

Guide to Assessing IRB Requirements

This guide is provided as a reference to help reviewers assess if IRB criteria and requirements are met, and includes the Criteria for Approval of Research with points to consider, and the Required Elements of Informed Consent.

The criteria for approval are also outlined succinctly in the following separate documents:

- Worksheet HRP-314 – Criteria for Approval, which provides a succinct outline of the IRB requirements.
- Other checklists applicable to specific situations and populations which outline additional requirements .

(References: DHHS 45 CFR 46 ¶111, 116 & 117; and FDA 21 CFR 50 ¶.20, 25 & 27; 21 CFR 56.111.)

Criteria for Approval of Research	
The following table provides points to consider when evaluating IRB requirements.	
Requirement	Considerations to Evaluate Whether Criteria Are Met
Use of Human Subjects 1. The use of human subjects in this research is appropriate	<ul style="list-style-type: none"> ● Has the proposal undergone scientific review? <ul style="list-style-type: none"> ▪ Is the hypothesis clear? Objectives and valid end-points provided? ▪ Study design appropriate to reasonably expect to answer hypothesis? ● Will the investigator have access to a population that would allow recruitment of the required number of participants? ● Will the research contribute to generalized knowledge and be worth exposing subjects to risk?
Staff and Facilities 2. The staffing and facilities for the research are appropriate	<ul style="list-style-type: none"> ● Are the research staff members qualified to conduct the procedures? ● Are there adequate numbers of qualified staff? ● Is there a process to ensure that the research personnel are adequately informed about the protocol and their research-related responsibilities? ● Does the investigator have adequate facilities to conduct the research? ● Will investigator have sufficient time to conduct/complete the research? ● Are the medical or psychological resources that participants might require as a consequence of the research available?
3. Risks to Subjects are Minimized (i) Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. (ii) Risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	<ul style="list-style-type: none"> ● Consider the physical, psychological, social, legal, and economic risks. ● Would fewer procedures answer the scientific question? ● Will procedures that may answer the scientific question be done regardless of the research? If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm? ● Would alternative procedures with reduced likelihood or magnitude of harm answer the scientific question? ● Would fewer participants answer the scientific question?

<p>4. Risks to Subjects are Reasonable</p> <p>Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and to the importance of knowledge that may reasonably be expected to result</p>	<ul style="list-style-type: none"> ● What are the 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). ● What does the IRB consider the level of risk to be? What does the PI consider the level of risk/discomfort/inconvenience? ● Is there prospect of direct benefit to subjects? <p>Note: The regulations indicate that 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.</p>
<p>5. Data Safety Monitoring</p> <p>If the research involves more than minimal risk to participant, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</p>	<ul style="list-style-type: none"> ● When will the data be monitored? ● What data will be monitored? ● Who will be doing the monitoring?
<p>6. Privacy and Confidentiality</p> <p>a. There are adequate provisions to protect the privacy of subjects.</p> <p>b. There are adequate provisions to maintain the confidentiality of data.</p>	<ul style="list-style-type: none"> ● Are the research procedures designed to minimize invasion of privacy? ● Will subjects think their information is any of the researcher's business? ● Will subjects be comfortable with the research setting provided? ● Is confidentiality pledged? ● Are there legal or ethical requirements to maintain confidentiality? ● Will data release cause a risk of harm? ● Are there access restrictions (e.g., locks/passwords, etc.) in place? ● Are techniques used to protect the data from re-identification? ● Is a Certificate of Confidentiality needed to protect the researcher and institution from being compelled to release information that could identify the study participants?
<p>7. Subject Selection</p> <p>Subject selection is equitable</p>	<ul style="list-style-type: none"> ● Consider the purpose of the research purpose and recruitment methods when assessing subject selection. ● Who will be enrolled (healthy volunteers, patients, children, etc.)? ● Is the rationale for inclusion/exclusion addressed? ● The target population should make scientific and ethical sense. ● Are there special problems associated with a vulnerable population?
<p>8. Vulnerable Populations</p> <p>When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.</p>	<ul style="list-style-type: none"> ● Additional requirements are outlined in separate, supplemental IRB checklists for use when the research will involve any of the following populations: Children; Decisionally Compromised; Pregnant Women, Fetuses or Neonates; Prisoners; Research to be Conducted in Emergency Settings. or Fetal Tissue for Transplantation ● Will the research include subjects likely to be vulnerable to coercion or undue influence, such as students, employees, military, socially or economically disadvantaged? If so, consider these issues: <ul style="list-style-type: none"> ▫ Is there a power differential? ▫ Excessive motivation? ▫ Is there a decisional or communication issue? ▫ If so, are appropriate protections in place to protect the rights and welfare of the subjects?

