

DEPARTMENT OF PUBLIC HEALTH INSTITUTIONAL REVIEW BOARD

REQUEST FOR EXEMPTION OR EXPEDITED REVIEW

Please check the appropriate boxes and attach any additional explanation. Justification and support for the requested exemption or expedited review should be explicit or clear in other documents submitted as part of this application.

Check either main heading I and subsection A or B, or main heading II and subsection 1, 2, 3, 4, 5, 6, 7, or 8.

I. Request for Exemption from Detailed IRB Review

A.  **Exempt as Non-Research** Activities involving data collection from or about human subjects is considered **research** under federal regulations if it, in whole or in part, constitutes “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” If you believe your project is exempt as non-research, check the category below which best fits or explain after checking “other.”

a. **Routine public health activity**, such as disease surveillance, outbreak investigation or standard service delivery.

b. **Program evaluation**, of an existing public health program or a new or adapted program involving standard, accepted methods or interventions. “Non-research” program evaluation may be of general interest and publishable, but its purpose is to monitor the implementation and/or effectiveness of an accepted program in a given area. Program evaluation may also contain elements of research or have the dual purpose of contributing to generalizable knowledge that advances the field and if so, should be submitted for either expedited or full committee review rather than for exemption.

c. **Program planning**, such as focus groups or key informant interviews with current or potential clients and/or service providers, for the primary purpose of assessing the need and most effective means of providing a possible service or program.

d. **Other** (specify)

B.  **Research of an Exempt Type**, because it is in one or more of the following categories, and does not involve prisoners as research subjects:

a. Research involving surveyor interview procedures, except where all of the following conditions exist: (1) if the subjects responses became known, they could place the subject at risk of criminal, or civil liability, or be damaging to the subjects’ financial standing or employability, or (2) the research deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. *In other words, exempt research cannot involve sensitive subject matter.*

b. Research involving the observation of public behavior, except where responses are recorded in a manner that subjects can be identified.

c. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified. *Under this category, the data must be either publicly available or de-identified from the outset.*

II. Request for Expedited Review

A. Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the expedited review procedure. *Please note that eligibility does not automatically guarantee expedited review. The IRB Chairperson or designee has complete discretion to refer any application for full committee review.*

1. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, w-rays and microwaves).

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- 2. Collection of blood samples by venipuncture in amounts not exceeding 450 millimeters in an eight week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
- 3. Collection of both supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- 4. Voice recording made for research purposes such as investigations of speech defects.
- 5. Moderate exercise by healthy volunteers.
- 6. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- 7. Research on individuals or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- 8. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

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