

| Wayne State University<br>Human Investigation Committee |   |
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| <b>SUBJECT</b>  | Types of IRB Reviews  |
| <b>Section</b>  |   |
| <b>Form Date</b>  |   |
| <b>Approvals</b>  | 3/27/97 Steering Committee, 8/97 IRB Committees, 4/25/98, Steering 10/12/06, Administrative, 10/26/06 |

## Background

There are several types of Institutional Review Board (IRB) reviews based on the type of protocol submitted. The following is intended to assist the investigator in directing their protocol to receive the appropriate type of review. Ultimately, the Human Investigation Committee (HIC) will decide the type of review of a protocol will require. The types of reviews are:

- A. Exempted Reviews
- B. Expedited Reviews
- C. Full Board Reviews
- D. Single Use of a Test Article Review

## HIC Procedure

### A. Exempted Reviews

Below is a description of research projects at Wayne State University (WSU) that may qualify for exemption from review by the IRB for medical research. Research is defined as "*a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.*" If an investigator believes that his/her project qualifies for exemption, this form should be completed and submitted with the original complete protocol. A designated member of the HIC must "*concur*" that the project qualifies for exemption. Please call (313) 577-1629 for a list of members of the HIC who are designated to "*concur*" with an investigator's recommendation.

If identifiers that can be linked directly to an individual research subject (Name, Social Security Number, Hospital Admission Number, Specimen Number, etc.) are to be collected, the research project does not qualify for **Exemption** and the investigator must submit the project for **Expedited or Full Board** review.

A research project cannot start until after "*concurrence*" by a designated member of the HIC or reviewed by one of the Institutional Review Boards. Retroactive "*concurrence*" or review by an Institutional Review Board cannot occur.

Investigators should submit a copy of the completed *Exempted Medical Protocol Review Form* and one copy of the research project.

**Exemption Categories:** Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from review by the WSU IRB.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - a. research or regular special education instructional strategies; or
  - b. 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:
  - a. Information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subject; and
  - b. any disclosure of the human subjects' responses could reasonably place the subjects at criminal or civil liability, 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:
  - a. the human subjects are elected or appointed public officials or candidates for public office; or
  - b. 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 subject. (*Note: To qualify for this exemption, the data, documents, records, or specimens must be in existence before the project begins.*)

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- a. public benefit or service programs;
- b. procedures for obtaining benefits or services under those programs;
- c. possible changes in, or alternatives to, those programs or procedures; or
- d. 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;

- a. if wholesome foods without additives are consumed, or
- b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural, chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

**Deadline:** There is no deadline. Requests for exempt status will be reviewed as they are received.

**Submission:** One copy of the full research proposal and the Exempted Medical Protocol Form.

**Investigator Notification:** Notification will be mailed to the investigator. Concurrence by the designated HIC member will be provided within 5 working days.

## B. Expedited Reviews

### 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).<sup>1</sup> 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 normal.

(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.

### 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<sup>2</sup>, 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.
3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples are:
  - a. hair and nail clippings in 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 internal 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 after 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 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.

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 subject. 45 CFR 46-101(b)(4). This listing refers only to research that is 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, 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.)

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.
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.

<sup>1</sup> 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.

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

**Deadline:** There is no deadline for submission of expedited reviews.

**Submissions:** One copy of each of the following:

*Full Research Proposal*

*Completed Protocol Summary Form*

*Consent Form*

*Brochure*

*Miscellaneous Material*

**Investigator Notification:** Notification will be mailed to the investigator within 5 working days of receipt in the HIC office.

### C. Full Board Reviews.

All proposals that are not exempted or expedited go for a full board review.

**Deadline:** All documents must be received 15 calendar days before the next IRB meeting. Medical IRBs meet as follows: M1 meetings are held on the 1<sup>st</sup> Thursday of every month; MP2 meetings are held on the 2<sup>nd</sup> Thursday of each month; B3 meetings are held on the 3<sup>rd</sup> Thursday of the month and MP4 meetings are held on the 4<sup>th</sup> Thursday of every month.

**Submission:** The following documents should be submitted:

*Full Research Proposal 3 copies*

*Brochure 3 copies*

*Protocol Summary Form 25 copies*

*Miscellaneous Materials 25 copies*

**Investigator Notification:** Notification will be mailed to the investigator within 5 working days following the IRB meeting.

#### D. Single Time Use of a Test Article Reviews

Adult or pediatric subjects whose condition mandates the need for medical care which falls outside the standard of practice, or for which there is currently no available HIC approval research protocol.

**Deadline:** There is no deadline

**Submission:** Descriptive letter indicating the patient's medical condition, an abstract of the medical care planned, the informed consent form, and the introduction questionnaire, plus 3 additional copies of the entire submission. Verbal approval will not be given without a review of the aforementioned material.