EXEMPT STATUS INSTRUCTIONS AND DEFINITIONS

The instructions and definitions below are organized following the order of questions on the IRB *Application for Exempt Status*, and supplement the instructions on that form. Applicants must follow all instructions provided, both on the application form and as explained below.

In General

Exempt Status means the IRB application is reviewed by just one member of the IRB, not by the full IRB. The proposed research still must meet requirements for protection of human subjects, including informed consent in most cases. The IRB reviewer determines if the application meets the requirements for Exempt Status under at least one of the exempt categories listed on the *Application for Exempt Status* at https://provost.umw.edu/irb/instructions-and-forms/ .

To meet the requirements for Exempt Status, the research must involve no more than minimal risk to participants. ***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.

A. Project and Primary Investigator

The individuals named in Part A of this form will receive copies of the official IRB approval notice. The IRB reviewer will communicate with one or both of these individuals during the review process.

B. Exempt Status Categories

Select the category that you believe applies to your research, as listed on the application form and explained below. Under Part C "Description of Research" provide detail about how your proposed research meets the category criteria and definitions.

1. Research in Educational Settings

To qualify for this category the educational practices must not be likely to adversely impact students' opportunity to learn required educational content and not likely to adversely impact the assessment of educators who provide instruction. Under Part C "Description of Research" include the research setting and educational practices to be investigated, according to the following definitions.

An ***established or commonly accepted educational setting*** is a space used for teaching and learning in or by an educational organization. Examples of places that would *not* be established or commonly accepted educational settings would include spaces used for home-schooling or spaces used for occasional training in a business or other noneducational organization.

Research to investigate ***normal educational practices*** may involve regular or special education instructional strategies or the effectiveness of instructional or assessment techniques, curricula, or classroom management methods, etc. Any research design that withholds instruction from participants entitled to it would not be normal. The IRB does not consider audio or video recording of minors used as data for research to qualify for exempt status; an Application for Expedited Review will be required.

2. Research Involving Tests, Surveys, Interviews, or Observation

To qualify for this category, the research may not include procedures under any other Exempt Status categories. Research on adults in this category may include voice, video, digital or image recordings only when the subjects know they are being recorded. The IRB must verify that adequate privacy and confidentiality measures are in place.

At least one of the following criteria must be met for research in this category: (a) information obtained is recorded in such a manner that human subjects cannot be identified, 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, or reputation; or (c) the IRB determines that privacy and confidentiality measures are in place if any information obtained about subjects is recorded in such a manner that they can be identified directly or through identifiers linked to the subjects.

Research on children can qualify for Exempt Status under subsections (a) and (b) of this category only if there is no interaction between the researcher and the child. Research on children cannot qualify for exempt status under subsection (c) of this category.

3. Research Involving Benign Behavioral Interventions

This category is only for the collection of information from adult subjects and only includes protocols in which subjects give informed **consent before the intervention**. The IRB must verify that adequate privacy and confidentiality measures are in place. Research in this category may occur in conjunction with the collection of data from subjects through verbal or written responses (including visual or auditory recording or data entry). If the study involves **deception**, subjects must give prior consent that they will be unaware of or misled regarding the purpose of the study or intervention, and also be debriefed following the procedure. This category does not apply to any research involving medical interventions, including medical tests, procedures or devices.

To qualify for this category, at least one of the following criteria must be met: (a) information obtained is recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained directly or through identifiers linked to the subjects; (b) any disclosure of the 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 IRB determines that privacy and confidentiality measures are in place if any information obtained about subjects is recorded in such a manner that they can be identified directly or through identifiers linked to the subjects.

A ***benign behavioral intervention*** is defined as an activity that participants undergo which is brief in duration, harmless, painless, not physically invasive, and 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 intervention offensive or embarrassing. If all of these criteria are met, the following would be examples of benign behavioral interventions: having subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of money between themselves and someone else.

4. Secondary Research for Which Consent is Not Required

To qualify for this category the research must meet at least one of the following criteria: (a) the information or specimens are publically available; (b) the information is recorded by the investigator so that the identity of the human subjects cannot be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects at any time, *and* the investigator will not re-identify the subjects; (c) the research involves collection and analysis of identifiable health information only for health care or public health activities and purposes; or (d) all of the identifiable private information is collected or maintained by a federal department or agency in compliance with all applicable privacy laws.

Under Part C "Description of Research" identify the data or specimen repositories being used. Research use of data from students' private school records must meet the requirements of the federal Family Educational Rights and Privacy Act (FERPA).

Secondary research refers to use of data not collected by the researcher for the proposed study. It means reusing identifiable information and identifiable biospecimens that are collected for some other primary or initial purpose, such as information found by the investigator in some type

of record or specimen repository, such as stored by a hospital. It may include data collected by the researcher for a previous study for which consent was obtained. Secondary research data or specimens do not all have to exist prior to beginning the proposed research; some may be placed in the data repository after the proposed research begins.

