

UCSD IRB Updates Regarding COVID-19

Issued 13 March 2020, Updated 18 March 2020

3/18/20 updates in RED text

General Information

1. This document will be updated as new information or guidance emerges.
2. The UCSD IRB office, committees and eIRB services are fully operational, **with staff working mostly remotely and IRB meetings occurring via Zoom. The IRB database does not fully support remote work, so there may be delays in processing certain tasks.**
3. Operating status is subject to change based on a number of factors, including official announcements and instructions from the University.
4. **If your current IRB approval expires before April 30, 2020 and you have not yet submitted your Continuing Review (renewal) application, please submit your application immediately.**
5. The IRB office is prioritizing handling of submissions or questions related to COVID-19. This includes:
 - New proposals for research about the disease or its impact (clinical or non-clinical)
 - Single patient expanded access to investigational drugs or devices
 - Amendments or reports about the impact of COVID-19 on existing studies
6. **In eIRB services, the pulldown menu for uploads in “My Protocols at a Glance” now offers the opportunity to choose a COVID-19-specific label for certain document types.**
7. In parallel with any submission for priority review, please also:
 - Send an e-mail to hrpp@ucsd.edu
 - Mark the e-mail as High Priority.
 - Use the subject line “COVID Submission.”
 - Include the IRB number and a summary of the COVID-19 connection in the e-mail body.
8. **If your study is overseen by a central/single IRB at another institution and you receive guidance that is inconsistent with the information below, please contact IRBrely@ucsd.edu for help.**
9. **If you are the PI of a multi-site study and the UCSD IRB is the central IRB, please forward this guidance to your collaborating PIs for consideration.**

Considering COVID-19-Related Changes to Existing Studies

1. For sponsored projects, consult with your sponsors about any plans to modify procedures, **notification requirements, or for guidance about flexibilities and allowable unanticipated costs. Include your sponsored projects analyst/officer on these communications.**
2. For each study consider the risks to your subjects based on factors such as:
 - The nature of your subject population (for example, age or immune status)
 - The location and number of people gathered for visits
 - Whether there is flexibility for when and where procedures can take place
 - Possible disruptions to staffing levels or supply chains
3. **For UCSD research activities happening off-campus, especially if outside California or the United States, also consider local conditions or any applicable laws or advisories.**
4. Based on your risk assessment of the study, consider changes to minimize risks. This could include, but is not limited to:
 - Changing the location of study visits
 - Using phone, video or other electronic means to interact with subjects
 - Delaying or cancelling study visits
 - Additional screening for COVID-19 risk factors prior to study visits
 - Temporarily halting enrollment of new subjects

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5. Consent forms do not need to be updated to describe a risk of COVID-19 or temporary risk mitigation measures.
6. To maintain appropriate confidentiality protections, remote work arrangements need to follow applicable University or Health Sciences information security guidelines.

What COVID-19-Related Changes to Report to the IRB and When

1. Complying with mandated risk mitigation (for example, as described in this [Campus Notice](#)) is not a change to research procedures and does not require IRB review.
2. If the study is classified as “Exempt” or “Not Human Subjects Research”:
 - You do not need to report COVID-19 risk mitigation measures to the IRB office before or after implementing such measures.
 - Plans to add new procedures to collect data about COVID-19 for research purposes should be sent to the IRB office for confirmation the classification is still valid.
3. If your study has IRB approval, changes (such as those listed in item 4 above) normally need further IRB approval prior to implementation. **However, regulations allow for changes without prior IRB approval if necessary to avoid “apparent immediate hazards to the subject.”**
 - Mitigation of COVID-19 risk **for current subjects** meets the above standard and does not need prior review.
 - This also means that the IRB does not need to review e-mails, text messages, telephone scripts or other communications to subjects about COVID-19 risk mitigation.
 - In all cases, changes to research must be documented in your research records.
 - **Please see items 4-7 below for additional important guidance about this.**
4. The study’s next **Continuing Review** (renewal) can generally be used to notify the IRB about **temporary** deviations made without prior approval to minimize COVID-19 risks to **current** subjects.
5. **Submit an amendment to the IRB before implementing any change to the format of your consent procedures for new subjects (e.g., switching from in-person to video).**
6. Submit an **amendment** to the IRB (possibly with consent modification), either before the change or within 10 business days after the change, in the following circumstances:
 - The changes are expected to remain in place permanently after the pandemic resolves
 - The changes are designed to support new or modified research aims in addition to minimizing COVID-19 risks
7. Submit a **report** to the IRB within 10 business days after the change if it:
 - Disrupts **procedures** (e.g., safety evaluations or study drug dosing) to an extent that substantially alters risks
 - Will involve extended study drug administration or data collection by another institution not otherwise a site for the research (e.g., hospital closer to subject’s home)

Guidance About New COVID-19-Related Proposals

1. For the following types of new proposals, contact hrpp@ucsd.edu **before** preparing an application. Please mark your e-mail as High Priority with “COVID Consult” as the subject line.
 - Single patient expanded access to investigational drugs or devices
 - Proposals that might not constitute “human subjects research” (e.g, secondary use of deidentified specimens or data, oral history, public health surveillance, QA/QI)
 - Proposals that might qualify for administrative exemption review (e.g., educational research, surveys or focus groups, benign behavioral interventions, or some records-based research)

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2. When planning new multisite proposals in which UCSD will rely on another IRB's review or other institutions will rely on UCSD IRB review, contact irbrely@ucsd.edu with "COVID Reliance" as the subject line.

Links to Additional UCSD and Other Information

UCSD Coronavirus [website](#)

UCSD Continuity of Research [website](#)

New link: Reducing On-Site Activity [Guidance](#) from VC Brown (March 17, 2020)

New link: Human Subjects Research [Guidelines](#) from

AVC Firestein, VC Brown and VC Brenner (March 13, 2020)

Research Clinic [Phone Screen](#) (March 12, 2020)(requires UCSD AD login)

Script for [In-Person Screening](#) (March 12, 2020) (requires UCSD AD login)

In-Clinic [Testing Process](#) (March 12, 2020)(requires UCSD AD login)

New link: [Guidance](#) on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic from US Food & Drug Administration (March 18, 2020)