# Tip Sheet 27: Developing and Applying Equivalent Protections

## Related Accreditation Elements: I.1.D., II.2.A., II.2.E., II.3.F., II.3.G., II.4.A. and Standard I-3.

Organizations must apply the applicable U.S. federal regulations for protecting research participants when research is sponsored by a federal agency. Research on drugs, biological products, and medical devices that fall under the jurisdiction of the Food and Drug Administration (FDA) must also follow the regulations published in 21 CFR 50, 56, 312, and 812. Organizations with a federalwide assurance (FWA) may choose to apply the regulations in 45 CFR 46 subpart A, or subparts, A, B, C, and D to research that is not federally funded as well.

AAHRPP's Evaluation Instrument for Accreditation states that: "Organizations that must follow a certain set of regulations (e.g., DHHS or FDA) must meet the regulatory requirements. Organizations that are not bound to follow a particular set of regulations are not required to meet them, but they should describe and provide equivalent protections, when applicable." AAHRPP requires accredited organizations that do not voluntarily apply each subpart of 45 CFR 46 to all human research to provide equivalent protections to participants in non-funded research. This pertains to all organizations, regardless of FWA status.

## Recommended Content:

***I. Why might an organization choose to apply equivalent protections?***

I.A. In some cases, organizations can improve their ability to protect participants by adapting policies and procedures to accommodate differences in types of research (e.g., biomedical, social science, behavioral science research) instead of applying the same regulatory requirements to all human research activities. Adopting equivalent protections can allow for greater flexibility in oversight of research for which federal regulations might not be appropriate and can reduce unnecessary administrative burdens on the HRPP.

***II. When to apply equivalent protections rather than federal regulations***

II.A. When any part of a research study receives funding from a federal agency that has adopted regulations for human research, the study must meet all applicable federal regulatory requirements. This includes when study personnel receive federal funding, even if the funding is not specifically intended to support research activities (i.e., scholarships, fellowships, training programs, etc.). It is important that the HRPP have procedures for tracking the funding sources associated with all studies to determine whether federal regulatory requirements apply. Policies and procedures providing protections that are different from, though equivalent to, federal regulations can only be applied to studies that do not receive funding from a federal agency that has adopted regulations for human research.

II.B. IRB members, staff, **and** researchers should be trained to determine whether federal regulations apply to a study.

II.C. IRB staff should be aware that a study that begins without federal funding may gain such funding or may add personnel with federal funding over the course of the study. If a previously approved study gains funding from a U.S. federal agency that has regulations for protecting research participants, the IRB that approved the research must apply the regulations to the study in reviewing and approving the funding as a modification of the protocol.

II.D. IRB members and staff should further consider that non-federally funded studies may be required to apply the federal regulations on the basis of agreements with sponsors or when the research is subject to FDA regulations.

***III. Developing Policies and Procedures to Provide Equivalent Protections***

III.A. When developing policies and procedures intended to provide protections equivalent to federal regulations, HRPPs might use the language of the federal regulations as a starting point and make clear where policies and procedures differ from the requirements of the federal regulations.

III.B. The language adopted in policies and procedures should define appropriate limits for the conduct of research not subject to federal regulations and should be consistent with the ethical principles described in the organization's policies.

***IV. Areas to Consider Applying Equivalent Protections***

Below are some examples of areas in which organizations might choose to apply policies and procedures developed by the organization, rather than federal regulations, to non-federally funded research. This is not an exhaustive list of policies and procedures that provide protections equivalent to the federal regulations, but suggested areas of review in which organizations have found it useful to apply equivalent protections. The suggestions offered below might or might not be relevant to a given organization, depending on the types of research conducted at the organization.

*IV.A. Consent Procedures*

1. Policies and procedures might modify or add additional elements of disclosure in order to clarify ethical requirements or account for ethical concerns not addressed by the federal regulations. For example, in clinical trials researchers might be required to disclose that by signing the consent document, participants agree to grant access to their original medical records to monitors, auditors, and IRB members for the purpose of verifying clinical trial procedures and data. Researchers might also be required to inform prospective participants of the probability of random assignment to each treatment.

2. Policies and procedures might contain statements that elements of disclosure required under federal regulations, such as disclosure of alternative procedures or treatments and foreseeable risks or discomforts to participants, need not be included if they are not applicable. Multiple consent templates might be made available for types of research in which the relevant elements of consent differ.

3. Policies and procedures might describe conditions under which researchers will be required to obtain the re-consent of participants over the course of the study. For example, investigators might be required to obtain participants' re-consent after notifying them of an unanticipated problem involving risks to study participants or when the protocol undergoes significant modifications.

4. Policies and procedures might include additional categories of research for which the requirement to obtain participants' consent or to document consent may be waived. For example, they might permit waivers of consent documentation for all research involving no greater than minimal risk. They might also permit alternative forms of documentation of consent for certain types of research, such as completed survey forms in research involving only distribution of surveys, audio or video recordings of consent, documentation by a witness, or having participants click "I Agree" on a website.

*IV.B. Criteria for Approval*

1. Policies and procedures might modify or add additional criteria for approval in order to account for ethical concerns not addressed by the regulations. For example, IRB members might be required to review terms for the distribution of compensation to participants according to specified criteria, such as the following:

a. The amount of compensation and the proposed method and timing of disbursement is neither coercive nor presents undue influence.
b. Credit for compensation accrues as the study progresses and cannot be contingent upon the subject completing the entire study.
c. Any amount provided as a bonus for completion cannot exceed 25% of the sum of the compensation for all visits, not including the completion bonus.

2. Policies and procedures might also suspend criteria for approval not relevant to certain types of research, or require different criteria for approval in minimal risk and greater than minimal risk research. For example, in studies that are not exempt from review but involve only analysis of existing medical data, the requirement that selection of participants be equitable might not apply, because the study data have already been collected for non-research purposes.

