Institutional Review Board (IRB) – Applications

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Policy 3.01

Topic: Initial review of research
Date of implementation: May 19, 2008
Revised: March 23, 2015

Applications for initial review of research are submitted to the IRB through the online submission system. In the online system, researchers provide a summary of the proposed research, identities and roles of all researchers who will have access to data, responses to the application questions, and supporting documents.

Once an application is submitted through the online system, the IRB will respond to the applicant with either 1) suggestions for revisions, 2) notification that the application has been approved, 3) notification that the applications has been deemed as research not requiring IRB approval, or 4) notification that the application will be reviewed by the fully convened board at the next IRB meeting.

The IRB office staff performs protocol review utilizing a checklist covering topics such as the purpose of the research, description of the population, recruitment and consent plan, methodology, confidentiality, assessment of risk, tutorial completion, and type of review (i.e., exempt, expedited, or full board).

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Policy 3.02

Topic: File composition
Date of implementation: May 19, 2008
Revised: August 28, 2012

The IRB office maintains applications and all attached materials for a period of five years or longer. Complete files consist of any or all of the following:

a. the initial application for review;
b. CITI tutorial confirmations of all researchers;
c. informed consent documents;
d. data collection materials;
e. letters of support, permission, or consent from external research sites;
f. print outs of email correspondence between the researchers and IRB office;
g. Applications for Continuing Review and related documents;
h. Research Amendment forms and related documents;
i. approval letters from the IRB.

Policy 3.03

Topic: Tutorial completion prior to application review
Date of implementation: March 10, 2008
Revised: August 28, 2012

The NAU IRB uses The Collaborative Institutional Training Initiative (CITI) program as its required tutorial. All NAU faculty, staff, and students planning to conduct research or work on a research project as key personnel must successfully complete the tutorial with a pass rate of 80% correct or better.

The CITI program is an online collection of learning modules, each of which focuses on a different aspect of IRB. At the end of each module is a short quiz. Tutorial completion reports are required with your application for approval for research. Updated tutorial completion is required every three years.

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Prior to submitting their IRB applications, all researchers and key personnel must complete the CITI tutorial that is appropriate for them. In the CITI system, researchers select from among social and behavioral research, biomedical research, or data on specimens only research. Student researchers, in most cases, take the series of tutorials for “students conducting no more than minimal risk research.”

Policy 3.04

Topic: File new application every three years
Date of implementation: May 19, 2008
Revision date: June 17, 2008

Research that continues beyond one year must be re-approved via an Application for Continuing Review process (see policy 4.06, Continuing Review of Research). However, some research lasts several years and federal guidelines may change during that time. Therefore, the IRB requires researchers to fill out a new IRB application upon expiration of the second renewal of approved research projects.

Research that is initially approved can be renewed for two consecutive years only. If a research project extends into a fourth year of participant enrollment, data collection, or analysis, a new IRB application must be submitted and evaluated to ensure compliance with current regulations.

Policy 3.05

Topic: Applications not yet approved
Date of implementation: March 10, 2008
Revision date: October 6, 2014

Applications, amendments, Human Subjects Research determinations, and other documents submitted to the IRB office will be reviewed in the order of priority. Submissions are generally prioritized based on date of receipt, but prioritization can also be affected by project funding status, IRB review category, and other factors.

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Investigators who receive requests for revisions or support documents from the Board or the IRB office staff have 45 calendar days from the date of that communication to respond to the request. If 45 calendar days elapse and the investigator has not responded, the application will be permanently closed.

Policy 3.06

Topic: Collection of data for unpredetermined uses
Date of implementation: April 14, 2008
Revision date: June 17, 2008

This policy is for researchers who are interested in collecting data on human subjects for the purpose of long-term research (more than one year) or for research purposes that have not yet been specifically defined. For example, a researcher collecting data from participants who cycle in and out of a program annually in order to use that data for possible future research projects that may or may not have been conceived by the researcher would be subject to this policy. This policy should be followed by the researcher collecting the data and any other potential future researchers who wish to use the collected data for follow-up or secondary research projects.

