Expedient Review

The OU IRB Chair and one member of the OU IRB review expedited research studies. The protocol and accompanying forms will be distributed to the additional reviewing member of the IRB. . In reviewing the research, the reviewer may exercise all of the authorities of the full Board except that the reviewer may not disapprove the research. Additionally, the reviewer may refer the application to the full Board for review as warranted. Once approved, they are continually reviewed by the IRB, usually on an annual basis. The principle investigator is responsible for submitting all required documentation noted in the Initial Review section of this document to the IRB Chair or designee. The OU IRB Chair or designee will notify the principle investigator in writing of the IRB review and if any modifications or clarifications are required by the IRB as a condition for IRB approval of proposed research, date for continuing review and action on investigator responses. All members of the Oakwood IRB , Director of Research and the Vice President of Academic Affairs will be notified of all IRB reviews, findings and activities in semi to annual reports.

Research approved for Expedient Review

Appropriate Use of Expedited Review Procedures. Federal regulations limit the use of expedited review procedures to specific research categories published in the Federal Register. Use of expedited review by the IRB must be restricted to those applications that fulfill one of the following nine categories. The categories on the list apply regardless of the age of subjects, except as noted.

a. Minimal Risk. Research activities that (A) present no more than minimal risk to human subjects, and (B) involve only procedures listed in one or more of the specific nine categories (see paragraph 4 below), may be reviewed by the IRB using the expedited review procedure.

i. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

ii. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

iii. The nine categories should not be deemed to be of minimal risk simply because they are included on the list.

iv. Inclusion on the 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 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. Additionally, the

expedited review procedure may not be used for government classified research involving human subjects.

According to 63 FR 60364-60367, November 9, 1998 and 63 FR 60353-60356, November 9, 1998 www.hhs.gov/ohrp/humansubjects/guidance the following categories of research are permitted to receive expedient review

(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 www.hhs.gov/ohrp/humansubjects/guidance 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 www.hhs.gov/ohrp/humansubjects/guidance] 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 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 non-disfiguring 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 DHHS regulations for the protection of human subjects--see Exempt Research and 45 CFR 46 101(b)(4)--www.hhs.gov/ohrp/humansubjects/guidance
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, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects--see Exempt Research and 45 CFR 46.101(b)(2) and (b)(3)-www.hhs.gov/ohrp/humansubjects/guidance
-this listing refers only to research that is not exempt).

(8) Continuing review of research that is greater than minimal risk and has been initially reviewed and approved by the convened full-board 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.

Research that Cannot Be Expediently Reviewed

According to 45 CFR 4.110; 21 CFR 56.110 (www.hhs.gov/ohrp/humansubjects/guidance) expedited review procedure may not be used for the following research protocols, even if the research falls under one of the 9 categories of research that may be reviewed through an Expedited review procedure.

1 Research 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.

2.Classified research involving human subjects.

3.Research that involves more than minimal risk to human subjects (i.e. the probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

Submission Deadlines

Expedited protocols must be submitted to the OU IRB for review at least two weeks prior to the date on which investigators plan to start data collection and include requirements identified in previous section Initial Review. Human subjects may not be recruited or research initiated until final IRB approval has been received in writing. If the investigators wish to begin collecting data during a long break (e.g. winter break or summer break), then the protocol should be submitted for review at least two weeks prior to the start of the break.

Expedited research is approved for a maximum period of one year. Renewal requests must be submitted at least two weeks prior to the approval expiration date. The approval expiration date is clearly noted on all OU IRB certifications sent to the principal investigator and must be strictly adhered to. If the approval expiration date occurs during a long break (e.g. winter break or

summer break), then the request for continuing review should be submitted at least two weeks prior to the start of the break.

Continuing Review and Modification of Active Expedited And Full Board Reviews

Ongoing expedited research studies and Full Board approved research studies must be reviewed by the OU IRB at least annually, or more often, if the IRB finds that the degree of risk to subjects warrants more frequent review This renewal must take place prior to the approval expiration date; otherwise, subject recruitment/enrollment must be suspended and, if the research is DHHS-sponsored, the agency must be notified. The continuation of research after expiration of IRB approval is a violation of the regulations
If the IRB has not reviewed and approved a research study by the study's current expiration date (i.e. IRB approval has expired), research activities should stop. The Continuing Review section of this document addresses specific requirements of the principle investigator. A Continuing Review and Termination Form must be completed by the Principle Investigator

Modification of an Approved Expedited And Full Board Protocols

Investigators must seek OU IRB approval before making any modifications or amendments to approved research, even if the changes are planned for the period for which IRB approval has already been given, unless making a prompt change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified at once). Please note that IRB approved modifications or amendments to ongoing research do NOT extend the original approval expiration date. Modifications may be approved if they are within the scope of what the OU IRB originally authorized.

Required Reports of Approved Expedited and Full Board Protocols

Adverse Events Report
Submitting an Adverse Events Report within 10 working days to the OU IRB chair is required when any unanticipated problem or serious adverse event involving risks to subjects or others occurs. This includes study-related injuries or events, including those that are previously unknown reactions that are more severe than mild, as well as expected or well-described reactions that are either life-threatening or fatal. If any aspect of the research involves FDA oversight, any adverse event or unexpected problem involving risks to human subjects or others must be reported to the FDA as well as the IRB. The Principle Investigator is responsible for submission of an Adverse Event Form being submitted to the OU IRB.