WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

I. Categories of Exemption

Applicable Category	
1 ☐	Research will take place in an established or commonly accepted educational setting (not restricted to K-12), involving normal educational curriculum (appearing as normal classroom activities. Research activities must be unlikely to adversely impact students' opportunity to learn required educational content, or the assessment of educators who provide instruction. 1) Most research on regular and special education instructional strategies, or 2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
2 ☐	Research that ONLY includes interaction involving the use of 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: 1) Information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; 2) 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, or reputation; or 3) The information obtained is recorded by the investigator in such a manner that the identity of the participants 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 section 45 CFR 46.111(a)(7). Children may only be included in research under this exemption when involving educational tests or observation of public behavior if the investigator(s) do not participate in the activities being observed and the information obtained is recorded by the investigator in such a manner that the identity of the participants cannot be readily ascertained, directly or through identifiers linked to the participants.

WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

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: 1) 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; 2) Any disclosure of the human subjects responses outside of 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 3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review to make the determination required by section 45 CFR 46.111(a)(7). Children may not be included in research under this exemption
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: 1) The identifiable private information or identifiable biospecimens are publicly available; or 2) 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; or 3) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 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 4) The research is conducted b, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

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: 1) Public benefit or service programs; (this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency) 2) Procedures for obtaining benefits or services under those programs; 3) Possible changes in or alternatives to those programs or procedures; or 4) 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**, if: 1) Wholesome foods without additives are consumed; or 2) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or 3) 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.

IMPORTANT NOTE: Exempt criteria 7 and 8 below require the use of a new requirement in the revised Common Rule called "broad consent" as well as Limited IRB review. UH is not formally implementing use of "broad consent", so exempt criteria 7 and 8 should not be used.

WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

	7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by section 45 CFR 46.117; 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: 1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with section 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); 2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with section 45 CFR 46.117; 3) An IRB conducts a limited IRB review and makes the determination required by section 45 CFR 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) of this section; and; 4) 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.

WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

II. Application

Completed	
☐	The PI and other staff assisting PI in conducting the project have completed CITI training and provided certificate of completion to the HSP office.
☐	If the project is based on a previous pilot study, results described to demonstrate that this intervention exposes participants to less than minimal risk of harm.
☐	Where and how participants will be recruited is described**.**
☐	How the PI will obtain consent from participants is described both in ICF and Description of Project.
☐	Study does not involve "friending" participants to view their posting. "Friending" is not public since participants would need to provide restricted access. Must delete from study or study must move to expedited/full review.
☐	**Use of Children as Participants** Category 2 permits research involving children in the following research **ONLY**. 1. Research involving the use of educations tests or 2. Research involving observation of public behavior only when PI does not participate in the activities Categories 1, 3-6 apply to research involving children.
☐	**Use of Students as Participants – Exception: Students from PI's own class may not be recruited unless the project is from the College of Education and their Action Research projects.** **1. If yes, is there a recruitment script? The recruitment script must state that "The Study Recruiter and Data Collector are not the class teacher. The class teacher will not see study data until after the class has ended and grades are submitted."** **2. There are provisions for students who do not want to participate in the study.** **3. Project state process for requesting names and email addresses for students interested in participating.**

WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

III. Informed Consent/ Information Flyer

Completed	
☐	If requesting waiver of written informed consent, the following must be met. An information flyer should be included in lieu of a written informed consent.
	☐ **1.** The research involves no more than minimal risk to subjects ☐ **2.** Waiver or alteration will not adversely affect the rights and welfare of the subjects ☐ **3.** Research could not be practicably be carried out with the waiver or alteration ☐ **4.** When appropriate, subjects will be provided additional pertinent information after participation
☐	If the research involves participants whose primary language is not English, is there a translated informed consent submitted in the language of the participants' primary language? Is the informed consent written at a reading level appropriate for the participant population? *Note: standard level is no more than 8th grade.*
☐	Lay language is used and not language specific for academic areas.
☐	If the information flyer/consent is posted on a website, is the screenshot included?
☐	For research involving audio taping, a section for participants to initial/check to consent or not consent to recording is provided.
☐	For research involving audio taping, **The project includes a statement identifying the destruction date or definitive statement on what will happen to the audio or video recordings.** If the audio/video taping will not be destroyed, that should be stated.
☐	It is clearly stated in the ICF if performances are being recorded.
☐	It is clearly stated in the ICF if performance recordings will be used, i.e. part of a publication or presentation.

WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

☐	The study indicates the number of participants to be recruited.
☐	Information about the amount, type (cash, gift card), and frequency of giving compensation is included in question 6 and in the ICF(s).
☐	The project does not include a raffle. Raffles are not permitted since each participant must be treated equally and all receive the same amount of monies, gift certificates or merchandise.
☐	All acronyms are defined in the ICF.
☐	The consent form contains an explanation of the **purpose(s) of the research.**
☐	The **amount of time** participation in the entire project is expected to require is stated. For an interview, the length of time the interview will last should be stated.
☐	A description of the **procedures to be followed**.
☐	A statement describing the extent, if any, to which **confidentiality of records** identifying participants will be maintained.
☐	The protocol title is identified on the signature page.
☐	The electronic ICF includes a statement toward the end of the document which asks the participant to print the form for their records.
☐	The process of how the PI will obtain signatures with participants who will be exclusively contacted via email and/or Skype is described.
☐	**Anonymous Issues**: (anonymous pertains to individual's information, confidential pertains to data). An anonymous survey does not ask participants to email back their responses. It is not anonymous since PI can see email addresses.
☐	If the project indicates there is more than 1 phase of the study, (i.e. follow-up surveys, follow-up interview, future studies, there is a question asking the participant for permission for the PI to contact the participant in the future. Question should have boxes for "Yes" or "No" response.
☐	Elements of the ICF as shown on the HSP website are used as appropriate. If used, there are separate sections for "Benefits," "Risk," and "Compensation."
☐	The name and **contact information for HSP** is correct (email and phone only).

WORKSHEET 302– REQUIREMENTS FOR EXEMPT APPROVAL

IV. Recruitment Flyers

Completed	
☐	Does the flyer include the word "research" in the text?
☐	Does the application include email recruitment script, if using email to recruit participants?
☐	Doe the application include telephone script, if using phone to recruit participants?
☐	If recruitment flyer is posted on a website, is the screenshot included?
☐	The compensation language on the flyer should not include a dollar amount or $$ amount.

V. Other Attachments

Completed	
☐	Survey Instruments: If viewed online, is the screenshot included?
☐	The project states when participants will complete surveys. Survey handed out during class? End of class? Emailed to participants?
☐	The project states that for a survey conducted online, the ICF also be online or sent as part of a recruiting email. Is it clear how this will be done?
☐	There is a submitted email template for participants asked to forward the survey link.
☐	For participants whose primary language is not English, are the surveys/instruments translated to the language of use included?
☐	If applicable, endorsement letters are included in the application if study involves schools or resources from institutions.