UNIVERSITY OF MIAMI
HUMAN RESEARCH EXEMPT PROTOCOL

Instructions for Investigators

Under the exempt review procedure the review will be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. The reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. Protocols not approved by exempt review will be submitted to the chairperson for expedited review.

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

Research activities in which the only involvement of human subjects will be in one or more of the following are exempt from federal regulations 45 CFR 46;

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (I) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (I) the human subjects are elected or appointed public official or candidates of public office: or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the

information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted or subject to the approval of Department or Agency heads, and which are designed to study, evaluate or otherwise examine: (I) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (I) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, the Food and Drug Administration or approved by he environmental protection Agency of the food Safety and inspection service of the U.S. Department of Agriculture.

(Areas to Pay Special Attention To)

Linking Information:

Item (4) notes that the review of medical records is exempt if the information collected is recorded by the investigator in such a manner that subjects cannot be identified. This means that an investigator must not maintain some type of linkage in order to go back and review the record at a later time. If linkage needs to be maintained, the protocol should be submitted for expedited review. Please review the guidelines and protocol form for Expedited Review.

Existing Data:

Collection of extra blood samples or tissue samples that are obtained at the time of a routine medical procedure are not considered to be “existing” since they were not stored and available prior to submission of the protocol to the IRB. This type of research will not qualify for exemption, but should be submitted for expedited review. Please review the guidelines and protocol form for Expedited Review.

Collection of “existing” blood samples or tissue for which additional information must be obtained from medical records will not qualify for exemption since there must be link through identifiers to match the samples to the records.

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.

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.

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 exempt protocols. However, if the chairperson or designee does not approve the exempt protocol, the protocol will be submitted for expedited or full committee review.

If the protocol is sent to the full committee, the 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” on our website 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.