

The Carle Foundation

IRB Policy 401

Subject	Expedited Review				
Approval	Dec 2006	Review	Apr 2011	Revision	Apr 2011
Scope	This policy applies to all research that qualifies for expedited review under the jurisdiction of the Carle IRB.				
Purpose	To state the requirements and process for expedited review classification of research.				

Statement of Policy

1. An expedited review procedure consists of a review of research involving human subjects by the IRB Chairperson or other designated member of the committee in accordance with federal regulations. Only studies that meet federal criteria for expedited review will be considered for expedited review.
2. The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that are described in the OHRP and FDA guidances on expedited review listed in the Reference section.
3. Authority of the Expedited Reviewer: The Reviewer may exercise all of the authorities of the IRB, except that the Reviewer may not disapprove the research. A research proposal may be disapproved only after review by the full IRB.
4. Applicability-Activities for which the use of the expedited review procedure is permissible
 - a. Research activities that:
 - Present no more than minimal risk to human subjects, and
 - Involve only procedures listed in one or more of the following categories listed under item 5., may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
 - b. The categories in this list apply regardless of the age of subjects, except as noted.
 - c. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
 - d. The expedited review procedure may not be used for classified research involving human subjects.
 - e. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.
5. Research categories which the IRB can conduct the expedited procedure.
 - a. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (**Note:** Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - Research on medical devices for which:
 - An investigational device exemption application (21 CFR Part 812) 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.
 - b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - From other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
 - c. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
 - Hair and nail clippings in a nondisfiguring manner
 - Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction

Statement of Policy (cont.)

- Permanent teeth if routine patient care indicates a need for extraction
 - Excreta and external secretions (including sweat)
 - Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
 - Placenta removed at delivery
 - Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
 - Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
 - Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
 - Sputum collected after saline mist Nebulization
- d. 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 subjects privacy
 - Weighing or testing sensory acuity
 - Magnetic resonance imaging
 - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
 - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (**NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- f. Collection of data from voice, video, digital, or image recordings made for research purposes.
- g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (**NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)
- h. Continuing review of research previously approved by the convened IRB as follows:
- 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; **or**
 - Where no subjects have been enrolled and no additional risks have been identified; **or**
 - Where the remaining research activities are limited to data analysis.
- i. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (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.
- j. For research previously approved by a convened IRB, the IRB may use the expedited review procedure to review minor changes in previously approved research during the period (one year or less) for which the approval is authorized. A change is minor if it does not represent a material change in the research so that
- The change does not adversely alter the overall risk/benefit ratio;
 - The change will not potentially adversely affect the willingness of current participants to remain in the study or the willingness of potential participants to enroll in the study;
 - The change will not diminish the scientific validity of the study; and
 - Any change involves no more than minimal risk to subjects.

Statement of Policy (cont.)
<p>6. Documentation</p> <ol style="list-style-type: none"> a. If the study qualifies for expedited review, the IRB Chairperson or designee will document his/her determination of the level of risk and the applicable expedited review category(ies). b. The minutes will include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that IRB members had concerning the research reviewed. c. The review procedures relating to this policy shall be documented in written procedure(s) that document the application of the above category(ies).
Definitions
<p>Human Subjects Protection Office (HSP) – Human Subjects Protection office at Carle, which supports the Carle IRB administratively.</p> <p>Institutional Review Board (IRB) - Means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.</p> <p>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.</p> <p>Principal Investigator - The investigator/ researcher who is responsible for the conduct of a research study at an institutional site.</p> <p>The Carle Foundation – Includes all legal entities part of The Carle Foundation such as Carle Foundation Hospital, Carle Physician Group, Mills Breast Cancer Institute, and Carle Cancer Center.</p>
Procedures
<ol style="list-style-type: none"> 1. All human subjects research proposals, continuing review submissions, and modification proposals are submitted to the Carle IRB via IRBNet. The Carle IRB Chair or designee conducts expedited reviews on behalf of the Carle IRB. 2. To adequately document that a continuing review submission has been thoroughly reviewed, the expedited reviewer completes the “Reviewer’s Worksheet for Research Study.” HSP staff may complete the “pre-reviewer’s checklist” section of these worksheets during the intake and pre-review process. This “Reviewer’s Worksheet” covers the HHS “Criteria for IRB Approval of Research” described in 45 CFR 46.111 as well as the HHS categories of research that qualify for expedited review as described above. 3. Based on this review, the expedited reviewer may approve a project’s continuing review or may ask for additional information or changes before a project can be approved. If the expedited reviewer does not approve of a project’s continuing review submission, the submission will be reviewed by the convened Carle IRB. 4. Once a determination has been made, the HSP office will draft a determination letter to be submitted to the Principal Investigator via IRBNet. 5. When the expedited review procedure is implemented, all other members of the Carle IRB shall be informed of actions taken by the expedited reviewer at the next convened meeting.
References
<p>45 CFR 46.110 OHRP Guidance on the Use of Expedited Review Procedures dated August 11, 2003 Categories of Research That May Be Reviewed by the IRB Through an Expedited Process www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm</p> <p>21 CFR 56.110 Categories of Research That May Be Reviewed by the IRB Through an Expedited Review Procedure http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm119074.htm</p> <p>HSP Procedure 102</p>
Electronic Approval on File

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