EXEMPT DETERMINATION TOOL

All UD research involving human subjects, identifiable biospecimens, and/or identifiable private information, must be submitted to the UD IRB for review via www.IRBNet.org. Appropriate level of review required is to be determined by the IRB after submission is received.

This tool describes the requirements for research to be eligible for exempt status under the Common Rule. Submissions of new projects to the IRB must include a properly filled out Protocol Form. In addition, the following documents should be also uploaded as applicable; informed consent form, proposed advertisement and recruitment materials, and any other research measures (e.g., surveys, questionnaires, etc.). ***If your answers to this exempt determination tool indicate the proposed research is likely to be deemed exempt, the corresponding "Exempt Research Informed Consent" template available in IRBNet may be used to developed informed consent documents.***

A. GENERAL EXCLUSIONS FROM EXEMPTIONS (If one or more can be checked, the research IS NOT EXEMPT)

☐	**A.1 More than minimal risk.** The research involves more than minimal risk to subjects (***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 psychological examinations or tests.*)
☐	**A.2 FDA-regulated**. Exempt status is not granted to research subject to the regulations of the Food and Drug Administration
☐	**A.3 Access to, and use of identifiable Protected Health Information (PHI)** that would require a signed HIPAA Authorization from the participants
☐	**A.4 Prisoners**, unless the involvement of prisoners is limited to research aimed at involving a broader subject population that only incidentally includes prisoners
☐	**A.5 Deception or concealment,** unless the research qualifies for exempt category 3, and the subjects agree to be deceived (see the description of the category, below)
☐	**A.6 IRB application is for only part of a study.** A federally-supported study must be considered as a whole when making an exempt determination. The entire study must be exempt (i.e., all-or-none).
☐	**A.7 Does not fit into one of the categories listed below.** The research must fall into one or more of the exempt categories described below in Section 2 to be deemed Exempt

B. CATEGORIES OF EXEMPT RESEARCH - REVISED COMMON RULE (Effective 1.21.2019)

☐ **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.

This category would apply to most research on regular and special educational instructional strategies, and research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

- ***Established or commonly accepted educational settings*** *are settings where one would go in order to have an educational experience that is regularly offered, or that is commonly accepted in a specific culture or population.*
- ***Normal educational practices*** *are activities that could occur in the specific educational setting regardless of whether the research is conducted. This includes a variety of activities that normally occur in the classroom or that are considered "best practice". Examples include established teaching methods (not considered to be experimental) or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher.*

☐ **CATEGORY 2. Educational tests, surveys, interviews, observations of public behavior**:

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 recordings) if 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 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, educational advancement, or reputation.
3. 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 that**, when appropriate, **there are adequate provisions to protect** the **privacy** of subjects **and to maintain** the **confidentiality** of data.

- ***Research involving children does not qualify for this exempt category if****: (1) the research involves surveys, interviews, and/or observations of public behavior when the research team participates in the activities being observed, or (2) if Limited IRB Review is required.*
- ***Observation of public behavior must not be influenced by the investigator and cannot involve an intervention*** *(e.g., research involving observation of public behavior does not qualify for this exemption if the investigator intervenes with subjects by asking a question or posting a comment with on a public chat room with the intent to change the environment to observe behavior changes.*

☐ **CATEGORY 3. Benign behavioral interventions**.

Research involving benign behavioral interventions in conjunctionwith 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** i**s 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 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 readily be ascertained**, directly or through identifiers linked to the subjects, **and an IRB conducts a limited IRB review to determine** that the research (when appropriate) has **adequate provisions to protect** the **privacy** of subjects **and to maintain the confidentiality of data**.

Research involving children does not qualify for this exempt category.

- ***Benign behavioral interventions*** *are defined as brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the researcher has no reason to think that the subjects will find the interventions/ interactions/observations to be offensive or embarrassing.*
- ***Prospective agreement.*** *Subjects must be asked to agree to participate in the research. This is not the same as the requirement for consent, or for documentation of consent. The request may be tailored to the nature of the specific study.*
- ***Deception.*** *If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subjects authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.*

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

1. **Publicly available.** The identifiable private information or identifiable biospecimens are publicly available.
2. **Not identifiable as recorded.** 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.
3. **Use of PHI.** The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA regulations, for the purposes of health care operations, research, or public health activities and purposes (as those purposes are described in the HIPAA regulations).
4. **Use of federally generated or collected information or biospecimens.** The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information originally obtained for non- research activities, if the original collection and the secondary use of the information or biospecimens occurs in compliance with three specific federal statues meant to safeguard privacy.

*- **Secondary** means re-using identifiable information and identifiable biospecimens that are collected from some other "primary" or "initial" activity; in other words, not for the purpose of the specific proposed study.*

*- **"For which consent is not required"** is interpreted as there are no federal or state laws that require subject consent for the proposed secondary use. During the original collection of the information or biospecimens, the individuals (if asked) agreed to secondary uses that were described in a manner consistent with the proposed research.*

☐ **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, 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.**

All of the following criteria must be met under this exemption:

- ✓ *The program under study delivers a public benefit or service.*
- ✓ *The project must be conducted pursuant to specific federal statutory authority.*
- ✓ *There must be no statutory requirement that the project be reviewed by an IRB.*
- ✓ *The project does not involve significant physical invasions or intrusions upon the privacy of participants.*
- ✓ *The funding agency concurs with the exemption.*

Requirement for the federal department or agency conducting or supporting the project.** The federal department or agency conducting or supporting the project must establish, on a publicly accessible federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects the federal department or agency conducts or supports under this exempt category. The department or agency head can determine what sort of information will be included on this list and maintains its oversight. **The project must be published on the list before the researcher can begin the project; however, exempt status can be granted before the publication occurs.

☐ **CATEGORY 6. 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 and for a use found to be safe, or agricultural chemical or

(iii) 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 Department of Agriculture.

The UD IRB does not currently grant exempt status under categories 7 and 8 due to the lack of federal guidance for proper implementation as well as the complex nature of the required tracking of broad consent associated with these categories. Brief descriptions are provided here for information purposes

CATEGORY 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 all of the following determinations:

- ✓ Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements prescribed by the Rule
- ✓ Broad consent is appropriately documented or waiver of documentation is appropriate.
- ✓ 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 the data.

CATEGORY 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 all of the following criteria are met:

- ✓ Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or biospecimens was obtained in accordance with all of the requirements described for exempt category 7.
- ✓ Documentation of informed consent or waiver of documentation of consent was obtained.
- ✓ An IRB conducts a limited IRB review and makes the following determinations:
    - When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
    - The research to be conducted is within the scope of the broad consent provided by the subjects. The investigator does not include returning individual research results to subjects as part of the study plan. (Note: this provision does not prevent an investigator from abiding by any legal requirements to return individual research results.)