Identifiable means that the identity of the subject is or may readily be ascertained by the investigator either directly or through identifiers linked to the subject's information.

5. Research and Demonstration Projects for a Federal Agency

This exempt status category includes research on adults or children conducted under contracts or consulting arrangements, cooperative agreements, or grants with a federal department or agency, or research otherwise subject to the approval of federal agencies. It covers projects which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures of obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Under Part C "Description of Research" include the federal department, agency, etc. that authorizes the proposed research.

6. Research on Taste and Quality of Foods

If the food contains additives, indicate under Part C "Description of Research" how you verify that it meets standards of the Food and Drug Administration, the Environmental Protection Agency, or the Food Safety and Inspection Service of the Department of Agriculture (e.g., by providing package labeling or product website).

7. Storage or Maintenance for Secondary Research Data

This is not a category of research per se, but relates to the process for obtaining secondary research data (see definition of ***secondary research*** under Category 4 above). For example, if you are collecting data for potential use in future research by yourself or others, then this category would apply. Broad consent is required, and the IRB must verify that adequate privacy and confidentiality measures are in place.

Broad consent refers to prior consent given by participants for unspecified future research use of their identifiable private information or identifiable biospecimens (see definition of ***identifiable*** information under Category 4 above). For example, broad consent for use of medical information may be provided through use of HIPPA forms (Health Insurance Portability and Accountability Act). For information on Broad Consent forms and procedures, consult with the IRB Chair.

8. Secondary Research Requiring Broad Consent

To qualify for this exemption, *all* of the following criteria are met: (a) broad consent from subjects was obtained; (b) signed informed consent was obtained from participants, or waiver of such documentation was obtained from the IRB; (c) the IRB determines that the proposed research is conducted within the scope of broad consent and approves the procedures used to obtain broad consent; *and* (d) the research plan does not include returning individual research results to the subjects.

Under Part C "Description of Research" indicate how you verify that the required broad consent was obtained, and attach the Broad Consent form. The IRB must verify that adequate privacy and confidentiality measures are in place.

See definitions of ***secondary research*** and ***identifiable information*** under Category 4 above; and of ***broad consent*** under Category 7 above. Regarding waiver of signed consent forms, see the instructions for Part D "Informed Consent" below.

C. Description of Research

In this section provide sufficient information for the IRB reviewer to make the determination that the proposed research meets the criteria for the Exempt Status category selected, according to the guidance in Part B above. Give separate answers for each question in Part C, or indicate "None" if irrelevant.

Privacy and confidentiality: The IRB is required to review measures taken to ensure the privacy of participants and the confidentiality of data during the research and in any reports or presentations. Be specific in describing the confidentiality measures in place for each type of data being collected, including what is on paper and in digital form. ***Privacy*** refers to the rights individuals have over others' access to themselves, physically, behaviorally and intellectually. Violations of privacy can occur during participant recruitment, informed consent, and/or data collection, and may involve circumstances such as being photographed or recorded without their knowledge, being asked questions in a public setting, being observed while conducting personal behavior, etc. ***Confidentiality*** refers to the treatment of participants' information (including data, biological specimens, etc.) and prevention of disclosure of the information. If research is being conducted ***anonymously***, it means that the researchers do not know the identity of participants and are unable to link data to individual participants directly or through the use of identifiers.

Risks to participants: These include physical, psychological, economic or social risks or discomforts, even if minimal. Risks may include risks of disclosure of private information about participants. Such risks may include placing participants at risk of criminal or civil liability, or be damaging to their financial standing, employaility, educational advancement, or reputation. If any risks can be anticipated in the proposed research, describe the measures to minimize them.

D. Informed Consent

This section pertains to use of written informed consent, assent, and debriefing forms, which may be read aloud to potential participants exactly as written. In any case, the written forms should be given to participants to keep for later reference. However, in some circumstances written consent is not possible or appropriate, and an oral consent procedure requiring witnesses should be used. For information on this oral consent procedure, consult with the IRB Chair.

When preparing these forms, **follow the detailed instructions** for Adult Informed Consent (including translations and waivers), Parent-Child Consent, and Debriefing, which are available at https://provost.umw.edu/irb/instructions-and-forms/ .

For information on **Broad Consent** forms and procedures, consult with the IRB Chair.

E. Attachments

Attachments may be typed as additions to the IRB application or sent as separate documents accompanying the IRB application. The certificates of ethics training should be the PDFs downloaded from the CITI website after completion of the training (see instructions at https://provost.umw.edu/irb/irb-training/).

Signatures Page

All researchers should be listed and sign the form. Authentic signatures may be inserted as digital copies into the typed application form, or the Signatures Page may be signed by hand, scanned, and submitted as a PDF document.

For IRB purposes, ***researchers*** (or ***investigators***) are defined as those individuals who are involved in conducting human subjects research studies. Such involvement would include: obtaining information about participants or interacting with them for research purposes; obtaining informed consent of participants; and/or studying, interpreting, or analyzing participants' information or data for research purposes.