Randolph College
Institutional Review Board

Guidelines for Submitting a Human Subjects Research Proposal

Procedures for Submitting a Proposal
The following procedures are available on the IRB webpage on the Center for Student Research and Dean of the College website:
1. Investigators must complete a Human Subjects Research Proposal.
2. Investigators must include research instruments such as surveys, questionnaires, interview scripts, manipulation protocols, debriefing forms, etc.
3. Investigators must attach an informed consent document for the research and, if needed, a script to inform participants of research procedures, surveys, interviews, etc. Guidelines to completing an informed consent document are attached.
4. Investigators must include the following attachments as appropriate:
   a. evidence of permission from cooperating institutions (if any).
   b. relevant grant application(s).
   c. non-disclosure or other agreements with owners of restricted data sets.
5. Investigators must attach certificate(s) verifying that all investigators involved in the project have completed the CITI training program at http://www.citiprogram.org.
6. If a student is the investigator, the faculty supervisor must submit the proposal and supporting documents via email to the Chair of the IRB at irb@randolphcollege.edu. The faculty supervisor should include a statement that s/he has read and approved the proposal.
7. Investigators must complete an End of Project Report at the completion of the study and email it to the IRB Chair.

Application Time Frames and Approval Decisions
The IRB accepts applications for approval of research involving human subjects between the first and last day of class of each semester.

Investigators must submit research proposals a week in advance of an IRB scheduled meeting. The meeting dates are listed on the IRB website and under “IRB Meeting Dates” noted earlier in this document.

Investigators should allow one week for an expedited review decisions and up to three weeks for full review decisions.

Winter Break/Summer IRB Reviews
Applications received during the winter or summer break will be reviewed at the beginning of the following semester. Upon notice to the IRB Chair before the end of the semester, an exception may be made for student-faculty research projects conducted through the Summer Research Program. Exceptions for other summer or winter research may be granted only under unusual circumstances. For almost every research project, applicants should expect the IRB committee to review applications only during each semester.

An administrator or staff member will initiate research reviews and facilitate meetings during the winter and summer breaks according to the policy for accepting applications during these periods, as stated in the committee description. During these periods, the IRB chair or, when the chair is unavailable, a sufficiently qualified faculty member appointed by the Dean of the College will write and sign official IRB letters of approval or disapproval.
Proposal Decision Categories
Once a proposal is submitted and reviewed by the IRB, it will be designated as approved, not approved, or approved with conditions.

Approved
The Chair will email the investigator a dated approval letter. It will state that the investigator should promptly report changes to project procedures or personnel, and any unanticipated problems or adverse events encountered during the study. The letter will include the category of review designation and the duration of the IRB approval, which will end one year to the date of the initial approval. If the project goes beyond a year, the project must be re-approved through the IRB. The investigator must submit an End of Project Report at the completion of the study. The Adverse Event forms and the End of Project Report are located on the IRB webpage.

The investigator is responsible for implementing all minor changes suggested by the IRB (e.g., change a word in a survey, clarifying terminology in an informed consent document, etc.). The Board will not monitor progress on any of its suggestions for expedited projects or suggestions that do not affect the risk of the study. In this case, the IRB comments or suggestions are meant to draw attention to ways in which a project may be made even less stressful to the human participants.

Not Approved
If the Board does not approve a project or grant an exemption, it will provide justification and suggest ways in which the project might be revised to meet approval. In this case, the revised proposal must be resubmitted with a new Human Subjects Research Proposal.

Approved with Conditions
The IRB may “approve with conditions” research proposals, consistent with OHRP guidelines. By IRB approval with conditions, OHRP means that at the time when the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of approval that the investigator (a) make specified changes to the research protocol or informed consent document(s), (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submit additional documents. The investigator must provide the IRB with a letter or email stating specifically how the conditions will be met before the project begins. The IRB Chair will respond as to whether the conditions have been satisfied and include a final approval letter with the conditions noted in “approved” above. Normally, in this case, a re-submission of the original proposal will not be required.