

Chico State Enterprises Announcements
Wednesday, April 28, 2021

**Process for Resuming or Initiating In-Person Human Subjects
Research Suspended Due to COVID-19**

Dear Campus Community,

On March 20, 2020, precautionary measures were implemented to suspend all human subjects research involving in-person interactions. Researchers were – and still are – encouraged to explore alternative methods for conducting their studies (e.g., online interviews or surveys). As a reminder, study modifications aimed at mitigating COVID-19-related risks (e.g., transitioning from in-person to online interviews) do not require HSRC review or approval prior to implementation. All other study modifications, including those to approved online or remote studies, require HSRC review and approval.

Although the general suspension of in-person human subjects research remains in effect, the Human Subjects in Research Committee (HSRC) will adopt the following process for reviewing and approving human subjects research that cannot feasibly be conducted remotely or by other means. Effective April 27, 2021, researchers seeking to resume or initiate in-person research of this nature must complete the following steps prior to beginning their research:

1. Prior to submitting applications to the HSRC, researchers seeking to resume or initiate in-person research should complete and submit the appropriate parts of the Return to Campus Request forms to their Dean for signature/approval. Request forms can be located on the [Chico State Return to Campus Guidelines and Expectations page](#) for campus-related activities or the [CSE Return to Campus Guidelines and Requests page](#) for Chico State Enterprises (CSE) related activities. CSE-related activities include all CSE employees, externally funded projects, or if the activity will be located on a CSE property.

Chico State Activities:

- a. [Part 1 \(Instructions/Employee Review\)](#)
- b. [Part 3 \(Academic Instructional / Research / Off-Campus Activity Space Risk Assessment\)](#)

Chico State Enterprises Activities:

- a. [CSE Part 1 \(Instructions/Employee Review\)](#)
- b. [CSE Part 3 \(Academic Instructional / Research / Off-Campus Activity Space Risk Assessment\)](#)

Researchers must explicitly state in the description area of Part 3 of the request form that the activity involves in-person human subjects research. Justification should also be provided for the in-person conduct of the research (i.e., why the research cannot feasibly be conducted remotely or by other means).

The Dean shall consider approving in-person human subjects research requests when:

- a. the research cannot feasibly be conducted remotely or by other means; AND
 - b. the risk of COVID-19 can be mitigated to an acceptable level; AND
 - c. the research is deemed “essential.” Examples of “essential” research may include—but are not limited to—research that must be conducted in order to:
 - i. maintain grant funding;
 - ii. continue faculty development; and/or
 - iii. fulfill graduation criteria (e.g., thesis research).
 - iv. Additional criteria may be applied at the Dean’s discretion to determine what constitutes “essential” research in their area.
2. Once approval has been obtained from the Dean, researchers should submit Parts 1 and 3 of the Return to Campus Request to the Emergency Operations Committee (EOC) (eoc@csuchico.edu) for review and approval. For CSE-related activities, CSE CEO, Mary Sidney, must first review and approve. Please forward CSE-related requests to CSE Administration representatives, [Coleen Stewart](#) and [Gina McCammon](#). Once CSE’s review is complete and upon approval, requests will be forwarded to the EOC. Concerns raised by the EOC must be addressed by the Dean and the researchers prior to HSRC approval.
3. Once approval has been obtained from the EOC, researchers should submit their request to the HSRC to resume or initiate in-person human subjects research:
- a. To resume previously approved in-person research, researchers should submit an amendment to their existing protocol. The amendment request should include a modified informed consent form that addresses COVID-19 associated risks and safeguards.
 - b. To initiate new human subjects research, researchers should submit an application and supporting materials. The application and informed consent forms should explicitly address specific COVID-19 risks and safeguards.
 - c. Copies of approved Return to Campus Request documents (Parts 1 and 3) should accompany HSRC submissions seeking to resume or initiate in-person human subjects research.
 - d. Amendment and application forms can be found on the [HSRC website](#).

Please note that COVID-19 conditions may worsen and prompt a reevaluation of this process and any in-person human subjects research that received approval through this process. Researchers

must have a plan to immediately cease research activities should any condition warrant that necessity, by the HSRC, EOC, CSE, or the University Administration. Any decisions related to human subjects research will be consistent with guidance from the federal Office for Human Research Protections and will prioritize the safety and well-being of research subjects, as well as faculty, staff, and student researchers, and the community at large.

Lastly, in an effort to accommodate Chico State faculty, staff, and students seeking to conduct in-person human subjects research warranting Full Board Review, the HSRC is planning to convene an ad hoc meeting in May 2021 (date TBD). Please submit study materials to the HSRC by e-mailing them to irb@csuchico.edu **prior to Friday, May 7, 2021**. Full board applications received after this deadline will be scheduled for review when the HSRC reconvenes in September 2021. HSRC applications submitted under the Exempt and Expedited review categories that elect to use in-person methods will continue to be reviewed on a rolling basis, year round.

If you have any questions or concerns related to this process please contact Dr. Patrick S. Johnson (HSRC Chair) at psjohnson@csuchico.edu or Sharon Ruggirello (HSRC Coordinator) at irb@csuchico.edu.