Exempt Categories Eligible for Exempt Review

All human subjects research projects must undergo review and approval by an IRB prior to ini a on of research ac vi es. Exempt reviews are conducted by at least one reviewer, and an exempt determina on requires that the research must be minimal risk and fall into one or more of the exempt categories described below.

Minimal risk as defined by federal regula ons is the probability and magnitude of harm or discomfort an cipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of rou ne physical or psychological examina ons or tests.

Exempt Categories:

1. Educa onal research
2. Surveys, interviews, educa onal tests, public observa ons (that do not involve children)
3. Benign behavioral interven ons
4. Analysis of previously collected iden fiable info/specimens
5. Federal research/demonstra on research
6. Taste and food evalua on research
7. Storage or maintenance of iden fiable info/specimens
8. Secondary research use of iden fiable info/specimens

Category 1 -

Research, conducted in established or commonly accepted educa onal se ngs, that specifically involves normal educa onal prac ces that are not likely to adversely impact students' opportunity to learn required educa onal content or the assessment of educators who provide instruc on. This includes most research on regular and special educa on instruc onal strategies, and research on the e ec veness of or the comparison among instruc onal techniques, curricula, or classroom management methods.

Examples:

- A study comparing the two di erent teaching methods in public high schools.
- An experiment evalua ng the impact of a new technology tool in a college course.
- A study assessing the e ects of class size on engagement in elementary schools.

Category 2 -

1. The informa on obtained is recorded by the inves gator in such a manner that the iden ty of the human subjects cannot readily be ascertained, directly or through iden fiers linked to the subjects.
2. 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, educa onal advancement, or reputa on; and

Category 4 -

Secondary research for which consent is not required: Secondary research uses of iden fiable private informa on or iden fiable biospecimens, if at least one of the following criteria is met:

1. The iden fiable private informa on or iden fiable biospecimens are publicly available;
2. Informa on, which may include informa on about biospecimens, is recorded by the inves gator in such a manner that the iden ty of the human subjects cannot readily be ascertained directly or through iden fiers linked to the subjects, the inves gator does not contact the subjects, and the inves gator will not re-iden fy subjects;
3. The research involves only informa on collec on and analysis involving the inves gator's use of iden fiable health informa on whehuse c hu Ɔ o rma oaato h h

or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consul ng arrangements, coopera ve agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authori es such as sec ons 1115 and 1115A of the Social Security Act, as amended.

Examples:

- A federally funded research project evalua ng the e ec veness of a new online system for applying for unemployment benefits.
- A demonstra on project conducted by a federal agency to evaluate the e ec veness of a new public housing program.
- A federally funded research project inves ga ng the e ec veness of di erent methods of payment for Medicare services.

Category 6 -