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Healthcare Compliance Forms and Tools
Sample Flexible Guidance Summary

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Research, Discovery & Innovation	Flexible Guidance

IRB Review Guidance for Research not Covered by the Federalwide Assurance

Background

The organization has elected to limit the scope of its Federalwide Assurance (FWA) to federally funded or supported research, the terms of which allow an appropriate level of flexibility for research funded from sources other than federal agencies or are unfunded. **Federally funded or supported includes awards to the organization that are made directly by a federal sponsoring agency, subfederal awards where the organization receives a subcontract issued from a nonfederal entity's prime federal award, or any nonfederal sponsored research that invokes the code of federal regulations as a condition of award.**

Protections equivalent to the principles of the Belmont Report and respective to the degree of risk will be applied to all projects. Nonfederally funded and unfunded research projects fall outside the scope of the FWA and will be reviewed under this guidance and will afford protections commensurate with risk as determined by the institutional review board (IRB).

Purpose

This guidance creates flexible review options for the IRB for projects funded or supported from sources other than federal agencies. This guidance applies to all research under the jurisdiction of the IRB.

All human subject research projects conducted or supported at the organization remain subject to our IRB policies and review, whether they qualify under this guidance or not. Inclusion/exclusion of any research project will be at the discretion of the IRB. Should the funding status of a study reviewed under this guidance change, it is the responsibility of the principal investigator to notify the IRB.

This guidance *does not apply* to projects that receive federal support as those projects are subject to the organization's FWA and will be reviewed according to the policies of the granting agency, except for project updates from July 19, 2019, forward as noted later. Projects that anticipate receiving federal funds, where a grant proposal is pending or planned, are not subject to this guidance and will be reviewed as if they were supported by a federal agency.

Data repositories containing data that are intended to be used to support applications to the Food and Drug Administration are not eligible for review under this guidance.

Mandatory Exclusions

- Federal sponsorship, including federal training grants, and agencies or organizations that have signed on to the Common Rule (http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html);
- Federal no-cost extensions;
- Projects where a student is paid/supported from a federal training grant or otherwise paid/supported directly from the faculty advisor's federal funds;
- Studies with Food and Drug Administration–regulated components;
- Studies with contractual obligations or restrictions that preclude eligibility in this policy;
- Studies seeking or obtaining Certificates of Confidentiality.

Flexible Guidance

1. **Minimal risk research:** Research projects or changes in approved research that do not appear on the list of expedited or exempt categories as outlined in the federal regulations for protection of human research will be reviewed as "minimal risk." These projects will not be granted any specific category beyond "minimal risk."
2. **Project update requirements**: Effective July 19, 2019, the Human Subjects Protection Program (HSPP) implemented the three burden-reducing provisions in the new federal rules. One of the provisions is the removal of a continuing review requirement for minimal risk research that is federally funded or supported. Projects instead are reviewed every three (3) or (5) years depending on whether the projects would traditionally have fallen into the expedite or exempt categories, respectively, as identified in the Common Rule. This renewal requirement will be limited to a project update. Researchers are still required to submit all protocol amendments and notify the IRB of any problems or reportable items as outlined in the "Investigator Responsibilities after IRB Approval" guidance.
3. **Expansion of research involving children:**
    a. Research projects involving children are subject to the regulations and tiered review standards at 45 C.F.R. § 46.401-409 . Requirements for assent and parental permission may be altered or waived for reasons other than those outlined in 45 C.F.R. § 46.408 .
    b. Research that would otherwise be subject to the requirements at 45 C.F.R. § 46.407 may be handled locally, not through the Secretary of HHS.
    c. Online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk (exempt category 8).
4. **Expansion of research involving prisoners:**
    a. Research projects involving prisoners are subject to the same requirements for review as those at 45 C.F.R. § 46.101–46.505 , with the exception of the requirement for review by the Secretary of HHS cited at 45 C.F.R. § 46.306 . Unfunded or nonfederally funded research is not required to get approval from the Secretary of HHS.

b. Individuals incarcerated during participation in research may continue participation in nonfederally funded projects without an IRB re-review with the prisoner representative.

c. The HSPP will not consider persons in transitional custody whose liberty is restricted such as halfway houses, electronic monitoring, probation, or house arrest to meet the federal definition of prisoner. For those individuals, the criteria at 45 C.F.R. § 46.111 offer sufficient protection for their level of vulnerability.

d. Data analysis of information collected from court records may be deemed exempt (exempt category 8).

