

## EXPEDITED RESEARCH CATEGORIES

The following types of research may be reviewed by the Institutional Review Board under an expedited review procedure (45 CFR 46.110 and 21 CFR 56.110). These research activities 1) present no more than minimal risk to human subjects, and 2) involve only procedures listed in one or more of the following categories. [Note: 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.]

### CATEGORY 1

Clinical studies of **drugs and/or devices** only when:

- a) Research on drugs for which an investigational new drug [IND] application is not required (21 CFR Part 312). (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 [IDE] is not required (21 CFR Part 812); **or**
  - ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

#### **Information Required for Justification**

1. State the name of the commercially available drug to be used as described in the above requirements, **or** state the name of the approved device and confirm its use as described above.
2. Confirm that the research does not increase the risks or decrease the acceptability of the risks associated with the use of the product.

### CATEGORY 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.

#### **Information Required for Justification**

1. State how the blood sample(s) will be collected.

2. Provide the health status of the research population and state whether pregnant women are eligible to participate.
  - (a) For healthy, nonpregnant adults who weigh at least 110 pounds –  
Confirm that the amounts of blood to be drawn will not exceed 550 ml in an 8 week period **and** will not occur more frequently than 2 times per week.
  - (b) For other adults (e.g., with an illness) or children\*  
Confirm that the amount of blood to be collected will not exceed the lesser of 50 ml or 3 ml p/kg in an 8 week period and not occur more frequently than 2 times per week.

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

### **CATEGORY 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.

### **Information Required for Justification**

1. State the biological specimen(s) to be collected.
2. Describe the noninvasive method by which the specimens will be collected.

#### **CATEGORY 4**

The 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 of such procedures:

- a) physical sensors applied 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 (MRI);
- d) electrocardiography (ECG or EEG);
- e) thermography;
- f) detection of naturally occurring radioactivity;
- g) electroretinography;
- h) ultrasound;
- i) diagnostic infrared imaging;
- j) doppler blood flow;
- k) echocardiography;
- l) moderate exercise. . . where appropriate, given age, weight, and health of the individual.

#### **Information Required for Justification**

1. State the type of data to be collected.
2. State the source of the data and the procedure that will be used to collect the data.

#### **CATEGORY 5**

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for *non-research* 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.)

#### **Information Required for Justification**

1. State the type of materials and the purpose for which it was, or will be, collected.
2. State the source of the material and whether it is currently existing (i.e., on the shelf at the present time) or will be collected prospectively.

## **CATEGORY 6**

Collection of data from voice, video, digital, or image recordings made for research purposes.

### **Information Required for Justification**

1. State the type of data and its original (clinical or research) purpose(s); how data will be stored; and who will have access.
2. State whether there will be identifiable information on the tapes and when the tapes will be destroyed.

## **CATEGORY 7**

Research on individual or group characteristics or behavior including, but not limited to, research on:

- |                                       |           |                                       |
|---------------------------------------|-----------|---------------------------------------|
| a) perception,                        |           | <u>Research employing -</u>           |
| b) cognition,                         |           | l) survey                             |
| c) motivation,                        |           | j) interview                          |
| d) identity,                          | <b>OR</b> | k) oral history                       |
| e) language,                          |           | l) focus group                        |
| f) communication,                     |           | m) program evaluation                 |
| g) cultural beliefs or practices, and |           | n) human factors evaluation, or       |
| h) social behavior,                   |           | o) quality assurance<br>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.)

### **Information Required for Justification**

1. State whether this is research on individual or group characteristics or behavior.
2. State the method to be used to gather the data.

Your research is renewed, usually annually, with an expedited review allowable if the research was originally approved under an expedited review process. At renewal time you will be required to complete an IRB Form CR to satisfy the regulatory requirements for continuing review of research.