

## Chapter 9

# TYPES OF REVIEW

Two types of review will be conducted by the Institutional Review Board to insure that all research involving human subjects conforms to federal regulations:

1. Administrative Review  
Exempt review is conducted by the Research & Grants Review Coordinator.  
Expedited review is conducted by the Chair of the IRB and/or his/her designee(s), and
2. Full-Board Review.

The type of review a project receives depends upon the risks to potential subjects posed by the research. The probability and severity of possible harm (physical, psychological, social or economic) may vary from minimal to significant. Federal regulations define only minimal risk (46.102(i): "that the probability and magnitude of harm or discomfort anticipated in the research are no greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests". This definition of minimal risk serves as the benchmark to determine whether proposed studies are eligible for an abbreviated administrative review or require the review of the full Board.

Research that is eligible for administrative review is termed either "exempt" or "expedited." Before preparing an IRB protocol, the types of research that are eligible for administrative review should be checked.

The preliminary determination that a research project is eligible for review, according to one of the these categories, may be made by the investigator, according to these guidelines, or the investigator may contact the Office of Research and Grants Administration to request assistance from the IRB Staff Assistant in determining the appropriate review process for the particular study in question. The sections that follow outline the specific criteria to be used to determine whether a study is eligible for exempt, expedited or full board review.

**Note:** Due to the different categories of research, each protocol will vary in the requirements for forms that need to be completed.

### A. *EXEMPT STATUS*

**Definition:** Exempt Research is research that does not require expedited or full-board review by the IRB, although it does require an "exemption approval".

**Categories for Exemption from Board Review:** A project is exempt if all the research activities belong in one or more of the following categories:

**(1) Educational Research Conducted in Educational Settings:** "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) Survey/Interview/Observational Research:** “Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or 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.” **For surveys/questionnaires, a cover letter containing 1) purpose of study, 2) statement that responses will be kept anonymous and/or confidential, 3) statement that subject is being audiotaped (if applicable), 4) statement that not all questions must be answered, 5) statement that participation is voluntary, and 6) if a student or employee, a statement that class standing, grades or job status will not be affected. Include a copy of the survey/questionnaire(s).**

**(3) Survey/Interview Research not Exempted in (2), Above:** “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 (2) of this section, if : (i) the human subjects are elected or appointed public officials or candidates for 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.” **For surveys/questionnaires, a cover letter containing 1) purpose of study, 2) statement that responses will be kept anonymous and/or confidential, 3) statement that subject is being audiotaped (if applicable), 4) statement that not all questions must be answered, 5) statement that participation is voluntary, and 6) if a student or employee, a statement that class standing, grades or job status will not be affected. Include a copy of the survey/questionnaire(s).**

**(4) Secondary Use of Existing Data:** “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.” **Attach Form 7 if using pathological or diagnostic specimens. Note: Protocol termination date must be prior to date of protocol submission to the IRB for data to qualify as “existing” data.**

**(5) Evaluation and Demonstration Projects of Federal Programs:** “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: (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 Studies:** “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, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.”

**Note:** Any research in which the subjects or their legal representatives sign a consent form can not qualify as exempt and must undergo expedited or quorum review.

Any research in which the subjects are filmed or videotaped can not qualify as exempt and must undergo expedited or full-board review. However, some benign studies in which subjects are audiotaped may qualify for exemption.

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## **Exempt Research Involving Children**

Exemption category (2) above is NOT applicable to research involving children or minors. Children or minors are defined as persons under 18 years of age (in some cases this may be 21 years of age.)

## **Procedures for Requesting an IRB Exemption**

### **1. Application**

The Application for Exemption is obtained by contacting the Office of Research and Grants Administration. Following a determination of exemption by the investigator and Research and Grants Administration, the Application for Exemption must be completed and returned to the Office of Research and Grants Administration along with all appropriate attachments for review and approval.

### **2. Attachments**

- **Exempt Application**
- **Special Clearance Forms. The signed Administrative Signature Approval Form for Human Subject Research is required at the time of submission of the application.**
- **Data Forms** - include questionnaires, surveys and data collection form(s). If questionnaires or surveys are to be used, you must attach a copy to the application. Questionnaires that will be administered via telephone interview will require submission of the interviewer's text.

