NATIONAL AMERICAN UNIVERSITY

INSTITUTIONAL REVIEW BOARD (IRB) PROCEDURES

July 2016

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National American University Mission

National American University welcomes students of diverse interests, cultures and abilities and prepares them for careers in technical and professional fields by providing quality higher education in a caring and supportive environment.

The university builds learning partnerships with students and other institutions and organizations locally, nationally and internationally through its private, regionally accredited system of campuses and education centers offering courses in traditional, accelerated and distance learning formats.

As a comprehensive technical and professional institution of higher learning, the university responds to the changing needs of students, employers, and their communities by providing undergraduate and graduate programs and continuing education opportunities to serve an evolving global society.

Purposes

1. Offer quality technical and professional degree programs, as documented by institutional and academic assessment processes at the associate, bachelor's and graduate level, diplomas, certificates and adult degree completion programs to traditional, adult and international learners.

2. Provide a general education program to build awareness, abilities and interests to empower lifelong learners as knowledgeable citizens of the global community.

3. Provide a collegiate experience through instructional and support services that creates a stimulating, caring and supportive learner-centered environment in which students are encouraged to achieve the educational goals established by the university.

4. Promote a learning and working environment by providing new technologies, methodologies and practices that enhance and extend quality programs and services.

5. Prepare students to provide leadership and services for the employment needs of business, industry and government worldwide.

6. Pursue communication, cooperation and alliances with educational institutions, organizations and associations on a local, regional, national and international basis.

7. Respond to the ever-changing societal demands for personal and professional development and continuing education through flexible scheduling and convenient access via traditional, accelerated and distance delivery methodologies.

8. Assist students in the development of ethical values and behaviors.

9. Foster an environment that encourages involvement by employees in the innovation and solution-seeking processes and provide an opportunity for personal and leadership development while promoting diversity in culture and perspective.

10. Provide a stable institutional environment where human, financial and physical resources are sufficient to accomplish its educational and institutional goals as a sound basis for continued growth and development.

Core Values

- A caring and supportive learning environment
- Quality instructional programs and services
- Technical and professional career programs

Institutional Review Board Policy

It is morally and ethically imperative that the rights and welfare of research subjects be protected. In accordance with federal, as well as applicable state regulations, National American University (NAU) has established an Institutional Review Board (IRB) and policies and procedures for research involving human subjects, or data or materials derived from humans. Safeguarding the rights and welfare of human subjects utilized in research protects not only the individual subject but also the researcher and the institution sponsoring the research project.

IRB Mission Statement

The mission of the National American University Institutional Review Board is to assure highest quality research involving human subjects conducted under the auspices of the university. In that regard, safeguarding the rights and welfare of human subjects in research is a general institutional policy delegated by the president through the provost to the (IRB). Therefore, any research project involving human subjects which is conducted by NAU faculty, staff, students, or external persons (or that takes place on any NAU campus or as a part of an academic affiliation agreement) is subject to review and approval by the IRB. The IRB's main purpose is to ensure protection of human subjects through the review, approval, modification, or disapproval of research applications submitted by faculty, staff, student, and/or external investigators. The IRB is further responsible for communication, recordkeeping, reporting, monitoring, education of the university community about ethical issues, and oversight of all research activity involving human subjects. The IRB is guided by ethical principles outlined in the Belmont Report (1979) and legal mandates outlined in the Code of Federal Regulations Title 45 Part 46 (1994).

Committee Composition

Federal regulations require that membership of the IRB include, at a minimum, one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, other members representing more than a single profession, and at least one individual not affiliated with the university.

Definitions

For purposes of this policy, "Human Subject/Participant" is defined as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." "Research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge."

IRB Procedures

In order to approve proposed research protocols, the IRB shall determine if the research is exempt or non-exempt. In the case of non-exempt research the IRB shall ensure that all of the following requirements are satisfied:

- Risks to subjects are minimized by using tests or procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and whenever appropriate, use tests or procedures already being used for learning, diagnostic, or treatment purposes.
- Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in the research).

- Selection of the subjects is equitable. In making this assessment, the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
- Voluntary informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Title 45 Code of Federal Regulations, Part 46.116 (see Informed Consent).
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to attempt to insure the safety of subjects. If any serious breach in the procedure or harmful event occurs with a subject it should be reported to the IRB as soon as possible.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects.

