



# An-Najah National University

## Institutional Review Board (IRB) Quick Guidelines

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## 1. Introduction

The IRB guidelines at An-Najah National University are based on the American Code of Federal Regulations, specifically 45 CFR 46 and Maryland law, which draw extensively from the principles outlined in the Belmont Report. These guidelines were developed to provide essential protections for human subjects participating in biomedical and behavioral research. The document includes direct quotations from the 45 CFR 46 regulation.

## 2. Types of IRB Review

There are three types of review for an IRB application: Full Board, Expedited, and Exempt. The appropriate review path is determined by the following factors:

- The level of risk posed to participants by the project
- The nature of research (e.g., educational intervention, survey, ethnographic observation, etc.)
- The sensitivity of the research questions or the complexity of the study design
- Whether vulnerable populations are involved as research subjects

## 2.1. Exemption (waiver) review paths

Research activities found by the IRB Chairperson (or his/her designee) to involve no more than minimal risk and in which the only involvement of non-vulnerable human subjects will be in one or more of the following categories are considered exempt from IRB policy (Please note that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of whether the proposal is considered exempt). The following conditions comply with the exemption criteria:

### 1. **Educational Practices:**

Research conducted in established educational settings involving normal educational practices that do not adversely impact students' ability to learn or affect the assessment of educators (e.g., instructional strategies or classroom management).

### 2. **Tests, Surveys, Interviews, and Public Observations:**

Research using educational tests, surveys, interviews, or observations of public behavior, provided:

- The data cannot identify subjects, or
- Disclosure would not risk subjects' criminal or civil liability, financial standing, employability, or reputation.

### 3. **Benign Behavioral Interventions:**

Research involving brief, harmless, painless, not physically invasive interventions, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing with adult subjects who provide informed consent. Examples include solving puzzles or playing games, provided:

- Data collection does not identify subjects, or
- Disclosure poses no significant risk to subjects.

Note: If the research includes deceiving participants about its nature or purpose, this exemption does not apply unless the participant consents to the deception in advance. This requires the participant to agree to take part in the research, knowing that they will be unaware of or misled about certain aspects of the study.

### 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Studies that are meant to evaluate the outcome of procedures, programs and services are exempt because they are designed to produce information leading to improvement in delivery of procedures, programs and services. Such studies usually evaluate measures that are already in use and considered part of standard practice. They may include collection and analysis of data or collection of new data but they do not involve allocation into groups or randomization.
6. **Secondary Research (Consent Not Required):**  
Use of identifiable private information or biospecimens, if:
  - The information or biospecimens are publicly available, or
  - The information is recorded in such a way that subjects cannot be identified.
7. **Taste and Food Quality Evaluation:**  
Research involving the consumption of wholesome foods or food ingredients determined to be safe by local authorities and international regulatory agencies such as the FDA.
8. **Storage or Maintenance for Secondary Research:**  
Storage of identifiable private information or biospecimens for secondary research, provided broad consent has been obtained and a limited IRB review is conducted (refer to PMID: [32284687](#) for more details)
9. **Secondary Research with Broad Consent:**  
Research using identifiable private information or biospecimens for secondary research, under broad consent and IRB review, without returning individual research results to participants (refer to PMID: [32284687](#) for more details).

All studies that are categorized under the exempt research studies, should be subject to submission to the local regulatory authority for approval or notification as applicable.

## 2.2. Expedited Path

According to **45 CFR 46**, an expedited review process may be used for:

- Research involving minimal risk to human subjects that falls within one or more of the American [Office for Human Research Protections](#) (OHRP) Expedited Review Categories.
- Minor modifications to research that were previously approved by the full board.

However, it should NOT be assumed that research poses minimal risk simply because it involves interviews or surveys. Sensitive questions can induce distress, potentially exposing participants to more than minimal risk. Additionally, violating of confidentiality could harm participants, their families, or others.

Applications eligible for expedited review are accepted and evaluated on an ongoing basis by Expedited reviewers, who are experienced IRB members appointed by the IRB Chair. These reviewers have the authority to make a determination or, if necessary, transfer a submission to the full board for further

review (e.g., for clarification or specific expertise). Only the full board holds the authority to disapprove of a study.

Please note that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of IRB review.

Research categories that fall with expedited path criteria:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
  - b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
  - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  - b. where no subjects have been enrolled and no additional risks have been identified; or
  - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

### 2.3. Full Board Review

The IRB Full Board Review is required for applications where the research involves **more than minimal risk** to human subjects or has been referred to the committee by an expedited reviewer or the Chair. Regardless of risk level, IRB may require full board review when the research involves:

- Clinical trials

- Vulnerable populations (e.g. children, elderly, pregnant women, prisoners, racial/ethnic minorities, Individuals with cognitive impairments, individuals with impaired decision-making capacity, Individuals in emergency situations or terminal illnesses)
- Sensitive/stigmatic or embarrassing questions (e.g. illegal behavior, alcohol use, addiction, sex issues, AIDS...etc.)
- Research involving genetic testing

Applications requiring full board review are accepted by the submission deadlines and reviewed by the full board on the scheduled IRB meeting dates. The IRB Chair assigns submissions to a primary and secondary IRB reviewer for presentation at the full board meeting. Investigators are welcome to attend the meeting to answer questions from the board. At the conclusion of the meeting, the board votes and issues a determination.

