

IRB Submission Process for CWRU School of Dental Medicine

This process is required when:

The Case Western Reserve University Institutional Review Board (IRB) must review and approve all research involving human subjects (including use of data on individuals) conducted by faculty, staff, and students. The Case Western Reserve University (CWRU) Institutional Review Board reviews social science/behavioral studies, and low-risk biomedical research not conducted in a hospital setting.

Steps:

A study will need to be created in spartaairb.case.edu

- A CWRU Faculty member needs to be listed as the PI on the IRB submission. Students/residents can be listed as a co-Investigator on the Study Team Member page.
- On the Basic Information page, choose “no” to question #8 and choose “single site” to question #9 unless you have discussed reliant review with the IRB office and have been instructed to answer differently.
- IRB protocol template document will need to be completed and uploaded to the Basic Information page (see additional information below). Do not upload any other documents on the Basic Information page.
- On the Funding Sources page, make sure to choose a funding source even if you have no funding. There is an option for “internal/departmental/not external” if you have no formal funding.
- On the Local Site Documents page, upload consents and consent scripts in the #1. Consent Forms section, recruitment related materials to #2. Recruitment materials and all other documents to #3. Other attachments.

After the study has been created, it will need to be sent for an ancillary review if you are a student, resident or fellow in the School of Dental Medicine. The purpose of the ancillary review is to assist with an accurate submission. On the left, there is a link to Manage Ancillary Review – click and choose School of Dental Medicine Ancillary Review. (You will see Manage Ancillary Review in the History log once this has been requested).

Once the Ancillary Review is complete, submit to Department Scientific Review through the SpartaIRB system. Once that has been completed, the PI will need to login and submit the study to the IRB.

A detailed help guide for new protocol submissions can be found in the SpartaIRB Help Center.

Always needed for IRB Submissions:

PI and all CWRU study team members will need an account in SpartaIRB

- The link for the request form can be found at spartaairb.case.edu (text under login button)

- If the work is determined to be human subjects research, all study team members will need to be certified in the [CWRU CREC program](#), and complete an Outside Interests Disclosure form. The Outside Interests form will be issued after submission to the IRB.

A protocol template form will need to be completed as part of the IRB submission. These templates can be found in the SpartaIRB Library under the Templates tab. In most cases, one of these templates should be completed:

- CWRU SBER Protocol – complete for studies that have social/behavioral research questions
- Chart Review, Data & Specimens Protocol – complete if doing a chart review or receiving human specimens (with or without data)
- CWRU Data Protocol – complete if receiving data on individuals
- CWRU Exemption Protocol – complete only if research activities meet the criteria of an exemption category. Note: if this protocol is submitted and it is determined that the research does not meet the criteria for exemption, you will need to complete a different template protocol.

For chart review studies, a HIPAA Request for Waiver form will also need to be included with the submission. This document can be found in the SpartaIRB Library under Templates.

Who can help:

If you are a student, resident or fellow, we strongly encourage you to work closely with your faculty advisor on your submission. The time to approval is highly dependent upon the quality of the submission and the accuracy of the responses to the IRB requests.

CWRU IRB Office: cwru-irb@case.edu

UTech IT Security Office (for data security questions): Cal Frye at 216.368.3769 or cxf244@case.edu

Additional information can be found on the CWRU IRB website:

<https://case.edu/research/faculty-staff/compliance/institutional-review-board-cwru-irb>