In conformity with Federal Regulations, the IRB will determine which of three separate avenues for review of research involving human subjects will be utilized:

- Full IRB Review. Research involving more than minimal risk to the subject requires review by the full IRB using current scientific and ethical standards. All research using children or vulnerable populations requires review by the full IRB.
- Expedited Review. Research involving no more than minimal risk and in which the only involvement of subjects will be in one or more of the categories defined by Federal Policy 46.110 requires review by the chair and selected members of the IRB.
- Exempt Review. Research of minimal or no risk as defined by Federal Policy 46.101b requires review by the IRB chair only. Some types of activities are specifically exempt from IRB review. They include:
  - Non-intrusive observation of subjects in public places,
  - Data-gathering from class members for classroom purposes (e.g., class exercises, course evaluations), and
  - Needs assessment or evaluation data intended to remain within the university community.

For more information regarding The US Department of Health and Human Services policies please see: HHS.gov Policy & Guidelines: http://www.hhs.gov/ohrp/policy/index/index.html

IRB Membership

Purpose The purpose of this procedure is to describe IRB membership requirements and responsibilities, 45 CFR 46.

The IRB will have at least five (5) members, see http://ohrp.cit.nih.gov/search/search.aspx

A. Members will represent varying academic disciplines and have the necessary credentials to provide appropriate review of protocols submitted for review. The IRB will represent the diversity of the community in order to provide guidance on varying perspectives and sensitivities. The IRB will be sufficiently qualified through experience, expertise, and diversity to provide appropriate review of research with a primary focus on protection of human participants.

B. The IRB will include at least one member that is not affiliated with NAU. The unaffiliated member must not: 1) have any professional relationship with NAU as an employee, consultant, volunteer faculty, or student, and 2) be a family member (first and second degree relative), which has a professional relationship with NAU.

C. The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

Training

Purpose The purpose of this procedure is to describe training requirements for all personnel, including IRB members, involved in conducting human participant research.

A. Personnel involved in the conduct of exempt and non- exempt human participant research must receive training in the protection of human participants.

B. Collaborative IRB Training Initiative (CITI)
https://www.citiprogram.org/default.asp?language=english
Training in the protection of human participants is primarily accomplished through completion of this web-based training program.

C. Personnel to be certified include research personnel listed on the IRB application and consent document(s) by name must complete one of the existing CITI trainings.

Records

Purpose The IRB Committee shall prepare and maintain adequate documentation of IRB Committee activities, including the following:

1. Institutional Registration
2. IRB membership required by 45 CFR 46.103 (b) (3).
3. Written procedures for the IRB Committee as required by 45 CFR 46.103 (b) (4)
4. Training of IRB members
5. Meeting minutes
6. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by research investigators and reports of injuries to subjects.
7. Records of continuing review activities.
8. Copies of all correspondence between the IRB Committee and the research investigators.
9. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116 (b) (5).

Initial review of research

Purpose The purpose of this procedure is to describe the initial review of research for NAU to fulfill the requirements from the Department of Health and the Human Services Office of Human Research Protection (OHRP).

1. NAU has determined that ***all*** human participant research will be governed by the Health and Human Services regulations at 45 CFR §46 and ethical standards regardless of funding source.

2. NAU has designated establishment and registration of one IRB with provisions for sufficient meeting space and staff to support the IRB's review and recordkeeping duties.

3. NAU will maintain a list of IRB members identified by name, earned degree, representative capacity, as well as maintenance of current curriculum vitae. Changes in IRB memberships will be reported to OHRP through filing an IRB Registration Update.

4. NAU has established HRPP written policies and procedures as required under the Health and Human Services regulations at 45 CFR §46.103.

    A. The IRB will conduct initial and continuing review of research (at intervals appropriate to the degree of risk, but not less than once per year). The investigator and NAU will be file written record of the findings and actions taken by the IRB.

    B. The IRB shall ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate immediate risk to the participant.

    C. The IRB shall ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate immediate risk to the participant.

    D. The IRB shall have the authority to observe, or have a third party observe, the consent process and the research.

    E. The IRB shall ensure prompt reporting to the IRB, appropriate institutional officials, and federal regulatory):

        1. All incidences of unanticipated problems involving risk to participants and others.
        2. Any serious or continuing noncompliance with federal or IRB requirements.
        3. Suspension or termination of IRB approval.

    F. The IRB shall require confirmation by a qualified person, other than study personnel that a research proposal qualifies for *exempt* status.

Resources: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Continuing Review of Research

Purpose The purpose of this procedure is to describe the continuing review of research for NAU to fulfill the requirements from the Department of Health and the Human Services Office of Human Research Protection (OHRP).

1. Continuing review will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.109(e) and OHRP guidance on continuing review.

