**NEBRASKA WESLEYAN UNIVERSITY**

**Institutional Review Board (NWU-IRB)**

5000 Saint Paul Avenue; Lincoln, Nebraska 68504

FWA 00024370

**Categories for Exemption of NWU-IRB Protocol Review [45 CFR §46.101(b)[[1]](#footnote-1)]**

**Research projects that meet one or more of the following categories are EXEMPT from Review by the IRB**

*(Principal Investigators must fill out the Application for NWU-IRB Protocol Review to receive the exemption)*

In order to establish that a research project is exempt, the Principal Investigator (PI) must complete the *Application for NWU-IRB Protocol Review* and clarify that the research project poses no more than minimal risk to the research participants[[2]](#footnote-2). If the PI is a student, the initial determination will be made by the student’s research advisor. Final determination as to whether a research project is exempt rests with the NWU-IRB. If the project is judged to be exempt, the PI need not resubmit the *Application for Continuation Review* as long as there are no modifications in the exempted procedures. An IRB Co-Chair, or his/her designee, may review individually *Applications for Exemption from NWU-RRB Review*.

Generally, research that does not propose to disrupt or manipulate participants' normal life experiences, or incorporate any form of intrusive procedures, may be declared exempt from NWU-IRB review. Research activities are exempt from the NWU-IRB review when the ONLY involvement of human participants falls within one or more of the following categories:

**Note: Research projects involving vulnerable populations or the collection of biological samples cannot be granted exemption.**

**Categories for Exemption under 45 CFR 46.101b:**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

* 1. research on regular and special education instructional strategies, or
  2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

* + 1. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    2. 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; and
    3. the research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, and alcohol use.

3. 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:

1. the human subjects are elected or appointed public officials or candidates for public office; or
2. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. 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 participants cannot be identified, directly or through identifiers linked to the participants.

5. 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:

1. public benefit or service programs;
2. procedures for obtaining benefits or services under those programs;
3. possible changes in or alternatives to those programs or procedures; or
4. possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies if:

1. wholesome food without additives are consumed,
2. 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety Inspection Service of the US Department of Agriculture.

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| EXEMPTIONS DO NOT APPLY TO RESEARCH INVOLVING pregnant women, fetuses, human in vitro fertilization, and prisoners. Further, the exemption in item two, above DOES NOT APPLY TO CHILDREN, EXCEPT for research involving observations of public behavior when the researchers do not participate in the activities being observed. |

**NOTE: STUDENT INITIATED RESEARCH**

All NWU-IRB applications arising from student research will first be submitted to the student's research advisor. Following that, the procedure will be the same as for faculty/staff research. **One electronic file (PDF format) including the application and all supporting documents** will be submitted to NWU-IRB Coordinator, Stephanie Plummer, [nwuprovost@nebrwesleyan.edu](mailto:nwuprovost@nebrwesleyan.edu).

For student projects, all NWU-IRB communication will be directed to the student's research advisor. The NWU-IRB will communicate directly with the student's research advisor. It is the responsibility of the research advisor to communicate with and work with the student if any changes or clarifications are necessary.

**CHECKLIST FOR COMPONENTS OF A COMPLETE PROTOCOL REVIEW APPLICATION**

Complete the training module available at <http://phrp.nihtraining.com> and submit a copy of the certificate provided.

Determine the appropriate Exempt Review category/categories, and note on application.

Complete the **Application for NWU-IRB Protocol Review, and check the box for Exempt category**.

Obtain needed signatures: Principal Investigator(s), Faculty Advisor, etc.

As applicable, submit a permission letter from any performance sites or other outside organizations involved in your research.

Note: Approval for specific performance sites will be granted on a site-by-site basis as the permission letters are received and approved by the NWU-IRB.

Submit copies of all recruitment materials, such as fliers, newspaper ads, brochures, posters. They must be approved by the NWU-IRB prior to use.

Submit copies of all informed consent forms.

Submit copies of all survey instruments, questionnaires, or any other such data collection materials.

Include a Reference List for academic studies cited.

1. <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.101> [↑](#footnote-ref-1)
2. *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. [↑](#footnote-ref-2)