

HUMAN RESEARCH DETERMINATION CHECKLIST

Principal Investigator:

Study #:

Review Date:

DHHS REGULATIONS

- I.** The activity involves research because all of the following are true (**A & B**):
- A.** The activity is a systematic investigation, including research development, testing and evaluation;
 - B.** The activity is intentionally designed to develop **OR** contribute to generalizable knowledge.
- II.** The activity involves human participants because both of the following are true (**C & D**):
- C. The data the investigator is planning to obtain are about living individuals;**
 - D. Either or both of the following is true (1 or 2)**
- 1.** The investigator plans to obtain the data through one or more of the following, one of the following must be applicable (**a, b, c, d, or e**):
 - a.** Physical procedures performed on those individuals
 - b.** Manipulation of those individuals
 - c.** Manipulation of those individuals' environments
 - d.** Communication with those individuals
 - e.** Interpersonal contact with those individuals
 - 2. The information to be obtained is both of the following must be true (a & b):**
 - a. Private** because either of the following is true (**i or ii**):
 - i.** The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place;
 - ii.** The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record)
 - b. Individually identifiable** because either of the following is true (**i or ii**):
 - i.** The identity of the participant is or may readily be ascertained by the investigator;
 - ii.** The identity of the participant is or may readily be associated with the information
- The activity is not “human participant research” because (**I or II**) is false (45 CFR 46).
- The activity is “human participant research” because (**I and II**) are true (45 CFR 46). The Exempt Review Form (pages 4-5) must be completed.

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FDA REGULATIONS

- I.** The activity involves an FDA regulated test article because one or more of the following is true (**A, B, or C**):
- A.** The activity involves the use of a drug, other than the use of an marketed drug in the course of medical practice, both of the following are true (**1 & 2**):
- 1.** The activity will involve the use of a drug, meaning one of the following must be true (**a, b, c, or d**):
- a.** An article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them
 - b.** An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals
 - c.** An article (other than food) intended to affect the structure or any function of the body of humans or other animals
 - d.** An article intended for use as a component of any article specified in the above items
- 2.** Either of the following is true (**a or b**):
- a.** The drug is **NOT** approved by the FDA for marketing
 - b.** The drug is **NOT** being used in the course of medical practice
- B.** The activity involves the evaluation of the safety or effectiveness of a medical device, both of the following must be true (**1 & 2**):
- 1.** The activity will involve the use of a medical device, meaning one of the following must be true (**a, b, or c**):
- a.** Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
 - b.** Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals
 - c.** Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes
- 2.** The activity evaluates the safety or effectiveness of the device.
- C.** The activity is otherwise subject to FDA regulation meaning both of the following must be true (**1 & 2**):
- 1.** Data from the activity will be submitted to, or held for inspection by, the FDA.
- 2.** The activity involves an FDA-regulated article one or more of the following must be applicable (**a, b, c, d, e, or f**):
- a.** Food or dietary supplement that bears a nutrient content or a health claim
 - b.** Food or color additive for human consumption

- c. Infant formula
- d. Biological product for human use
- e. Electronic product for human use
- f. Other article subject to the FD&C Act

II. The activity involves human participants because one or more of following is true (**A or B**):

A. The test article will be used on one or more humans

B. All of the following are true (**1, 2, 3, & 4**):

- 1.** The test article is a medical device
- 2.** The medical device will be used on human specimens
- 3.** The activity is being done to determine the safety or effectiveness of the device
- 4.** Data from the activity will be submitted to, or held for inspection by, the FDA.

According to FDA regulations the activity is not “human participant research” because (**I or II**) is false.

According to FDA regulations the activity is “human participant research” because (**I and II**) are true. The Exempt Review Form (pages 4-5) must be completed.

EXEMPT REVIEW FORM

Principal Investigator:

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___1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- (i) research on regular and special education instructional strategies, *or*
- (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (iii) The research is not FDA-regulated

___2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, in which:

- Information obtained is recorded in such a manner that human subjects can not be identified, directly or through identifiers linked to the subjects; *and*
- Any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; *or*
- The research does not involve surveys of children, interviews of children, or observation of public behavior of children where the investigator(s) participate in the activities being observed.
- The research is not FDA-regulated

___3. Research involving the use of educational tests, survey or interview procedures, or observing public behavior that is not exempt under number 2 above, if the subjects are public officials or candidates for public office or a federal statute requires that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter. The research is not FDA-regulated

___4. Research involving the collection or study of existing data, documents, records, pathological 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, either directly or through identifiers linked to the subjects. To qualify for exemption, the data, documents, records or specimens must be in existence before the project begins. The research is not FDA-regulated

___5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate; or otherwise examine:

- i. Public benefit or service programs;
- ii. Procedures for obtaining benefits or services under those programs;
- iii. Possible changes in-or alternatives to those programs or procedures; *or*
- iv. Possible changes in methods or levels of payment for benefits or services under those programs.
- v. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
- vi. The research or demonstration project must be conducted pursuant to specific federal statutory authority;
- vii. There must be no statutory requirement that an IRB review the project;
- viii. The project must not involve significant physical invasions or intrusions upon the privacy of

- participants;
- ix. The funding agency must authorize or concur with this exemption.
 - x. The research is not FDA-regulated

___6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Regulatory Requirements:

___1. The research does not involve prisoners (individuals involuntarily confined or detained in a penal institution) as participants.

University of Texas at Austin Requirements:

___1. The research does not involve interactions or interventions with individuals confined in mental hospitals, nursing homes, or other related facilities where the individual's freedom of movement is restricted.

___2. The research does not involve video recording.

___3. The research is minimal risk.

Additional Points (per Belmont Report):

Autonomy:

___1. All participants entered the study voluntarily.

___2. Informed consent was provided to all participants, when appropriate.

___3. Informed consent will be documented, when appropriate.

___4. All subjects were adequately informed about research procedures, risks, and benefits.

___5. The researchers attempted to minimize any unintended coercion of included populations, and did not involve participants with a diminished capacity to consent (e.g., prisoners).

Beneficence:

___6. The risks are reasonable in relation to the benefits of the study.

Justice:

___7. All participants were selected equitably.

___8. Efforts were made to include women and members of minority groups, if appropriate to the research purpose.

___9. The sampling efforts did not favor some classes solely due to ease of availability, compromised positions, or manipulability.

___ Waiver of Documentation of Consent

___ Waiver of Informed Consent

Approve as Exempt: _____

Signature: _____

Date: _____