

## Application for Expedited Review by The UHSC

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip \_\_\_\_\_

Telephone: (     ) \_\_\_\_\_ Email: \_\_\_\_\_

Course Title & Number (if applicable): \_\_\_\_\_

Course Instructor (if applicable): \_\_\_\_\_  
Signature Date

Research conducted may receive expedited review by the UHSC if the research involves no more than minimal risk and fully meets at least one of the following (please check all that apply):

\_\_\_\_\_ 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. (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.

\_\_\_\_\_ 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.

\_\_\_\_\_ Prospective collection of biological specimens for research purposes by noninvasive means.

\_\_\_\_\_ 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).

\_\_\_\_\_ 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 UHSC 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.

\_\_\_\_\_ 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 UHSC 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).

I hereby certify that my research fully meets the categories indicated above. In the event that my research becomes ineligible for such expedited review, for any reason, I will re-apply for appropriate UHSC review.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date