III.L. POLICY REGARDING HUMAN SUBJECT RESEARCH IN THE SOCIOBEHAVIORAL SCIENCES

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Scope

This policy is applicable to all employees, students, trainees, faculty, and other persons working for or in facilities owned and operated by the University of Pennsylvania and conducting sociobehavioral research. This policy is meant to apply University-wide to all research involving human subject data, and inclusive of biomedical research protocols applying sociobehavioral techniques (e.g., survey research). Depending on the type of research, other policies (e.g., those pertaining to biomedical research) may apply as well. Relevance is determined by the involvement of living human subjects in observational or experimental research, or in the use of records or specimens that may conceivably place the subjects of these records at risk, as per the Common Rule.

The term "sociobehavioral sciences" (or the term "social and behavioral sciences") must be understood as a shorthand term for the set of inquiries involving human subjects not otherwise subsumed under the biomedical sciences. It includes fields of research specifically defined as behavioral and social sciences in federal manpower reports; that is, "anthropology, demography, the non-clinical fields of psychology, sociology, and the speech and hearing sciences." It also includes human subject research in economics, business, education, and history, among others (see the Common Rule). Thus, the proposed policy applies to all sociobehavioral research irrespective of its institutional setting within the University or its source of funding. Note that disciplinary predilections—for example, rejection of the rubric "science"—are insufficient warrant for self-abstention from the policy promulgated here.

Regulatory Background

In the context of Institutional Review Board (IRB) oversight of human subject research, the Common Rule specifies three levels of review of proposed research, which can be summarized as follows:

1. *full board review*—a convened IRB committee must approve the proposed research, applying criteria set forth in the Common Rule, before the research can be conducted;
2. *expedited review*—certain kinds of research involving no more than minimal risk, as well as minor changes in approved research, can be approved by an administrative mechanism not requiring a convened IRB committee;
3. *exempt from review*—minimal risk research activities in a number of specified categories, involving human subjects not from vulnerable populations, are exempt from full review as per the Common Rule.

These three levels of review require submission of a research protocol to the IRB. Specific submission requirements for each category can be found at the IRB website.

At the University of Pennsylvania, "expedited review" is typically performed by Office of Regulatory Affairs personnel. The University is also required to have a mechanism in place for determining whether a proposed research protocol is "exempt from review." As per the federal-wide assurance (FWA) that the University has in place, this determination is made by an administrative mechanism6 similar to that for "expedited review." In addition, there are certain kinds of research not covered by the Common Rule. Such research does not require any involvement of the IRB, even at the level of "exempt from review."

This policy clarifies that specific activities in the social behavioral sciences do not require IRB involvement. As a category distinct from "exempt from review," it is referred to as "*not under the purview of the IRB*."

Implementation

Implementation of the policy outlined below will be the responsibility of the Office of the Vice Provost for Research. In consultation with the Schools and their faculty, the Vice Provost will create a training program, and a certification process documenting successful completion of the training program. Any sociobehavioral research activities involving human subjects or human subject data will require prior official certification once this policy becomes effective.

Policy

Education and Certification

All personnel—faculty, research fellows, students and staff—engaging in sociobehavioral research must have documented discipline-appropriate education regarding human subject protection, in accordance with certification standards defined by the Vice Provost for Research.

The training program and certification process are to be kept current under the auspices of the Vice Provost for Research and in consultation with the Schools and their faculty.

Survey Research

Survey research, which includes face-to-face or telephone interviewing, or self-administered questionnaires (as through the mail or via the Internet), generally has a low cost of participation, since it usually requires only a small amount of subjects' time. According to the Common Rule, such research is "exempt from review" and does not require written consent, as clarified below.

2a. Survey research is exempt from review if the survey is anonymous or protection of the confidentiality of research subjects is adequately demonstrated, and if all other applicable criteria for exempt from review are fulfilled (e.g., research must not involve vulnerable populations or put subjects at more than minimal risk).

2b. For research that is exempt from IRB review, human subjects responding to a survey are automatically considered to have given informed consent.

In order to qualify for a default waiver of written consent as per policy item 2b, an exemption form5 must be presented to the IRB showing that:

i. human subjects will be informed of all applicable elements of consent prior to responding to the survey; and
ii. all criteria for "exempt from review" are fulfilled.

Secondary Data Analysis

Secondary data analysis is the (usually statistical) investigation of individual-level data records collected in another study, with the following characteristics:

1. no direct contact with or experimental manipulation of human subjects;
2. no new data collection; and
3. no identification of individual research subjects. In agreement with recommendations 1 and 6 of the Draft Recommendations Regarding Public Use Data Files issued by the National Human Research Protections Advisory Committee (NHRPAC), this policy states that such research may either be "exempt from review" or "not under the purview of the IRB," as clarified below.

