

Student Research Policy: Activities that Do and Do Not Require CSUSB IRB Review and Approval


The investigator has the responsibility for initial determination as to whether an activity is human subjects research but for class activities the instructor has this responsibility. The University will hold investigators and instructors responsible if an IRB application was not submitted when required. As such, it is strongly recommended that investigators and instructors contact the Office of Academic Research for guidance and confirmation regarding the applicability of the federal human subjects research regulation and CSUSB policy.

This guidance document provides descriptions of activities and associated determinations regarding the requirements to submit to the CSUSB IRB.

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Class Assignments Research Methods Classes	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge or contribute to generalizable knowledge. <u>Activities may be presented in the course (oral or written) with no dissemination outside of the class (e.g. published or disseminated as a capstone or at a conference).</u> Activities are not intended to be used as part of an honor's or master's thesis or doctoral dissertation.	<p>NO (<i>but instructors have an obligation to ensure students meet professional and ethical standards</i>)</p> <p><i>Students are restricted from using campus email (bb, campus, forum) for recruitment of participants. Otherwise, they need to go through the IRB process.</i></p> <p><i>Students are restricted from recruiting vulnerable populations as noted by the Office of Human Research Protections and include pregnant women, prisoners, children, and those with impaired decision capabilities. If using vulnerable populations, the student IRB protocols must be submitted and reviewed by the CSUSB IRB. Note that recruiting vulnerable populations requires full board review.</i></p>
Class Assignments Research Methods Classes	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge or contribute to generalizable knowledge. Activities may be presented in the course (oral or written) with no dissemination	<p>YES (<i>if recruiting from campus email listservs (bb, campus, forum, colleagues).</i>)</p> <p>YES (<i>if recruiting vulnerable populations as described by the Office of Human Research Protections (45 CFR 46 subparts b, c, d)</i>)</p>

	outside of the class (e.g. published or disseminated as a capstone or at a conference). Activities are not intended to be used as part of an honor's or master's thesis or doctoral dissertation.	<i>which includes pregnant women, neonates, and fetuses, prisoners, children, and those with impaired decision capabilities).</i>
Honor's thesis Master's thesis Doctoral dissertation Capstone research Synthesis projects	Undergraduate or graduate studies which involve human subjects or a clinical investigation which results in a thesis, a dissertation research, or capstone.	YES (<i>unless the project fits another category where IRB submission is not Required</i>). Please note that in some cases a exempt determination is required and an IRB application must be submitted.
Internet Research	<p>Research involving online interactions with human subjects where identifiers are known or can be ascertained such as email addresses, certain websites and bulletin boards. Also includes data collected where an individual cannot be directly identified and data are collected through online intervention or interaction with research subjects.</p> <p>and;</p> <p>Research involving online interactions with/data collection from human subject internet community members that may expect a level of privacy and confidentiality such as vulnerable populations (HIV patients, alcoholics anonymous, sexual abuse survivors etc.). Also includes data collected where an individual cannot be directly identified and data are collected through online intervention or interaction with research subjects.</p> <p>and;</p> <p>Research using social media tools (for example: Twitter, Instagram, Facebook, Snapchat) where the information collected is existing (posted) on the social platforms. The data can be used as long as there is no way to link that person to their real identity. Every precaution must be made to de-identify the social media user names to ensure their anonymity and/or confidentiality. De-identifying social media user names can be done by creating pseudonyms (fake names), or other manners of de-identifying user names.</p>	<p>YES</p> <p>YES</p> <p>NO</p>

	<p>and; Research using social media tools (for example: Twitter, Instagram, Facebook, Snapchat) where the information is not existing such as within a blog or chatroom the investigator must let the social media user know they are a researcher collecting information for research purposes. This is the ethical responsibility of the researcher.</p> <p>and; Use of documents that organizations regularly post on their website may be used (for example, organizational facts, policies, procedures, resources and other documents about the organization).</p>	<p>YES</p> <p>NO</p>
Research Using Publicly Available Data Sets*	Use of publicly available data sets that do not include information that can be used to identify individuals.	YES – IRB application required for Exempt Determination.
	Data requiring a data use agreement, confidentiality agreement, etc. may not be considered publicly available. The data provider may consider the data identifiable or the risk of deductive disclosure such that human subjects research review is required.	YES
Secondary Use of Research Data	<p>Projects that involve only the secondary analysis of data collected as part of a different research project, if:</p> <ul style="list-style-type: none"> • The data set is publicly available; • The data were collected anonymously, or • The data set has been de-identified - any data elements that could be used to identify an individual have been stripped. 	NO
Research on Organizations	Information gathering about organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources. Does not include identifiable private information about individual members, employees, or staff of the organization.	<p>NO, if not publishing.</p> <p>YES, if publishing.</p>
Oral History	Interviews concerning the past that collect, preserve, and interpret the	YES <i>(must meet professional</i>

	<p>voices and memories of people, communities, and participants in past events as a method of historical documentation. The intent is to document a particular past or unique event in history.</p> <ul style="list-style-type: none"> • focus exclusively on past events; • are conducted to understand or explain a particular past or unique event in history; and • the anonymity of the narrators is not preserved. <p>Must conform to the Principles of Best Practices of the Oral History Association: http://www.oralhistory.org/about/principles-and-practices</p> <p>In contrast, although activities described in the category at 45 CFR 46.102(l)(1) may sometimes be performed in such academic fields as anthropology or sociology, a significant portion of the activities that are characteristic of these fields fall outside of the category and therefore remain within the scope of 45 CFR part 46. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals, but also of the community or group to which they belong, would not meet the category found at 45 CFR 46.102(l)(1). The purpose and design of such studies or activities is to reveal something about the community or group – that is, to develop generalizable knowledge. Because the purpose of such studies or activities is not to limit the inquiry to knowledge about the particular individuals being observed, the protections provided by the requirements of 45 CFR part 46, such as the requirement to minimize any harm to the specific individuals from which the information was collected, are appropriate. Such activities would continue to fall within the scope of the definition of "research" under the 2018</p>	<p><i>and ethical standards</i>). IRB application required for Exempt Determination.</p> <p>YES, if guidance in bold applies.</p> 
--	---	---

	<p>Requirements. https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html</p>	
Journalism	<p>Activities focused on the collection, verification, reporting, and analysis of information or facts on current events, trends, issues or individuals involved in such events or issues. There is no intent to test hypotheses, and activities cannot reasonably be characterized as comprising systematic investigation. Must conform to the Code of Ethics of the Society of Professional Journalists http://www.spj.org/ethicscode.asp</p>	NO (<i>meet professional and ethical standards</i>)
Case Study	<p>A single subject study with clear intent before recruiting or interacting with the participant, to use data that would not ordinarily be collected in the course of daily life. The intent is to contribute to generalizable knowledge including reporting or publication.</p>	YES
	<p>Analysis and publication of treatment provided in a single case where research is not prospectively planned, and no procedures are performed or information collected beyond what would be done for regular (or innovative) clinical care and treatment. There is no intent or plan to develop or contribute to generalizable knowledge.</p>	NO
Pilot Studies	<p>Pilot studies used to determine if a study is feasible. Although the data derived from a pilot activity may not be included in the full-scale research project, the activity would still need IRB review prior to conducting the activity.</p>	YES
	<p>Activities intended to refine data collection procedures – time to participate, testing survey questions, etc. where any data collected are only used to plan and/or improve a future research study.</p>	NO