



IRB Guidelines for Research Conducted by Unaffiliated Investigators

CSUSM is supportive of research conducted by others who want to collect data from human subjects at CSUSM, while at the same time being mindful of the impact on resources and implications for the campus. Individuals may of course collaborate with members of the CSUSM faculty and staff to conduct investigations of mutual interest; this section is **not** meant to address or restrict such collaborations. However, there may be persons without direct or formal association to CSUSM who request authorization to use CSUSM facilities or the campus population in order to conduct a study involving human participants.

Definition. An "unaffiliated investigator," as used in this policy, is any researcher who is not either (1) a student, (2) a faculty member, (3) a staff member at CSUSM or have an official affiliation with CSUSM (e.g., UARSC employees or approved volunteers). The unaffiliated investigator may be affiliated with another *bona fide* research organization, termed here as the "home institution." It may be the academic institution or a research agency (e.g., contract, governmental, or not-for-profit) with which the investigator is currently affiliated or the degree-granting institution in which the investigator is enrolled as a student. An unaffiliated investigator without another affiliation must work with a collaborating faculty member from CSUSM to conduct research at CSUSM or use a CSUSM population

Conduct of research. Responsibility for the actual conduct of the research remains solely with the unaffiliated investigator. It is understood that approval to conduct human subjects research at CSUSM in no way implies that either the CSUSM IRB, the Office of Graduate Studies and Research, or any official of CSUSM assumes responsibility for the conduct of research on campus by unaffiliated investigators. The unaffiliated investigator may independently enlist the aid of someone on campus (a "facilitator") to assist with logistical matters, such as aiding in the distribution of recruiting materials. Researchers wishing to use campus facilities or research spaces should consult with the AVP for Research to determine if a contract or other agreement with CSUSM may be required. Access to student records or mail lists for broad groups within the campus community will require permission of the appropriate department authority for such information.

IRB Approval. The CSUSM IRB retains oversight of human research conducted on campus by unaffiliated investigators and such investigators will be expected to comply with all CSUSM IRB policies and procedures. An unaffiliated investigator seeking to conduct research at CSUSM

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must have approval of the CSUSM IRB and show prior approval from their home institution's IRB, if any. The IRB may require that the researcher identify a collaborating faculty member.

The unaffiliated investigator must provide to the CSUSM IRB the final protocol (including surveys, consents, etc.) along with the approval memo from the home institution IRB, if any. The unaffiliated investigator is responsible for ensuring that all matters of concern in CSUSM's review of the protocol are addressed in the protocol of the home institution, if any, as well. The CSUSM IRB reserves the right to ask for and obtain other evidence from the unaffiliated investigator to authenticate the proposed research to be conducted at CSUSM. This could include authorizations for the use of survey instruments and data collecting equipment and financial information for when participants are to be monetarily compensated.

Indicating affiliations in documents. Documents such as recruitment flyers and emails, consent forms, surveys, etc., must include the investigators' names, home institution affiliation, and contact information for the unaffiliated investigator(s). Consent documents must indicate that IRB approval has been obtained from the home institution to which the CSUSM IRB would add their approval stamp when approved.

Training in human subjects research. Unaffiliated investigators must demonstrate their training in human subjects research equivalent to what the CSUSM IRB would require of a CSUSM investigator to possess in a similar research study. The CSUSM IRB expects at minimum the training equivalent to the CSUSM modules on CITI (www.citiprogram.org).

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