

Prior to involving participants in research, their legally effective informed consent, or the consent of their legally authorized representative must be obtained, unless the IRB has approved a waiver of the requirement.

#### 1.0 Legally effective informed consent.

As autonomous agents, individuals have the right to determine what will be done to them, and what private information they will share with others. The process of informed consent involves obtaining the voluntary agreement of individuals to take part in a research project. This communication process begins with the initial approach of an investigator to the subject, which may include use of recruitment or subject selection procedures, and continues until the completion of the research project.

A legally effective consent process will:

##### 1.1 Provide sufficient information.

Prior to their involvement in research, provide potential participants with sufficient information about the research (i.e., its' purpose, procedures involved, potentials risks and benefits, etc) in order to make an informed decision. Communicate this information, referred to as the 'elements of informed consent', to participants in any one of a variety of ways: face-to-face, phone, video, fax, internet or mail. Allow participants an opportunity to ask any questions prior to, during or after their involvement in the research. Most research projects will also require printed information to be provided to subjects.

Refer to *9.2 Documentation of Informed Consent* for a description of the elements of informed consent, and *Informed Consent Templates* on the 'Forms' page of the IRB website.

##### 1.2 Facilitate understanding.

Provide any written or oral information about the research project in language understandable to the least educated of potential participants or their representatives, avoiding use of technical terms and jargon, unless explained. In general, an 8<sup>th</sup> grade reading level is recommended. Adjust the language appropriately for children, subjects with low literacy levels, cognitively impaired subjects, or non-English speaking subjects. Conduct the process in a language understandable to the participant, and provide written documents translated into that language. The IRB may require verification of any translated documents.

Investigators may also choose to gauge understanding by allowing time for questions, or asking participants to describe the research in their own words.

##### 1.3 Ensure voluntariness.

The setting and timing of the invitation to take part in research should allow potential participants a free choice, adequate time to consider, and minimize the possibility of coercion or undue influence. Individuals must be free to decline research participation, or also withdraw from participation, or refuse to answer questions or complete certain tasks without penalty or loss of other benefits they are already otherwise entitled to.

No informed consent, whether oral or written, may include any exculpatory language through which the participant or their representative is made to waive or appear to waive any of their legal rights, or releases or appears to release the investigator, the sponsor, institution or its agents from liability for negligence.

The existence of dual relationships between investigators and potential participants, as well as offers of excessive compensation may also affect the voluntariness of the consent process; see sections 2.0 and 3.0 below.

#### 1.4 Be repeated, supplemented or revised as necessary.

Informed consent is an ongoing process of communication between the investigator and participant. Repeat, supplement, or revise the informed consent process when:

- new information becomes available that may affect the willingness of a subject to continue in the research
- deficiencies or inaccuracies are identified in the consent process
- research design or risks have changed
- a substantial period of time has elapsed between the time consent was obtained and research begins, or the research takes place over an extended time period

The IRB prospectively reviews and approves all changes to the consent process or documentation, unless the changes are necessary to eliminate apparent immediate hazards to subjects.

As part of the requirements for review of research, the IRB determines that legally effective informed consent will be sought from each potential participant or their legal representative, unless a waiver or alteration of this requirement would be appropriate. A detailed description of the consent process in the protocol application provides the IRB with sufficient information to make this determination.

#### 2.0 Dual relationships.

Voluntariness may be affected by the existence of an authority relationship between the investigator and potential research subjects. Potential participants could feel compelled to participate in research for fear of losing status or services with an instructor, employer, or physician, for example. Design research to minimize any potential coercion. Slight changes in the study design may alleviate the concern, such as recruiting from a different pool of participants, or involving an objective third-party in the process.

#### 3.0 Compensation.

Voluntariness may be affected by offers of excessive compensation for research participation. Offering monetary or other types of compensation commensurate with a participant's time, effort and inconvenience is acceptable. However, compensation that is either excessive, and/or withheld until completion of the research may cause participants to accept risks that would not otherwise consider, or affect their right to voluntarily withdraw. Some groups of people may be more susceptible than others, i.e., economically disadvantaged persons, to offers of compensation.

When research involves an offer of extra credit or course credit to students, an alternative, non-research method (equal in time and effort to research participation) for obtaining the credit is required. Include the details of any offer of compensation (and alternatives, if applicable) in the consent form. In addition, describe the chances of winning any drawing or raffle to participants.

#### 4.0 Recruitment and subject selection.

The process of informed consent begins with the initial approach to potential participants to invite them to take part in research. This may include use of advertisements, public or private records, or screening tests to select or locate potential participants or determine their eligibility for research.

##### 4.1 Recruitment messages or advertisements.

As a part of the process of informed consent, the IRB prospectively reviews all advertisements, notices, or messages used to invite individuals to take part in research. Provide brief, factual information about the research in the recruitment notice; printed materials may include NDSU letterhead or equivalent information. Typically a recruitment ad does not include all the same information required in the consent document.

Recruitment notices in printed or electronic format must include:

- NDSU department name, and contact for the research team
- an indication that the project involves ‘research’
- basic information about the research purpose and procedures
- any applicable eligibility criteria
- approximate time commitment for participation
- a statement of any compensation that will be offered

Recruitment notices must not:

- over-emphasize compensation
- make a claim for safety or effectiveness
- over-state potential benefits

Sometimes it may be necessary to informally query individuals to determine if an adequate # of eligible participants would be available for a research project. Informal queries of this nature may be made prior to submitting a protocol for review, although a recruitment process may not be initiated prior to IRB approval.