Furthermore, it might not be necessary to ensure that additional protections for populations vulnerable to coercion or undue influence have been considered, since their conditions do not put them at any additional risk of harm and consent may be waived when research involves only collecting and analyzing existing data (provided appropriate protections for participant confidentiality are maintained).

*IV.C. Exempt Research*

1. Policies and procedures might modify or include additional categories of exempt research beyond those approved in the federal regulations. For example, all studies that involve only review of existing data, even when the data are identifiable, might be designated as exempt provided no prior agreements (such as the terms of consent for obtaining the data) restrict the use of the data and the study does not involve interaction with participants.

*IV.D. Expedited Research*

1. Policies and procedures might modify or include additional categories of research that may be reviewed by the expedited procedure. For example, they might allow all research involving no greater than minimal risk that is not subject to federal regulatory requirements to be reviewed using the expedited procedure. Policies and procedures might also allow qualified IRB staff members who are not IRB members to conduct review by the expedited procedure.

*IV.E. Approval Periods*

1. In order to decrease the administrative burden on the IRB, policies and procedures might extend the approval period to two to three years or indefinitely for certain categories of research that qualify for review using the expedited procedure provided doing so will not result in increased risk to participants. For example, continuing review might be required no more frequently than every two years for studies that involve no greater than minimal risk and do not involve clinical interventions or vulnerable populations. Proposed changes to studies granted an approval period of longer than one year should be reviewed and approved by the IRB before they are implemented.

2. Policies and procedures might allow a brief (for example, 30-day) grace period after expiration of the previous approval for processing of applications for continuing approval before study activities must stop.

*IV.F. Vulnerable Populations*

1. Prisoners
    a. On policies and procedures for review of research involving prisoners, see Tip Sheet 18.

2. Children
    a. Policies and procedures might modify the categories of research involving children as participants that qualify for exemption from IRB review. For example, they might permit exempt determinations in non-federally funded research involving survey procedures, interview procedures, or observation of public behavior (as described in paragraph 45 CFR 46.101 (b)(2)) when children are participants.
    b. Policies and procedures might clarify the meaning of minimal risk in the context of research involving children to describe the probability and magnitude of harm or discomfort as encountered by average, healthy, normal children, taking account of prospective participants' ages.
    c. Policies and procedures might describe requirements for the qualifications and expertise of IRBs who review research involving infants, children, or adolescents.
    d. Policies and procedures might permit IRBs to waive the requirement to obtain parental permission in studies where:
        i. procedures do not ordinarily require parental consent outside of the research context;
        ii. the investigator has presented evidence that prospective participants who are children or adolescents can understand the study information and consent document on their own behalf; and
        iii. appropriate safeguards are in place.
    e. For studies that extend over long periods of time, policies and procedures might include requirements that participants who are children be presented with more sophisticated information and re-assent or consent to participate as they mature.
    f. Policies and procedures might establish criteria for approval of research not otherwise approvable under the criteria in paragraphs 46.404-406 of 45 CFR 46, for example, by:
        i. establishing an expert panel affiliated with the organization who will review the research;
        ii. establishing procedures for consulting with an external IRB to review the research; and
        iii. outlining additional criteria for approval of such research.

3. Pregnant women and fetuses
    a. Policies and procedures might suspend additional criteria for IRB approval of research required by federal regulations in research involving no greater than minimal risk to pregnant women or fetuses.
    b. Policies and procedures might modify the criteria for approval described in paragraphs 45 CFR 46.204 (b) and (d) and 45 CFR 46.205 (b)(1)(ii) and (c)(4) to permit research involving pregnant women, fetuses, or neonates that is intended to generate "generalizable" or "scientific" knowledge, rather than limiting permissible research under those criteria to that intended to generate "biomedical" knowledge.
    c. Policies and procedures might specify ethical requirements for review of research involving pregnant women that is not funded by federal agencies for political reasons, such as research involving in-vitro fertilization as a treatment for infertility.

*IV.G. Research Conducted by Students*

1. Policies and procedures might specify that students may only conduct research that meets the organization's criteria for exemption or review using the expedited procedure. They might also designate as exempt from IRB review certain categories of research conducted by students that is intended to benefit their education and not to contribute to generalizable knowledge. For example, they might designate as exempt student research in which:
    a. results of the research are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes;
    b. results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.);
    c. research procedures involve no more than minimal risk;
    d. vulnerable populations are not targeted (e.g., children under age 18, prisoners, persons who are cognitively impaired);
    e. data collected are recorded in such a manner that the participants are not identifiable (images in videotapes and photographs and voices on audiotape are identifiable); and
    f. when appropriate, a consent process is in place.

2. Policies and procedures might also describe how students and instructors should treat student research which might or might not be subject to IRB review, including:
    a. instructors' responsibilities pertaining to educating and advising students on requirements for submitting research protocols to the IRB;
    b. the status of independent studies, theses, and dissertations as research subject or not subject to IRB review;
    c. conditions under which a student may serve as a principal investigator; and
    d. ethical requirements for student research not subject to IRB review.

*IV.H. Review of Modifications*

1. Policies and procedures might describe categories of minor changes to research protocols that do not require IRB approval. For example, IRB staff might be permitted to approve administrative changes such as:
    a. translation of approved consent documents and recruitment materials;
    b. minor changes to contact information; and
    c. changes to key study personnel who are not a principal or local site investigator.

*IV.I. Reporting Requirements*

1. Policies and procedures might specify that incidents such as adverse events and participant complaints must be reported to the IRB and organizational officials but not to the Office for Human Research Protections or FDA. In this way, they can improve participant protections by easing the administrative and institutional burden involved in reporting such incidents.