



## GUIDANCE ON EXEMPT CATEGORIES

How do you know if your research project fits an Exempt category? What elements of your project design might change the IRB review designation from 'Exempt' to 'Expedited' or even 'Full board review'? **IT DEPENDS.** The following information provides guidance on each Exempt category. If your project meets an Exempt category this does not mean that IRB review is not needed. A protocol application must still be submitted for approval of exemption determination. **When in doubt, contact the Compliance Office to discuss your project!**

### **EXEMPT CATEGORY 1**

*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.*

#### **Guidance**

Research involving *normal educational practices* in *established or commonly accepted educational* setting may meet this Exempt category.

**Commonly accepted educational settings** include but are not limited to K-12 schools and college classrooms. They may also include after-school programs, preschools, vocational schools, alternative educational programs, and other sites where educational activities occur. This might also include non-school settings, such as libraries, training centers or workplaces such as hospitals.

**Normal educational practices** include established teaching methods, curriculum content and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher. These activities typically occur in a classroom or other educational setting. Examples include:

- Test development
- Innovative instructional methods
- Assessment of attitudes about learning or curriculum
- Evaluation of classroom or school activities
- Use of educational tools such as computers or smart phones

Thus, a study that evaluates a radically new instructional strategy or curriculum, or that randomly assigned students to different instructional strategies/curricula for comparison, would probably not be Exempt, since these are not *normal educational practices*. Studies that involve surveys and interviews with minors that are outside of *normal educational practices* also do not qualify for Exempt approval determination.

Even when research meets an Exempt category, researchers using student educational records must meet the requirements of the Family Education Rights and Privacy Act (FERPA).

This category does not apply to Food and Drug Administration (FDA) regulated research.

**Examples**

Exempt under Category #1	Not Exempt under Category #1:
<p>A teacher, student teacher, or school counseling intern uses his/her students' pre- and post-test results to assess the effectiveness of a implementing the reading curriculum that meets state standards in a modified way.</p>	<p>A researcher wants to use an elementary school classroom to assess the effectiveness of a new reading curriculum using interviews, surveys and researcher designed tests. Generally this is not exempt because it is not a normal educational practice for an outside researcher to interview students about a new educational program and the program is untested. However, in certain situations [e.g. literacy facilitators using their time in another teacher's classroom], this example could be considered 'exempt' or if the researcher is commonly part of the classroom in some manner, this example could be considered exempt.</p>
<p>A teacher, student teacher, or school counseling intern uses his/her students' pre- and post-test results to assess the effectiveness of a new reading program. In addition to using the test scores, the researcher also wants to survey (or interview) all the students to ask them questions about the new reading program.</p>	<p>A teacher surveys his/her students in the classroom about their after-school activities or characteristics of the child. (The setting is typical but the activity is not <i>normal</i> educational practice.)</p>
<p>A high school teacher wants to compare two math curricula being implemented at the school. One section/group of his/her students (e.g. 1<sup>st</sup> period math students) receive one curricula and the second section/group of students (e.g. 2<sup>nd</sup> period math students) receives the second curricula. The activity would be considered 'exempt' under Exempt #1. Each group is learning the same curriculum in a <i>normal</i> educational setting but in using different instructional techniques.</p>	<p>A high school teacher randomly divides his/her single class into two groups and conducts an experimental/untested math curriculum with one group and conducts the normal educational program with second group for research purposes. (The activity is not <i>normal</i> educational practice.)</p>

**EXEMPT CATEGORY 2**

*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.*

**Guidance**

Many survey/interview projects fall within this Exempt category. The research must meet either of the following two conditions to meet this category.

- The data are collected anonymously, which means that no identifiers can be connected to the data, either directly or through a coding system. Video recordings and photographs are considered to be identifiable; therefore data collection that involves video recording or photographs of participants

would not be considered anonymous. Audio recordings may or may not be considered to be identifiable. It is also possible that multiple pieces of information about a person, none of which are identifiable on their own, may uniquely identify a person when brought together; in this case, the data would be identifiable and would not be considered anonymous. OR

- The information collected is not anonymous (because, for example, the researcher has a key linking respondents' names to coded identifiers), but the information is so innocuous that in the event of disclosure outside of the research there would be no significant detrimental consequences to the subject.

**Public behavior** refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, a government building). If subjects have a reasonable expectation of privacy at the location where the researcher is conducting the observation, the project may not qualify for this Exempt category.

**Children:** Research involving surveys or interviews with children or observation of public behavior when researchers interact with the children does not qualify for this Exempt category.

This category does not apply to Food and Drug Administration (FDA) regulated research.

