

Incidents (Non-compliance/Problems)

Per HRPP policy 8.4 non-compliance (NC) involving the PI and/or study personnel must be promptly reported to the IRB. This non-compliance could involve failure to comply with the Federal Regulations related to the protection of human subjects of research, HRPP policies, or the requirements/determinations of the IRB.

Research related problems are incidents that do not involve NC on the part of the PI and/or study personnel. These occur during the course of the study and may include things such as: subject incorrectly adhering to instructions (taking a wrong dosage of study drug), research records being stolen/lost, etc. Research related problems must also be promptly reported to the IRB.

NC and problems are reported to the IRB by submission of an Incident Report Form. The Incident Report form is located in the Forms section of RSS. The PI is responsible for ensuring that the required reports are submitted promptly following discovery of the incident in accordance with HRPP policy 8.4.

If you have any questions regarding this submission process, please contact the IRB Office at irbora@unmc.edu

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