2. Continuing and full board protocols are approved for one year and valid for up to five years but must be renewed annually by completion of an Application for Continuing Review form.

3. The IRB must re-review and approve the protocol prior to the IRB approval expiration date, in order for a study to continue without interruption. Continuing Review has to occur as long as the research remains active for long-term follow-up of subjects. If an investigator does not provide continuing review information to the IRB, or the IRB has not approved the protocol by the expiration date, the investigator will be instructed to stop all research activities.

4. The enrollment of new participants is not allowed after the expiration of IRB approval.

Resources: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Reporting Findings and Actions

Purpose The purpose of this procedure is to describe reporting IRB findings and actions to investigators and the institution.

The IRB determines if the criteria for IRB approval have been met and then may take one of the following actions:

- APPROVE: the research procedures as being adequate to protect the rights and welfare of human subjects and to meet the standards for informed consent;
- APPROVE SUBJECT TO MODIFICATIONS: regarding the treatment of human subjects to protect their rights and welfare;
- DISAPPROVE: research procedures as violating the rights and welfare of human subjects; or
- DEFER ACTION on the proposal pending receipt of more information or further clarification of specific items.

If an Application for Research is disapproved by the IRB and the investigator wishes a further hearing on the matter, an appeal may be made.

HHS.gov Guidance on Reporting of Incidents: http://www.hhs.gov/ohrp/compliance/reports/index.html

Review More Than Annually

Purpose The purpose of this procedure is to describe IRB actions for determining projects that require review more often than annually.

Unless waived by the IRB, research that meets any of the following criteria requires review more often than annually:

The following factors will determine which studies require review more frequently than on an annual basis:

1. The probability and magnitude of anticipated risks to participants;
2. The likely medical condition of the proposed participants;
3. The overall qualifications of the researcher and other members of the research team;
4. The specific experience of the researcher and other members of the research team in conducting similar research;
5. The nature and frequency of adverse events observed in similar research at this and other institutions;
6. Any other factors that the IRB deems relevant.

HHS.gov Guidance on IRB Continuing Review of Research:
http://www.hhs.gov/ohrp/policy/continuingreview2010.html

Verification from Other Sources Other than the Investigator

Purpose The purpose of this procedure is to verification from sources other than the investigator circumstances that may require verification that no material changes have occurred since the previous IRB review.

The IRB will determine whether a research project requires verification from sources other than the investigators that no material changes have occurred since the previous IRB review, for example:

1. Noncompliance
2. Delays in submitting amendments
3. High number of approval expirations
4. Failure to respond to IRB review letters in a timely manner

When the IRB determines that verification from sources other than the investigator is necessary, the IRB will perform the necessary verification by conducting an audit.

Eliminate Immediate Hazard

Purpose The purpose of this procedure is to address the actions of the researcher and IRB to eliminate immediate hazards to participants.

Change that is initiated without any IRB approval in order to eliminate immediate hazards to the participants require notification to the IRB no later than two (2) business days from the time the change was initiated.

1. The investigator is authorized to implement changes without IRB approval in order to eliminate apparent immediate hazards to participants.

2. The IRB chair or designee has no authority to approve more than minor changes to eliminate immediate hazards to participants. After the immediate hazard has been mitigated, changes other than minor require IRB approval.

HHS.gov Reporting Unanticipated Problems: http://www.hhs.gov/ohrp/policy/advevntguid.html

Prompt Reporting

Purpose The purpose of this procedure is ensuring prompt reporting to OHRP or Department and Agency Heads: 1) unanticipated problems involving risk to the participants or others, 2) serious or continuing noncompliance (with 45 CFR § 46), and 3) suspensions or terminations of approved research by the IRB.

Reporting to OHRP and other relevant federal agencies unanticipated problems involving risk to the participant or others, which occur at institutions not under the jurisdiction of the IRB are the responsibility of the external institution.

Submission of all required written reports to OHRP, and/or Department or Agency heads.