5. **Expansion of research involving pregnant women, human fetuses and neonates:**

   a. Research projects involving pregnant women, human fetuses, and neonates are subject to the requirements at 45 C.F.R. § 46.201-46.207, with the exception of the requirement at 45 C.F.R. § 46.204(d) , which requires the research develop "important biomedical knowledge." Social and behavioral research or medical research that does not involve greater than minimal risk are not required to meet the requirement of "important biomedical knowledge."

   b. Neonates of uncertain viability and nonviable neonates may be in involved in retrospective medical chart reviews without requiring the legally effective informed consent of both parents as required at 45 C.F.R. §§ 46.205(b)(2) and 46.205(c)(5) .

   c. Research projects that are funded by sources other than federal agencies that involve greater than minimal risk; involve physical intervention; and include pregnant women, human fetuses, or neonates will be subject to the requirements of 45 C.F.R. § 46.201-46.207 irrespective of the funding source.

6. **Determination of engagement:** Multicenter or multisite research projects involving other "engaged" institutions that are funded outside the federal funding stream are not subject to the same formal interinstitutional agreements or assurance requirements as federally funded projects. Other forms of communication documenting collaborations are sufficient. For research that involves a nonaffiliated investigator and/or an outside institution that is considered engaged, this policy allows for the following:

   a. Unaffiliated investigators are required to sign an Unaffiliated Investigator Agreement, but the institutional official (IO) signature is not required. The signature of the IRB director or IRB chair can substitute for the IO signature.

   b. Outside institutions determined to be engaged will not be subject to the filing of an IRB Authorization Agreement, unless required by the outside institution. If the outside institution requires an IRB Authorization Agreement, the organization will comply with their requirements. Additionally, the organization may require an IRB Authorization Agreement at its discretion. The determination of engagement is at the discretion of the IRB. The signature of the IRB director or IRB chair can substitute for the IO signature.

7. **Reporting requirements:** Research projects that fall outside the scope of the FWA are not subject to the same federal reporting requirements as federally funded projects for reporting requirements of serious or continuing noncompliance, suspensions or terminations, or reporting of unanticipated problems involving risk to subjects or others. The HSPP does not report those matters to the federal agencies but follows internal reporting requirements.

Archived Flexible Review

The use of the categories below were archived for any new submissions effective January 21, 2019, with the implementation of the 2018 human subjects rules. Projects approved under these archived flexible review options will maintain their status as originally approved, but no new projects will be evaluated under these criteria.

1. **Additional exempt categories:** The categories were used for pre-2018 human subjects projects that did not directly conform to a specific exempt category under 45 C.F.R. § 46.101(b) , and therefore were placed into two new exempt categories 7 and 8 not found in the federal regulations. Projects were reviewed using an approval process identical to that used for exempt research under 45 C.F.R. § 46.101(b) .

    a. **Exempt 7**: Projects that do not conform to a specific exempt category under45 C.F.R. § 46 . Examples include:

        i. Online surveys, in-person focus groups, and/or interviews involving*minors* as long as the information collected does not place the individual at greater than minimal risk;

        ii. Behavioral games;

        iii. Studies of traits of nonpublic, nonelected officials;

        iv. Studies requiring performance of tasks that incur no risk; and

        v. Studies involving focus groups, oral histories, ethnographies, or studies using eye-tracking.

    b. **Exempt 8**: Research, involving no greater than minimal risk, where activity is limited to study of identifiable data. Examples include:

        i. Medical or educational record reviews where data is extracted from records;

        ii. Data analysis of information collected from court records; and

        iii. Collection or analysis of audio, video, or digital images.

    Exempt category 8 may still be require a HIPAA waiver. Studies that typically fall under expedited category 5 (involving analysis only of already collected data/documents/records) may now qualify for exempt category 8.

2. **Removal of continuing review requirements:** Two-year approvals for projects involving no greater than minimal risk and fall under expedite categories 3–7. These projects will be processed under expedited review according to 45 C.F.R. § 46.110 , but approval will be valid for two years rather than one as required in 45 C.F.R. § 46.109(e) . Studies limited to data analysis may qualify for exempt 8.

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