BAYCARE Institutional Review Board **POLICY/PROCEDURE**

TITLE: Expedited Review Policy	**POLICY NUMBER:** IRB-E05W61 **PAGE:** 1 of 9
ISSUED FOR: All BayCare, Investigators and Research Personnel **SPONSORED BY:** BayCare Institutional Review Board	**ORIGINAL ISSUE DATE:** 05/14 **REVISION DATE: 01/18, 04/19** **REVIEW DATE: 09/19**
APPROVED BY: BayCare Health System (BCHS) Institutional Review Board (IRB)	

PURPOSE:

The purpose of this policy is to describe requirements and procedures for research that may be reviewed by expedited means rather than full board IRB review, pursuant to applicable federal regulations

The IRB members conducting the expedited review may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research. The reviewers must refer any research protocol that he/she would have disapproved to the Full IRB for review. The reviewers may also refer other research protocols to the Full IRB whenever the reviewer(s) believes that Full IRB review is warranted.

DEFINITIONS

Minimal risk (as it applies to the research procedure or investigational article) means that 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.

Minimal risk (as it applies to the risk of violating a research subject's privacy rights) means that the investigator has provided (1) an adequate plan to protect the subject's identifiers from improper use or disclosure; (2) an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except for those individuals or entities who are also conducting the research studies or are disclosed in the authorization, as required by law, or for authorized oversight of the research study.

POLICY:

An expedited review procedure consists of a review of research involving human subjects by one or more experienced reviewers designated by the IRB Co-Chair(s) from among members of the BCHS IRB. An IRB may use the expedited review procedure to review the nine categories that may be eligible for expedited review provided that other requirements are met.

(1) Some or all of the research found by the reviewer(s) to involve no more than minimal risk;

(2) Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized;

(3) If the convened IRB has determined that an expedited review is appropriate for research approved with modifications, to ensure that requested modifications have been adequately addressed by the investigator;

(4) Continuing approval of the use of HUDs not used in research; if no unexpected occurrences manifested since the last IRB review.

PROCEDURE:

5.1 Expedited Reviewers

The following individuals may review research activity (new submissions or changes to previously approved research) by expedited means:

a. IRB Co-Chair(s). An IRB co-chair (or designated reviewer(s) – see below) may exercise all of the authorities of the IRB during the expedited review, except that he/she may not disapprove the research activity (new submission or modification to previously approved research). A research activity may be disapproved only after review by the convened IRB.

b. Designated Reviewers. By way of this policy, the IRB co-chair(s) designates any individual who meets the following criteria as an expedited reviewer:

i) a BCHS IRB member(s); and

ii) meets one or more of the following:

- Certification as an IRB professional (CIP) manager or administrator (CIM); or over 10 years experience in an IRB coordinating capacity.
- Has, in the IRB Chair's opinion, demonstrated extensive knowledge of the ethical principles, federal regulations and applicable laws governing human subject research.

iii) An expedited reviewer may seek expertise from or consult with an external entity or person to aid in the review.

5.2 Criteria for Expedited Review of Newly Submitted Research

The reviewer(s) will use the Expedited Reviewer Checklist to ensure that all of the following criteria are met:

a. The activity must present no more than minimal risk (as defined above) to subjects; and

b. The protocol procedures must be of the type that may qualify for an expedited review process as listed under Categories of Review.

Categories of Review:

Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) 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); or

(b) Research on medical devices for which (i) an investigational device exemption application (21CFR812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, 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

(b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

(a) hair and nail clippings in a non-disfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) 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;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

Category 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:

(a) 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;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research 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 research participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7: 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 research participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

c) Studies undergoing expedited review are also subject to the following requirements:

i) The categories in the expedited research list apply regardless of the age of subjects, except as noted.

ii) The expedited review procedure may not be used for classified research involving human subjects.

iii) 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.

Categories 8 and 9 are for Continuing Review only and may be used only if the IRB has informed the PI that the future review(s) may used the expedited review process unless otherwise decided; with an explanation given by the IRB.

If the IRB warrants that due to modifications to the study since the last IRB approval, that the current submission should now be submitted for a full-board review; then the expedited category will no longer apply.

Category 8: Continuing review of research previously approved by the convened IRB as follows:

(a) where

(i) the research is permanently closed to the enrollment of new participants;

(ii) all participants have completed all research-related interventions; and

(iii) the research remains active only for long-term follow-up of participants; or

(b) where no participants have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

1. Continuing review of research, nit conducted under an investigational new drug application (IND) or investigational device exemption (IDE) where categories two (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.

2. 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.)

Categories 8 and 9 are for Continuing Review only and may be used only if the IRB has informed the PI in writing that future reviews may use the expedited review process.

9. Continuing review of research, not conducted under an investigational new drug application (IND) or investigational device exemption (IDE) 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.

Additional information pertaining to the expedited categories above may be found at:

http://www.hhs.gov/ohrp/policy/exprev.html
http://www.hhs.gov/ohrp/policy/expedited98.html
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm119074.htm

5.3 Expedited Review of Changes to Previously Approved Research

Changes in approved research may not be initiated without prior IRB review and approval except where necessary to eliminate apparent immediate hazards to human subjects.

