Faculty & Student Research Guidelines:
Activities that Do and Do Not Require
CSUSB IRB Review and Approval

While the investigator has the responsibility for initially determining if an activity is human subjects research, 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 subject's research regulation and CSUSB policy. This guidance document provides descriptions of activities and associated determinations regarding the requirements to submit to the CSUSB IRB.

Definitions

Institutional Review Board
The University's Institutional Review Board (IRB) is responsible for protecting the rights and welfare of human subjects participating in research projects. The IRB acts according to policies set forth by the US Department of Health and Human Services (HSS) and Office of Human Research Protections (OHRP). Compliance with these federal regulations not only safeguards human subjects and the institution sponsoring the research project, but also protects the researcher. The IRB is in compliance with the Federal Wide Assurance (FWA) between CSUSB and OHRP.

Research
The Department of Health and Human Services (HHS) Code of Federal Regulations has defined research as, *"a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102l). As described in the Belmont Report, "*...the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

Human [Subject] Participant
A human subject is defined as "*a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens*." (45 CFR 46.102e(1))

Non-Human Subject Research (NHSR)
Studies are considered "NHSR" when they do not meet the 45 CFR 46 definitions of human subjects research. The project is not considered "research" if the intent of the project is not for research purposes (e.g. research publication, research presentation).

IRB Requirements for Student Research Guidelines			
ACTIVITIES	**DESCRIPTION**	**SUBMISSION REQUIRED TO IRB -YES**	**SUBMISSION REQUIRED TO IRB -NO**
Student Class Assignments	• Activities, practices, projects, posters, presentations, or papers designed for demonstrating course concepts or teaching human subjects research methods (e.g., the practices of questionnaire and survey research, interviews, participant observation, experimental designs, focus groups).	• If activities are for research **presentations inside** (i.e., Meeting of the Minds) CSUSB campus conferences but not if only for a class • If activities are for research **presentations outside** (i.e., professional conference) CSUSB campus • If activities are for **publications** in paper or online formats (e.g., Scholarworks). ✔ Note: If the project is *only* planned to be published in Scholarworks and nowhere else, an application for NHSR (non-human subjects research) may be submitted to IRB. But for all research that meets the OHRP's requirements of human subject's research, an IRB application must be submitted. • If activities involve recruiting participants from campus email listservs (Blackboard, Campus, Forum, Colleagues, etc.); • If activities involve recruiting vulnerable populations, such as pregnant women, neonates, and fetuses, prisoners, children, and those with impaired decision	• If activities are reviewed only by instructors or students within a class, except all circumstances that are under the "YES" column.
Honor's thesis; Master's thesis; Doctoral dissertation; Undergraduate capstone research and culminating projects	• Undergraduate or graduate studies involving human subjects or a clinical investigation which results in a thesis, a dissertation research, or any culminating project.		

		capabilities (as defined by the Office of Human Research Protections, 45 CFR 46 subparts b, c, and d).	

IRB Requirements for Different Types of Research			
	DESCRIPTION	**SUBMISSION REQUIRED TO IRB -YES**	**SUBMISSION REQUIRED TO IRB -NO**
	Literature Review: Reviewing published articles or other scholarly work		NO
Internet Research	Research involving online interactions with human subjects where identifiers are known or can be ascertained such as email addresses, IP addresses, geolocations, certain websites and bulletin boards. Also includes data collected where an individual cannot be directly identified and data collected through online intervention or interaction with research subjects (including experiments).	YES	
	Research involving online interactions with or data collection from human subject internet community members that may expect a level of privacy and confidentiality, such as members of vulnerable populations (HIV patients, alcoholics anonymous, sexual abuse survivors etc.).	YES	
	Research using social media tools (for example: Twitter, Instagram, Facebook, Snapchat).	YES	NO

Internet Research (cont'd)		If information is not strictly observational but has interactions or investigators have access to private accounts or groups. The investigator must let the social media users know they are a researcher collecting information for research purposes. This is the ethical responsibility of the researcher.	If the information collected is existing (posted) on public 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.
	Use of documents that organizations regularly post on their websites (for example, organizational facts, policies, procedures, resources and other documents about the organization).	YES If it is private access to information via blogs, chats, groups, etc. on the internet.	NO Use of publicly available information on the internet.
Research Using Publicly Available Data Sets	Use of publicly available data sets that do not contain individuals' personal identifiable information.		NO ● However, a limited IRB can be submitted to get a determination letter for Non-Human Subjects Research
	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 is such that human subjects research review is required.	YES	

Secondary Use of Research Data	Projects that involve only the secondary analysis of data collected as part of a different research project, if: ● 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 ● However, a limited IRB can be submitted to get a determination letter for Non-Human Subjects Research
Research on Organizations	Information gathering about CSUSB or other organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources.	YES- ● If collecting individual or organizational private information about individual members, employees, or staff of the organization. ● Yes if publishing or presenting at a professional conference.	NO ● If no individual private information about individual members, employees, or staff of the organization are collected. ● No human subject's data collected at CSUSB or at another college/university can be presented without IRB approval, exempt or No Human Subjects Research Determination
Oral History	Interviews concerning the past that collect, preserve, and interpret the 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. ● 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.	YES ● IRB application required for Exempt Determination. ● Must meet professional and ethical standards. ● If the following applies: **"...develop generalizable knowledge. Because the**	NO ● No intention for research

	Must conform to the Principles of Best Practices of the Oral History Association: http://www.oralhistory.org/about/principles-and-practices	**purpose of such studies or activities is not to limit the inquiry to knowledge about the particular individuals being observed….”** https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html	
Journalism	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		NO ● *meet professional and ethical standards*
Autobiography and Auto-ethnography	Autobiography- written description of PIs personal experiences. Autoethnography- the PI is the only participant in the study.	YES ● If for thesis, project, or dissertation but can be submitted as a NHSR ● Research ethics and standards should be practiced when mentioning other people information	NO

Case Study	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.	YES	
	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.		NO
Pilot Studies	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. 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.	YES ● If you collect data with anticipation that it will be potentially used for a full-scale research project. ● If a systematic pilot study with a large random sample	NO ● No part of the data will be used or incorporated for a full-scale research project