Review Criteria for Research Involving Human Subjects

The first issue that must be determined is whether the proposed research is subject to the IRB review. This decision can be determined by the following two questions:

1. Does this activity involve human subjects?

   Human subjects are defined by *45 CFR 46.102* [1]:

   > *"living individual(s) about whom an investigator (whether professional or student) conducting research obtains*
   > *1. data through intervention or interaction with the individual, or*
   > *2. identifiable private information."*

2. Does this activity involve research?

   Research is defined in *45 CFR 46.102* [1]:

   > *"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."*

If the answer to BOTH of these questions is "Yes" then the investigation is Research Involving Human Subjects. Even if the investigation does not involve Research but does involve Human Subjects, the IRB would be a good resource to verify that adequate protections are in place.

Use the remainder of this document to determine the type of review required.

Attach only the appropriate page(s) to the application PDF.

Please review all the criteria carefully; there may be one or more that seem applicable but differ in slight but important ways.

[1] HHS.gov. "Engagement of Institutions in Human Subjects Research (2008)." *HHS.gov*, Retrieved 02/12/21, www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.

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 Institutional Review Board (IRB). All of the project activity must qualify as exempt according to one of the criteria below for the project to be ruled exempt from IRB review. Criteria are paraphrased from HHS 2018 Decision Charts (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html); all clarifications should refer to this document.

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: This research is conducted in established or commonly accepted educational settings **AND** the research involves normal educational practices not likely to adversely affect students' opportunity to learn the content or assess educators providing instruction (*45 CFR 46.104(d)(1)*)

☐ EX2: This research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **AND** the information is recorded in such a way that the identity of the subjects cannot be ascertained (*45 CFR 46.104(b)(3)*)

☐ EX3: This research involves children **AND** the research consists of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behavior in which the investigator DOES NOT participate in the activities being observed **AND** the information is recorded in such a way that the identity of the subjects cannot be ascertained (*45 CFR 46.104(b)(3)*)

☐ EX4: This research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **AND** the disclosure of responses outside the research would not reasonably place subjects at risk of criminal or civil liability or be damaging to financial standing, employability, educational advancement, or reputation **AND** does NOT involve children (*45 CFR 46.104(b)(3)*)

☐ EX5: This research involves children **AND** the research consists of the use of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behavior in which the investigator DOES NOT participate in the activities being observed **AND** the disclosure of responses outside the research would not reasonably place subjects at risk of criminal or civil liability or be damaging to financial standing, employability, educational advancement, or reputation (*45 CFR 46.104(b)(3)*)

☐ EX6: This research involves benign behavioral interventions in conjunction with collection of information from adults through verbal or written responses (including data entry) or audiovisual recording **AND** the subjects have agreed to information collection **AND** the information is recorded in such a way that the identity of the subjects cannot be ascertained (*45 CFR 46.104(d)(3)*)

☐ EX7: This research involves secondary uses of identifiable information or biospecimens which are publicly available (*45 CFR 46.104(d)(4)(i)*)

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☐ EX8: This research involves secondary uses of identifiable information or biospecimens **AND** the information is recorded in such a manner that the human subjects cannot be identified directly or through linked identifiers, the investigator will not recontact the subjects, and the data will not be re-identified (*45 CFR 46.104(d)(4)(ii)*)

☐ EX9: This research involves secondary uses of identifiable information or biospecimens **AND** the information is for use in "healthcare operations" or "research" as defined under *45 CFR 164.501* or for "public health activities and purposes" as defined under *45 CFR 164.512(b)* (*45 CFR 46.104(d)(4)(iii)*)

☐ EX10: This research involves secondary uses of identifiable information or biospecimens **AND** is being conducted or supported by a Federal agency using government-generated or -collected information originally obtained for non-research activities **AND** the identifiable private information that is or will be maintained on information technology subject to relevant federal privacy regulation (*45 CFR 46.104(d)(4)(iv)*)

☐ EX11: The research is conducted or supported by a Federal department or agency **AND** the research is designed to study, evaluate, improve, or examine public benefit service programs including procedures for obtaining benefits, making changes or alternatives to these programs, or making changes to levels of payment for those services (*45 CFR 46.104(d)(5)*)

☐ EX12: The research involves evaluation of taste and food quality or study of customer acceptance **AND** the food is wholesome and without additives (*45 CFR 46.104(d)(6)*)

☐ EX13: The research involves evaluation of taste and food quality or study of customer acceptance **AND** the food has been deemed safe by the Food and Drug Administration or approved by the Environmental Protection Agency (*45 CFR 46.104(d)(6)*)

Research falling under one of the criteria listed below may be Exempt from federal regulations, but will require Limited IRB Review before being allowed to proceed:

☐ LI1: This research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **AND** the information is recorded in such a way that the identity of the subjects can be ascertained **AND** does not involve children (*45 CFR 46.104(b)(2)(iii)*)

☐ LI2: This research involves benign behavioral interventions in conjunction with collection of information from adults through verbal or written responses (including data entry) or audiovisual recording **AND** the subjects have agreed to information collection **AND** the information is recorded in such a way that the identity of the subjects can be ascertained **AND** the disclosure of responses outside the research would not reasonably place subjects at risk of criminal or civil liability or be damaging to financial standing, employability, educational advancement, or reputation (*45 CFR 46.104(d)(3)*)

☐ LI3: The research involves storage or maintenance of identifiable information or biospecimens for potential secondary research **AND** broad consent for storage, maintenance, and secondary research has been obtained and documented **AND** adequate protections have been put in place to protect privacy of the data (*45 CFR 46.104(d)(7)*)

☐ LI4: The research involves storage or maintenance of identifiable information or biospecimens for potential secondary research **AND** the requirement for broad consent has been waived **AND** adequate protections have been put in place to protect privacy of the data (*45 CFR 46.104(d)(7)*)

☐ LI5: The use of identifiable information or biospecimens for secondary research **AND** broad consent for storage, maintenance, and secondary research was obtained and documented **AND** the researcher will not return individual results to subjects (*45 CFR 46.104(d)(8)*)

☐ LI6: The use of identifiable information or biospecimens for secondary research **AND** the requirement for broad consent was waived **AND** the researcher will not return individual results to subjects (*45 CFR 46.104(d)(8)*)

Expedited Review of Research Involving Human Subjects Criteria Form

Project Title: _____

Principal Investigator: _____

Criteria are paraphrased from HHS 1998 guidance (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html); all clarifications should refer to this document.

The listed expedited 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 **OR**
- 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 my 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

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☐ 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) This listing refers only to research that is not otherwise Exempt under 45 CFR 46.101(b)(4).

☐ 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 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 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.

☐ 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) when the investigator participates in the activities being observed.

☐ 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 such as mentally disabled persons or economically or educationally disadvantaged persons