

Infographic Examples of HRPP/IRB Exemption Categories

These images and guides are intended to provide examples and basic explanation of the allowable exemption categories under Common Rule Regulations. They may not represent every case, but should provide a starting point for those applying for exempt research with human participants.

All exemption categories are in reference to the [US Department of Health and Human Services](#).



PURDUE
UNIVERSITY®

Office of Research

Category 1

Educational Practices

Research in educational settings may be eligible for exemption under Category 1. The research must not jeopardize students' ability to learn or instructors' standing or assessment. Also, consider the release of information covered under the [Family Educational Rights and Privacy Act \(FERPA\)](#). Release of data covered under FERPA is handled by each school. For information on data at Purdue, see the [Office of the Registrar](#). Otherwise, contact the school(s) before applying to the Purdue HRPP/IRB.



Category 2

Educational Tests, Surveys, Interviews or Observation of Public Behavior

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:

Survey Procedures



Interview Procedures & Focus Groups



The information obtained is the result of straight-forward survey, testing, or interview procedures which do not employ an intervention, application of independent variables, or experimental or quasi-experimental design.

Observation of Public Behavior (no intervention)



The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.



Category 3

Benign Behavioral Interventions

Research that involves a benign behavioral intervention in conjunction with the collection of information from an adult participant through verbal or written response (including data entry) or audiovisual recording.

The subject must prospectively agree to the intervention and the collection of data.

[Application Form Link](#)



To qualify under this category, at least one of the following criteria must be met:

- The information obtained is recorded in such a manner that the identity of the participant cannot be easily ascertained, directly or through identifiers linked to the participant.
- Any disclosure of the human subjects' responses outside of the research would not place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement or reputation.

The intervention must be:

- Behavioral, **not a medical intervention**
 - data cannot be collected via physical procedures (no blood pressure monitoring, EEG, activity trackers, eye trackers, or blood draws)
- Short in duration (**no more** than a few hours and only **once**)
- Harmless, painless, not physically invasive, **and** the investigator must have no reason to believe that the participant would find the intervention offensive or embarrassing



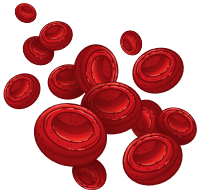
Deception/Incomplete Disclosure: If the research involves deceiving the subjects regarding the nature or purposes of the research, then the subject must authorize the deception through a prospective agreement to participate in research in circumstances in which they will be unaware of or misled regarding the nature or purposes of the research.



Category 4

Secondary Use of Data

Secondary research with identifiable information/specimens collected for some other initial activity, if ONE of following:



- Biospecimens or information are publicly available
Examples: biobank and data repository



- Information is recorded in a way that the subject cannot readily be identified (directly or indirectly); the investigator does not contact subjects and will not re-identify the subjects
 - For more details about data transfer and use agreements, please visit the [Sponsored Program Services webpage](#), or fill out the [Data Transfer and Use Request Form](#) and send to SPS Contracting before or in parallel with HRPP/IRB review.



- Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”

Category 5

Research and Demonstration Projects

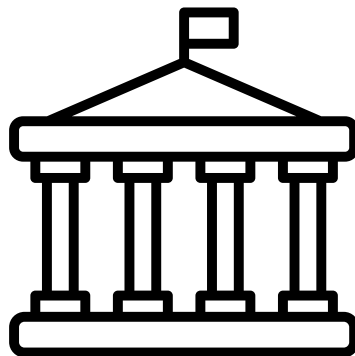
Very rarely used

- **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
- 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.



PURDUE
UNIVERSITY®

Office of Research

Category 6

Taste and Food Quality Studies

Taste and food quality evaluation and consumer acceptance studies fall under Category 6 when **ONE** of the following is applicable:

- a wholesome food without additives is consumed
- a food is consumed that contains a food ingredient at or below the levels and for a use found to be safe by responsible US federal agencies.