**Examples**

Exempt under Category #2	Not Exempt under Category #2
<p>Observation of children interacting on the playground OR adults' buying habits in a local McDonald's restaurant OR passively observing (with pencil and paper) the interaction of children with fathers at a public park (i.e., passive public observations, no identifiers, no-risk data, observations in a 'public' setting).</p>	<p>Observing the conduct of middle school students while interacting with them in a group game (NOTE: participatory observation of children is not exempt.)</p>
<p>A teacher, student researcher or counseling intern wants to survey adults about their recent experience with their health care service provider. (NOTE: Anonymous with no identifiers recorded.)</p>	<p>Surveying college students' drug and alcohol habits with considerable demographics collected (potentially harmful and information about unlawful acts collected, could be minors in the subject pool, demographics may allow identification) OR videotaping music practice sessions with teacher for research purposes (identifiers, risk of embarrassment or discomfort)</p> <p>Note: In general, videotaping allows identification and introduces risk which requires a higher level of IRB review.</p>
<p>Anonymous workplace satisfaction survey.</p>	<p>Survey about opinions on the managerial skills of a person's supervisor, without naming the supervisor. The survey is coded such that the researcher may determine who has and has not responded. The code links data with participant names.</p>

### **EXEMPT CATEGORY 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: (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.*

#### **Guidance**

This category is used for surveys or interviews with public officials that would not meet the criteria for Exempt category #2. Exempt category #3 has a different privacy standard for research involving public servants and does not require be either anonymous or innocuous.

A **public official** is considered to be an elected or appointed official (or candidate for office). Public employees are not considered to be “public officials.” The superintendent of schools may be a public official; a teacher would not. A senator would be a public official; a member of their staff would not.

Part (ii) of Exempt category #3 applies only to research on specific programs conducted or supported by the Department of Justice or the National Center for Education Statistics. These agencies have specific programs that create databases which are protected by law from being accessed by anyone other than those agencies. The data collected for these programs are immune from legal process and cannot be revealed or furnished for any purpose other than that for which they were collected.

This category does not apply to Food and Drug Administration (FDA) regulated research.

#### **Examples**

<b>Exempt under Category #3</b>
Interviews with public officials to solicit response to questions about politically sensitive issues that might have an impact on their reputation.
Interview or survey of public officials on local issues.
Comparing personality assessment scores of appointed judges in the state of NC.
Interviewing town mayors about their religious beliefs and views on the separation of church and state.
Study of candidates for the State Legislature that includes intelligence tests and interview questions about their finances, past employment, and drug use.

### **EXEMPT CATEGORY 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 subjects cannot be identified, directly or through identifiers linked to the subjects.*

#### **Guidance**

To meet Exempt category #4, the materials (information, data, documents, etc.) to be used in the research must be existing or “on the shelf” at the time that the research is proposed (i.e. at the time of IRB protocol submission). This category does not apply to prospective collection of data or specimens.

The language in the regulation was intended to apply to public sources of data, such as a local telephone directory information. Research may meet the Exempt category #4 if the data are publicly available (the

general public can obtain the data/specimens and they are available to anyone regardless of occupation, purpose, or affiliation). Student records covered by the Family Educational Rights and Privacy Act (FERPA) are not public records.

Research may meet the Exempt category #4 if the investigators initially and/or temporarily have access to identifiable private information, but abstract/extract the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include any direct identifiers (names, social security numbers, employee or student ID numbers, etc.) **or** indirect identifiers (codes or pseudonyms that are linked to the participant's identity).

This category does not apply to Food and Drug Administration (FDA) regulated research.

### **Examples**

<b>Exempt under Category #4</b>
Retrospective chart review where the researcher has access to identifiable data, but does not record it for research purposes.
Analyzing de-identified data or tissue samples.
A graduate student has access to coded data from a study previously conducted by his/her Responsible Faculty and records the information needed for the research without the code, so that the data being analyzed for the research can in no way be traced back to the individual subjects.

### **EXEMPT CATEGORY 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: (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; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.*

### **Guidance**

Exempt category #5 applies only to research on public benefit programs (such as Social Security) conducted by the federal government and therefore is rarely applied. Research and demonstration projects in general (e.g. state or city funded public service programs) do not meet this Exempt category. Projects that meet the Exempt category must be conducted pursuant to specific federal statutory authority.

This category does not apply to Food and Drug Administration (FDA) regulated research.

### **Examples**

<b>Exempt under Category #5</b>
Research sponsored by the Department of Housing and Urban Development to assess the effectiveness of a housing subsidy program.

### **EXEMPT CATEGORY 6**

*Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.*

**Guidance**

Taste and food quality evaluation studies conducted under this Exempt category may not involve consumption of any type or volume of food that would present any risk to the participants and should fall into what would be considered reasonable eating behaviors by the participant. Thus, the key element of this category is that the research can only involve foods that are known to be safe.

The food must be “wholesome” (no additives), or if it involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA. Studies involving the consumption of alcohol, vitamins, and other supplements do not qualify for this Exempt category.

**Examples**

<b>Exempt under Category #6</b>
Taste testing of new calcium-enriched soda.
Tasting of several yogurts to determine which texture is more pleasing.
Test testing of different varieties of a fruit to determine consumer preference, when the fruits do not have any additives and participants are asked to indicate which fruit they prefer.
Taste-testing pork products where the swine was fed corn and a chemical additive at a level designated below FDA guidelines that make the animal gain weight more quickly. The objective of the study is to determine whether the addition of the chemical changes the flavor of the pork.

**Adapted from:**

UNC Chapel Hill guidance  
University of Kentucky guidance