

Fresno State Committee for the Protection of Human Subjects

Exemption Category A Frequently Asked Questions

What is a commonly accepted educational setting?

In the context of Category A exemptions, *commonly accepted educational settings* include but are not limited to K-12 schools, college classrooms, after-school programs, preschools, vocational schools, alternative education programs, and other sites where educational activities regularly occur.

What is a normal educational practice?

In the context of Category A Exemptions, *normal educational practices* are established teaching methods, curriculum content, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher.

Normal educational practices are activities that would be occurring regardless of whether the research is conducted. Therefore, a study that evaluates a new instructional strategy or curriculum, or that randomly assigns students to different instructional strategies/curricula for the purpose of comparison, would probably not be exempt because these are not considered normal educational practices.

Consult the federal regulations with regard to the role of the researcher and intervention in the research process <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46>. A flow chart is also available at <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3>

What if my educational research involves surveys, interviews, or focus groups?

In the context of Category A Exemptions, studies involving surveys, interviews, or focus groups may or may not meet the criteria for a Category A exemption. If the surveys, interviews, or focus groups are being planned and implemented by the classroom teacher and would take place whether or not the research occurs, then the research could include them and still meet the criteria for the Category A exemption.

If the surveys, interviews, or focus groups are being planned and implemented by the investigator and would *not* be taking place if the research was not occurring, then the research may not meet the criteria for a Category A exemption. This would depend on the nature of the surveys, interviews, or focus groups. As long as the questions asked/information solicited are specific to established or commonly accepted educational settings and normal educational practices, study activities under Category A may involve surveys, focus groups, interviews.

However, if the questions asked/information solicited include any demographic questions to be asked of subjects, a discussion of how they are being utilized to evaluate the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods for the different groups for whom demographic data is being collected would need to be provided and the study may or may not meet the criteria for a Category A exemption.

What if my educational research involves parent focus groups?

A parent focus group may or may not meet the criteria for a Category A exemption. If the focus group is being planned and implemented by the classroom teacher and would take place whether or not the research occurs, then the research could include the parent focus groups and still meet the criteria for the Category A exemption.

If the parent focus group is being led by the investigator and would *not* be taking place if the research was not occurring, then the research may not meet the criteria for a Category A exemption. It may be the case, however, that the parent focus group portion of the research could qualify for a Category B

exemption. Category B exemptions do not apply to minors, but might apply to a parent focus group, where the information being collected would likely be very low risk.

What if my educational research involves audio/videorecording?

The exemption criteria for Category A says nothing specific about audio/videorecording. Audio/videorecording may be permissible in a Category A exemption, so long as the research will be taking place in a commonly accepted educational setting and will be examining normal educational practices. However, investigators should review and adhere to the school's or other educational institution's policies on audio/video-recording students and classroom instruction.

NOTE: It is within the authority of the Departmental Human Subjects Committee and the CPHS to determine whether the proposed research meets the exempt criteria. In instances where either of these committees determines the risk level to be minimal risk or at risk, the Principal Investigator will be notified in writing, and any additional reviews will be completed.

Sources:

Department of Health and Human Services Office for Human Research Protections

<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46> and

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3>

Office of Research, University of California, Santa Cruz

https://officeofresearch.ucsc.edu/compliance/services/irb13_exempt_categories.html#category-1-faqs

<https://www.fresnostate.edu/academics/humansubjects/>

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