##### 4.2 Screening for eligibility.

Some research projects may include use of inclusion or exclusion criteria to identify eligible research participants. Obtain informed consent from participants prior to use of any screening tests, if performed solely to determine eligibility for research. The investigator may use a separate consent process and document for screening, or may include the screening procedures with the research procedures in a single consent document. Describe use of any inclusion or exclusion criteria in the IRB protocol, as well as what data or information, if any, will be retained from non-eligible participants.

##### 4.3 Use of pre-existing records to select potential participants.

When research will involve use of private records to identify and contact potential research participants, access to the records may be governed by other laws and policies (i.e., private health information - HIPAA, or academic records – FERPA). When individuals will be

contacted for an invitation to participate in research on the basis of information in their private records, IRB approval is required prior to accessing the records for research purposes.

In general, researchers who do not otherwise have permissible access to private records should not attempt to contact potential participants directly. Instead, the initial contact should be made only by someone with permissible access to the records; those participants who are interested could then choose to contact the research team to find out more about the project.

#### 5.0 IRB review of consent process.

As part of the criteria for IRB approval of a new protocol, amendment, or continuing review, the IRB reviews the consent process to determine that the legally effective informed consent will be sought from participants, in accordance with the criteria described in section 1.0 above. Refer to *Section 7 IRB Review of Research*, and *Section 8 Criteria for IRB Approval* for more information.

#### 6.0 Waiver or alteration of consent requirements.

Some research will involve incomplete disclosure, use of deception, elimination of the entire consent process and/or elimination of the signatures. This is considered a waiver or alteration of the informed consent requirements. The IRB must make several additional determinations in order to approve research involving a waiver or alteration of informed consent requirements; refer to *9.3 Waiver or Alteration of Informed Consent Requirements*.

#### 7.0 Consent of legally authorized representatives.

When adult participants lack the capacity to consent, a legally authorized representative must give consent for their participation in research, unless the IRB has otherwise waived the requirement. This lack of capacity may be temporary or permanent, as a result of trauma, mental illness or cognitive impairments, for example. Research that is likely to encounter subjects with insufficient capacity should describe in the protocol a plan for determining when consent of a legally authorized representative is needed, and how that consent will be obtained. When reviewing research involving cognitively impaired individuals, the IRB must possess appropriate expertise, through its own membership or use of consultants.

#### 8.0 Consent process for exempt research.

In accordance with the Belmont ethical principle of respect for persons, NDSU requires that all potential research subjects be afforded the opportunity for voluntary consent to research participation, including those invited to take part in research certified by the IRB as 'exempt'.

The same requirements to provide sufficient, understandable information about the research and ensure voluntariness apply, although an 'implied' consent process could be utilized for exempt projects. For example, a participant's positive action (responding to questions, returning a survey, or performing a research task) may be considered their agreement to take part in research. Providing written information to, or obtaining a signature from participants is typically not required for exempt projects, but may be utilized where advisable or required by the IRB.

If obtaining participants' consent would not be feasible, the IRB may waive the requirement, provided an adequate justification is provided. Projects involving public observation, or use of

de-identified pre-existing materials, records, data, or specimens are several examples where eliminating the consent process may be justified. Refer to *7.1 Exempt Determinations and Informed Consent Templates* on the IRB website for more information and suggested formats.

#### **DEFINITIONS:**

Informed consent: the voluntary agreement of a participant, or their legally authorized representative, to take part in research, after being provided with sufficient information about the study, in a language and terminology understandable to them, and sufficient opportunity to consider their decision.

Investigator: anyone involved in conducting the research; ie, study design or supervision, data collection, obtaining informed consent, performing research procedures, obtaining coded private information or specimens, analyzing data.

Legally authorized representative: an individual authorized by a judicial body or other appropriate body to give consent on behalf of a prospective subject to the subject's participation in research. May include: a health care agent (named as a durable power for health care decision maker while the subject had competency), or a court-appointed guardian.

Coercion: occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance; ie, an investigator tells a potential subject they will lose access to health services unless they agree to participate in a research project.

Undue influence: occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance (ie, an investigator promises students extra credit to participate in research, when no other alternatives for extra credit are available). Undue influence can also be subtle (ie, patients feel obligate to take part in research if their physician is the investigator, or students feel pressure to participate if everyone else in a class is doing so). In addition, inducements that are ordinarily acceptable for some populations may become undue influences for vulnerable groups (ie, economically or educationally disadvantaged, children, prisoners or mentally disabled persons).

#### **REFERENCES:**

[45CFR46.116](#) General requirements for informed consent  
[45CFR46.111](#) and [21CFR56.111](#) Criteria for IRB approval of Research  
[45CFR46.109](#) and [21CFR56.109](#) IRB review of research  
[21CFR50, Subpart B](#) Informed Consent of Human Subjects  
[OHRP guidance on Written Procedures](#)  
OHRP FAQs: [Informed Consent](#)  
FDA Information Sheet, [A Guide to Informed Consent](#)  
FDA Information Sheet, [Recruiting Subjects](#)  
FDA Information Sheet, [Screening tests prior to study enrollment](#)  
NIH Points to Consider: [Impaired decisionmaking capacity](#)

#### **RELATED FORMS:**

IRB Protocol Form  
Exemption Protocol Form

Informed Consent Waiver Request Attachment form  
Informed Consent templates  
Protocol Amendment Request Form

**RELATED HRPP SECTIONS:**

9.2 Documentation of Informed Consent  
9.3 Waiver or Alteration of Informed Consent Requirements  
9.4 Children as Research Participants  
Section 7 IRB Review of Research  
Section 8 Criteria for IRB Approval  
11.6 Emergency Research  
Section 10 Vulnerable Groups