



Institutional Review Board

Request for Initial Review by Expedited Review Procedure

Instructions: To request an initial review by expedited procedure, please submit this form and associated documents to the Wellstar Research Institute (WRI) via the WRI Inbox (research@wellstar.org). If you have any questions about whether an activity meets the criteria for expedited review, please contact the WRI for guidance. Although you are requesting an initial review by expedited procedure, it still must have final approval by the IRB before initiation.

Principal Investigator
E-mail

Department
Phone

1. Protocol Information

Note – if you request review by an Expedited Review process and the research does not qualify for Expedited review, this may delay the review of your research.	
Sponsor	
Protocol Title	

2. Minimal Risk

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. (21 CFR 56.102 A (i))

Explain how the research activity presents no more than minimal risk (including risks of breaches of confidentiality of protected health information) to human subjects

3. Category for Expedited Review

Please indicate which of the categories below applies to the proposed research. Check all that apply. At least one category must be selected

- 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 (21 CFR Part 312) is not required.***
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.
- 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 eight week period, and collection may not occur more frequently than two 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 eight week period, and collection may not occur more frequently than two times per week.**

Category 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 the 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.

Category 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.

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve the 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.

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.)

Category 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). This listing refers only to research that is not exempt.

<input type="checkbox"/>	Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.
<input type="checkbox"/>	Category 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. This listing refers only to research that is not exempt.
<input type="checkbox"/>	Category 8: Continuing review of research previously approved by the convened 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.
<input type="checkbox"/>	Category 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.

Please attach the following documents to complete your submission:

1. Full research proposal or protocol
2. Informed consent document, if applicable
3. HIPAA Authorization, if applicable
4. All collection tools which will be shared with potential human subjects (e.g., fliers, script used to ask to collect samples, surveys, focus group questions)
5. Evidence of training in the protection of human subjects, good clinical practice, and conflicts of interest

Principal Investigator Assurance and Acknowledgement

I certify that the information provided in this application and supporting documentation is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protections of the rights and welfare of human subjects, and strict adherence to any situations designated by the IRB. I accept and will conform to all federal, state, institutional, and IRB provisions concerning the protection of human subjects in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project and in the protection of human subjects. I recognize that this study may not begin until it has the approval of the IRB as indicated by an IRB approval letter. I will submit any proposed changes for review and approval before they are implemented and notify the IRB of any unanticipated problems that may occur during the study.

Principal Investigator (printed name)

Date

Principal Investigator signature