

IRB Requirements for Analysis of Data Maintained in IRP Data Archive

The Office of Institutional Research and Planning (IRP) archives some data generated and maintained by other offices within the University, including data from various units within Student and Academic Services. One purpose of the Data Archive is to facilitate the use of previously collected data for new analyses. New analyses of existing data *may* fall under the purview of Cornell University's Human Research Protection Program [HRPP]; if so, the proposed research will require review by Cornell's Institutional Review Board [IRB] *or* formal exemption from such review. This document summarizes the research scenarios that would be covered under the HRPP and subject to IRB review or exemption.

I) Using data for institutional planning purposes

If data results from files maintained in the Data Archive are used strictly for internal planning purposes (e.g., program evaluation or review) and the dissemination of analysis results will be restricted to internal audiences (e.g., through presentations or reports shared only within Cornell), the researcher is under no obligation to submit an application for approval from Cornell's IRB.

However, while compliance with IRB regulations is not technically required for such internal purposes, it is clearly recommended that researchers fulfill general ethical considerations in research when conducting a study, including: informing participants about the purpose of the study; stating that their participation in a study is voluntary; explaining whether their responses will be anonymous or treated as confidential; and informing participants how data from the study will be used.

The following text is an example of language that should be included in invitations to participate in a study:

You are invited to participate in a survey about [brief description of focus of survey]. Your participation in this survey is voluntary and any information you provide will be kept completely confidential. Your survey responses will be used to plan and improve programs, services, and facilities for current and future undergraduate students at Cornell. Results from this survey will not be reported in any way that would permit identification of an individual student's responses.

II) Using data for research purposes

If data results from Data Archive files will be disseminated externally (e.g., published on a public web page, printed in a report available for distribution beyond Cornell, presented at a conference, or published in an external journal or monograph), this activity fits the institutional definition of "research" and thus falls under the purview of Cornell's HRPP. The researcher is required to work with HRPP staff to either (a) secure an administration exemption from IRB review or (b) have their research proposal reviewed and approved by the IRB.

a) Exemption from IRB Review

Research that poses negligible or no risk to participants may qualify for exemption from IRB review. The researcher can seek such exemption by submitting a *Request for Exemption from IRB Review Form* to the HRPP. This form and information about the categories of research that qualify for exemption are available online at: <http://www.irb.cornell.edu/requirements/exemptions.htm>.

In the case of research conducted within Student and Academic Services, either of two exemption categories would typically apply.

Exemption category #2 covers research involving surveys or interviews unless: the collected data includes personal identifiers *and* disclosure of individual responses would be damaging to participants. Conversely, if there are no personal identifiers collected (i.e., an anonymous survey) *or* no sensitive or potentially embarrassing data are collected, this exemption category would apply.

Exemption category #4 covers the study of previously collected data for new research purposes *if the data do not include personal identifiers*. Many of the data files in the Data Archive will contain personal identifiers that allow us to link participants' responses to institutional files and/or to other survey data files. However, analysis of existing data may still fall under this exemption category provided that Institutional Research and Planning strips the data file of all personal identifiers before sending it to an SAS researcher for analysis. In rare instances where the previously collected data is of a sensitive nature, and this will be the focus of the new analysis, the researcher may be asked to collect renewed consent from the original study participants.

b) Expedited Review

Research that does not fit the categories for exemption from IRB review (e.g., data are of a sensitive nature or data includes personal identifiers) must be reviewed and approved by the IRB. Research that is deemed to pose no more than minimal risk to participants will typically qualify for an expedited review – meaning the application will be reviewed by the IRB Chair or her/his designee rather than the full IRB committee. Applications for expedited review must be submitted a minimum of two weeks prior to the intended start date of the study. The *Initial Approval Request Form* is available at this url: <http://www.irb.cornell.edu/forms/>.

We expect that the bulk of research conducted using data stored within the IRP Data Archive will qualify for exemption from IRB review or for expedited IRB review. However, in practice, it may not always be clear if a particular study constitutes “research” or whether it qualifies for IRB exemption or review. Researchers are encouraged to consult with HRPP staff by phone (255-5138) or email (irbhp@cornell.edu) early in the planning stages of their research to clarify such questions and determine the appropriate protocol to follow. Further information concerning IRB requirements and required forms are available from the IRB website at: <http://www.irb.cornell.edu>.