse experience, and shall analyze the significance of the adverse experience in light of the previous, similar reports.”

Events meeting the criteria in this regulation should be reported to the Human Research Protection Office (HRPO) through the myIRB system as unanticipated problems involving risks to subjects or others and must include associated documentation and summary information from the sponsor. By their nature, such reports would likely require amendment of the IRB-approved study and associated documents to address the new information.

Federal regulations do not require immediate reporting to the IRB of IND/outside safety reports for events that do NOT meet the criteria outlined above UNLESS

- The information identifies a change to risks or potential benefits of the study OR
- If after review, the WUSTL Principal Investigator believes the information indicates a change to the risks or potential benefits of the study being conducted at WUSTL.

Thus, IND/Outside Safety reports that do NOT meet the regulatory requirement for immediate reporting and do NOT meet the exception criteria noted above may only be reported IN SUMMARY FORMAT on the study Continuing Review application.

Sponsors in disagreement with this policy must submit in writing to the investigator the specific Federal law or regulation under which they believe immediate reporting of other IND/Outside safety reports is required as well as written discussion of the basis for their disagreement.