

**California State University, Fresno**  
**Committee for the Protection of Human Subjects (CPHS)**

**What Type of Review Does Your Research Need?**

It is the personal responsibility of the principal investigator to evaluate the ethical acceptability of each study and to ensure that no one is subjected to unreasonable risk to health, well-being, or dignity. Responsibility for this determination resides at the departmental and CPHS levels. No assumption exists that “at risk” research is more or less ethical. The standards of care and review are stringent for each class of research proposal.

**\*NOTE THAT PROTOCOLS OF ALL RISK LEVELS - EXEMPT, MINIMAL RISK, OR AT RISK – MUST BE SUBMITTED THROUGH KUALI**

**No Review Needed**

- Data collected in Fresno State college classes or elsewhere by Fresno State students, faculty, or staff for programmatic/educational/evaluative purposes only. Refer to the CPHS Policies & Procedures Handbook section 3.2.1 regarding Student Research
- Studies involving Fresno State students, faculty, or staff as research subjects conducted by researchers not associated with Fresno State. Said researchers should have obtained and provide proof of IRB approval if requested by Fresno State, faculty, staff, or students participating in the study.
- It is recommended that principal investigators consult the Departmental Human Subjects Review Committee to confirm that no review is needed.
- A Fresno State Faculty member, who is collaborating with a PI at another institution where IRB approval has been obtained, is not required to undergo a separate review at Fresno State. In some cases, a Reliance Agreement may be required. Contact the CPHS Chair for more information.

**No Risk/Less Than Minimal Risk – Department or IRB Chair Review Only (Exempt)**

- Studies involving no possible physical or psychological risk to participants (e.g., studies of walking speeds in grocery store, obituaries in the *Fresno Bee*, anonymous computerized datasets, interviews or surveys with adults about non-sensitive topics)
- If a principal investigator has determined research to be exempt because it is wholly within one or more of the categories listed in section 3.5.4 in the CPHS Policies & Procedures Handbook, the researcher shall submit a proposal via Kuali for review by the Departmental Human Subjects Review Committee as exempted by policy, indicating the specific category by number. The principal investigator shall include all required documents that describe the research in full. The Departmental Human Subjects Review Committee shall give the researcher written verification whether the research is exempt or not. Federal regulations on what is considered ‘exempt’ can be found here <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104> and flow charts on exempt research can be found here <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3>

**Minimal Risk – Department IRB Committee Review Only (Expedited Review)**

- Studies with risk of physical or psychological harm equivalent to “daily life” (e.g., adults performing routine exercises)
- Studies including participants who are younger than age 18 participating in routine school activities on school grounds (e.g., observations of behavior with no intervention, administration of published standardized instruments commonly used by school

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psychologists or other school personnel [see <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104> and <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3>)]

- Some 'minimal risk' proposals may be forwarded to the CPHS for a secondary review when there are significant questions about the procedures of the proposal. This decision is within the purview and at the discretion of the CPHS Chair. In this instance, the Principal Investigator will be notified.

#### **At Risk – Department IRB Committee and University CPHS Review (Full Review)**

- Studies with genuine possibility of significant physical or psychological harm (e.g., interviewing victims of trauma)
- Studies involving deception (e.g., assigning impossible-to-solve mathematics problems to invoke frustration)
- Studies collecting confidential (not anonymous) reports of illegal or otherwise very sensitive behaviors or attitudes (e.g., studies of underage drinking, drunk driving, criminal acts performed)
- Studies including participants who are:
  - Younger than age 18 (see exceptions above) (45 CFR 46 Subparts A, D)
  - Prisoners (45 CFR 46 Subpart C)
  - Physically, cognitively, and/or psychologically disabled ([Questionable Capacity to Consent](#))
  - Pregnant Women and Fetuses (45 CFR 46 Subpart B)

#### **Funded Research**

Studies involving federal, state, or any external funding other than money given by Fresno State and CSU system require review by the University CPHS, regardless of the risk level of the proposed study, after department IRB review. With the exception of externally funded projects, proposals are reviewed during the academic year only.

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

For questions contact:

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