The IRB-related steps to follow in developing, maintaining, and sharing a database are:

• The researcher(s) collecting the data need to get IRB approval prior to data collection to construct the database and assure that data are collected ethically and according to IRB regulations.
• In the initial IRB application, the researcher(s) should describe limits for what the data will and will not be used.
• Signed or electronically approved informed consent must be attained from each participant whose data will be included in the database. Those informed consent forms should inform participants that their data will be part of a database and that the data could be used for any number of potential future studies, providing one or two examples of what those secondary studies might entail.
• The researcher(s) will re-apply annually for IRB approval to continue their database development.
• Researcher(s) wanting to conduct specific studies on the database will submit a new IRB application for approval of research for each study utilizing the data set.

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
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Policy 3.07

Topic: Research involving Native Americans
Date of implementation: March 26, 2009
Revision date: April 11, 2011

Research that specifically targets Native Americans as an identifiable participant population requires additional safeguards and procedures that vary depending on where the data collection takes place and on which tribes are included. The IRB requires researchers conducting research on tribal lands to seek the approval/permission of the specific tribes involved. The procedures for attaining approval/permission vary from tribe to tribe and can take from 18 months to two years to complete.

IRB applications that involve the collection of data on tribal lands will be reviewed by the IRB as a first step. Once the application is approved, the research may not include Native Americans living on tribal lands until approval/permission from each individual tribe of interest is obtained. In order to extend IRB approval for Native American participants living on tribal lands, the researcher(s) must acquire all tribal approvals/permissions. Once tribal approval has been acquired, the researchers must submit a research amendment to include each tribe for which approval/permission has been acquired.

Research that includes Native Americans as part of a more general population and/or does not take place on tribal lands does not necessitate approval/permission from tribal authorities. Such projects may still require IRB approval. The Human Protections Coordinator will classify the research as exempt, expedited, or full board review, and the application will follow the usual channels of review.

Policy 3.08

Topic: Student research
Date of implementation: March 2, 2009
Revised: August 28, 2012

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
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Student research is an important learning experience for undergraduate and graduate students at NAU. As such, it should be performed with full guidance from a faculty member who is knowledgeable about the research methodologies and practices in the academic discipline in which the student is doing research. The IRB holds faculty members sponsoring student research responsible for the ethical conduct of that research.

This responsibility constitutes the following:

• To guide the student researcher through the research design process;
• To be current in completing the CITI tutorial (required by IRB for all researchers), i.e., to have completed the tutorial within the past 3 years;
• To review the student’s research plan and IRB application to ensure a good quality research design and ethical conduct;
• To utilize the IRB submission system in signing off on the student’s IRB application and responding to the conflict of interest question;
• To remind students of their duty to apply for continuation if their IRB approval is going to expire and to file an amendment if there are changes in the research project.

Researchers who do not feel that they can satisfy the responsibilities outlined in this policy should advise students interested in conducting research to seek another faculty sponsor or mentor.

The IRB will hold both faculty sponsor and student researcher accountable for student research that encounters an adverse event or negative consequence. Faculty members should take this into account when considering sponsoring a student in research.

Policy 3.09

Topic: Collaborations with other institutions/researchers at other institutions
Date of implementation: June 4, 2012

NAU researchers who conduct research at institutions other than NAU or who collaborate with researchers who are employed by institutions other than NAU must seek approval from the NAU IRB. This includes research conducted at clinics, hospitals,

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hospices, schools, school districts, pre-schools, universities, colleges, community colleges, non-profit organizations, governmental organizations and agencies, non-governmental organizations, and any other type of formal institution or organization that provides data, participants or other research-related resources. This policy also includes research conducted in other countries.

In some cases, the researcher may also be required to seek approval from the other institution’s IRB or tribal IRB’s or research review boards. It is the responsibility of the researcher to find out if this is required by the other institution.

This policy applies to all researchers and NAU affiliates, including: faculty (adjunct, visiting, part-time, full-time, emeriti, etc.), staff, students, and any collaborators. This policy excludes NAU employees who are serving as consultants or external evaluators who will not be actively collecting data or recruiting or interacting with participants.

Also see Policy 3.07, Research Involving Native Americans and Policy 4.07, Reciprocal Agreement with University of Arizona and Arizona State University.

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