INFORMED CONSENT DOCUMENTATION

SOP #:	**703**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**05/01/09**	**SUPERSEDES DOCUMENT:**	**/ /**
THIS POLICY PERTAINS TO:			**ALL RESEARCH SUBMITTED TO THE IRB**				
RESPONSIBILITY FOR EXECUTING POLICY:			**ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB MEMBERS**				
LAST REVIEWED ON:		**/ /**		**RESULTS:**	**REVISED**		
APPROVAL AUTHORITY:			**Associate Vice President for Research and Economic Development**				
APPROVED BY:						**DATE:**	**/ /**

1. POLICY

Unless specifically waived by the IRB, all subjects, or their legally authorized representatives, must document that they are consenting to participate in any research project that is approved by the University of North Dakota Institutional Review Board.

2. SPECIFIC POLICIES

Each subject or his/her legally authorized representative must sign and date a copy of the current IRB approved consent form prior to enrollment or any participation in the study, and be given a copy of the document, unless the requirement is waived by the IRB.

The IRB may approve procedures for documentation of informed consent that involve (a) a written consent form signed by the subject; (b) a short form written consent form with oral presentation; or (c) in limited circumstances, waive the requirement for a signed written consent form. It is the responsibility of the IRB to determine which of these procedures is appropriate for documenting informed consent in protocols that it reviews. Usually, only option (a) will be appropriate.

2.1 Written Consent Form Signed by the Subject

2.1.1 Mentally disabled or cognitively impaired subjects: Studies involving subjects who may have impaired decision-making capabilities may take place over extended periods. The IRB should consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The IRB may require that the Investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included. Additionally, the IRB should consider whether and when to require a reassessment of decision making capacity.

2.1.2 The written informed consent should embody, in language understandable to the subjects of the study, all the elements necessary for legally effective informed consent.

2.1.3 Subjects who do not understand English should be presented with an informed consent document written in a language understandable to them.

2.2 Oral Presentation Using Short Form:

As an alternative to standard written informed consent documents, oral presentation of informed consent can be used. The Investigator must provide the IRB with a complete written consent document that includes all the elements of consent and the information that explains the study that will be provided to the subject. In such cases, the participant must be provided with both:

- A short form written informed consent document stating the elements of consent have been presented orally to the subject or the subject's legally authorized representative; and
- A written summary of the information that is presented orally.

2.2.1 A witness to the oral presentation is required. The witness must sign both the short form written informed consent document and a copy of the written summary. For participants who do not speak English, the witness will be conversant in both English and the language of the participant.

2.2.2 The subject or the legally authorized representative must sign the short form written consent document.

2.2.3 The person obtaining consent must sign a copy of the written summary of the information that is presented orally. The person obtaining consent may not be the witness to the consent.

2.3 Waiver of Documentation (45 CFR 46.117(c)) (21 CFR 56.109(c))

The IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all subjects if the IRB finds either:

- That the only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from breach of confidentiality and the research is not FDA regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; **or**

- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

2.3.1 In cases in which the documentation requirement is waived, the IRB may require the Investigator to provide subjects with:

- a cover letter explaining the research
- Implied Informed Consent: A consent with all the elements that states that by returning the survey etc. consent is implied.

2.3.2 The Investigator must provide the IRB with a completed written consent document containing all the elements of consent and study information that will be provided to the participant.

2.4 Consent for Mail, Telephone Surveys, and Internet Surveys

When research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, the following may be considered:

2.4.1 Consent by mail. The IRB may approve consents sent by mail in one of two ways:

1. The Investigator mails the consent document along with the survey. The subject signs the consent and returns it with their survey. If the study is to be anonymous, the consent form is mailed back separately, or is separated from the data immediately upon the opening the package.
2. The Investigator sends a letter requesting participation along with the survey to the subject. The letter should include a statement that by returning the completed survey, the subject is providing consent.

2.4.2 Telephone consent. The IRB may approve telephone consent for survey research. The Investigator must use a script when obtaining consent by telephone, and the Investigator must include the script in their IRB submission. The script must contain a comprehensive, succinct, description of the study and include the relevant elements of informed consent in narrative form. (All possible efforts should be made to mail or fax the informed consent document in advance to the subject). The interviewer solicits any questions about the research the potential subject may have and answers them. The Investigator needs to document that the script was read, that the individual was offered the opportunity to ask questions, and whether the subject agreed or declined to participate in the study. If an Investigator is taping his/her phone conversations with the subject, the interviewer must immediately inform the subject that they are being recorded.

2.4.3 Internet Surveys. For anonymous Internet-based surveys, it is sometimes appropriate to use implied informed consent. Subjects would still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey and/or clicking on an “I agree” or “I do not agree” button on the website.

2.4.4 E-mail Informed Consent. If the IRB determines that some sort of documented consent is required, the IRB may approve a consent sent via e-mail. The consent form is sent via e-mail to subjects who then type their name and date into the spaces provided on the consent form, and return it to the researcher via e-mail.

2.5 Use of Facsimile or Mail to Document Informed Consent

The IRB may approve a process that allows the informed consent document to be delivered by mail or facsimile to the potential subject or the potential subject’s legally authorized representative and to conduct the consent interview by telephone when the subject or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

3. RESPONSIBILITY

The IRB Chairperson and IRB members are responsible for determining circumstances when the IRB may waive the requirement to document informed consent.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24
21 CFR56.109(c), 56.109(d)
45 CFR 46.116

5. ATTACHMENTS

IC 702-A Waiver or Alteration of Informed Consent Decision Chart

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Chairperson, IRB Vice Chairperson, IRB Member	Review submission to determine if circumstances warrant that the IRB may waive the requirement to document informed consent.
IRB Secretary	If waiver of documentation of consent is granted for a Full Board proposal, include a reference to the regulation in the minutes.