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| ***UT Tyler Institutional Review Board*** |
| **Reviewer Checklist (Submit page 1 only to IRB Chair with final approved documents and approval letter)** |

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| --- | --- |
| **Reviewer Name** |  |
| **Protocol Number** |  |
| **Protocol Title** |  |

Conflict of Interest: Please indicate if you have any potential conflicting or competing interest with respect to this protocol: Yes  No

**Recommendations:**

Approve as Submitted

Approve with Modifications

Disapprove

More Information or Discussion required (e.g. invite the PI for review; provide a list of questions to PI, etc)

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| **Comments** |  |

**Continuing Review Frequency** (check one)**:**

**12 months  6 months  other:**

**Documents Reviewed:**

Prior to this approval I reviewed (check all that applies):

The IRB Application

Sponsor’s brochure (if applicable)

Informed consent document(s)

Study Materials for Subjects (i.e. questionnaires, surveys; if applicable)

Sample recruitment materials (if applicable)

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| **Reviewer Signature: Date:** |

**Designated Category of Research**

Full Board Review

Expedited Review (<http://www.hhs.gov/ohrp/policy/expedited98.html>)

Exempt Research (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b))>

You must provide the appropriate citation for the expedited review or exempt research

**Scientific Merits of the Study**

1. Statement of research, background and specific aims are adequate. Yes  No
2. Experimental design is sound and appropriate. Yes  No
3. Justification for involving human subject is appropriate. Yes  No

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| **Supportive Comments** |  |

**PI and the Research Staff Qualifications**

1. PI’s training and experience are adequate with the condition being studied. Yes  No
2. Are there any conflicts of interest disclosed by the research staff? Yes  No
3. Has the study staff received adequate training? Yes  No

**Risk/Benefit Ratio:**

1. Risks to the participants

***Risks*** *include physical, psychological, emotional and social harms. Examine the research plan, including research design and methodology, to determine that there are no flaws that would place subjects at unnecessary risk.* ***Risk/benefit analysis*** *evaluates the most current information about the risk and benefits of the interventions involved in the research, in addition to information about the reliability of this information.*

No risk

Minimal risk

More than minimal risk with potential benefits to participants

More than minimal risk with no potential benefits to participants

1. Were risks to participants minimized by using procedures that were a) already being done for standard treatment and/or b) consistent with sound research design and that did not unnecessarily expose participants to risk? Yes  No
2. Selection of subjects for this study is equitable Yes  No
3. All risks to subjects are clearly and accurately identified and considered Yes  No
4. Anticipated benefits to subject and importance of knowledge to be gained are clearly and accurately identified Yes  No
5. Risks are reasonable in relation to anticipated benefits Yes  No
6. Research personnel are adequately qualified to conduct this research Yes  No

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| **Supportive Comments** |  |

**Safety Monitoring Plan:**

1. Does the protocol describe a safety monitoring plan? Yes  No

**If yes:**

1. Does the plan appear adequate? Yes  No
2. Does the plan include provisions for the prompt review of serious adverse events and unanticipated problems and reporting such events to the IRB? Yes  No

**If no:**

1. Is it appropriate that there is no safety monitoring plan? Yes  No
2. If there is a medical record, should the medical record flagged to indicate that the patient is enrolled in a study? Yes  No
3. Are there adequate resources to conduct the research and ensure the safety of participants?

Yes  No

1. Have all involved in conducting the research received adequate training? Yes  No
2. Are adequate medical or psychological resources available to participants if needed as a consequence of the research? Yes  No
3. Does the study involve use of an investigational new drug(s) or device(s)? Yes  No
4. Does the study involve hazardous materials (biological, radiation, etc) that require review by other committee? Yes  No

**If yes:**

1. Document of additional review is provided? Yes  No

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| **Supportive Comments** |  |

**Privacy and Confidentiality**

1. Do the methods being used to collect data contain adequate provisions to protect the privacy interests of participants? Yes  No
2. Dose the research plan have adequate provisions to maintain the confidentiality of the data collected? Yes  No
3. Description of data collection and methods of data recording are adequate? Yes  No
4. Description of all activities involving human subjects is adequate? Yes  No
5. Description of data storage is adequate? Yes  No

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| **Supportive Comments** |  |

**Recruitments:**

1. Are the recruitment procedures appropriate? Yes  No
2. Are the justifications for subject selection with inclusion/exclusion criteria appropriate? Yes  No
3. Does the research involve vulnerable population? Yes  No

