

IRB PROCEDURE STATEMENT

Procedure: Exempt Category #1 Requirements

Procedure ID: 2002-05 **Effective:** April 5, 2017; May 2022

A. Background

Bowling Green State University (BGSU) policy requires that the Institutional Review Board (IRB) review all research involving human subjects.

If a project meets the Federal definitions of:

“Research” as defined by United States Department of Health and Human Services (HHS) *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(l): “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

and

“Human subject” as defined by HHS *Subpart A - Basic HHS Policy for Protection of Human Research Subjects* at 45 CFR 46.102(e)(1), “means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, or analyzes, the information or biospecimens; or (iii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” **the research project must be reviewed by the IRB.**

Exempt research is research with human subjects that typically involves no more than minimal risk to subjects. It is “exempt” from the provisions stated in the Common Rule (45 CFR 46, Subpart A); however, exempt research must comply with the ethical principles of *The Belmont Report*: Respect for persons, Beneficence, and Justice. Exempt status does not lessen ethical obligations to subjects. Exempt research does not require ongoing review by the IRB unless the project is amended in such a way that it no longer meets the exemption criteria.

The purpose of this procedure statement is to clarify the types of projects that fall under the **Exempt #1 category and the requirements that must be met in order to secure Exempt #1 status.**

B. Definition

[45 CFR 46.104(d) (1)]. **Exempt #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 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.”

C. Clarification

Commonly accepted educational settings include but are not limited to K-12 schools and college classrooms. They may also include other sites, including online platforms, where normal educational activities regularly occur.

Normal classroom practices include established teaching methods, curriculum content and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher. Normal educational practices are activities that would normally occur regardless of whether the research is conducted.

Note: “Studies that use surveys or interviews with minors that are outside of “normal educational practices” (i.e., beyond the assessment of educational practice) do not qualify for exemption.”

D. Examples of research covered under Exempt Category #1

Researchers observe classroom instruction and collect quizzes that are part of classroom practices.

Researchers interview instructors about their experiences implementing instructional materials. No specific information about students is collected.

Researchers conduct a comparison of classes using different teaching techniques by looking at test scores.

Researchers collect information from students regarding their attitudes about learning or curriculum.

Researchers test innovative instructional methods. Researchers create and develop educational tests.

E. Examples of research not covered under Exempt Category #1

Projects involving instructional or classroom management techniques that would not be considered to be best practice (e.g., using untested curriculum).

Interviews or surveys that collect information focused on characteristics of the children rather than the educational activity being tested.

F. Exempt Category #1 research requirements

In addition to submitting all regularly required protocol materials for review, note the following:

- Parental permission/consent is not required unless accessing student grades with identifying information. Signed parental permission is required in these cases per FERPA. Self-reporting of grades/GPA does not require parental permission.
- A letter must be sent home to parents to inform them of the research activities taking place in their child's classroom (**see Appendix A** in this document).
- Child assent is not required.

Appendix A

Print on University Letterhead

Parent Information Letter

March 1, 2017

Dear Parent(s)/Guardian(s),

My name is [insert name] and I am a(n) [insert rank] of [insert field] in the [insert department/school] at Bowling Green State University. This letter provides information about a study I am conducting in your child's classroom as part of the teacher's regular classroom instruction. The study will begin [insert start date] and end [insert end date].

The purpose of the study is to [insert main goal/objective]. All students in the teacher's classroom will receive the same instruction and take the same assessments as part of their regular classroom instruction. The teacher will use the assessments to [insert description of teacher use, such as providing student feedback, guiding instruction, and assigning grades] as part of his/her regular classroom practice.

I will use the results of the assessments to evaluate the impact of the instruction on student learning. I will not know your child's name or be able to match his/her name to the assessments. Your child will be assigned a special code and only the teacher will be able to link your child's name with his/her assessment results and the special code. I will keep hard copies of the assessments in a locked file cabinet in a locked office at Bowling Green State University. Results of the assessments will be entered into a computer and used to conduct statistical analyses. The electronic files will be password protected and stored on a password-protected computer. I [insert others as necessary, such as a GA] am the only one with access to either the cabinet or computer. Again, your child's responses are completely anonymous. I/We will not be able to trace responses on the assessments back to your child.

If you have any questions about this classroom study, please contact me at [insert campus phone number]. Thank

you.

[insert name, title, contact information]