3a. Research on a public-use data file, which contains only non-identifiable data or data for which a breach of confidentiality is not an issue (e.g., public business statements), is not considered human subject research for the purpose of IRB review and as such is not under the purview of the IRB.

3b. Research on a non-public-use data file—that is, non-identifiable data in a non-publicly available or proprietary file—is exempt from review, unless vulnerable populations are involved. Non public use data files may be submitted by a School to the IRB for approval. If approved, with the appropriate maintenance of safeguards, studies using these data sets are no longer human subject research and as such are not under the purview of the IRB.

Investigators must agree not to attempt to re-identify the human subjects.

Investigators planning to study non-public-use data files must demonstrate to the IRB that confidentiality of research subjects is protected, by providing direct evidence of protection procedures or by showing that the data supplier already received IRB approval in which non-identifiability was considered and confirmed. The latter does not necessarily require submitting to the IRB the survey instrument or consent form used in the research that yielded the data.

Researchers operating in one of the categories of the Health Insurance Portability and Accountability Act (HIPAA) should refer to the HIPAA regulations that contain a definition of identifiability.

Evolving Research

Evolving research is a class of research in the sociobehavioral sciences in which the questions that are posed evolve in the course of investigation. An example is ethnography, where research questions may only be clarified after a period of observation and where current findings drive the next steps in the study. This class of research typically involves studying human behavior in non experimental settings, with or without active participation by the investigator; but it can also occur in more structured observational settings (e.g., oral histories, focus groups). In specific cases, such research does not pose more than minimal risk to human subjects and is considered to be "exempt from review," as stated below. An approved mechanism is necessary for presenting to the IRB a research protocol that will evolve in the course of investigation. This policy institutes such a mechanism via certification.

4a. Research involving only non-interventionist observation of behavior occurring in public (including domains of the Internet clearly intended to be publicly accessible), for which no identifying information is recorded, is exempt from review.

4b. Investigators are allowed to use their certification, as per policy item 1, as a reference for describing evolving research activities to the IRB in lieu of a fixed research protocol.

This policy eliminates the need for investigators doing evolving research to spell out the details of a dynamic research protocol. The IRB can be assured that the research will be conducted in an ethically appropriate fashion, with full protection of human subjects, when certified investigators attest that their pre-registered research plan will be conducted within the ethical framework laid out in the training program for which they are certified.

Note that different studies by the same investigator(s) must be submitted to the IRB as separate research protocols. These must not be viewed as a single study evolving from one investigation into another.

Feasibility Assessment

Feasibility assessment (or exploratory research) is understood to involve the conceptualization or refinement of a research question through harmless observation, casual conversation, and browsing of extant data. The Common Rule applies only to generalizable research. Therefore, feasibility assessment is "not under the purview of the IRB" if a number of strict conditions are met, as specified below.

5. Feasibility assessment is not under the purview of the IRB, if and only if the following conditions are met:

a. the assessment involves no more than minimal risk;
b. the assessment does not involve any vulnerable populations, including prisoners, minors, pregnant women and fetuses, mentally impaired or disabled persons, terminally ill patients, the very elderly, and anyone incapable of self-determination;
c. the human subjects are not identifiable from any of the information acquired;
d. the assessment does not involve any deceptions;
e. the assessment data and results are not disclosed or published;
f. there is no systematic collection of data, or any systematic data collection serves only to calibrate a research instrument that involves no more than minimal risk.

If at any time any of these conditions cannot be satisfied, the project must be submitted to the IRB for review.

Adverse Effects

This policy prescribes the documentation of possible negative effects on human research subjects and how they can be reversed.

6. For research involving manipulations or deceptions of human subjects that may cause harmful or undesirable effects, research protocols submitted to the IRB must specifically describe the recovery or debriefing procedures of the study, and address how the effectiveness of these procedures will be assessed.

When a research study may have foreseeable untoward effects on human subjects, the investigator must explain in the research protocol how these effects will be mitigated.

The IRB must be informed of the occurrence of any adverse events that take place during the research study or as a result of the research study. For research protocols that are reviewed by the IRB in one of the three review categories (full board review, expedited review, or exempt from review), adverse events must be reported for the annual continuing review. Research protocols "not under the purview of the IRB" require reporting of any adverse events within a month of occurrence, as such events may change the review status of the study. Unanticipated events or effects on human subjects that may change the interpretation of

the risk of the protocol must be reported to the IRB as soon as they are identified.