<p>9. Informed Consent Process</p> <p>The investigator will obtain the legally effective informed consent of the subject or the subject's legally authorized representative.</p> <ul style="list-style-type: none"> • The circumstances of consent will provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate. • The circumstances of consent will minimize the possibility of coercion or undue influence. • The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. • The informed consent, whether oral or written, will not include any <u>exculpatory language</u> through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, the institution, or its agents from liability for negligence. 	<ul style="list-style-type: none"> • Is it clear who can serve as a legally authorized representative? • Will the participants or representatives: <ul style="list-style-type: none"> • understand the facts? appreciate the implications of the decision? • be able to decide? be able to communicate a decision? • What are the circumstances involved? • How much time will be devoted to the consent discussion? • How much time will be allowed for a decision? • Is there a power differential? Communication issues? • Are there issues regarding the capacity to make a decision; communicate? • If appropriate, is there an assent form? • Are there excessive motivating factors? <ul style="list-style-type: none"> • What language will the participants or representatives speak? • Can the research team communicate in understandable language to the participants or representatives? • Will the written information be in understandable language? <ul style="list-style-type: none"> • Is the information factual? (e.g., the policy, plan, expectation, or law) • Does it avoid stating an outcome (e.g., something will or will not happen)? <p>Criteria to alter or waive informed consent</p> <p>For the specific IRB findings required to waive informed consent, or to alter or waive some or all of the required elements of consent see below: <i>IRB Required Findings to Alter or Waive Informed Consent (or Documentation)</i>.</p>
<p>10. Documentation of Consent</p> <p>Informed consent will be appropriately documented, in accordance with and to the extent required by the regulations.</p> <p>The consent form may be either of the following:</p> <ul style="list-style-type: none"> • Written consent document that embodies the elements of informed consent • Short form written consent document stating that the elements of informed consent have been presented orally 	<p>a. If written consent (long form) is used:</p> <ul style="list-style-type: none"> • The consent document embodies the elements of informed consent required by the regulations. (<i>Listed in next section</i>) • The investigator will give either the participant or the participant's legally authorized representative (LAR) adequate opportunity to read the consent document before it is signed. • The participant or the participant's legally authorized representative (LAR) will sign the informed consent document. • If the research is subject to FDA regulation, the participant or the participant's LAR will date the informed consent document. • A copy of informed consent document will be given to the person signing the form. <p>b. If short-form method of consent documentation is used (e.g., for limited English participants):</p> <ul style="list-style-type: none"> • The short form consent document states that the elements of informed consent required by the regulations have been presented orally to the participant or the participant's LAR. • There will be a witness to the oral presentation. • For participants who do not speak English, the witness will be conversant in both English and the language of the participant or the participant's LAR. • A written summary of what is to be said to the participant or the LAR embodies the elements of informed consent required by the

	<p>regulations. (See elements, below)</p> <ul style="list-style-type: none"> • The informed consent document will be signed by both: <ul style="list-style-type: none"> ◆The participant or the participant's LAR and ◆The witness • If the research is subject to FDA regulation the participant or the participant's LAR will date the informed consent document. • The written summary will be signed by both: <ul style="list-style-type: none"> ◆The witness and ◆The person obtaining consent • The participant or the participant's LAR will be provided both: <ul style="list-style-type: none"> ◆A copy of short form informed consent document and A copy of the written summary <p>Criteria to waive documentation (i.e., waive signed consent form): For the specific findings to waive documentation of consent, see below: <i>IRB Required Findings to Alter or Waive Informed Consent (or Documentation)</i>.</p>
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Required Elements of Informed Consent

	<p>Basic Elements The consent process must:</p> <ul style="list-style-type: none"> ·Disclose that the study involves research ·Explain the purposes of the research ·Explain the expected duration of the subject's participation ·Describe the procedures to be followed ·Identify any procedures that are experimental & identify any investigational drugs/devices as being investigational if applicable ·Describe any reasonably foreseeable risks or discomforts to the subject ·Describe any benefits to the subject or to others which may reasonably be expected from the research ·Disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject ·Disclose the extent, if any, to which confidentiality of records identifying the subject will be maintained ·Notes the possibility that the FDA may inspect the records if the research is subject to the FDA regulation ·For research involving more than minimal risk, explain whether any compensation is available if injury occurs and if so, what the compensation consists of and where further information may be obtained regarding compensation ·For research involving more than minimal risk, explain whether any medical treatments are available if injury occurs and if so, what medical treatments are available and where further information may be obtained regarding those medical treatments ·Explain whom to contact for answers to pertinent questions about the research ·Explain whom to contact for answers to pertinent questions about research subjects' rights ·Explain whom to contact in the event of a research-related injury to the subject ·Disclose that participation is voluntary ·Disclose that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled ·Disclose that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled <p>Additional elements When appropriate, the consent process must:</p> <ul style="list-style-type: none"> ·Disclose that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable, if the risk profile of the research-related interventions is not well known and/or the research involves investigational drugs or devices ·Disclose that if the subject is or may become pregnant the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable, if the risk profile of all research interventions or interactions on embryos or fetuses is not well known ·Indicate the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent if there are any ·Disclose additional costs to the subject that may result from participation in the research if there are any ·Disclose the consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject, if there are adverse consequences (physical, social, economic, legal, or psychological) to this decision ·Indicate that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject, if this type of findings is likely during the course of the research ·Indicate the approximate # of subjects involved in the study, if this info. is important to a decision to take part in the research ·Indicate the amount and schedule of payments
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