Request for Expedited Review of Research

Investigator:	Date:
Title of Project:	

Directions: This form needs to be neatly typed and submitted with the Application form to the IRB only when the principal investigator (PI) is thinking about beginning a research project that the PI believes qualifies for an expedited review. Submit one signed original and one copy (not 14). Send the submission to the DSHS Program Contact.

Definition: **Expedited Review** -- Review of proposed research by the IRB Chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Notes: 1) Studies involving prisoners as subjects will not be accepted for expedited review.
2) In the context of research review by an IRB, expedited does not necessarily mean quick or fast.

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.

Categories Eligible for Expedited Review (Please check the relevant category.)

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 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), **or**

   (b). Research on medical devices for which (i) an investigational device exemption application 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 from:

   (a). 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). 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.

   Note: 'Children' in (b) above is defined in the HHS regulations as "persons who have not attained the legal age for consent for treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" [45 CFR 46.402(a)].

3. ☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples are:
   (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 gum base 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 sub-gingival 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, 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.)

8. ☐ Continuing review of research previously approved by the convened IRB as follows:
   ☐ (a.) Where:
      ☐ (1.) The research is permanently closed to the enrollment of new subjects, ***and***
      ☐ (2.) All subjects have completed all research-related interventions, ***and***
      ☐ (3.) 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 2 through 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.

Signature of Investigator Date