

Does my protocol qualify for Exempt Review?

You should be aware that exempt status does NOT mean the study is exempt from IRB review. Exempt is defined as being exempt from further review and approval beyond the Compliance Officer or one of the two IRB Co-Chairs. Research using data from living persons does not require IRB approval when the research does not involve human subjects as defined in [45CFR46](#), i.e. obtaining research data through intervention or interaction with an individual or with their identifiable private information; or the only involvement of human subjects is one of the below “exempt” categories. If you believe your study will fall into one of these categories, download the “IRB application for Exempt Reviews.”

As stated in 45 CFR 46.101(b):

- **45 CFR 46.101(b)(1): EVALUATION/COMPARISON OF INSTRUCTIONAL STRATEGIES/CURRICULA**
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.
- **45 CFR 46.101(b)(2): EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, OR 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.
- **45 CFR 46.101(b)(3): PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not covered under the previous paragraph 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. You will be asked in your application to describe how subjects may be identified or are at risk, or state the federal statute that allows the confidentiality of the subject to be maintained throughout the research and thereafter.
- **45 CFR 46.101(b)(4): COLLECTION OR STUDY OF EXISTING DATA**
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. Note: To qualify, the data, documents, records, or specimens must be in existence before the project begins. Additionally, an investigator (with proper authorization) may inspect identifiable records, but may only record information in a non-identifiable manner. For questions contact the MTSU IRB
- **45 CFR 46.101(b)(5): RESEARCH AND DEMONSTRATION PROJECTS**
Research and demonstration projects which are conducted by or subject to approval of federal Departmental or Agency heads (such as the Secretary of Health and Human Service), 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; (iv) possible cof payment for benefits or services under those programs.

Note: This applies to federally funded projects only and is most appropriately invoked with authorization or concurrence from the funding agency. Additionally, specific criteria must be satisfied to invoke this. Also, this category does not apply if there is a statutory requirement that this project be reviewed by an IRB or if the research involves physical invasion or intrusion upon the privacy of subjects.

- **45 CFR 46.101(b)(6): FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES**

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome food, 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 environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.