

METHODOLOGY CENTER PROFESSIONAL CONDUCT GUIDELINES

Guidelines document 5 HUMAN SUBJECTS AND IRB PROCEDURES

5.1 Protection of human subjects

Concerns about protection of human subjects are not limited to how subjects are treated during experiments or when data are being collected. They also apply to how the data are handled after they are collected and while they are being analyzed statistically. Even though most of the scientists in the Center do not collect empirical data and therefore do not have direct contact with human subjects, we nevertheless must be vigilant about protection of human subjects. This vigilance is required by Penn State and by our external funders, such as the National Institutes of Health and the National Science Foundation. We must all remember that access to data collected on human subjects is a privilege, and that such data must be handled with care, respect, and full regulatory compliance. Our Center relies heavily on such data. If we lost our privileges because of a failure to engage in proper human subjects procedures, it would be a serious, potentially fatal, blow to the Center.

5.2 Human subjects certification

It is the policy of The Methodology Center that all Center scientists must comply completely with the human subjects protection requirements of their university. It is important to be proactive about this. Remember that our continued funding is contingent on careful compliance with human subjects regulations.

Penn State scientists. It is a requirement of Penn State's Office for Research Protections, as well as the policy of this Center, that all Penn State employees who participate in research under the auspices of the Center must obtain human subjects certification. Before any Center-related research involving empirical data is done, even if the research involves only secondary data analysis, all Penn State employees must complete the human subjects certification and provide the Assistant to the Director with a copy. To learn about the procedure for obtaining certification, which includes an online training program, go to the Penn State Office for Research Protections web site, <http://www.research.psu.edu/orp/index.html> and select "Human Participants (IRB)" and then select "IRB Training Module" to begin the basic training course. If you encounter difficulties, consult the Center's Scientific Director.

Center scientists at other universities. Consult your Office of Research Protections to verify that you have completed any required training or certification programs. If you plan to conduct research using private data that is securely stored at Penn State, you may be required to complete the Penn State online human subjects certification, although in most situations adhering to your institution's requirements will suffice.

5.3 Institutional review board (IRB) approval

Approval from your university's IRB is required for every study involving human subjects, even for studies based exclusively on secondary data analysis. IRB regulations change frequently, usually in the direction of increased stringency. Thus it is imperative to seek IRB approval for each new project, even if you believe it is unlikely that such approval is needed. From the IRB's perspective, if you are using a different data set, or doing a substantially different set of analyses, it is a different project. In most cases, it is necessary only to complete a short application, and approval is granted in a matter of days. In some cases a more extensive application will be required.

Penn State scientists. For more information or to download an application for use of secondary data go to <http://www.research.psu.edu/orp/hum/apps/index.htm>. If you have questions about the process, check with the Center's Scientific Director.

Center scientists at other universities. Consult your Office of Research Protections. If you plan to conduct research using private data that is securely stored at Penn State, you may be required to apply for Penn State IRB approval, although in most situations providing a copy of your institution's approval will suffice.

5.4 Data confidentiality

Any data for use in this Center should be stored without any individual subject identifiers (e.g. names, addresses, social security numbers). Beyond this precaution, any procedures stipulated by an institutional review board, the NIH or other external funder, and the relevant data sharing agreement must be followed to the letter. For example, the agreement associated with some data sets stipulates that they can be stored only on an off-line, secure computer. Different data bases in use in the Center have different requirements for preserving data confidentiality. In general, public domain data bases have less stringent requirements than data bases for which we have a data sharing agreement (see Data Sharing, Number 3).