IMPORTANT: This guide sheet is provided to you in order to assist you in conducting your review. You may choose to fill out this form or use it as a guide. Before conducting your review consider if you have a potential financial or non-financial conflict of interest in this protocol. If you think a conflict exists, notify the IRB administrator who will advise you on how to proceed.

Reviewer/Board Determinations:

Part I- Protocol/Project Description:

1. Rate the overall level of risk involved with this project: (if greater than minimal exemption may not be granted).
   - no greater than minimal / greater than minimal

2a. Indicate ALL Applicable Category(s) (Refer to guidelines for complete descriptions and limitations):
   1. Research involving standard educational practices.
   2. Research using educational tests, surveys, interviews and public observations.
   3. Subjects are public officials or where federal confidentiality statutes apply.
   4. Existing data or specimens.
   5. Public benefit program evaluation.
   6. Consumer taste testing.
   7. Emergency use of a test article.
   - 1 / 2 / 3 / 4 / 5 / 6 / 7

2b. Do the study procedures fall completely within the applicable categories indicated in question 2a above? (If “No” the exemption may not be granted)
   - Yes / No

3. Is the purpose of the study clearly described, justified relative to risk and achievable given the scientific design? (If “No” the exemption may not be granted)
   - Yes / No

4. Is subject selection equitable? (If “No” the exemption may not be granted)
   - Yes / No

5. Are all reasonable physical, psychological, social, legal, employment or other risks to participants identified, minimized with appropriate safeguards and stated in both the project description and the consent process? (If “No” the exemption may not be granted)
   - Yes / No

6. Are adequate provisions described to protect the privacy of the research participants?
   - Yes / No

7. Are adequate provisions described to assure the confidentiality of the research participants including storage, coding procedures, destruction of and methods of dealing with identifiable records (tapes, pictures, etc.)? (If “No” the exemption may not be granted)
   - Yes / No

8. Is the consent process (written, oral, implied, waived) described, appropriate and adequate given the level of risk and interaction with participants? (If “No” the exemption may not be granted)
   - Yes / No

Part II- Consent process Elements. Where there are interactions with participants, except in cases where consent can be waived if the project were not exempt, does the consent process address all of the following items appropriately:

9. A statement that the activity involves research. (If “No” the exemption may not be granted)
   - Yes / No / NA

10. A description of the procedures. (If “No” the exemption may not be granted)
    - Yes / No / NA

11. A statement that participation is voluntary. (If “No” the exemption may not be granted)
    - Yes / No / NA

12. Name and contact information for the investigator. (If “No” the exemption may not be granted)
    - Yes / No / NA

13. Additional elements are appropriately included. (If “No” the exemption may not be granted)
    - Yes / No / NA

Part III- Determinations and Comments

14. Are any additional protections needed before exemption may be given (specify below)?
    - Yes / No

15. Recommend that research should be:
    a. Exempt “as is”
    b. Reconsidered for Exemption once the items below are addressed
    c. Denied exemption- requires expedited review
    d. Denied exemption- requires full board review
    - a / b / c / d

Comments and items to be addressed:

1.
2.
UB IRB Guide/Evaluation for Review of Exemption Requests

1. **The overall level of risk involved with the project must be no greater than minimal for the exemption to be granted.**

   Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2. **This study procedures must fall completely within the category(s) 1-7 below which encompass all applicable DHHS and FDA exemptions. If any of the research procedures are outside of these categories the exemption may not be granted.**

   **Limitations on applicability:**
   
   i. Classified research may not be granted exemption
   
   ii. The only exemption that can be granted for prisoner research is epidemiological research under #4

   iii. Children. Number 2 can NOT be applied to research involving children, except for research involving public behavior when the investigator does not participate in the activities being observed.

**DHHS Categories:**

(1) **Research involving standard educational practices.** 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 using educational tests, surveys, interviews and public observations.** 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.

(3) **Subjects are public officials or where federal confidentiality statutes apply.** 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) **Existing data or specimens.** 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) **Public benefit program evaluation.** Research and demonstration projects which are conducted by or subject to the approval of 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.

   o The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).

   o There must be no statutory requirement that the project be reviewed by an IRB.

   o The project must not involve significant physical invasions or intrusions upon the privacy of participants.

   o The exemption should have authorization or concurrence by the funding agency.

