

## UCSD COVER SHEET FOR EXEMPT STATUS APPLICATION

**Instructions:** This form should be used by researchers who propose to conduct human subjects research which they believe qualifies as **exempt according to federal regulations (45 CFR 46.101[b])**. The determination as to whether a study is exempt must be made by a UCSD IRB Chair or Director of the HRPP. **NOTE: No research activities may begin until the research has been reviewed and determined exempt by the IRB Chair, the HRPP Director, and/or the Chair's designee and notification received.**

**To apply for exempt status:**

1. Complete and sign this cover sheet
2. Complete and sign the [Biomed Standard Facesheets](#) or [Social or Behavioral Application Facesheets](#)
3. Complete appropriate Research Plan ([Research Plan for Categories 1, 2, and 3](#) or [Research Plan for Category 4](#))
4. Provide copy of additional protocol materials such as consent, survey, interview questions, etc., as needed.
5. Submit to HRPP Office using [eIRB services](#).

**Principal Investigator** \_\_\_\_\_

**Faculty Advisor (if needed)** \_\_\_\_\_

**Protocol Title** \_\_\_\_\_

**PROJECT CHARACTERISTICS**

Yes	No	
		Involves <b>prisoners</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>pregnant women</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>in vitro fertilization</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>deception</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>fetuses</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>decisionally impaired</b> (If Yes, does not qualify for IRB exemption)
		Involves the <b>use of school records of identifiable students or interviewing instructors about specific students</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>survey or interview procedures with children</b> (participants under the age of 18 years) (If Yes, does not qualify for IRB exemption)
		Involves <b>observation of public behavior when the investigator(s) participates in the activities being observed</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>data collected that includes protected health or medical information when there is a direct or indirect link that would identify the participant</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol</b> (If Yes, does not qualify for IRB exemption)
		Involves <b>FDA research except in emergency circumstances</b> (If Yes, does not qualify for IRB exemption)
		Involves research that requires <b>review by the UCSD Embryonic Stem Cell Research Oversight (ESCRO) Committee</b> (If Yes, does not qualify for IRB exemption)

**EXEMPTION CATEGORY CLAIMED (Check all applicable categories and sub-parts below)**

- 1. Exempt Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
  - a) research on regular and special education instructional strategies; **or**
  - b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
  
- 2. Exempt Category 2:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. Research involving these procedures is exempt, if:
  - a) the information obtained is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects; **and**
  - b) any disclosure of the subject's responses outside of the research could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation
  
- 3. Exempt Category 3:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2. Research involving these procedures is exempt, only if:
  - a) the subjects are elected or appointed public officials or candidates for public office; **or**
  - b) federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
  
- 4. Exempt Category 4:** Research involving collection or study of existing data, documents, records, or specimens, if:
  - a) these sources are publicly available; **or**
  - b) the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Faculty Advisor (if needed)

\_\_\_\_\_  
Date