

**Human Research Protection Office**

## MEMORANDUM

DATE: August 27, 2018

TO: Investigators and Sponsors

FROM: Human Research Protection Office

RE: Reporting Requirements for IND Safety Reports

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Washington University in St. Louis (WUSTL) complies with the federal regulations at 21 CFR 312.32(c) which outline sponsor and investigator requirements for IND safety reports.

Events meeting the criteria outlined in 21 CFR 312.32(c) 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 modification to 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 in 21 CFR 312.32(c).

Thus, IND/Outside Safety reports that do NOT meet the regulatory requirement for immediate reporting may only be reported IN SUMMARY FORMAT at the time of continuing review.

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.