

Important Announcements with COVID-19

IRB: In-Person Research Restart Plan Announcement; 4-12-2021, 9:00AM

The IRB will be accepting new applications or modifications of applications to conduct in-person research during the summer months. If you can still perform your research virtually, you are highly encouraged to continue to do so. **In addition to IRB approval, ALL research must be approved by the university. Please consult additional university requirements beyond IRB's human subjects concerns from the Academic Research [website](#) (Project Re-Start and Continuity Plan process).**

IRB will begin accepting in-person research applications on May 1, 2021, with the actual research start date no earlier than May 24, 2021.

Consider the following prior to submitting your new or modified IRB application for review:

- Only exempt or expedited studies will be reviewed at this time for in-person research (Full Board does not review over summer)
- Limit the number of researchers and participants in the research space (recommend one researcher with one participant in a 6-foot radius at one time)
- Research in the community will be reviewed on an individual basis that do not involve vulnerable populations
- Consider providing a COVID-19 fact sheet to participants prior and following participation.
- Investigators *must* address how participants will be protected (PPE, sanitizing, humidifiers, be outdoors when possible, social distancing, etc.) and the following [questions](#) will be asked on the IRB application and will be considered when determining IRB approval.

In addition to IRB requirements, you should also review the following **CSUSB Policies** related to COVID-19 prior to submitting your new or modified IRB application:

- It is recommended to view CSUSB's [COVID-19 Prevention Plan](#) where the university outlines how individuals should be protected when on campus (you will also have to submit a plan to risk management using these guidelines after IRB protocol is approved to be able to conduct your research)
- CSUSB requires all employees and students to self-report positive COVID-19 test using this [form](#)
- University Screening for COVID-19 each day on campus (with or without the COVID-19 vaccine)
 - All individuals with a Coyote ID must fill out the "[COVID-19 Daily Health](#)" questions found under MyCoyote and "pass" to be allowed to come to campus, if they do not pass, they should not come to campus

For any questions or concerns, please contact the IRB Research Compliance Officer, Michael Gillespie, mgillesp@csusb.edu or the IRB Chair, Nicole Dabbs, ndabbs@csusb.edu.

IRB Update on Human Subjects Research and COVID-19; 07-13-2020, 9:00 AM

Renewing Protocols during COVID-19: If you have an IRB application that is about to expire that involves in-person research and you want to keep open although you don't plan to collect data with the new COVID-19 restrictions, the IRB advises you to submit the renewal and state that you 1) want to keep the application open, 2) do not plan to collect data at this time, and 3) will submit a modification for COVID-19 related restrictions if you plan to continue with data collection. If you have an IRB application that is about to expire that involves in-person research, you want to keep open and you plan on collecting data; the IRB advises you to submit your renewal with explanations on how you will address the COVID-19 related concerns listed below.

IRB Update on Human Subjects Research and COVID-19; 07-02-2020, 9:00 AM

Resumption of In-Person Research: At this time, the IRB **strongly** recommends no in-person research for human participants. However, if you wish to commence or start new in-person research, there are some **required** precautions you will need to address. The IRB will only consider new applications, modification requests, or renewals if investigators have **adequately** demonstrated that they will minimize the risk of COVID-19 to participants. Below are items you **must** consider and include in your IRB application.

- How will social distancing be maintained between researcher and participants as well as among participants when applicable?
- What process will be used for contact tracing (i.e., identifying researchers or participants who may have come into contact with an infected person during the research process, and identifying who these individuals subsequently interacted with)?
- What process will be used for screening researchers and participants for COVID-19 (e.g., using screening questionnaires)? *See the example screening tool below.*
 - [COVID-19 Screening Tool](#)
- What procedures will be followed to decontaminate hard surfaces, research equipment, soft surfaces, clothing, and personal protective equipment (PPE)?
- How will you determine if your participants are at high risk of contracting COVID-19 and what measures will be taken to reduce their risk of participating in your research?
- Will other measures be taken to reduce the spread of COVID-19 within research spaces (e.g., improving ventilation, opening outside doors and windows to increase air circulation, conducting research in larger spaces, using sneeze guards to separate people)?
- If your research poses risks to individuals with lung, heart, clotting, or other health consequences associated with COVID-19, what measures will you take to reduce those risks (e.g., excluding participants who were previously diagnosed with COVID-19)?

Reviews of protocols will begin **July 20, 2020**. Once you have received IRB approval you need to obtain administration approval. It is CSUSB policy that you must obtain both IRB and administration approval to continue in-person research. Once your in-person research commences, you must continue to follow the newly approved protocol that includes COVID-19 restrictions to be considered compliant with federal regulations. Any IRB approval for in-person research is potentially temporary and changes may occur due to federal, state, local, and/or CSU directives.

IRB Update on Human Subjects Research and COVID-19; 05-29-2020, 9:30 AM

Resumption of Research: At this time, no in-person research can resume due to a lack of clear government and CSU guidelines for human subject research. The IRB Chair and Vice-Chair will attend a CSU webcast on June 9th and is hopeful for some guidance in the following weeks. In the meantime, the IRB will not review any new applications involving in-person human subjects research until we have received clear guidance from the Chancellor's and Governor's Offices regarding the resumption of such research.