**If yes:**

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| --- | --- |
| 1. **check all that apply:** | |
| □ Cognitively impaired | |
| □ Pregnant Women | |
| □ Fetuses | |
| □ Prisoners | |
| □ Minors, Not involving more than minimal risk | |
| □ Minors, Involving greater than minimal risk but of direct benefit to individual subjects | |
| □ Minors, Involving greater than minimal risk with no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject disorder or condition | |
| □ Others vulnerable to coercion (e.g. employees of research site or sponsor, students of investigator). | |

1. Have adequate safeguards for vulnerable populations been included in the protocol and consent?
2. If applicable are the advertisements appropriate? Yes  No Not applicable

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| **Supportive Comments** |  |

**Informed Consents and Consent Documents**

1. Will consent be obtained from the participants? Yes  No
2. Will consent be obtained from the participant’s legally-authorized representative? Yes  No
3. Does the informed consent process appear appropriate? Yes  No
4. Will participants or their legally-authorized representative be given a copy of the signed and dated consent form? Yes  No
5. Does the information given to the participant appear in a language and at an appropriate level to be understandable to the participant population? Yes  No
6. Does the information given to the participant include exculpatory language that may waive or appear to waive the participant’s legal rights? Yes  No
7. If a waiver of informed consent or a waiver of informed consent documentation has been requested, has the request been appropriately justified? Yes  No
8. If protected health information is being collected, does the consent contain the required HIPAA elements, or has a HIPAA waiver been requested and appropriately justified? Yes  No
9. Does the informed consent contain all the required elements of informed consent disclosure in the following table? Yes  No

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| **Required Elements of Informed Consent Disclosure** | **Missing or Requires Modification** | **N/A** |
| A statement that the study involves research. | □ |  |
| An explanation of the purposes of the research. | □ |  |
| The expected duration of the participant’s participation. | □ |  |
| A description of the procedures to be followed. | □ |  |
| Identification of any procedures, which are experimental. | □ | □ |
| A description of any reasonably foreseeable risks or discomforts to the participant. *(Not applicable if the research is minimal risk and there are none)* | □ | □ |
| A description of any benefits to the participant or to others, which may reasonably be expected from the research. | □ | □ |
| A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the participant. | □ | □ |
| A statement describing the extent to which confidentiality of records identifying the participant will be maintained. | □ |  |
| A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(Not applicable if research is not FDA-regulated.)* | □ | □ |
| An explanation as to whether any compensation is available if injury occurs and, if so, what they consist of, or where further information may be obtained. *(Not applicable if the research is minimal risk.)* | □ | □ |
| An explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. *(Not applicable if the research is minimal risk.)* | □ | □ |
| Who to contact for answers to pertinent questions about the research. | □ |  |
| An explanation of whom to contact for answers to pertinent questions about the research participants’ rights. | □ |  |
| An explanation of whom to contact in the event of a research-related injury to the participant. | □ |  |
| A statement that participation is voluntary. | □ |  |
| A statement that that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. | □ |  |
| A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. | □ |  |
| A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. *(Not applicable if the research involves only approved drugs and devices with well known risk profiles.)* | □ | □ |
| A statement that if the participant is or may become pregnant the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. *(Not applicable if the research does not involve pregnant women or women of childbearing potential)* | □ | □ |
| Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent. | □ | □ |
| Any additional costs to the participant that may result from participation in the research. | □ | □ |
| The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant. | □ | □ |
| A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant. | □ | □ |
| The approximate number of participants involved in the study (*may not be applicable if not relevant to a decision to participate)*. | □ | □ |

**Categories Exempt Review allowed under 45 CFR 46.101:**

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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. |
|  | (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.  \*\*\*Note: interview or survey research involving children does not qualify for exemption.\*\*\* |
|  | (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. |
|  | (4) 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, directly or through identifiers linked to the subjects. |
|  | (5) Research and demonstration projects which are conducted by or subject to the approval of [Federal] 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. |
|  | (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. |

**Categories of Expedited Review allowed under 45 CFR 46.101:**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
3. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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.
4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture within specified limits.
5. Prospective collection of biological specimens for research purposes by noninvasive means.
6. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
7. 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).
8. Collection of data from voice, video, digital, or image recordings made for research purposes.
9. 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.
10. Continuing review of research previously approved by the convened IRB as follows:
    1. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    2. where no subjects have been enrolled and no additional risks have been identified; or
    3. Where the remaining research activities are limited to data analysis.
11. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) 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.