

**Institutional Review Board (IRB) Guide**

This guide serves as a reference for faculty and staff at CCC who want to conduct human subjects research. The templates developed by the Institutional Review Board (IRB) help determine if a project is indeed human subjects research and, when it is, step a researcher through the process of submitting a research proposal to the IRB. CCC **requires** that all human subjects research projects are reviewed by the IRB before the project begins ([ISP 650](https://www.clackamas.edu/docs/default-source/about-us/accreditation-and-policies/institutional-and-student-services-policies-and-procedures/conduct-safety-and-security/isp-650-educational-research-involving-human-subjects.pdf?sfvrsn=1ae8768_0)).

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| **BEFORE YOU START** |

**What is the IRB?**

The IRB is a group of individuals who are formally designated to review and monitor research involving human subjects. Regulations for this type of research are maintained by the Office for Human Research Protections (OHRP) within the Department of Health and Human Services (HHS). A complete e-copy of these regulations are available in [the Code of Federal Regulations](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46). The IRB at CCC is responsible for ensuring compliance with these federal regulations. The IRB at CCC is chaired by the Director of Institutional Research and Reporting. Additional members include at least one Dean or Associate Dean and at least one faculty member.

**How long does IRB review take?**

The length of time needed for IRB review is generally dependent upon the level of risk associated with the research project. Plan for the IRB review process to take 8 weeks after all your materials are submitted to CCC’s IRB.

**What kinds of research are not allowed at CCC?**

CCC’s IRB has limited the types of research and study populations allowed to reduce risk and due to the expertise of staff on the IRB team. The following types of research / study populations are not reviewed, and therefore cannot be conducted, at CCC:

1. Studies involving any type of medical research, collection of biospecimens, or HIPAA data.
2. Studies involving drugs/substances, investigational devices, or food studies subject to FDA regulations.
3. Studies that include prisoners in the study population. If prisoners could be incidentally included (such as in an online survey), this study could be approved. However, studies that specifically target incarcerated individuals as study participants are not allowed.
4. Studies that take place outside the United States.
5. Studies that do not qualify for Exempt or Expedited review. These are typically studies with higher levels of risk. Refer to Form 2 and Form 3.

**Who can conduct research at CCC?**

Note that all research staff must complete research training prior to submitting an IRB application (see Form 4).

1. Faculty, staff, and administrators employed at CCC can submit IRB proposals for review.
2. CCC students cannot serve as the Primary Investigator (PI). CCC students can serve on a research team headed by someone employed by CCC (i.e., faculty, staff, administrator).
3. Faculty and staff who have IRB approval from an outside institution and want to conduct research at CCC can submit their IRB materials and IRB approval letter from that institution (IRB of record) to CCC’s IRB. CCC’s IRB will then review and approve or deny the request to conduct research at CCC.
4. Researchers not employed at CCC cannot use CCC’s IRB. Data requests for outside research projects should be directed to the Office of Institutional Research at IR@clackamas.edu

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| **STEPS TO COMPLETE** |

1. Fill out Form 1. This form will help you determine if your project meets the definition of “human subjects research”. If Form 1 indicates your project meets the definition of “human subjects research”, proceed to step 2 (below). **If your project does not meet this definition, you do not need to go through the IRB nor continue completing forms.**
2. Fill out Form 2. This form will help you determine if your project qualifies for an Exempt Review. This does not mean you do not have to go through the IRB process. Instead, this is an indicator that your study poses a low level of risk. If your project meets the requirements for an Exempt Review, follow the steps in Section 3 of Form 2 to submit your proposal to the IRB. **If your project does not meet the requirements for an Exempt review, proceed to step 3 (below).**
3. Fill out Form 3. This form helps you submit your request to the IRB for an Expedited Review. These studies are human subjects research, but do not qualify for an Exempt Review. Fill out this form and follow the steps in Section 10 of Form 3 to submit your proposal to the IRB. Note that after you submit this form, the IRB may determine that your project does not qualify for an Expedited Review and will not be approved. You may be able to use the feedback in the Expedited Review Form (completed by the IRB) to revise your research project so that it has a lower risk level. You may receive questions, suggestions, or changes that must be addressed in your protocol via the Expedited Review Form. Please respond promptly as an Expedited Review can take longer than 8 weeks.

Form 2 and Form 3 both include a checklist of items you will need to submit to the IRB for review. Please note that **all** research materials must be submitted with your IRB application.

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| **AFTER THE PROJECT IS REVIEWED** |

1. If you need to make any changes to your study, you must submit, and the IRB must approve, an Amendment Request prior to implementing changes.
2. If any of your participants experience adverse effects from your study, you must promptly notify the IRB.
3. Notify the IRB when your study has concluded.
4. The IRB will complete an annual review of active studies led by an investigator who is conducting their first IRB-approved study at CCC. The review will include asking if the research has started or concluded, and ensuring there are no changes that require IRB approval. A nonresponse will result in the suspension of IRB approval.

For any questions, please email CCC’s IRB at IRB@clackamas.edu