

**NIU Institutional Review Board policy regarding studies
conducted without prospective IRB review and approval
(Adopted 3/7/01)**

Since retroactive IRB approval (or disapproval) of a project is not possible under 45 CFR 46, the full IRB will review the project and report its findings and recommendations to the Vice President for Research and Dean of the Graduate School who would then consider the IRB's recommendations in determining what action will be taken. In reviewing the project the IRB:

- will determine what level of risk and category of review (exempt, expedited, full) would have been assigned to the project had the application been submitted and processed in the proper sequence (i.e., prior to data collection).
- will determine whether the subjects were harmed in any way or if their rights and/or welfare were infringed.
- may make a recommendation to the Vice President for Research and Dean of the Graduate School as to whether or not the investigators should be allowed to use the data.
- may make a recommendation to the Vice President for Research and Dean of the Graduate School that notification be provided to the funding agency and/or the appropriate publication outlet (journal or organization to which a manuscript or abstract has been submitted, thesis/dissertation office, etc.) that the data were collected without IRB approval. If the data were collected for a thesis or dissertation, the methods section must contain a statement that the data were collected without IRB approval.