COVID-19 preparations: As we start to plan for in-person research resuming, you as an investigator should start thinking about how you will protect participants in your research from COVID-19 risks. As you prepare for your research to resume, you should start to consider how you will minimize the risk of COVID-19 to your participants. Below is a list of questions that you might consider to help guide your preparations as they pertain to your research.

- How will social distancing be maintained between researcher and participants as well as among participants when applicable?
- What process will be used for contact tracing (i.e., identifying researchers or participants who may have come into contact with an infected person during the research process, and identifying who these individuals subsequently interacted with)?
- What process will be used for screening researchers and participants for COVID-19 (e.g., using screening questionnaires)?
- What procedures will be followed to decontaminate hard surfaces, research equipment, soft surfaces, clothing, and personal protective equipment (PPE)?
- How will you determine if your participants are at high risk of contracting COVID-19 and what measures will be taken to reduce their risk of participating in your research?
- Will other measures be taken to reduce the spread of COVID-19 within research spaces (e.g., improving ventilation, opening outside doors and windows to increase air circulation, conducting research in larger spaces, using sneeze guards to separate people)?
- If your research poses risks to individuals with lung, heart, clotting, or other health consequences associated with COVID-19, what measures will you take to reduce those risks (e.g., excluding participants who were previously diagnosed with COVID-19)?

Data storage: As a reminder, if you change the location of where your data is being securely stored because of COVID-19, you will need to make a modification via Cayuse to your approved

IRB protocol, unless you are moving your data electronically to the CSUSB secure google drive. If the change is to a location other than the google drive and is due to COVID-19, please indicate that information in the modification request form. If you plan to return your data to the original location following the lifting of COVID-19 restrictions, please indicate that intention on your modification as well. Giving that info ahead of time will prevent you from having to submit an additional modification once you return to campus.

IRB Update on Human Subjects Research and COVID-19; 03-24-2020, 9:00 AM

Dear Colleagues,

To receive an in-person research continuation approval, please submit a statement of justification for why the benefits of continuing your research outweigh the risks of potentially exposing participants to COVID-19. This justification should be emailed to the IRB compliance officer (Michael Gillespie, mgillesp@csusb.edu). In-person research that is continued without the approval of the IRB will be regarded as non-compliant and reported to the Federal Office for Human Research Protections. This policy is in effect until both the Office of Research *and* the IRB at CSUSB notify the campus that in-person research can recommence. Investigators can, however, submit a continuation request to the IRB for sites outside of San Bernardino located in geographical areas for which social-distancing advisements have been lifted by major health agencies and governmental organizations. These requests can be sent directly to the IRB via email.

As per the previous IRB communication on human subjects research and COVID-19, modifications to research protocols due to the virus must be first approved by the IRB through Cayuse. Before submitting a modification request, make sure to indicate in the Cayuse form's description box whether you are requesting permanent or temporary changes. If you state the changes are temporary, you will not need to submit a modification request to return to your original in-person protocol, once in-person restrictions are lifted by the CSUSB IRB.

Thank you for your cooperation,

Donna Garcia, IRB Chair (dmgarci@csusb.edu)

Nicole Dabbs, IRB Vice-Chair (ndabbs@csusb.edu)

Michael Gillespie, IRB Research Compliance Officer (mgillesp@csusb.edu)

IRB Statement on Human Subjects Research and COVID-19; 03-16-2020, 1:48 PM

Due to the rapidly evolving concerns and risks related to the COVID-19 outbreak, the CSUSB Institutional Review Board (IRB) requests that study investigators 1) take proactive measures to evaluate new physical and mental health risks posed to participants because of the virus, and 2) limit transmission of the virus by delaying or otherwise modifying person-to-person

interactions. In particular, the IRB requests that research involving immunocompromised, elderly, or other at-risk participants or group meetings or appointments is delayed or uses alternative interactions via electronic means if possible. If investigators are experiencing symptoms associated with the illness (fever, cough, and shortness of breath) or have visited a geographical area that has experienced an outbreak of the virus, they must avoid all physical interactions with participants. Investigators whose research involves human biological samples need to handle those samples with extra care (see CDC website). If any participants are exposed to COVID-19 in the course of a study, they must be informed immediately and advised to self-isolate. The IRB must then be promptly notified (within 24 hours) of the exposure and actions taken to notify affected participants.

All new potential or actual COVID-19 related risks posed to participants must be promptly reported to the IRB and the related research must be discontinued (unless the risks caused by the discontinuation exceed those presented by COVID-19) until the IRB has reevaluated and approved recommencement. For the purpose of protecting participants, investigators may suspend most research activities without first consulting the IRB. Investigators, however, are required to report the suspension of research if the suspension might affect the health or well-being of participants (e.g., removal of access to health-related treatments). Before any changes are made to existing research or recruitment processes, a modification request must be submitted to the IRB through Cayuse. The IRB will prioritize processing risk change and protocol modification requests that are intended to protect the well-being of participants.

(§46.108 (a)(3)(iii))

Your Institutional Review Board

Donna Garcia, IRB Chair

Nicole Dabbs, IRB Vice-Chair

Michael Gillespie, Research Compliance Officer