

APPENDIX D: EXPEDITED REVIEW CHECKLIST

*The following are research activities eligible for Expedited review. Note: the Expedited review procedure may not be used with human participant research involving prisoners (use Full Review Application). Place an X to the left of **Expedited Category(s)** that apply to your research assignment.*

- ☐ 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. **OR**
 - 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 FDA cleared/approved and the medical device is being used in accordance with its cleared/approved labeling.

- ☐ Collection of blood samples by finger stick or ear stick from healthy, non-pregnant adults who weigh at least 110 pounds. Collection may not occur more frequently than 2 times per week.

- ☐ Prospective collection of biological specimens for research purposes by noninvasive means. *For example:*
 - a. Hair and nail clippings in a non-disfiguring manner;
 - b. Excreta and external secretions (including sweat);
 - c. 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;
 - d. Placenta removed at delivery;
 - e. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - f. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

AND/OR

 - g. Sputum collected after saline mist nebulization, or inline suctioning.

- ☐ Collection of data through noninvasive procedures routinely employed in the research environment. *Examples include:*
 - a. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
 - b. 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;
 - c. Weighing or testing sensory acuity;
 - d. Magnetic resonance imaging;
 - e. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - f. Excluding clinical procedures involving x-rays or microwaves. 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.

- ☐ 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.

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

- ☐ Non-manipulative, non-stressful research on individual or group 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.

- ☐ Written or oral presentation of Exempt Research.

If one or more categories are checked, the research assignment is eligible for Expedited Review. Attach checklist to your Expedited Application and Protocol material. If NO box is checked, your research will need FULL BOARD review.