**Note: Not all research studies will contain all of these elements.**

### **3. Submission of Materials**

Submit the original of the Certification of Exemption at any time to the Office of Research and Grants Administration along with all appropriate attachments. **The Administrative Signature Approval Form for Human Subject Research must have all appropriate administrative approvals at the time of submission of the application.**

### **4. Review**

The Certification of Exemption is reviewed by the Research and Grants Review Coordinator. This process will usually take no longer than two (2) days. If there are any questions or concerns, the Coordinator will contact the Investigator(s) or designee directly for clarification or to request any written revision(s). The Chair of the CAMC/WVU IRB reviews the HIPAA portion of the submission and provides approval through his/her signature on the HIPAA document.

The Coordinator will:

- verify qualification of exemption

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- verify information provided
- refer the protocol for Expedited or Full-board review as needed
- provide a monthly report of exempted research to the IRB's regularly scheduled monthly meeting.

## 5. Approval

The Principal Investigator will receive a "Notification of Exemption" letter from the Office of Research and Grants Administration following protocol review and verification of exemption. The Investigator may not advertise, enroll participants or initiate data collection until he/she has received this letter. All projects that qualify for and which are granted exemption from IRB review will be reported to the IRB at the next regular monthly meeting.

## ***B. EXPEDITED REVIEW***

**Definitions:** **Expedited Review** is the review of a protocol by one or two board members and applies to certain types of "low" or "minimal risk" research, and is not meant to be indicative of the length of the review period.

**Minimal risk** means that the probability and/or magnitude of physical or psychological harm does not exceed that encountered in ordinary daily life or during routine physical or psychological examinations or tests.

### **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) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.

To qualify for expedited review, research must be included in one or more of the following categories.

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

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- (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, 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 less 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 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 subjects. 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,

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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.)

**Note:** All research eligible for expedited review remains subject to the requirements of informed consent.

### **Expedited Review of Research Involving Children**

See Section 2.0, Chapter 7, for special instructions regarding children as research subjects. If you request expedited review of research involving children, you must provide for obtaining consent (permission) of each child's parent(s) or legal guardian(s) and assent of the child.

### **Procedures for Requesting Expedited Review**

**Determination of Expedited Category:** If the investigator has determined that his/her study should receive an expedited review by the IRB, please adhere to the following application instructions:

#### **1. Application**

To apply for expedited review, the Investigator must complete the Application For Expedited Review which is contained as part of the entire Research Approval Forms packet and may be obtained from the Office of Research and Grants Administration.

#### **2. Attachments to Application**

- **Special Clearance Forms**
- **Data Forms** - include questionnaires, surveys and data collection forms. If questionnaires or surveys are to be used, you must attach a copy to the application. Questionnaires that will be administered via telephone interview will require submission of the interviewer's text.
- **Consent/Assent Forms**
- **Sponsor Agreement, Clinical Study Protocol and Sponsor Consent Form**

**Note:** Not all research studies will contain all of these elements.

#### **3. Submission of Materials**

Submit the original and 2 copies of the Application for Expedited Review by the first working day of the month. **Note: Investigator initiated protocols should submit the original application and enough additional copies for review by the Institutional Scientific Review Board.**

#### **4. Review**

All applications will be pre-screened by the IRB Staff Assistant and then assigned to one or two members of the IRB. Voting is done by ballot and on this ballot the IRB member

will indicate if the study will require continuing review more often than annually. This expedited review process usually takes no longer than two weeks unless the research is investigator initiated. If there are any questions or concerns by the IRB Reviewer, the IRB Staff Assistant will be responsible for contacting the Investigator(s) directly for clarification or to request any revision.

### **Approval**

The PI will receive a Letter of IRB Approval from the IRB Chairman following expedited review. The PI may not advertise, enroll subjects, or implement the study until receipt of the approval letter. All projects which qualify for and which are granted expedited review will be reported at the next regular monthly IRB meeting.