### 3. Guidelines for Informed Consent According to 45 CFR 46

**As stated by the American Federal law §46.116**, “no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.”

#### 3.1. General requirements for informed consent

##### 1. Purpose of the Study

The consent form must clearly explain the purpose of the research, including the study's objectives and the role of participants.

##### 2. Description of Procedures

Include a detailed description of what will happen during the study, including the methods, time commitment, and procedures involved.

##### 3. Risks and Discomforts

Outline any potential risks, discomforts, extra costs, or adverse effects participants might experience.

##### 4. Benefits

Describe any direct benefits to the participants, as well as the potential broader benefits to society or scientific knowledge.

##### 5. Confidentiality

Explain how the participants' personal information will be protected and how their data will be stored, de-identified, or secured. Inform them of any legal obligations to report or share data.

##### 6. Voluntary Participation

Clearly state that participation is voluntary and that participants may withdraw at any time without penalty or loss of benefits.

**7. Compensation or Incentives**

If applicable, provide information about compensation or incentives for participation, including how it will be managed if they withdraw early.

**8. Alternatives to Participation**

Explain any available alternatives to participating in the study (e.g., alternative treatments, if applicable).

**9. Contact Information**

Provide the contact information for the researchers and an independent party who can answer questions about the study, participant rights, and any research-related injuries.

**10. Written Consent**

Participants must provide written consent unless a waiver has been granted by the IRB. In such cases, the form should explain how consent will be obtained (e.g., oral consent).

**Additional Considerations**

1. **Comprehension:** Ensure the form is written in language that is easy to understand (8th-grade reading level recommended).
2. **Vulnerable Populations:** When the study involves vulnerable populations (children, prisoners, cognitively impaired individuals), extra precautions must be taken, such as obtaining assent from children or consent from legal representatives.

### 3.2. Documentation of informed consent

1. A written consent document that embodies the elements of informed consent specified above. The investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.
2. A short form written consent document stating that the elements of informed consent required by [§46.116](#) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

### 3.3. General conditions for waiver or alteration of all the elements of informed consent for research involving adult subjects

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects.
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
5. The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

## 4. Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

- **Definitions**

- a. Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
- b. Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.
- c. Fetus means the product of conception from implantation until delivery.
- d. Neonate means a newborn.
- e. Nonviable neonate means a neonate after delivery that, although living, is not viable.
- f. Pregnancy encompasses the period of time from implantation until delivery.
- g. Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

### 4.1. Research involving pregnant women or fetuses

Pregnant women or fetuses may be involved in research if all of the following conditions are met (§46.204):

- a. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
- b. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- c. Any risk is the least possible for achieving the objectives of the research;
- d. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions
- e. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity.
- f. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- g. For children who are pregnant, assent and permission are to be obtained

- h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- j. Individuals engaged in the research will have no part in determining the viability of a neonate.

## 4.2. Research involving neonates (§46.205)

- a. **Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:**
  - 1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
  - 2. Each participating individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
  - 3. Individuals engaged in the research will have no part in determining the viability of neonate.
- b. **Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:**
  - 1. The IRB determines that:
    - The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
    - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
  - 2. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.
- c. **Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:**
  - 1. Vital functions of the neonate will not be artificially maintained;
  - 2. The research will not terminate the heartbeat or respiration of the neonate;
  - 3. There will be no added risk to the neonate resulting from the research;
  - 4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
  - 5. The legally effective informed consent of both parents of the neonate is obtained. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph.

## 5. Additional Protections for Children Involved as Subjects in Research

### 5.1. Conditions for enrolling children as subjects in research

Research involving children as subjects to the study shall obtain approval on condition that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, in the following conditions where the IRB finds that:

1. No greater than minimal risk to children is presented and
2. The research involves greater than minimal risk but presenting the prospect of direct benefit to the individual subjects, provided that the risk is justified by the anticipated benefit to the subjects
3. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, in condition that the risk represents a minor increase over minimal risk.

### 5.2. Requirements for permission by parents/guardians and for assent by children and conditions for waiver of parents' permission (§46.408)

1. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.
2. If the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research, the IRB may waive the assent of the children if the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.
3. IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research not involving more than minimal risk. Where research involving more than minimal risk, permission must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
4. When the IRB determines that assent is required, it shall also determine whether and how the assent must be documented.
5. The IRB may waive the parent permission requirement if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children, alcoholism or addiction in teenagers, and teenagers admitted to detention centers), provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.
6. If the minor is married, he/she must consent for participation as a subject in research (reference: Maryland Law, Johns Hopkins Medicine).
7. If the married minor is the parent of a child, the minor must consent for all research for himself/herself and his/her child (reference: Maryland Law, Johns Hopkins Medicine).