INFORMED CONSENT WAIVERS

SOP #:	**702**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**5/1/09**	**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

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria. Projects that qualify for Exempt review do not require waivers.

2. SPECIFIC POLICIES

2.1 IRB Waives One or More Requirements of Informed Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   - Public benefit or service programs;
   - Procedures for obtaining benefits or services under those programs;
   - Possible changes in or alternatives to those programs or procedures; or
   - possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration, as in prospective emergency research conducted under 21 CFR 50.24, when time may not permit informed consent.
3. The research is not FDA regulated.

Or 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 research is not FDA regulated.

2.2 An Emergency Situation Prior to IRB Review and Approval

Obtaining informed consent shall be deemed feasible except in certain emergency situations where the Investigator has adequately documented the necessary exception under the guidelines described in 21 CFR 50.23 and 45 CFR 46.116. Data gathered as a result of an "Emergency Use" cannot be considered research data under the UND Federal Wide Assurance with the Federal Government. UND has a commitment to ensure this data not be used for academic advancement. Therefore, it is the Investigator's responsibility to ensure that data gathered in this manner not be misrepresented as having been obtained with IRB approval.

2.3 When Obtaining Informed Consent from a Parent is Not Reasonable

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or legally authorized representative permission is not a reasonable requirement to protect the subject (e.g. abused or neglected children), it may waive the consent requirements provided that:

1. an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and
2. the waiver is not inconsistent with Federal, State and local law, and
3. the research is not subject to FDA regulations.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

3. RESPONSIBILITY

The IRB Chairperson, IRB Vice Chairperson, or Primary Reviewer is responsible for determining whether informed consent waivers are applicable and appropriate.

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
IC 702-B Application for Waiver or Alteration of Informed Consent Requirements

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Chairperson, IRB Vice Chairperson or IRB Member	Review submission to determine if waiver is requested. If so, indicate on Report of Action form.
IRB Secretary	If waiver of consent is granted for a Full Board proposal, include a reference to the regulation in the minutes.