HUMAN RESEARCH PROTECTION

Criteria for IRB approval

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Resource type GUIDANCE

This document may be used by researchers to consider criteria for IRB approval of non-exempt research involving human subjects.

All requests for IRB approval must be submitted via the online IRB submission system, Cayuse Human Ethics (HE).

Visit the HRPO website for additional information: https://www.hhrinstitute.org/researcher-resources/ohsr/

1. IRB Criteria for Approval 45 CFR 46.111 (Original Common Rule (OCR) and 2018 Revised Common Rule (RCR). requirements) and 21 CFR 56.111

The study can be approved only if the completed IRB review determines the study meets **ALL** the applicable following criteria:

1.1	Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
1.2	Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
1.3	Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.[i]
1.4	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.
1.5	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
1.6	There are adequate provisions to protect the privacy of subjects, when appropriate.
1.7	There are adequate provisions to maintain the confidentiality of data, when appropriate.[iii]
1.8	When subjects are likely to be vulnerable to undue influence or coercion, additional safeguards have been included to protect the rights and welfare of those subjects.
1.9	Informed consent will be sought or waived or altered in accordance with 45 CFR 46.116 or 21 CFR 50.24, 25 for FDA regulated research with EFIC. **N/A** if study is closed to enrollment
1.10	Documentation of informed consent will be obtained or waived in accordance with 45 CFR 46.117 and/or 21 CFR 50.27 for FDA-regulated research **N/A** if study is closed to enrollment

2. Additional applicable criteria

2.1 When applicable, additional criteria must be met, e.g.:

- Drug and IND requirements
- Device and IDE requirements
- Research involving pregnant women, fetuses, and neonates
- Research involving prisoners
- Research involving children
- HIPAA waiver or alteration of authorization for research
- Data and safety monitoring
- Department of Defense criteria for approval
- Department of Justice Criteria for Approval
- Exception from Informed Consent (EFIC) requirements for emergency research

3. Additional considerations

3.1	No financial conflict exists, or it has been managed, reduced, or eliminated in an acceptable manner

IRB Actions

1 IRB decision

Approved: the submission is approved as submitted requiring no modifications or clarifications

Minor stipulations: minor modifications and/or clarifications are required and must be addressed before submission can be approved **Note:** For follow on submissions, the IRB letter will specify any impact of the stipulations on current study activitiess.

Deferred: substantive modifications and/or clarifications are required and must be addressed point by point by the investigator and subsequently reviewed by the IRB before the submission can be approved

Disapproved: the convened board identified major issues with the study or submission

Note: Research cannot be disapproved via the expedited review process.

2 IRB determination of risk level

No greater than minimal risk: The probability and magnitude of harm or discomfort anticipated in the research ARE NOT greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Greater than minimal risk: Does not meet the above definition of minimal risk.

3 IRB determination of continuing review requirement

Continuing review **is required** if **ANY** of the below are true:

- Review by the convened IRB is required
- Research is subject to the pre-2018 Rule
- Research is regulated by the FDA, DOJ, or Consumer Product Safety Commission (regardless of the level of risk)
- Research is eligible for expedited categories 8b or 9[iv]
- The IRB or designated reviewer requires it and documents the reason, even if it meets the regulatory criteria for not requiring continuing review.

Note: When continuing review is required, it may be appropriate to require **more frequent than annual review**, for example, when the risks to participants, the nature, magnitude, or probability of risks, subject vulnerabilities, adverse events, complaints or compliance issues, the investigator's experience, or other factors warrant more frequent reassessment.

Continuing review **is NOT required** – none of the above apply

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[i] In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

[ii] In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

[iii] The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

[iv] (i) the research is not being conducted under an investigational new drug application or investigational device exemption, (ii) categories two (2) through eight (8) of the OHRP Expedited Review Categories (1998) do not apply, and (iii) the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified (expedited review category 9). https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html