Institutional Review Board (IRB)  
Exemption Guidelines

Certain broad categories of research projects that involve human participants that do meet the definition under the regulations are “exempt” from IRB review.

“Exempt” in this context means that a project is not subject to, or is exempted from the requirements of the regulations spelled out in 45 CFR 46.

Federal regulations permit the principal investigator to make an initial judgment as to whether the project is exempt, however only the IRB must make the final determination that the activity is eligible for exemption.

Research activities in which the only involvement of human subjects will be in one or more of the following categories are eligible for exemption:

To qualify as an exempt study, the research must fall within one of the above-specified regulatory categories and satisfy all UAlbany institutional requirements. Only the IRB may determine when research is exempt or requires a full or expedited review. Therefore, researchers must submit an application, requesting exempt status to the IRB ensure that the research meets the criteria for an exemption.

The Following CANNOT be Exempted:

- research involving prisoners;
- surveys or interviews of children;
- observation of children when the investigator will interact with them;
- research procedures, otherwise eligible for exemption IF:
  1. the information is recorded in such a way that the identity of individuals can be identified either directly or through identifiers linked to the individuals
  AND
  2. disclosure of participants’ responses could reasonably place them at risk of criminal or civil liability or be damaging to an individual’s financial standing, employability, or reputation;
- observation of behavior that takes place in settings in which participants have a reasonable expectation of privacy;
- research techniques which expose participants to discomfort or harassment beyond levels encountered in daily life (i.e., greater than minimal risk);
Criteria for Protection of Human Subjects in Exempt Research

A research project that has received an Exempt designation is **not** exempt from protection of the human subjects. The following criteria to protect human subjects must be met:

1. The PI assures that all those persons listed on the application as being involved in the research have completed the IRB human subjects training requirements.

2. The PI assures that human subjects will voluntarily consent to participate in the research when appropriate (e.g. surveys, interviews, interactions with participants) and will provide subjects with pertinent information e.g. the activity involves research, a description of procedures, that participation is voluntary, risks and benefits, contact information for PI and IRB Chair, etc.;

3. The PI assures that human subjects will be selected equitably, so that risks and benefits of the research are justly distributed;

4. The PI assures that the IRB will be immediately informed of any information, unexpected or adverse events that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full review;

5. The PI assures that the IRB will be immediately informed of any complaints from participants regarding their risks and benefits; and

6. The PI assures that confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects, and there are adequate provisions to maintain the confidentiality of the data if there is any recording of identifiable information.

These criteria are specified on the *Principal Investigator Assurance Form of an Exempt Project*, and the PI’s signature acknowledges that s/he understands and accepts these conditions.