BayCare Health System Institutional Review Board

Expedited Review **Federalwide**

Assurance 00006065

IRB ACTION ONLY

IRB File#: _____ Agenda Date: _____ Reviewer: _____

Please Type

This form will assist investigators in determining if the proposed research is expedited and specifying under which of nine categories on the following pages of this form the expedition occurs.

1. **Principal Investigator:** **Phone:**

   Mailing Address: **Email:**

   Co-Investigator(s):

2. **Sponsor:** **Protocol No:**

3. **Protocol Title:**

4. **Total project period: _____** 5. **Expedited Category (identify by number): _____**

6. **Description of Human Subjects: Number of Subjects to be enrolled in this study: _____**

   Describe the subject population: Sex: _____ Adult(s) _____ Minor(s) _____

   Description of Study, Reason for Claiming Expedition and how you will maintain the subject's confidentiality: (Attach sheet if more space needed):

   Please indicate whether or not your protocol involves more than minimal risk*: ____ Yes ____ No

7. **For nursing projects, approval from the BayCare Health System Nursing Research Council is required with this Submission. Have you received approval? _____Yes _____No**

***Minimal risk means that the probability and magnitudes of harm or discomfort anticipate in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or test. 45 CFR 46.102(i)*

DHHS Categories of Research That May Be Reviewed Through Expedited Review
Revised November 9, 1998 (63 FR 60364-60367)

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, 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.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

EXPEDITED CATEGORIES (45 CAR 46.110 and 21 CAR 56.110) 1-9

OHRP and FDA Expedited Categories –

Note: Categories one (1) through seven (7) pertain to both initial and continuing IRB review. Categories eight (8) and nine (9) pertain only to continuing IRB 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.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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, 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

b. from other adults and children, 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.

Category 3

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;
- permanent teeth if routine patient care indicates a need for extraction;
- excreta and external secretions (including sweat);
- un-cannulated 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.

Note: On October 4, 2010, OHRP clarified that it agrees with the FDA's position that the following procedures are considered noninvasive:

- Vaginal swabs that do not go beyond the cervical os;
- Rectal swabs that do not go beyond the rectum; and

- Nasal swabs that do not go beyond the nares.

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:

- 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.

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).

- 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 category includes materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.
- The phrase "**…or will be collected solely for non-research purposes**" pertains to the origin of the materials. For example, blood samples that were collected for a clinical test or the results of a course driven exam given in a history class.

Category 6

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

Expedited Review does not apply if 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.

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 subjects. 45 CFR 46.101(b)(2) and (b)(3).

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 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

b. where no subjects have been enrolled and no additional risks have been identified; or

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

Clarifiers regarding category (a):

- Closure of enrollment only has to apply to the local site, not to all sites,
- Long-term follow-up may include research **interactions** (as opposed to intervention) that involve no more than minimal risk to subjects (e.g., quality of life surveys);
- Long-term follow-up may include collection of follow-up data from **procedures** or **interventions** that would have been done as part of **routine clinical practice** to monitor a subject for disease progression or recurrence, **regardless of whether the procedures or interventions are described in the research protocol**.

Clarifiers regarding category (b):

- "no subjects have been enrolled" means no subjects enrolled at the local site
- "no additional risks have been identified" means no additional risks identified at the local site or any other institution engaged in the research project or from any other relevant source since the IRB's most recent prior review.

Clarifiers regarding category (c):

- The only remaining human subjects research activity is the analysis of data that includes identifiable private information and the IRB reviewer has determined that this activity involves no more than minimal risk.
- Simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects research and thus does not require continuing review.

Category 9

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.

[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

The Principal Investigator must certify the following statements by signing below:

"The proposed investigation involves the use of human subjects. I am submitting this form with a description of human subjects participating in research. I understand BayCare's policy concerning research involving human subjects and agree to:

a. obtain informed consent of subjects who are to participate in this project if required;
b. report to the IRB any serious adverse effects on subjects which become apparent during the course or as a result of experimentation and the actions taken as a result (IRB FORM 6);
d. obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form (IRB FORM 4);
e. maintain documentation of consent forms and progress reports as required by institutional and Federal policy (IRB Guidelines).

_____ _____

Signature of Principal Investigator Date

Location: BayCare Health System IRB Office

2995 Drew St.
BSO East MS #: 1059
Clearwater, Florida 33759

Questions: Call the IRB Office at (727) 467-4577

FOR CLARIFICATION CALL YOUR IRB COORDINATOR

INCOMPLETE PROPOSALS WILL BE RETURNED TO THE INVESTIGATOR.