

Form A: Procedural Key for Submitting Human Subjects Research for Institutional Review

I. Submitting Proposals for Review

1. What is the status of the Principal Investigator?
 - a. NCWU Faculty Member → Step 6
 - b. NCWU Student → Step 4
 - c. NCWU Staff Member → Step 7
 - d. Non- NCWU Individual → Step 2
2. Non- NCWU individual submits research proposal and necessary forms (such as B1, B2, B3 or B4) to the Provost and Senior Vice President for Academic Affairs, and the Vice President of Student Affairs and Dean of Students. The proposal must be approved by both Deans in order to be considered by the NCWU IRB.
 - a. → Step 03
3. The Provost and Senior Vice President for Academic Affairs, and the Vice President of Student Affairs and Dean of Students decide if the proposed research is appropriate for NCWU.
 - a. Appropriate for NCWU – Provost and Senior Vice President for Academic Affairs forwards package of materials to the Chair of NCWU IRB for initial review of the proposal.
 - i. → Step 8
 - b. Inappropriate for NCWU – Provost and Senior Vice President for Academic Affairs notifies principal investigator in writing that the request has been rejected.
4. NCWU student submits description of proposed research to faculty sponsor/adviser for initial review. Sponsor discusses project with student and provides instruction on the institutional and federal requirements for the protection of human research subjects. Sponsor then decides if:
 - a. Changes are required to protect human subjects.
 - i. → Step 5
 - b. Human subjects are sufficiently protected. Sponsor assists students in completing the necessary forms (including Self-Assessment Form B-1 and other appropriate forms such as B2, B3, or B4) for institutional review and forwards the package of materials to the Chair of NCWU IRB. With the forms, PI's should also attach a summary of the research project.
 - i. → Step 8
5. NCWU student revises research design in accordance with the recommendations of the faculty sponsor to ensure the protection of human subjects.
 - a. → Step 4

6. NCWU faculty member submits research proposal and necessary forms (including Self-Assessment Form B-1) for initial review to the to the Chair of NCWU IRB.
 - a. → Step 8
7. NCWU staff member submits research proposal and necessary forms (including Self-Assessment Form B-1) to the chair of the Institutional Review Board (IRB) for initial review.
 - a. → Step 08

II. Initial Assessment of Risk and Category of IRB Review

8. The Chair of NCWU IRB reviews the degree of risk associated with the proposed research and assigns the proposal to a corresponding category of review.
 - a. If the category of review differs from the self-assessment of the PI (Form B-1), the Chair of NCWU IRB discusses the differences in risk assessment with the PI.
 - i. If they reach an agreement on the category of review: → Step 8b
 - ii. If they cannot reach an agreement on the category of review, the IRB chair will make the final decision. → Step 8b
 - b. If the reviewer's assessment is:
 - i. No foreseeable risk - exempt → Step 9
 - ii. Minimum risk – expedited review → Step 10
 - iii. More than minimum risk – full IRB review → Step 13

9. Review Process

9. Based on the assessment of “no foreseeable risk,” the proposed research is placed in the category of “exempt” by the Chair of NCWU IRB. The Chair of NCWU IRB sends the Principal Investigator written notice (email) of this decision. Research may commence immediately. No further review is necessary, except under the following specified conditions: → Step 14
10. Based on the assessment of “minimum risk,” the proposed research is placed in the category of “expedited review” by the Chair of NCWU IRB. The IRB chair arranges for an expedited review of the research proposal by one of the following methods, selected at the discretion of the chair:
 - a. The IRB chair alone → Step 12
 - b. One other member of the IRB → Step 12
 - c. The chair AND one other member of the IRB → Step 12
11. Based on the assessment of “more than minimum risk,” the proposed research is placed in the category requiring **full IRB review** by the Chair of NCWU IRB. The chair of the IRB schedules a review of the research proposal at the next regularly scheduled meeting of the full IRB, and distributes copies of all relevant materials in advance of the meeting. The review of the research proposal may also

be completed via email communications between the Chair of the NCWC IRB and the members of NCWU IRB.

- a. → step 12

IV. Outcomes of IRB Review

12. The principal investigator will receive written notice of one of four possible outcomes of either expedited or full IRB review:
 - a. **Approved.** Research may commence immediately. Further review is not necessary except under the following specified conditions:
 - i. → Step 18
 - b. **Conditional Approval.** The proposal is approved with relatively minor changes or conditions.
 - i. → Step 13
 - c. **Revise and Resubmit.** The proposed research design constitutes significant risks to human subjects. Substantial revisions are necessary, followed by another review by the full IRB.
 - i. → Step 14
 - d. **Denial.** The proposed research is deemed too risky to human subjects and cannot be permitted at NCWU. Principal investigators may appeal the decision of the IRB.
 - i. → Step 20
13. Under **conditional approval**, research may not commence until the Principal Investigator demonstrates to the satisfaction of the chair that he/she has fulfilled the conditions specified by the NCWU IRB. The full IRB does not need to convene to review these changes.
 - a. The chair approves the changes and authorizes research to commence without further review, except under specified conditions. → Step 18
 - b. After continued interaction with the PI, the chair is not fully satisfied that the required conditions have been met. A resubmit for a full IRB review is required.

V. Conditions Requiring Re-Consideration by the IRB

14. Certain conditions or changes in ongoing human subjects research projects require immediate written notice to the IRB and/or reconsideration by the full IRB.
 - a. If the project has been terminated: → Step 16.
 - b. If the research will extend longer than one year (continuing project), it must undergo an annual review. → Step 17.
 - c. If there been a substantive change in research protocol or data collection procedures: → Step 15.
 - d. If new subjects will be recruited under conditions that are significantly different than those described in the original proposal: → Step 17.
 - e. If there have been any changes in and/or adverse effects of your ongoing human subjects research project, inform the Chair of the NCWU IRB

immediately and in writing. If the IRB chair determines that a re-consideration of the project by the IRB is required

15. Inform the Chair of the NCWU IRB **immediately** and in writing of any changes in and/or adverse effects of your ongoing human subjects research project. If the NCWU IRB Chair determines that a re-consideration of the project by the IRB is required. → Step 4b.
16. Please notify the Chair of NCWU IRB in writing.
17. Please notify the Chair of NCWU IRB in writing and resubmit proposal and related forms.

VI. Appeals Process

18. A Principal Investigator who disputes a decision by the NCWU IRB (e.g., a denial) may request in writing that the decision be reconsidered at the next regularly scheduled meeting of the IRB. That request should be accompanied by appropriate written arguments and supporting materials. The PI may also choose to appear before the IRB at the meeting at which the appeal is being considered. There are two possible outcomes:
 - a. The decision of the IRB is changed based on new evidence. Follow IRB directives.
 - b. The original decision of the IRB is upheld. The decision is final.