Notification of Institutional Officials-- Copies of the letter sent to the OHRP and any necessary supporting documents must be provided to:

1. Name of Institution (NAU).
2. Protocol number.
3. The individual(s) directly responsible for the noncompliance.
4. Name of researcher
5. The IRB
6. Chair of the researcher's Department
7. The Federal sponsor
8. Other Institutional officials as determined by the IRB.
9. Health and Human Services Office of Human Research Protection (OHRP)

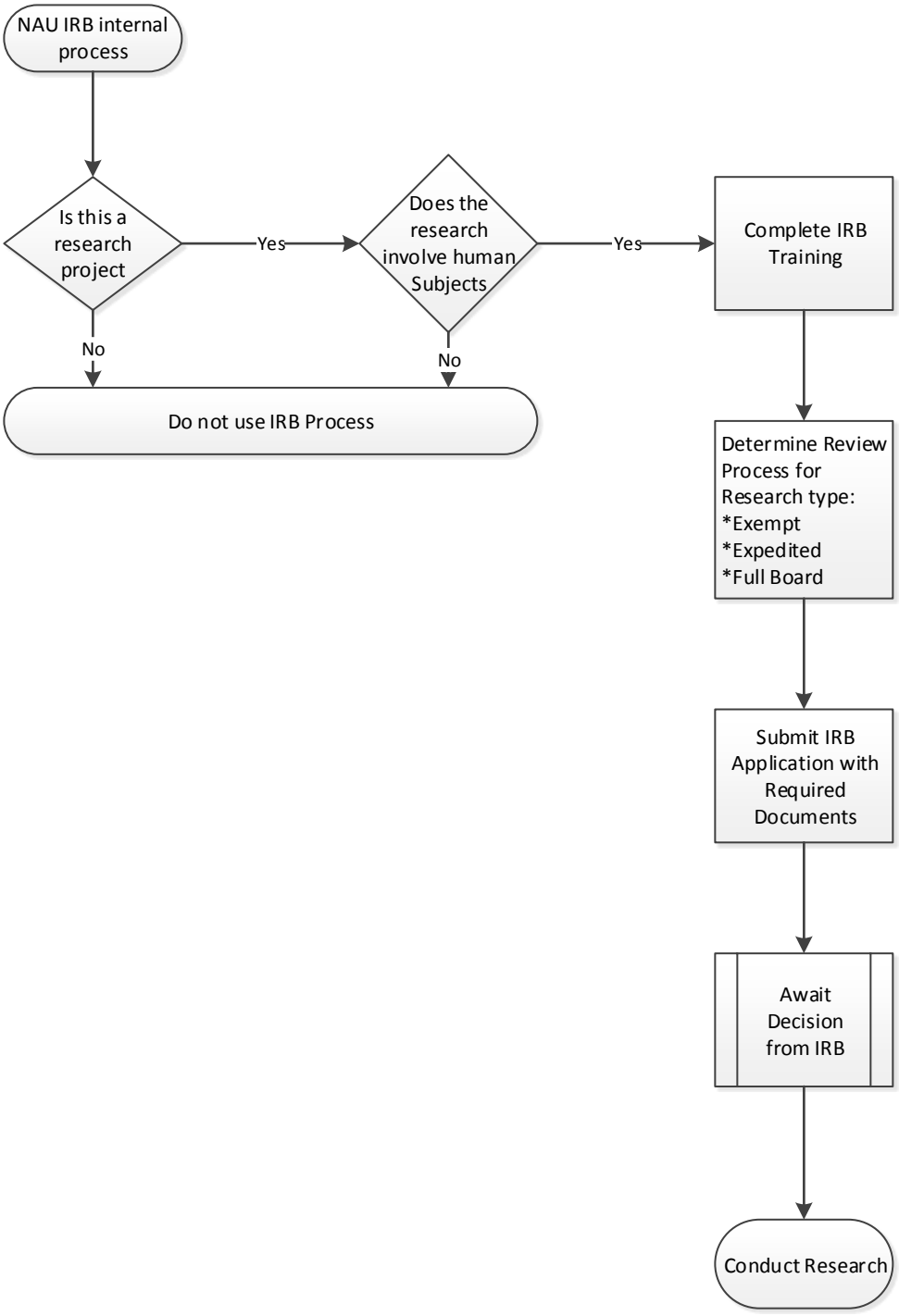
Within five (5) business days of the full board decision, send a formal letter to the OHRP Director of Compliance Oversight. The letter must include the following:

A. Identification of the protocol.
B. Funding of the protocol (federally or non-federally funded, commercially sponsored).
C. Timeline and description of the noncompliance.
D. Copy of the IRB application and applicable consent document(s).
E. Applicable reports from IRB consultants.
F. Other documentation pertaining to the event.
G. Corrective action plan approved by the full IRB.

Mailing address: Division of Compliance Oversight, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD.

HHS.gov Reporting Unanticipated Problems: http://www.hhs.gov/ohrp/policy/advevntguid.html

Internal IRB Process Flow



HHS.gov Checklists and Decision Trees: http://www.hhs.gov/ohrp/policy/checklists/index.html

