Choosing Your Type of Review

I. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Generalizable knowledge can include, but is not limited to, publication or presentation to an audience outside of the organization, activities that are designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program.

If your project does NOT meet this definition, submit a Not Research application.
If your project DOES meet this definition, move to the next definition below.

II. **Human Subjects Research** is research that involves a living individual about whom an investigator (whether professional or student) conducting research:
   a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **OR**
   b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

If your project does NOT meet this definition, submit a Not Human Subjects Research application.
If your project DOES meet this definition, move to the next definition below.

III. **Exempt Research** – research that presents no more than minimal risk to subjects and **ALL** activities that will be conducted fit into one or more of the below categories of review. If **any aspect** of the research does not fit into these categories of Exemption, the research is Non-Exempt.

Exempt Category Number	Short Name	Definition
Category 1	Normal Educational Practices **NOTE:** These activities must be planned to take place whether research is occurring or not.	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.
Category 2	Interactions involving educational tests, surveys, interviews, or 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 recording) if **at least one of the following criteria is met:** (i) 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. (ii) 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; (i) (iii) 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 required by §46.111(a)(7).
Category 3	Benign Behavioral Interventions with adults **NOTES:** 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. "Brief in duration" means that all of the research activities take no more than a few hours over the course of one day. If the research involves deceiving, misleading, or giving incomplete disclosure to the subjects regarding the research purpose or activities, the subjects must agree to the deception/incomplete disclosure prospectively during the consenting process. After their research participation is complete, subjects must be given the full, accurate information and be provided the opportunity to withdraw their data.	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:** (A) 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; (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, educational advancement, or reputation; or (C) 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 required by §46.111(a)(7).

Category 4	Secondary research for which consent is not required **NOTE:** "Secondary Research" means that the data/specimens were either originally collected for non-research purposes or were collected for a separate research project under a different IRB approval, subjects provided consent for the data to be used for future research, and there was no intention at the time to use the data or specimens for the current proposed research.	Secondary research uses of identifiable private information or identifiable biospecimens, **if at least one of the following criteria is met:** (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) 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;

* This list of Exemptions has been adjusted to remove aspects of the regulations that do not typically apply to research at CMU such as research conducted directly by governmental agencies or consumer food tasting studies.

If all aspects of your research fit into one or more of the above Exempt Categories of review, submit an Exempt application.

If any aspect of your research does not fit into the above Exempt categories, submit a Non-Exempt application.

Please note that final IRB determinations of the applicable review category for your research will be made by the IRB upon review of your application. Based on details in your protocol and research application, you may be asked to change the type of review selected.