

# Exemption for Research Involving Human Subjects Criteria Form

Project Title: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Unless otherwise required by Department or Agency heads, research activities in which the involvement of human subjects will be in one or more of the following categories are exempt from review by the entire Committee for the Protection of Human Research Subjects (CPHRS). All of the project activity must qualify as exempt according to one of the criteria below for the project to be ruled exempt from CPHRS review.

Note: listed exemption categories do not apply when the research activities include:

- a. **prisoners, fetuses, pregnant women or human in vitro fertilization**
- b. **survey or interview techniques which include minors (under 18 years of age) as subjects**
- c. **research involving the observation of the public behavior of minors (under 18 years of age)**
- d. **the deception of the subjects**
- e. **techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life (the research activity presents more than minimal risk to human subjects)**

**Instructions:** check the applicable category(s) which make this research applicable for exempt review.

- \_\_\_\_\_ EX1: Is this research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular and special education instructional strategies, **OR** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- \_\_\_\_\_ EX2: Does this research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **WITHOUT** : information being obtained and recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, **OR** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- \_\_\_\_\_ EX3: Does this research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **EXCLUDING**: human subjects who are elected or appointed public officials or candidates for public office, **OR** federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research thereafter.
- \_\_\_\_\_ EX4: Does this research, involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens where the subjects cannot be identified, directly or through identifiers linked to the subjects?
- \_\_\_\_\_ EX5: Is this research or demonstration project(s) subject to the approval of department or agency heads designed to study, evaluate, or examine (**ONLY ONE CRITERIA NEEDS TO APPLY**): Public benefit or service programs? Procedures for obtaining benefits or services under programs? Possible changes in or alternatives to those programs or procedures? Possible changes in methods or levels of payment for benefits or services under those programs?
- \_\_\_\_\_ EX6: Do these taste and food quality evaluations and/or consumer acceptance studies **INCLUDE (ONLY ONE MUST APPLY)**: wholesome foods without additives being consumed? a food that is consumed containing a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

## Expedited Review of Research Involving Human Subjects Criteria Form

Project Title: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

The listed expedite categories DO NOT APPLY when the research activities include the following:

- a. prisoners, fetuses, pregnant women or human in vitro fertilization
- b. survey or interview techniques which include minors (under 18 years of age) as subjects
- c. research involving the observation of the public behavior of minors (under 18 years of age)
- d. the deception of the subjects
- e. techniques which expose the subjects to discomfort or harassment beyond levels encountered in daily life (the research activity presents more than minimal risk to human subjects).
- f. identification of subjects/responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects 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.
- g. classified research involving human subjects

Check the applicable category(s) which make this research eligible for expedited review.

- \_\_\_\_\_ED1: 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 is not required
  - b. Research on medical devices for which (i) an investigational device exemption application 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.
- \_\_\_\_\_ED2: 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. (Amounts drawn may not exceed 550ml in an 8 week period and collection cannot exceed more than 2 times per week.
  - 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. (Amounts drawn may not exceed the lesser of 50ml or 3ml per kg in an 8 week period and collection may not occur more than 2 times per week.
- \_\_\_\_\_ED3: Prospective collection of biological specimens for research purposes by noninvasive means.
- a. hair and nail clippings in a nondisfiguring 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
- \_\_\_\_\_ED4: 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.
- 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 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.

- \_\_\_\_\_ED5: 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)
- \_\_\_\_\_ED6: Collection of data from voice, video, digital, or image recordings made for research purposes.
- \_\_\_\_\_ED7: 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.
- \_\_\_\_\_ED8: Continuing review of research previously approved by the convened IRB (the CPHRS) as follows:
- a. where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and 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
- \_\_\_\_\_ED9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories ED2 through ED8 do not apply but the CPHRS has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- \_\_\_\_\_ED10: Minor changes in previously approved research during the period (of one year or less) for which approval is Authorized.

# Request for Full Review of Research Involving Human Subjects Form

**Project Title:** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**Instructions:** Check the applicable category(s) which make this research applicable for full review.

\_\_\_\_\_ FR1: Research in which more than minimal risks are involved (techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life)

\_\_\_\_\_ FR2: Research in which identification of subjects/responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject'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 not greater than minimal.

\_\_\_\_\_ FR3: Research involving prisoners, fetuses, pregnant women, or human in vitro fertilization

\_\_\_\_\_ FR4: Research involving survey or interview techniques which include minors (individuals under 18 years of age) as subjects

\_\_\_\_\_ FR5: Research involving the observation of the public behavior of minors (individuals under 18 years of age)

\_\_\_\_\_ FR6: Research involving the deception of the subjects

\_\_\_\_\_ FR7: Research which compromises informed consent

\_\_\_\_\_ FR8: Research which involves the use of information that is not publicly available such as student records or medical charts. Even if the researcher has routine access to such records, if individual identifiers are included in these records, they must be reviewed by full committee.  
FR9 Research involving vulnerable populations

\_\_\_\_\_ FR9: Research involving vulnerable populations such as mentally disabled persons or economically or educationally disadvantaged persons