UNIVERSITY OF OREGON

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

RESEARCH COMPLIANCE SERVICES

EXEMPT APPLICATION WORKSHEETS
DEFINITIONS & TERMS

Exempt Category 1	
Established or commonly accepted educational settings	Settings where specific educational offerings normally take place or a setting where one would go in order to have an educational experience. Examples include K-12 schools and college classrooms, after-school programs, preschools, vocational schools, alternative education programs, professional development seminars, and religious education settings.
Normal Educational Practices	The term "normal educational practices" refers to proven instructional techniques already in use or classroom management. Examples of research that would fall under this category would be a study to evaluate the use of accepted or revised standardized tests or evaluation of a continuing education program. However, a randomized controlled trial with the control group receiving the "normal educational practice" and the experimental group receiving a new or innovative practice would generally not fall under this exemption. This exempt category 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.
Exempt Category 2	
Educational tests	Tests of cognitive, diagnostic, aptitude, or achievement. Examples include the SATs, ACTs, and placement tests to determine if a student should be placed in an advanced or intermediate class.
Identity of human subjects cannot readily be ascertained	Research information that does not contain directly identifiable information (e.g., name, address or email address) or details that would allow the researchers to figure out who the subject is (e.g., by using a code that can link back to a subject, or data elements that could be combined to readily re-identify a subject).
Interviews	Information collected about individuals through conversations or discussions. Interviews can be in person, over the phone, or online using platforms such as zoom. They may be audio or video recorded. Interviews can be individual or can include activities such as focus groups.
Public behavior	Behavior that occurs in a public place where there is no expectation of privacy and where no special permission is required to observe others. Public behavior is behavior that can be observed by anyone and observations should not be considered inappropriately intrusive. Behavior in classrooms or other venues that require special permission to access or behavior in restrooms or other venues where there is an expectation of privacy are not considered public behavior.
Surveys	Information collected about individuals through questionnaires or similar procedures

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Exempt Category 3	
Adults	Persons who have attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In most cases, adults will be individuals over the age of 18. However, there may be contexts and jurisdictions where individuals under the age of 18 could be considered adults (e.g., emancipated minors, minors 15 years old or older giving consent for medical treatment).
Benign Behavioral Intervention	Benign behavioral interventions are harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and are neither offensive nor embarrassing. Medical interventions (including medical tests, procedures and devices) may not be used. Behavioral intervention employ research procedures in the study of psychological states and processes, cognition, ideas and attitudes, or behavior. They do not include physical (bodily) tasks or physical manipulations unless these are minor activities that are incidental to the behavioral intervention and do not increase risk. Behavioral interventions typically rely only on communication or interpersonal contact with the subject, the performance of a cognitive, intellectual, educational or behavioral task, or manipulation of the subject's physical, sensory, social, or emotional environment. This exemption is limited to interventions that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or offensive. Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of the exemption. Similarly, while research cannot meaningfully eliminate all risk of embarrassment or offense, the research should include only interventions that the researcher has no reason to think subjects will find offensive or embarrassing considering the characteristics of the subject population, the research context, and how they might impact the subject's experience of the research intervention.
Brief in Duration	Brief in duration refers to the intervention itself. Data collection activities can proceed over a longer period of time separate from the intervention. However, if the intervention and the data collection are intertwined or difficult to separate, the entirety of the activity should be brief in duration. To qualify as "brief in duration", the benign behavioral intervention should last a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should only add up to no more than a few hours. The more irritating or unpleasant the intervention will be, the less time a participant can be involved before it stops being 'brief'. For example, looking at images that are not upsetting may be brief for a few hours, while sitting in a particularly uncomfortable chair may stop being brief within a few minutes.
Data Collection Methods	For this exemption, only certain data collection methods can be used. Even very low risk physical procedures are not allowed such as using sensors on the body (e.g. blood pressure monitors, EEGs, wearable activity trackers like Fitbits), minimally invasive procedures (e.g. blood draws), and collecting bodily fluids (e.g. buccal swabs).

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Deception	Deception involves intentionally providing inaccurate or false information to subjects. For example, telling participants that they will be interacting with another participant online by playing a game together when they are actually playing against a computer. Incomplete disclosure is another form of deception that involves withholding information about the study purpose and/or details about the study procedures. Incomplete disclosure is often used to minimize the chance of biasing results or priming participants. For example, telling participants that they will be asked to provide information about their perceptions about people based on their photographs but not informing them that researchers are interested in seeing how the race or gender of the person pictured impacts their perceptions. For exemption under this category, no deception may be used or if deception is used, the participants must be told that they will be kept unaware of or misled regarding the nature or purpose of the research. For example, participants may be informed that they will not be told the purpose of the research until after the study session is completed as long as they are informed of what will occur during the session.

Exempt Category 4	
Identifiable biospecimen	A biospecimen (e.g., tissue, cells, blood, saliva, urine) for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
Identifiable Private Information	Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
Publicly Available	Data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges. Access may be free or provided at a nominal cost. The source may be from a commercial entity if the information can be obtained by members of the general public. Examples include data/biospecimens available for public purchase, searchable online, or available at a library.
Secondary Research	Research with specimens and/or data that was initially collected for purposes other than the planned research. The specimens/data might have initially been collected for non-research purposes (for example, as part of routine clinical care) or as part a different research protocol.

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Exempt Category 5	
Demonstration Projects	Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.