UNIVERSITY OF MIAMI
HUMAN RESEARCH EXPEDITED PROTOCOL

Instructions for Investigators

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among member of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. Protocols not approved by expedited review will be submitted for full IRB review.

Those protocols approved by expedited review are placed on the agenda to keep all members informed of which protocols have been approved under this procedure. The members may either; note the expedited approval, request additional protocol information, request changes to the protocol or consent form, or withdraw expedited approval.

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.

(Revised 6/04)

Research Categories:

(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.

(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 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 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   (a) hair and nail clippings in a nondisfiguring 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 gumbase 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 aster saline mist nebulization.

(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 devices 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 or 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.

(5) 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)(2) and (b)(3). This listing refers only to research that in not exempt)

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

(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). This listing refers only to research that in not exempt)

INFORMED CONSENT:

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained informed consent of the subject or the subject's Health Care Surrogate.

An informed consent form should include:

a. A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
b. A description of any reasonable foreseeable risks or discomforts to the subjects;
c. A description of any benefits to the subject;
d. A disclosure of appropriate alternative procedures of courses of treatment;
e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
f. An explanation as to whether any compensation is available;
g. An explanation as to whether any medical treatments are available if injury occurs and, if so, who will be responsible for the costs;
h. An explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of research-related injury to the subject;
i. An explanation of whom to contact for any questions about the subject's research rights;
j. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
k. Any additional costs to the subject that may result from participation in the research;
l. A statement should be added that subjects will receive a copy of the signed consent form.

All approved consent forms are stamped with an approval date by the Human Subjects Office. The investigators must have his/her subjects sign the approved IRB stamped consent form.

ASSENT FOR CHILDREN:

The age of majority in Florida is 18. For subjects under 18 years of age, consent must be obtained from the parent or court appointed legal guardian. In addition, the IRB requires assent from children 7 through 17 years of age. For these children, the following assent statement should be added to the informed consent form. This is to be filled in and signed by the child:

> "I agree_____ I do not agree _____ to participate in the above outlined study, which I have read or has been explained to me by_____."

Signature lines for the child, parent, and witness will be needed.

Non-English speaking participants:

If it is anticipated that non-English speaking subjects will participate in the study, a translated written consent form must be used and the consent interview must

be conducted in the same language as that of the translated written consent. The IRB must approve the written translation.

If a potential study participant is unexpectedly encountered who speaks a language that differs from any of the written informed consent(s) forms that have been prepared, a written translated consent form should be prepared. If the participant must be entered immediately for the well-being of that participant, it is required that the consent be fully verbally translated and that a "short form" be obtained. The "short form" should document that all of the elements of the full informed consent were presented orally and that a witness was present to observe the process. The participant and the witness must sign the "short form". The "short form" must be written in the participant's own language.

WAIVER OF INFORMED CONSENT:

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waives the requirements to obtain informed consent provided that the IRB finds;

(1) the research involves no more than minimal risk to the subjects;
(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) the research could not practicably be carried out without the waiver or alteration; and,
(4) whenever appropriate, the subjects will be proved with additional pertinent information after participation.

MODIFICATIONS AND ALTERATIONS TO THE PROTOCOL AND/OR CONSENT FORM:

No change in the protocol or consent form will be effective without prior approval by the IRB.

ADVERTISEMENT:

IRBs should review the methods that investigators use to recruit subjects. One method of recruitment is through advertisements. When advertising is to be used, the IRB must review and approve the information contained in the advertisement, and the mode of its communication, to determine that the procedure for recruiting subjects affords adequate protection.

CONTIUNING REVIEW:

A continuation report must be submitted by the investigator annually, unless the IRB requires more frequent reports. As a courtesy, the Human Subjects Research Office will send you a reminder.

If the continuation report is not submitted the study will be expired and notification will be sent to the Departmental Chairperson, Division Chief, and IRB. When the study is expired the Principal Investigator is notified that he/she cannot enroll new participants into the study effective immediately. If there are participants' safety concerns, the Principal Investigator is to notify the IRB

immediately. If the study is sponsored, the funding agency will be notified. If the study is expired, and the Principal Investigator wishes to continue the study, he/she will be required to submit an explanation as to why a continuation report was not submitted and a request for reactivation must be submitted along with the continuing report. The IRB could require that a new protocol be resubmitted to the IRB.

FINANCIAL CONFLICT OF INTEREST

Investigators signing this form certify that none of the individuals named in the proposed protocol (or their spouse or dependent children) have a financial interest in the sponsoring entity or any organization involved in this project or in the article(s), product(s), drug(s) or device(s) that may be used or involved in the study.

PRINCIPAL INVESTIGATOR STATEMENT OF ASSURANCE

This is a sequence of promises: that you won't make important changes in procedure without prior approval of the committee, that you will prepare timely annual and final reports as needed, that you will notify the IRB in writing within 10 working days of any adverse events according to the Policies and Procedures for the Protection of Human Research Subject, and that you will notify the IRB immediately upon termination of this study/and or departure from this institution or change in PI.

UM SIGNATURES

Signatures are required from the PI, Division Chief (if applicable), and Departmental Chair. A copy with the original signatures is required at the time of submission. If you are using the e-Prost system, “signatures” will be obtained electronically.

JMH SIGNATURES

Signatures are required from the PI, Division Chief (if applicable), and Departmental Chair. A copy with the original signatures is required at the time of submission. If you are using the e-Prost system, “signatures” will be obtained electronically.

WHO SHOULD SUBMIT A PROTOCOL

The University of Miami requires review and approval by and IRB of all research involving human subjects, whether conducted by its faculty, staff, or students. IRB review by the University’s IRBs applies to research conducted by the University and Jackson Memorial Hospital faculty, students, staff, or others, either on the University of Miami/Public Health Trust premises or elsewhere. The requirements apply to all research regardless of funding source or University support.

IRB CERTIFICATION

All key personnel must be IRB-certified before they can conduct human subjects research. Key personnel are defined as individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project. UM key personnel must take the Collaborative IRB Training Initiative (CITI) online for certification or receive certification by other means approved by the Assistant Provost for Human Subjects Research. Re-certification of key personnel will be conducted as required.

OUTSIDE FACILITIES/PHYSICIANS/COLLABORATORS

If you are conducting a study using the following:

- Facilities not affiliated with the University of Miami or JMH.
- Physicians who are not University of Miami, JMH or VA affiliated.
- Collaborators who are not University of Miami, JMH or VA affiliated.

You may be required to submit an agreement and letters of collaboration before conducting the study.

DEADLINES

There are no deadline dates for submitting expedited protocols. However, if the chairperson or designee does not approve the expedited protocol, the protocol will be submitted to the full committee.

The IRB committees meet twice a month. Please visit the IRB Web Page at hsro.med.miami.edu to obtain a list of the submission deadline dates.

WHERE TO SUBMIT

We are now accepting new protocol submissions only through the e-prost system. Please visit our website at hsro.med.miami.edu and request an account to enter the e-prost system. Please refer to the eProst: User Guide for Investigators under the e-Prost link in Investigator's Resources for guidance in using the system.

If you are sending your submission by campus mail, direct it to: "Human Subjects Research Office, Jackson Medical Towers, Suite 1000, interoffice mailing code (M-809), Medical Campus." If you are mailing it through the U.S. Mail, send it to Human Subjects Research Office, University of Miami School of Medicine (M-809), P.O. Box 016960, Miami Florida, 33101.