(6) **Consumer taste testing.** 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 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.

(7) **Emergency use of a test article,** provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

3. **Is the purpose of the study clearly described, justified relative to risk and achievable given the scientific design?**

   a. Are the objectives or hypotheses clearly specified and likely to be accomplished within the stated time period?

   b. Are adequate background, preliminary data, and references provided/cited to justify the research?

   c. Is there appropriate scientific justification for proceeding with this research study?

   d. Is the scientific design described adequate to achieve the stated objective?

4. **Is subject selection equitable?**

   a. Is the choice of participants appropriate for the question being asked?

   b. Selection of the proposed study population(s) may not be solely based on their easy availability, compromised position, or susceptibility to manipulation.

   c. If used, are inclusion and exclusion criteria clearly specified and appropriate?

   d. Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research protocol? The research may not unduly involve individuals from populations unlikely to benefit from any subsequent beneficial applications of the research.

   e. If the study is restricted to individual groups (children, vulnerable populations, gender) is this appropriate for this study and does the project description include proper procedures for protection of these participants?

   f. If the study excludes individual groups (children, vulnerable populations, gender) is this appropriate for this study or is the prospect of a significant benefit being withheld by not allowing participation to be as broad as possible across various populations?

   g. Are vulnerable populations specifically targeted for inclusion only when needed to answer the scientific hypothesis posed?
5. Are all reasonable physical, psychological, social, legal, employment or other risks to participants identified, minimized with appropriate safeguards?
   a. Exempt status may not be granted where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
   b. Are risks (including physical, psychological, social, legal, or economic risks) adequately and consistently described and in both the protocol and the consent procedures?
   c. Are risks appropriately minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?
   d. Have the potential risks to subjects associated with the research, been distinguished from the risks of therapies the subjects would receive even if not participating in the research?

6. Are adequate provisions described to protect the privacy of the research participants?
   a. Privacy protection measures are adequate
   b. If privacy is to be invaded, does the importance of the research justify the intrusion and any provision for informing the subject of the invasion of privacy?
   c. Does any combination of data present the risk of subject identification?
   d. Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy?
   e. Will subject identifiers be destroyed as soon as possible?
   f. Any data to be retained in subject’s medical or other records is described and justified.
   g. If investigators want to review existing records to select subjects for the project, how will this be accomplished?
   h. Will access to the data be limited and how/to whom?

7. Are adequate provisions described to assure the confidentiality of the research participants including storage, coding procedures, destruction of and methods of dealing with identifiable records (tapes, pictures, etc.)?
   a. Are there alternatives to the proposed method of doing the research that would yield the same quality of results but lower the risks to confidentiality?
   b. Are there adequate plans to store and code identifiable data to protect confidentiality?
   c. Are the use of identifiers or links to identifiers necessary or could the data be collected anonymously?
   d. If identifiers or links to identifiers are used, are these adequately protected?
   e. If audio or videotapes are produced, is the disposition of the tapes described adequately?
   f. Will the data be stored in a secure area and will electronic files be coded or encrypted?
   g. Disclosures to subjects about confidentiality are adequate and that the confidentiality of identifiable data will be maintained in accordance with agreement between investigators and participants.
   h. Should documentation of consent be waived in order to protect subject confidentiality?

