



<b>IRB USE ONLY</b> Protocol No. _____ Program(s) Review: _____ Date of Review: _____
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**APPLICATION FOR EXPEDITED PROTOCOL  
OHIO DEPARTMENT OF HEALTH (ODH)  
Institutional Review Board (IRB)**

Complete this form to request expedited review of the proposed research. If the research meets the conditions for expedited review, the review of the protocol will be carried out by the IRB chairperson. See [45 CFR 46](#) and [21 CFR 56](#) for more information.

<b>Principal Investigator (PI) Name:</b>	
<b>Project Title:</b>	
<b>Project Description:</b> <i>(You may extend the size of the text box or attach additional documentation if necessary)</i>	

**Conditions required for expedited IRB review:**

- 1) The Federal Regulations establish two main criteria for an expedited review:
  - a) The research may not involve more than "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" ([45 CFR 46.102\(i\)](#) and [21 CFR 56.102\(i\)](#)).
  - b) The entire research project must be consistent with one or more of the federally defined categories (listed below).
- 2) The categories in this list apply regardless of the age of the participants, except as noted.
- 3) The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participant's 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.
- 4) The expedited review procedure may not be used for classified research involving human subjects.
- 5) Investigators and IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review (i.e., expedited or convened) utilized by the IRB.

**NOTE: Previously collected data does not necessarily qualify the protocol for expedited review.**

**Indicate all categories that describe the research project.**

<input type="checkbox"/>	(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 ( <a href="#">21 CFR 312</a> ) 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 ( <a href="#">21 CFR 812</a> ) 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.
<input type="checkbox"/>	(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, 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.

	(b) from other adults and children (defined as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” <u>45 CFR 46.402(a)</u> ), considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.
<input type="checkbox"/>	(3) Prospective collection of biological specimens for research purposes by non-invasive means. <u>Examples:</u> (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 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.
<input type="checkbox"/>	(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.) <u>Examples:</u> (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 participant or an invasion of the participant’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.
<input type="checkbox"/>	(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 <u>45 CFR 46.101(b)(4)</u> . This listing refers only to research that is not exempt.)
<input type="checkbox"/>	(6) Collection of data from voice, video, digital or image recordings made for research purposes.
<input type="checkbox"/>	(7) Research made 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 <u>45 CFR 46.101</u> (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

<b>Additional Information</b>	
Why do you believe your request for data meets the minimum criteria for expedited review?	

Are any data sets from ODH being requested?

Yes (If Yes, this form MUST be signed by the ODH data steward who will be providing the requested data.)

No

Data Steward Name: \_\_\_\_\_

Program: \_\_\_\_\_

I certify that the data being requested for this protocol is de-identified according HIPAA and state law standards and publicly available.

Data Steward Signature: \_\_\_\_\_