



INSTITUTIONAL REVIEW BOARD Submission, Review, and Follow-Up Procedures

IRB Submission Procedures

1. Each member of the Research Team must complete the [online Human Subjects Research training](#) and retain a copy of their training certificate. Submit the training certificate with each Human Research Application as an addendum. (The CSU IRB will not retain copies of the training certificates. All members of the research team (e.g., principal investigator, co-principal investigator, and key personnel) involved with the project should complete the online training and submit their training certificates should be attached for all personnel involved with the study.)
2. Read all CSU IRB [Policies](#) and [Procedures](#).
3. Complete the [Human Research Application](#). (For student project, thesis, or dissertation, the faculty supervisor serves as the Co-Principal Investigator. If you are not affiliated with CSU, then you must list a faculty member as the Co-Principal Investigator.)
4. Complete the [Informed Consent template](#) if applicable, which is available on the CSU IRB website.
5. Obtain a Letter of Cooperation from each off-campus site if applicable. (A Letter of Cooperation written on the institution's letterhead and signed by the appropriate authorized official(s) is required from each off-campus site where the research project will be conducted.)
6. Email the completed application as an attachment to irb@columbusstate.edu from the researcher's CSU email account. All supporting materials (e.g., informed consent form, measures, human subjects training certificates, and letters of cooperation), should be merged into one PDF or Word file and emailed as a secondary attachment.

IRB Submission Procedures for Lab Personnel Forms

1. The director of the lab will complete the [Lab Personnel Form](#) at the beginning of each academic year.

2. Submit the form along with one addendum, which contains the human subjects training certificates for all personnel listed on the form.
3. Email the completed form and addendum to irb@columbusstate.edu from the director's CSU email account.

**The director should revise this form each semester, if needed.

IRB Review Procedures

1. After submission, applications will be reviewed for completeness by the Office of Academic Affairs:
 - a. Does the application include copies of the informed consent form, all measures, and/or other required materials?
 - b. Do all members of the research team have a current certificate of online training attached to the application?
 - c. If the researcher is a student, has approval been obtained from a faculty supervisor? (Note: Research completed as part of a class assignment and approved by an instructor will not receive IRB approval after data has been collected.)
2. Incomplete applications will be sent back to the researcher with a list of necessary items. The researcher will need to resubmit the application with the incorporated items.
3. Completed applications will be reviewed for exempt, expedited, or full board review status.
4. Once classified, applications will be sent to the IRB Chair or designate for processing. If the IRB Chair is the researcher or faculty supervisor for the project, then another designated member of the IRB (e.g., Assistant Chair) will make the final decision regarding status and process the approval.
5. If the application is determined to be exempt, the IRB Chair will approve the application and send appropriate notifications to the researcher. The IRB Chair may seek feedback from IRB members regarding exempt applications.
 - a. If any changes are recommended, the Chair will communicate with the researcher regarding these issues and any suggested modifications.

- b. The researcher will need to resubmit the application with the incorporated suggestions. The Chair may seek feedback from IRB members if applicable.
 - c. If the issues with the application are not resolved after one resubmission, then the researcher must wait 30 calendar days before resubmitting another revised application to the IRB.
6. If the application is determined to be eligible for expedited review, the IRB Chair will send the application and all supporting materials to at least two members of the IRB for review.
- a. If possible, one of these members should be working in a closely related field and/or familiar with the general type of study being proposed.
 - b. These two members will independently review the application and report back to the Chair with a recommendation regarding whether the project should be amended or approved.
 - c. In order to expedite this process, the members should make every effort to review each application and send feedback to the Chair within one week. If this timeline is not possible, then the members should notify the Chair immediately.
 - d. If any changes are recommended, the Chair will communicate with the researcher regarding these issues and any suggested modifications.
 - e. The researcher will need to resubmit the application with the incorporated suggestions. The Chair will consult with the two designated reviewers and make a final judgment regarding the application.
 - f. If the issues with the application are not resolved after one resubmission, then the researcher must wait 30 calendar days before resubmitting another revised application to the IRB.
 - g. Once the project is approved, the Chair will send appropriate approval letters to the researcher.
7. If the application is determined to require full board review, the following procedures will be followed:
- a. The application will be scheduled for review at the next regular IRB meeting.
(The IRB will meet once a month, excluding summer months, unless there are no

applications to review.) Any application requiring full board review must be submitted 10 business days prior to the next regularly schedule IRB meeting.

- b. A copy of the application and all supporting materials will be sent to each board member.
- c. The researcher will be notified of the time and place of the meeting during which his or her application will be reviewed.
- d. The researcher will present his or her IRB application to the Board and answer any questions from the board members during the scheduled IRB meeting.
- e. Each application that requires full board review will be discussed by board members in a closed IRB meeting.
- f. Following the discussion, IRB members will vote whether to approve the project and/or suggest modifications.
- g. If any changes are recommended, the Chair will communicate with the researcher regarding these issues and suggest modifications.
- h. If the application is approved, the Chair will follow-up with appropriate approval letters to the researcher.
- h. If the application is not approved, the Chair will communicate with the researcher regarding these issues and any suggested modifications.
- i. The researcher will need to resubmit the application with the incorporated suggestions. The application will be scheduled for review at the next regular IRB meeting.
- j. If the issues with the application are not resolved after one resubmission, then the researcher must wait 30 calendar days before resubmitting another revised application to the IRB.

IRB Follow-up Procedures

1. Records will be stored in the Office of Academic Affairs in Richards Hall.
2. If any adverse events, unexpected problems, or incidents occur that involve risks to participants and/or others, the research must notify the CSU IRB immediately. Document the occurrences using the [Final Report Form](#), which is available on the IRB website.

3. If the data collection and/or interventions for a given research project needs to continue beyond the protocol's expiration date without any protocol modifications or minor modifications, the researcher must complete a [Project Continuation Form](#), which is available on the IRB website, and submit it for IRB review.
4. If the Research Team needs to modify a currently approved research project with minor protocol modifications, complete a [Project Modification Form](#) and submit it for IRB review. Minor modifications include change of study title, changes to the research team, changes with participants, and procedural changes. Note: If the data collection and/or interventions for a given research project are determined to be major protocol modifications, then the Research Team will be asked to revise the approved [Human Subjects Application](#) and submit it for IRB review.
5. If the data collection and/or interventions for a given research project needs to continue beyond the protocol's expiration date with major modifications to the protocol, the researcher must complete another [Human Subjects Application](#), indicate it as a "Continuing Project", and submit it for IRB review.
6. At the conclusion of all research projects that receive expedited and full board reviewed approval, a [Final Report Form](#) must be submitted to the CSU IRB using the template provided.