8. Is the consent process (written, oral, implied, waived) described, appropriate and adequate given the level of risk in this study?
   a. Is waiving consent appropriate for any or all participants?
   b. Are the individuals presenting information to and obtaining consent from the subject appropriate?
   c. Is the location and manner of obtaining consent appropriate?
   d. Who will provide consent or permission? Will consent be sought from each prospective participant or their legal representative? Where surrogates/legally authorized representatives will consent, the required additional safeguards are in place, including VAMC requirements where needed.
   e. When will consent be obtained? Will there be a sufficient time period allowing participants to consider their options between presenting information to the subject and obtaining consent?
   f. Are the issues of participant’s comprehension and autonomy considered and adequately addressed?
   g. Does the consent process minimize the possibility of coercion or undue influence?
   h. Unless the requirement for documentation is waived, how will documentation of consent be accomplished?
   i. The consent process may not include exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant’s legal rights or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
   j. Are there adequate plans to inform enrolled participants about any new information relating to the research (clinically relevant results; risk of depression, suicidality, incidental findings, etc.) that might affect their willingness to continue participation in the study?
   k. Except where consent could be waived for non-exempt research, that the required elements of disclosure for exempt research will be provided to each participant or a legally authorized representative in accordance with university policy. [see 9-13]
   l. Will information in the consent document be presented in a manner appropriate to the subject population?
   m. Is the consent process executed in plain language and at an age-appropriate level?
   n. Will communications with the participant, both written and verbal, be in a language understandable to the participant or representative?
   o. If those who do not use English as a primary language will be enrolled, application indicates how translated consent procedures will be achieved.
   p. All translated consent documents are included with the application. Translator’s qualifications are given.
   q. Is written information legible? Are there any mechanical problems of grammar, spelling, punctuation, etc?

9. Purpose in lay language including a statement that the study involves research;
UB IRB Guide/Evaluation for Review of Exemption Requests

10. Design including duration, procedures (identified if experimental), alternative treatments, disclosure of new findings if applicable.
   a. Expected duration of subject participation.
   b. The approximate number of subjects involved in the study (optional).
   c. Study design described that is appropriate to the level of disclosure justified by the protocol.
   d. Study procedures or treatments are described and experimental procedures identified.
   e. Statement that significant new findings will be disclosed (if applicable).
   f. For clinical trials, disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

11. Voluntary nature with no penalties or loss of benefits, withdrawal/termination methods and consequences.
   a. A statement regarding voluntary participation, (e.g. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled).
   b. The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
   c. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (Optional).
   d. Anticipated circumstances under which a participant's participation may be terminated by the researcher or staff and policies relating termination to compensation (Optional).

12. Researcher/faculty sponsor, IRB and research related injury contact (if > minimal risk).
   a. Information for researcher & faculty sponsor contact for questions about the research.
   b. Information for IRB contact for purpose of rights as a participant in research.
   c. Information for research related injury contact.

13. Additional consent elements to consider including.
   a. A statement of any risks or discomforts
   b. Statement of any benefits
   c. Statements regarding compensation and costs to the participants
   d. Researcher/faculty sponsor, IRB and research related injury contact (if > minimal risk).
   e. Confidentiality procedures and protections including checks offs for identifiable information (tapes, pictures, quotes)
   f. For FDA regulated research, is there a disclosure that FDA may inspect records

14. Additional protections or revisions needed before exemption may be given.

   Any additional items that would typically be required in an expedited or full review of the protocol may be requested before approval is granted. These may include but are not limited to additions or changes related to:
   a. Recruitment and participant selection
   b. Safeguards for vulnerable populations
   c. Research procedure information and safety protections
   d. Data analysis procedures
   e. Maximization of benefits
   f. Compensation Procedures
   g. Protections from Undue influence and coercion
   h. The consent process
   i. Deception and debriefing procedures
   j. Supplementary documentation (consent forms, screening instruments, survey/interview questions, data collection forms used by participants)
   k. Protocol consistency

15. Exemption Recommendation

   1. Approved “as is” should be used only when
      a. The risk level is not greater than minimal
      b. Question 2b is answered “Yes”
      c. All other items are adequately addressed and no changes are requested
   2. Reconsidered for Exemption once the items below are addressed
      a. The risk level is not greater than minimal
      b. Question 2b is answered “Yes”
      c. There remain items to address or changes are requested but if your requests are adhered to the protocol exemption will be approvable.
   3. Deny exemption- requires expedited review (review should be conducted using the Initial Review Guide)
      a. The risk level is not greater than minimal
      b. Question 2b is answered “No” such that even when requested changes are made the protocol will not, suggestions are
   4. Deny exemption- requires full board review (review should be conducted using the Initial Review Guide)
      a. The risk level is potentially greater than minimal