

Health Sciences Institutional Review Boards: Guidance

Guidance for Investigators Regarding Closure of IRB Protocols

Federal regulations and University of Wisconsin-Madison policies require initial and continuing review of human subjects research that is not determined to be exempt from Institutional Review Board (IRB) oversight. IRB oversight of a research protocol is required as long as the activities conducted involve human subjects. Even if all study interventions are complete, the following activities are considered research activities involving human subjects and thus require continued IRB oversight and submission of continuing review progress reports:

- Collecting identifiable *private information* about individuals, including long-term follow-up or observation of subjects; or
- Conducting data analysis of *private information* that is directly or indirectly identifiable¹.

Once data analysis has concluded, a human subjects research protocol can be closed with the IRB using the [protocol closure form](http://info.gradsch.wisc.edu/research/compliance/humansubjects/hsirbs/2.submissionforms.html) located on the Health Sciences IRB website at:
<http://info.gradsch.wisc.edu/research/compliance/humansubjects/hsirbs/2.submissionforms.html>.

Please note the University of Wisconsin Faculty Legislation recommends retention of data for 7 years after the completion of data analysis should an issue of scientific misconduct arise (www.secfac.wisc.edu/governance/legislation/Pages300-399.htm#314).

Protection of Subject Confidentiality. Individually identifiable data from study participants should be de-identified, and coded if necessary, as soon as possible after collection to protect participant confidentiality. Long-term maintenance of individually identifiable data, particularly when the information is sensitive or constitutes protected health information, requires justification and ongoing IRB review.

Transfer of Identifiable Data from Another Institution. If an investigator collects data at another institution and continues to analyze individually identifiable data under a University of Wisconsin-Madison appointment, such activities require review by a University of Wisconsin-Madison IRB.

New Uses of Collected Data. Reanalysis of identifiable subject data for a new research question requires review by an IRB. New use of already collected data that are identifiable can be submitted as a change of protocol if the study is still active with the IRB. If the protocol has been closed with the IRB, an Initial Review Application or Application for Exemption would be required. Analysis of data that are no longer identifiable (either directly or indirectly) is exempt from IRB review (a determination of exemption is made by the IRB). Under the HIPAA Privacy Rule, a new use of protected health information (PHI) triggers the need for the investigator to either obtain a new authorization from the subject or submit a new request for a waiver of authorization, even when an authorization or waiver of authorization was obtained for the original use of the data.

Multicenter studies. For multi-center studies, continuing review of the research by a University of Wisconsin-Madison IRB is no longer required after all human subject research activities have been completed by the UW investigator, even if (i) interactions or interventions with subjects may be occurring at other study sites; or (ii) data analysis of identifiable private information is ongoing at another central site that collects and analyzes data from all study sites.

¹ *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)]