IRB Reviewer Checklist for Exempt Studies

Reviewer name: Signature:

IRB Meeting Date: IRB Control #: PI:

Do you have a financial or other conflict of interest regarding this protocol? \_\_\_\_Yes \_\_\_\_No

If yes, please contact the Office of Human Research so that another reviewer can be assigned.

**Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review except that such activities must comply with the requirements specified in each category (45 CFR 46.104).**

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. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Note: This category only applies to primary, secondary, collegiate, and medical (including resident and fellowship) settings.

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 audio recording) if at least one of the following criteria is met:

**Data de-identified** - 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 **(When children involved, this category is limited to educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed);**

**Data identified; no risk** - 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 **(Child exclusion same as above)**

**Data identified; limited risk\*** - 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

Limited IRB review: When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

**(\*Children are excluded from this subcategory of research)**

3.Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject only **(children excluded)** 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:

**Data de-identified** - 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;

**Data identified; no risk** - 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;

**Data identified; limited risk** - 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

Limited IRB review: When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

**Confirm that benign behavioral interventions are:**

brief in duration

harmless, painless, not physically invasive

not likely to have a significant adverse lasting impact on the subjects, and,

the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

**If the research involves deceiving the subjects** regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that s/he will be unaware of or misled regarding the nature or purposes of the research. (**Exemption cannot otherwise apply.)**

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:

The 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 or

The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to applicable regulations (ref. 45 CFR 46.104)

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 and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. (Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.)