UIS Institutional Review Board for the Protection of Human Subjects

Reviewer Checklist for New Protocols

Protocol Number: Date Received:

Project title:

Principal Investigator:

Section I. Determine if the protocol under review requires IRB approval.

1. *Is the proposed project research?* Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge?
   ☐ Yes, proceed to question 2.
   ☐ No, This type of project is not considered research and does not require IRB review.
2. *Does the project involve human subjects?* According to 45 CFR 46.102(e)(1)(i) and (3)(1)(ii), ii), human subjects means a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction; i.e., communication or interpersonal contact, with the individual and uses, studies, or analyzes the information or biospecimens. Does this project involve human subjects?
   ☐ Yes, proceed to Section II.
   ☐ No, This type of project is not classified as Humans Subject Research and does not require IRB review.
3. Will research involve prisoners, fetuses, children or pregnant women?
   ☐ Yes, proceed to Section IV.
   ☐ No, proceed to Section II.

Section II. Determination of Exempt Level IRB Review:

Exempt Review Categories. Research activities that present no more than minimal risk to human subjects and where the **only** involvement of human subjects will be in one or more of the following categories, may qualify for *exempt review*.

Check all that apply.

☐ **Exemption 1**. Research conducted in established or commonly accepted educational settings, involving normal education practices. For more information on whether Exemption 45 CFR 46.104(d)(1) may apply, go to https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3

☐ **Exemption 2**. Research only including interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior, if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

For more information on whether Exemption 45 CFR 46.104(d)(2) may apply, go to https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c4

☐ **Exemption 3**. Research involving benign behavioral interventions and collection of information from adults through verbal or written responses or audiovisual recording if the subject agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Deception caveat: In the situations above, Exemption 45 CFR 46.104(d)(3) may apply UNLESS the research involves deceiving subjects about the nature or purposes of the research, although Exemption 45 CFR 46.104(d)(3) may still apply IF subjects authorize the deception through prospective agreement. For more information, go to https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c5

☐ **Exemption 4**. Secondary research use of identifiable private information or identifiable biospecimens. For more information on whether Exemption 45 CFR 46.104(d)(4) or (d)(8) may apply, go to https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c6

☐ **Exemption 5**. Research studying, evaluating, or examining public benefit or service programs. For more information on whether Exemption 45 CFR 46.104(d)(5) may apply, go to https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c7

☐ **Exemption 6**. Research involving taste and food quality evaluation of consumer acceptance studies. For more information on whether Exemption 45 CFR

46.104(d)(6) may apply, go to https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c8

☐ **Exemption 7**. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research use. For more information on whether Exemption 45 CFR 46.104(d)(7) may apply, go to https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c9

☐ **Exemption 8**. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

iii. An IRB conducts a limited review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i); and

iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

☐ Yes; if one or more of Exemptions 1 – 8 above is selected, then this project is classified as **Exempt**. Research activities involving human subjects that are exempt from IRB review are identified in 45 CFR 46.104. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html#46.104(d)(1))

Limited IRB review required by § 46.104(d)(7)): the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § 46.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § 46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

"Limited IRB review requires that certain exempt research be reviewed by an IRB chair or designee for privacy and confidentiality under requirements in 45 CFR §46.111(a)(7) or §46.111(a)(8).11 The regulations at §46.111(a)(7) state, "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data,"

and §46.111(a)(8) states, "… (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." This process is only applicable to certain new provisions in the **exempt categories 2, 3, 7, and 8**." (Walch-Patterson, 2020)

___ No; this project is not eligible for Exempt determination if NONE of the exemptions above are selected, then this project could be classified as **Expedited** or require **Full Board** Review. Proceed to **Section III** below.

Yes, if Exemption 8 above is selected, then this project requires **Limited IRB Review**.

Section III. Determination of Expedited Level IRB Review:

Expedited Review Categories. Research activities that present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the *expedited review* procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.110; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=56.110&SearchTerm=expedited)
Reference: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

Check all that apply.

☐ **Expedited Category 1**. 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 (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. 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.

☐ **Expedited Category 2**. 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. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children2, 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. For these subjects, the amount drawn

may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

- ☐ **Expedited Category 3**. Prospective collection of biological specimens for research purposes by noninvasive means.
- ☐ **Expedited Category 4**. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays, microwaves, general anesthesia, or sedation.
- ☐ **Expedited Category 5**. Research involving materials that have been collected, or will be collected solely for non-research purposes.
- ☐ **Expedited Category 6**. Collection of data from voice, video, digital, or image recordings made for research purposes.
- ☐ **Expedited Category 7**. Non-Exempt research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- ☐ **Expedited Category 8**. 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.

Section IV. Determination of Full Board IRB Review

___ If no Exempt or Expedited categories are selected, then this project requires **Full Board Review**.

SUMMARY OF THE REVIEW PROCESS:

I determine that the proposed human subjects research:

- ☐ qualifies as Exempt
- ☐ qualifies for Expedited Review
- ☐ qualifies for Limited IRB review of secondary research for which broad consent is required
- ☐ requires Full IRB review

By signing below, I attest that:

(1) Risks to the subject are minimized By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should not consider possible long-range effects of applying knowledge gained in the research.

(3) Selection of subjects is equitable considering the research purposes and setting with special consideration for vulnerable subjects.

(4) Informed consent or assent will be sought.

(5) Informed consent will be appropriately documented or appropriately waived.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

IRB Reviewer Name:_____ Signature:_____ Date: _____