## ***C. FULL-BOARD OR QUORUM REVIEW***

**Definition.** Full-Board or Quorum Review is the review of a protocol by a quorum of board members attending the monthly IRB meeting.

### **Procedures for Requesting Full-Board Review**

**Determination of Full-Board Review:** If the proposed research does not satisfy the guidelines for exempt or expedited review, the IRB, as a full committee, will consider the proposal. The following review process and schedule will be followed throughout the year:

#### **1. Application For Full-Board Review**

To apply for full-board review, the Investigator must complete the Human Subjects Protocol Statement which is contained as part of the entire Research Approval Forms Packet, and may be obtained from the Office of Research and Grants Administration.

#### **2. Attachments to Application**

- **Special Clearance Forms**
- **Data Forms** - include questionnaires, surveys and data collection forms. If questionnaires or surveys are to be used, you must attach a copy to the application. Questionnaires that will be administered via telephone interview will require submission of the interviewer's text.
- **Consent/Assent Forms**
- **Advertisements**

Advertisements used to recruit subjects must be approved by the Board. Recruiting advertisements must contain:

- a. the name and address of the investigator;
- b. the purpose of the research and, in summary form, the eligibility criteria for subjects;
- c. the location of the research;
- d. if appropriate, a brief description of the procedures;

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- e. a description of the potential benefits;
- f. the person to contact for further information;
- g. time or other commitment required of the subjects.

For drug or device studies, no claims may be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation or that the drug or device is in any way equivalent or superior to any other drug or device.

- **Sponsor Agreement, Clinical Study Protocol and Sponsor Consent Form**

### **3. Submission of Materials**

The Investigator must submit the original and enough copies (see application 3 for number of copies) of all appropriate research materials to the Office of Research and Grants Administration by the 1st working day of the month, except as holidays impact the schedule. **Note: Investigator initiated protocols should submit the original application and enough additional copies for the Institutional Scientific Review Board.**

### **4. Review**

All IRB meetings are scheduled for the **FOURTH TUESDAY OF EVERY MONTH**. There can be no exceptions to this deadline. Any protocols which arrive after the deadline will be put on the next month's agenda.

The Investigator or his/her designee is required to attend the IRB meeting for which their protocol is being reviewed. Failure to attend the meeting will postpone review of the protocol by the IRB. In emergent situations, the Investigator may request in writing to the chair that he/she send a designated person to represent him/her at the meeting. The designee must be well versed on the protocol and consent document.

### **5. Approval**

#### **Results of Full-Board Review:**

At its monthly meeting, the Board may:

- approve the protocol as submitted,
- require modifications (changes must be made within 90 calendar days),
- request additional information (information must be received within 90 calendar days),
- disapprove the protocol
- \* table the protocol

The PI will receive a Letter of Approval from the IRB Chairperson following Full-board review along with the stamped approved consent/assent form. The PI must use a copy of the stamped consent form when obtaining patient/subject informed consent. Any changes to the consent/assent form must be submitted to the IRB for approval prior to implementation.

### **6. Board Voting Process**

At the full board meetings, the Board members vote by written ballot on study actions such as initial study review and approval, full board continuing review, full board amendments/revisions,

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full board adverse event reviews. The ballots allow for each member to vote for approval, approval pending request for changes, approval pending receipt of more information, disapproval, abstention, recusal, and tabled. The majority vote rules, but all votes are indicated in the minutes. Study ballots are kept on file with the individual study folders. The Ballot also asks for each Board member to indicate an interval for continuing review. The options are 3 months, 6 months, 9 months and the default is annual review if none of the others are checked on the ballot. The majority vote on the interval rules. If the review is to be less than annually, this will be indicated in the minutes.

#### **7. Conflict of Interest for Board Members and the Voting Process**

A member will leave the room during the discussion and voting of a study for which he/she has a conflict of interest unless asked to provide information to the Board. The member will also either mark abstain or recuse on the ballot, as appropriate, when he/she has a conflict of interest on a study that is being voted on by the Board.