Exempt and Not Human Subject Research Reviewer Checklist

Reviewer: _____ Submission ID: _____

Principal Investigator: _____ Protocol #: _____

If you have a conflict of interest with this study, ask the coordinator to assign this submission to another reviewer.

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1. Does the proposal involve the use of fetal or embryonic tissue (regardless of whether it is deidentified)?
   - ☐ Yes (**Consult with COMIRB Director on need for an Ethics Committee on Fetal Tissue review prior to COMIRB approval**)
   - ☐ No

2. Does this protocol involve any subjects or data (including deidentified data) from the UK or European Union/European Economic Area?
   - ☐ Yes (**Consult with the COMIRB Director, Assistant Director, or Brie about GDPR**)
   - ☐ No

3. Is it research?
   - ☐ The project is research, a systematic investigation designed to contribute to generalizable knowledge.
   - ☐ The project is not research, and serves as quality improvement, quality assurance, or program evaluation, intended to benefit a specific program/department and not to be generalized (**If checked, go to determination**).

4. Does it involve human subjects, defined as a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens?
   - ☐ Yes
   - ☐ No (**Go directly to determination**)

5. Is this a VA protocol?
   - ☐ Yes (**Protocol must be reviewed by a VA representative and this checklist must be retained electronically**)
   - ☐ No

6. Does the study involve a Certificate of Confidentiality (either due to funding or sensitive subject matter)?
   - ☐ Yes (**Ensure that consent contains CoC language**)
   - ☐ No

Exempt Categories

☐ **Category 1**. Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. "Commonly accepted settings" usually involve schools but also includes non-academic settings where education of patients, professionals, clients, or other populations is commonly conducted. This includes:

a) most research on regular and special education instructional strategies
b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

*If the research is conducted in a public school, ensure that there is a permission letter from school administration. If a COMIRB determination is required before school permission can be granted, add language in the determination noting that research cannot begin until COMIRB receives school permission.

☐ **Category 2**. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

☐ A. 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;

☐ B. 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

☐ C. 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 there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. **A Limited IRB Review is needed.**

- If the PI is a mentee (i.e., student, resident, fellow, etc.), do not use exempt category 2C. Review under expedited procedures, category 7, if research poses minimal risk.

*If the study involves children, it is only eligible for exemption under this category if the research is limited to educational tests and/or observations of public behavior when the investigators do not participate in the activities being observed, and only under conditions (A) or (B).

☐ **Category 3**. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

☐ A. 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;

☐ B. 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

☐ C. (Limited IRB Review) 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 there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*If the research involves deception, it is not eligible for exemption unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research.

☐ **Category 4**. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

☐ identifiable private information or identifiable biospecimens are publicly available;

☐ information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

☐ the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA (i.e., 45 CFR parts 160 and 164, subparts A and E), for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or

☐ the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities and conducted in compliance with 45 CFR 46.104(d)(4)(iv).

☐ **Category 5**. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine:

- ☐ public benefit or service programs;
- ☐ procedures for obtaining benefits or services under those programs;
- ☐ possible changes in or alternatives to those programs or procedures; or
- ☐ possible changes in methods or levels of payment for benefits or services under those programs.

*For VA studies: The determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.

☐ **Category 6**. Taste and food quality evaluation and consumer acceptance studies, if

- ☐ wholesome foods without additives are consumed, or
- ☐ 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 FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.

Data Management and Security

1. Will computer data be held in a secure manner?	☐ Yes	☐ No	☐ N/A
2. Will audio/visual data be held in a secure manner?	☐ Yes	☐ No	☐ N/A
3. Is there a plan to disguise or destroy unintentional identifying information collected during the recordings?	☐ Yes	☐ No	☐ N/A
4. Will paper records be held in a secure manner?	☐ Yes	☐ No	☐ N/A
5. Will biological samples be stored securely?	☐ Yes	☐ No	☐ N/A
6. Is the data destruction plan acceptable?	☐ Yes	☐ No	☐ N/A

Criteria for exempt determination

☐ The research involves no more than minimal risk to subjects **(required)**.

☐ Selection of subjects is equitable **(required)**.

☐ If there is recording of identifiable information, adequate provisions are in place to maintain the confidentiality of the data.

☐ There are interactions with subjects.

- ☐ There is a consent process that will disclose:
  - ☐ the activities involve research
  - ☐ the procedures to be performed
  - ☐ that participation is voluntary
  - ☐ the name and contact information for the investigator
  - ☐ adequate provisions to maintain the privacy interests for subjects

Does this protocol use data, records, or samples collected from a previously approved research protocol? ☐ Yes ☐ No

If yes:

a. Did subjects consent for samples to be stored/used for future unspecified research? ☐ Yes ☐ No

b. Did subjects consent to data/specimen use in line with aims of the current project? ☐ Yes ☐ No

Waiver of HIPAA Authorization

☐ **N/A, continue to reviewer recommendation**

☐ **Part A**

The use or disclosure of the requested information involves no more than minimal risk to the privacy of the individuals because:	☐ Yes	☐ No
a. There is an adequate plan to protect the identifiers from improper use and disclosure;	☐ Yes	☐ No
b. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining identifiers or such retention is otherwise mandated by applicable law;	☐ Yes	☐ No
c. There is adequate written assurance that the requested information will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the study or otherwise permitted by the Privacy Rule.	☐ Yes	☐ No
d. The research cannot practicably be conducted without the waiver	☐ Yes	☐ No
e. The research could not practicably be conducted without access to and use of the requested information.	☐ Yes	☐ No

☐ **Part B**

The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and:	☐ Yes	☐ No
a. is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) 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	☐ Yes	☐ No
b. could not practicably be carried out without the waiver or alteration.	☐ Yes	☐ No

For Part A or Part B:

Check the PHI for which use or disclosure is determined to be necessary:

☐ Names/Initials
☐ Geographic subdivisions smaller than a state, including street, address, city, county, precinct, and zip code
☐ All elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89.
☐ Telephone Number
☐ Fax Number
☐ E-mail Address
☐ Social Security Number
☐ Medical Records Number
☐ Health plan beneficiary numbers
☐ Free Text Fields
☐ Account Numbers
☐ Certificate/License Number
☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ Device identifiers and serial numbers
☐ Web Universal Resource Locators (URLs)
☐ Internet Protocol (IP) Address Numbers
☐ Biometric Identifiers (including figure or voice prints)
☐ Full Face Photographs and Comparable Images
☐ Any other unique identifying number, characteristic, or code
☐ Scans (e.g., MRI, CT, X-ray files)

Specify the justification for granting the Waiver of HIPAA Authorization:

The request for Waiver of HIPAA Authorization determination is:

☐ Approved

☐ Approved with requested changes

☐ Denied (comment below)

Additional comments (if needed): ☐ See Comments in InfoEd

Reviewer Recommendation:

☐ Approved for Exemption

☐ Not Human Subject Research

☐ Minor Modifications Required

Additional comments (if needed): ☐ See Comments in InfoEd

Reviewer Signature

Date