Changes to eliminate apparent immediate hazards to human subjects will be reviewed in accordance with the Reporting and Review of Unanticipated Problems in Human Subject Research Policy.

In accordance with 45 CFR 46.110(b) (2), 38 CFR 16.110(b) and 21 CFR 56.110, IRBs may utilize expedited procedures to review a proposed change to previously approved research if it represents a minor change to be implemented during the previously authorized approval period.

a. A minor change is one which, in the judgment of the IRB/reviewer(s), makes no substantial alteration in:

i) The level of risk to subjects (may not involve an increase in risk that is more than minimal)

ii) The research design or methodology;

iii) Study procedures which would then fall outside of Categories 2-7 of research that qualify for review by expedited review

iv) The rights and welfare of subjects,

v) The subject population;

vi) The qualifications of the research team;

vii) The facilities available to support the safe conduct of the research

viii) Any other factor which would warrant review of the proposed changes by the convened IRB.

b. **Examples of minor changes to already approved research include, but are not limited to:**

i) Basic informational revisions (changes in telephone numbers or contact persons on the consent form)

ii) Addition or deletion of associates or staff. Changing the Principle Investigator

iii) A change in the number of research participants anticipated to be enrolled at the local site only

iv) The deletion of questions in a questionnaire

v) Changing the amount of blood that is drawn or the frequency of the blood draws provided it remains within the expedited category limitations

vi) Adding **non-sensitive** questions to a questionnaire

vii) Revising the format of the consent form or other minor changes to the consent form

viii) Adding a standardized test (standard of care); in certain circumstances

ix) **Decreasing** the drug dosage or the frequency of drug administration;

x) Changing the recruitment plan; new or revised recruitment materials, advertisements or scripts

xi) Adding a standard quality of life questionnaire

xii) Extending the time period of the study to include follow-up with the research participants

xiii) **in some circumstances**, revising eligibility to include or exclude study participants

xiv) Adding a research site; or changing the principal investigator.

xv) Translations: Non-English translations of IRB approved consent documents may be reviewed in an expedited manner. The translated document must be accompanied by a certification of accuracy and the qualifications of the translator. Translation by a certified translator is recommended.

xvi) For changes to a research study in which an already enrolled subject becomes a prisoner, but the focus of the study does not involve a prison population, expedited review of changes to the approved protocol may be appropriate.

c. **Major changes to previously approved research are changes that do not qualify as minor. These changes are any that entail more than a minimal risk, affects the regulatory criteria for approval, or affects the rights and welfare of subjects. Such changes must be reviewed by the convened IRB**.

5.4 Continuing Review of Research Previously Approved at Convened IRB Meeting

Federal regulations allow the IRB to use the expedited review procedure to provide continuing review of research previously approved by the convened IRB. In order for the reviewer(s) to approve the continuing review of research by expedited review, the reviewer(s) must ensure that the research has met either (a) or (b) below:

a. One of the following applies to the research:

i) the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects;

ii) where no subjects have been enrolled and no additional risks have been identified; or

iii) where the remaining research activities are limited to data analysis.

b. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 5.2(b)(ii) – (iv) and 5.4(a) 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.

5.5 Expedited Review Determinations

These determinations apply to Research that qualifies for an expedited review.

a. *Approval*: The protocol and accompanying documents may be approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or the IRB Chair or designee, and expires no later than one year from date of approval.

The IRB may recommend minor language changes to the consent or submission documents that clarify information provided by the Principal Investigator/sponsor, but do not alter the IRB's determination that the regulatory criteria for approval remain satisfied.

b. *Approved with Modifications*: The protocol and accompanying documents may be approved with conditions at the time of initial review of the research, continuing review, or review of proposed changes to previously approved research if, given the scope and nature of the conditions, the IRB is able to determine that with satisfaction or the conditions, all of the regulatory criteria for approval are met.

Final approval will commence on the day conditions are determined to be met, and expires no later than one year from date of approval.

The revisions to consent documents, submission forms and other clarifications requested during convened IRB review as a condition of final approval may be reviewed by the IRB Chair or designee. Final approval will be issued provided that the revisions, or clarifications do not indicate or result in a change to the study or affect the regulatory criteria for approval.

Conditions of approval of research may include, but are not limited to**:**

i) Confirmation of specific assumptions or understandings regarding how the research will be conducted (e.g., confirmation that the research excludes children);

ii) Submission of additional documentation (e.g., documentation that physician-investigators of a device trial have been trained by the sponsor, as indicated in the protocol, prior to the enrollment of subjects); or

iii) Precise language changes to protocol or informed consent documents.

When the IRB approves research with conditions, verification procedures must be included as part of the IRB approval process. An individual designated by the IRB will

review responsive materials from the investigator and determine whether the conditions of approval have been satisfied.

c. *Disapproval*: Disapproval cannot be determined through expedited review and requires majority vote of the convened IRB.

5.6 IRB Notification

When the expedited review procedure is used for any research activity, IRB members shall be informed of such actions in the IRB meeting agenda.

Investigators will be notified of the results of the expedited review. The approval date serves as the date that reviewer(s) in conjunction with the IRB approved the protocol. The reviewer(s) will state the approval period, which may not exceed 1 year. Prior to study expiration, the investigator should submit a *Renewal Research* form and other required documents as indicated.