Institutional Review Board (IRB) – Reporting of changes, adverse events, and non-compliance

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Policy 5.01

Topic: Amendments to approved research
Date of Implementation: April 13, 2009
Revised: August 28, 2012

All changes in NAU IRB-approved research protocols must be reported to the NAU IRB in writing using the Research Amendment form. Examples of changes include:

- increase or expansion of participant pool;
- addition or alteration of data collection instruments;
- addition of research personnel;
- alteration in compensation to research participants;
- change in recruitment plan;
- revision of informed consent documents;
- any other change that impacts participants, researchers, methodology, confidentiality, or consent.

Investigator(s) submit the Research Amendment form to the Human Protections Coordinator for review. If the changes involve increasing risk to participants, the Amendment application may be turned over to the fully convened board for review. Also, if the study was originally approved under full board review, then the amendment must be reviewed by the fully convened board at the next scheduled meeting.

If the changes are minor and do not increase risk to participants and the application was not originally approved under full board review, the change is approved by the Human Protections Coordinator, who is a member of the board designated by the NAU IRB

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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Chair to review and approve studies qualifying for expedited review. Once the amendment is approved, either by the Human Protections Coordinator or the fully convened board, the investigator(s) will receive an approval letter for the change via email. The investigator must not initiate the changes in the research protocol prior to receiving the amendment approval letter from the Human Protections Coordinator. Non-compliance with this policy will be handled on a case by case basis.

Policy 5.02

Topic: Adverse events
Date of implementation: April 13, 2009
Revised: August 28, 2012

Any adverse event is any injury, trauma, or illness experienced by a participant that required medical or psychological treatment or had the potential to require medical or psychological treatment. Investigators are required to report adverse events that were not anticipated and therefore not listed on the consent form. Any risks that were listed on the consent form do not constitute adverse events and do not have to be reported to the IRB.

Unanticipated problems involving risks to participants or others are:

1. unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research, meaning that there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
3. indicators that the research places subjects or others at a greater risk of harm, including physical, psychological, economic, or social harm, than was previously known or recognized.

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The PI (or LI with faculty sponsorship) must make the initial determination that the event is an unanticipated problem involving risks to others. Unanticipated problems and unexpected adverse events experienced by a research participant must be reported to the IRB within 5 business days of the researcher becoming aware of them by filling out the Adverse Reaction and Event reporting form. The form should be submitted to the Human Protections Coordinator, who will report it to the IRB Chair, Institutional Official, US Office of Human Research Protection, and any funding agencies. All aspects of the research project must be halted until further notice from the IRB. Non-compliance with this policy will be handled on a case by case basis.

Policy 5.03

Topic: Serious adverse events
Date of implementation: April 13, 2009
Revised: August 28, 2012

A serious adverse event, as defined by the OHRP “Guidance on Reviewing and Reporting Unanticipated Risks to Subjects or Others and Adverse Events” (see http://www.hhs.gov/ohrp/policy/advevntguid.html), is any adverse event that:

- results in death;
- is life-threatening (places the participant at immediate risk of death from the event as it occurred);
- results in inpatient hospitalization or prolongation of existing hospitalization;
- results in a persistent or significant disability/incapacity;
- results in congenital anomaly/birth defect; or
- based upon appropriate medical judgment, may jeopardize the participant’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

A serious adverse event must be reported to the IRB within 24 hours of the researcher becoming aware of it. Using the Adverse Reaction and Event reporting form, the PI

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describes the nature of the event, the medical treatment that the participant received, the likelihood that the event was related to the research protocol, and any changes in the protocol or informed consent that are needed to protect other subjects. A consulting physician must also comment on the severity of the event and the likelihood that it was related to the research protocol. The form should be submitted to the Human Protections Coordinator, who will report it to the NAU IRB Chair, Institutional Official, US Office of Human Research Protection, and any funding agencies. All aspects of the research project must be halted until further notice from the NAU IRB. Non-compliance with this policy will be handled on a case by case basis.

Policy 5.04

Topic: Failure to seek IRB approval
Date of implementation: April 13, 2009

The IRB requires the review and approval of all research protocols involving human research participants prior to recruitment or contact of potential participants or the collection of data. Researchers who do not comply with this requirement will have their research halted by the IRB.

Any person can make an allegation of non-compliance with this requirement. The IRB will seek information concerning allegations of non-compliance by any Northern Arizona University student, faculty, or staff. If non-compliance has occurred, the board will determine if the non-compliance was due to lack of knowledge or awareness of the requirement or if it was due to a knowing and willful disregard of the requirement.

The IRB may forward its findings to other disciplinary committees at Northern Arizona University with its recommendations for sanctions. Sanctions for failure to receive IRB approval for research involving human participants range from a written reprimand to disallowing all further research projects at Northern Arizona University.

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The IRB may also prohibit the use of all data collected prior to the IRB review and approval. Non-compliance with this policy will be handled on a case by case basis.

Policy 5.05

Topic: Follow-up to complaints of non-compliance
Date of implementation: April 13, 2009

All researchers conducting human subjects research are expected to conduct research within the guidelines of 45 CFR 46. Any person can make an allegation of non-compliance with this requirement. Researchers may be subject to sanctions if his/her project falls out of compliance. Disciplinary action by the IRB may include, depending on the severity of the infraction:

- a written reprimand
- suspension of the research project
- termination of the project
- suspension of all future research conducted by the individual researcher
- seizure of all research data

At a minimum, the occurrence of non-compliance will be documented by the Human Protections Coordinator using the Internal Incident Report, filed with the researcher’s IRB materials in the IRB office. The report may or may not be shared with the researcher’s departmental chair or college dean.

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