

EXPEDITED REVIEW CHECKLIST

Initial Review, Continuing Review, or Minor Modification

Reviewer:	PI:
IRB #:	Sponsor:

Check one: Initial Review Continuing Review Minor Modification

Expedited Review Criteria [45 CFR 46.110](#) [All criteria must be checked.]

<input type="checkbox"/>	The research is no more than minimal risk OR the modification to more than minimal risk research is minor.
<input type="checkbox"/>	The research is not classified.
<input type="checkbox"/>	Identification of the subjects and/or their responses either: <ul style="list-style-type: none">would NOT place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing; ORmay place them at such risk but are mitigated to such an extent that risks related privacy/breach of confidentiality are no more than minimal.

Minor Modifications [Skip for Initial or CR. All criteria must be checked for minor modifications.]

<input type="checkbox"/>	The modifications do not affect the design of the research.
<input type="checkbox"/>	The modifications add no more than minimal risk to subjects.
<input type="checkbox"/>	All added procedures fall into categories 1-7 (see expedited categories). [Check N/A if research falls into category (8)(b).] <input type="checkbox"/> N/A

Expedited Categories [Check all that apply.]

<input type="checkbox"/>	(1)(a) Clinical studies of drugs when an IND is not required.
<input type="checkbox"/>	(1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
<input type="checkbox"/>	(2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh at least 110 pounds where the amount drawn is less than 550 ml in an 8-week period and collection occurs at most 2 times/week.
<input type="checkbox"/>	(2)(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (at most 50 ml or 3 ml/kg/8 week period), and the frequency with which it will be collected (at most 2 times/week.)
<input type="checkbox"/>	(3) Prospective collection of biological specimens for research purposes by noninvasive means. [Examples: saliva collection, buccal swab, hair/nail clippings]
<input type="checkbox"/>	(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. [Examples: physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; MRI; EKG, ultrasound, moderate exercise, muscular strength testing, body composition assessment, and flexibility testing.]
<input type="checkbox"/>	(5) Research involving materials (data, documents, records, or specimens) that have been collected for any purpose or will be collected solely for non-research purposes.
<input type="checkbox"/>	(6) Collection of data from voice, video, digital, or image recordings made for research purposes.
<input type="checkbox"/>	(7)(a) Research on individual or group characteristics or behavior
<input type="checkbox"/>	(7)(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

<input type="checkbox"/>	(8)(a) Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)
<input type="checkbox"/>	(8)(b) Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.
<input type="checkbox"/>	(8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)
<input type="checkbox"/>	(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but 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.

Criteria for Approval of Research [45 CFR 46.111](#) [All criteria must be “YES.” If any responses are “NO,” the submission requires modification or referral to full board.]

<input type="checkbox"/> YES <input type="checkbox"/> NO	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. .111(a)(1)
<input type="checkbox"/> YES <input type="checkbox"/> NO	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. In evaluating the 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). .111(a)(2)
<input type="checkbox"/> YES <input type="checkbox"/> NO	Selection of subjects is equitable. .111(a)(3) .
<input type="checkbox"/> YES <input type="checkbox"/> NO	Informed consent process, documentation (if any), and waiver (if any) are acceptable in accordance with .116 and .117 ... 111(4) ..
<input type="checkbox"/> YES <input type="checkbox"/> NO	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. .111(a)(6) .
<input type="checkbox"/> YES <input type="checkbox"/> NO	There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. _111(a)(7) .
<input type="checkbox"/> YES <input type="checkbox"/> NO	Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence.
<input type="checkbox"/> YES <input type="checkbox"/> NO	When the research involves vulnerable subjects, the research satisfies the additional requirements for IRB approval under DHHS regulations at 45 CFR 46 subpart B, C, or D, respectively.

Informed Consent [45 CFR 46.116](#) [All criteria must be “YES” or “N/A”. If any responses are “NO”, the submission requires modifications.]

<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	The investigator will obtain the legally effective informed consent of the subject or the subject’s legally authorized representative. .116(a)(1) .
<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	The circumstances of consent provide the prospective subject or legally authorized representative sufficient opportunity to discuss and consider whether or not to participate. .116(a)(2) .
<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	The circumstances of consent minimize the possibility of coercion or undue influence. .116(a)(2) .
<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Information to be given to the subject or legally authorized representative shall be in language understandable to the subject or legally authorized representative. .116(a)(3) .
<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	There is no exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. .116(a)(6) .

<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	All required elements and appropriate additional elements of informed consent will be presented OR appropriately waived.
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Screening, recruiting, or determining eligibility [45 CFR 46.116\(g\)](#)

<input type="checkbox"/>	<p>An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:</p> <ul style="list-style-type: none"> • The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, OR • The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
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General waiver or alteration of consent [45 CFR 46.116\(f\)\(3\)](#)

<input type="checkbox"/>	<p>In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:</p> <ul style="list-style-type: none"> • The research involves no more than minimal risk to the subjects; • The research could not practicably be carried out without the requested waiver or alteration; • If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; • The waiver or alteration will not adversely affect the rights and welfare of the subjects; and • Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
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HIPAA Privacy Rule, Waiver of Authorization [45 CFR 164.512\(i\)\(2\)\(ii\)](#)

<input type="checkbox"/>	<p>The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:</p> <ul style="list-style-type: none"> • The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: <ul style="list-style-type: none"> ○ an adequate plan to protect the identifiers from improper use and disclosure; ○ an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and ○ adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart; • The research could not practicably be conducted without the waiver or alteration; AND • The research could not practicably be conducted without access to and use of the protected health information.
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Waiver of documentation of informed consent [45 CFR 46.117\(c\)](#)

<input type="checkbox"/>	<ul style="list-style-type: none"> • An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following: <ul style="list-style-type: none"> ○ That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; ○ That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or ○ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. • In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.
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Determination for Protocol

<input type="checkbox"/>	Approve
<input type="checkbox"/>	Approve with required modifications
<input type="checkbox"/>	Approve with conditions
<input type="checkbox"/>	Defer
<input type="checkbox"/>	Recommend to Full Board; Rationale:

Duration of Approval [Initial and CR only]

<input type="checkbox"/>	1 year [ex. FDA regulated, oversight concerns, etc.] Rationale:
<input type="checkbox"/>	Other and rationale:
<input type="checkbox"/>	No expiration. Continuing review not required.

Consent Alteration/Waiver

<input type="checkbox"/>	Approve
<input type="checkbox"/>	Approve with required modifications
<input type="checkbox"/>	Refer to Full Board; Rationale:
<input type="checkbox"/>	N/A

Waiver of Documentation of Consent

<input type="checkbox"/>	Approve
<input type="checkbox"/>	Approve with required modifications
<input type="checkbox"/>	Refer to Full Board; Rationale:
<input type="checkbox"/>	N/A

HIPAA

<input type="checkbox"/>	HIPAA Waiver granted for screening
<input type="checkbox"/>	De-identified
<input type="checkbox"/>	Waiver approved
<input type="checkbox"/>	In ICF
<input type="checkbox"/>	Limited Data Set
<input type="checkbox"/>	N/A; NO PHI

Comments/Notes:

Signature

Date