POLICY REGARDING HUMAN SUBJECT RESEARCH IN THE SOCIOBEHAVIORAL SCIENCES

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.1

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,2 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 Rule3). 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,4 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,5 involving human subjects not from vulnerable populations,6 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.5

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

This policy extends to the sociobehavioral sciences a requirement currently in place in the School of Medicine that has been enforced outside of the School of Medicine only for key personnel submitting grants to federal agencies. The requirement now becomes University-wide, covers sociobehavioral research, and is not restricted to federal grant activity.

1. 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,6 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,4 and if all other applicable criteria for exempt from review are fulfilled (e.g., research must not involve vulnerable populations5 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
appropriate fashion, with full protection of human subjects, when IRB can be assured that the research will be conducted in an ethically
research to spell out the details of a dynamic research protocol. The
This policy eliminates the need for investigators doing evolving
fixed research protocol.

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.

1  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
2  http://books.nap.edu/books/0309069815/html/31.html
3  Briefly, these include research conducted in established or commonly accepted educational settings involving normal educational practices; certain research involving the use of educational tests; certain research on elected or appointed public officials or candidates for public office; research involving the collection or study of publicly available or non-identifiable existing data; certain research on public benefit or service programs; and certain taste and food quality evaluation and consumer acceptance studies.
4  According to the Common Rule, vulnerable populations include minors, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons. Other categories of human subjects may be considered vulnerable depending on the research activities.
6  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116
7  Demonstrating adequate protection of the confidentiality of research subjects does not necessarily imply a requirement to submit the survey instrument to the IRB.
8  For survey research, pregnant women are not considered a vulnerable population.
9  http://www2.asanet.org/footnotes/feb02/indexone.html
10  https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

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