# IRB GUIDELINES
# FOR DEVELOPMENT OF THE ADULT CONSENT FORM

## BIOMEDICAL RESEARCH

The following instructions and examples are provided to assist in development of the Adult Consent Form. Additional information is available from the IRB Office and website regarding development of parental and proxy consent forms, and youth and child assent forms. Consent forms used to enroll Nebraska Medical Center patients must be printed on Nebraska Medical Center consent form stationery. All forms should be submitted suitable for reproduction (printed single sided) using a 12 point font and 1 inch margins. Each page of the consent form should be full without inappropriate divisions: sections can be split (some on one page, some on another page) so that large blank areas do not exist. Upon final approval, all pages must include the IRB number in the upper left corner, the page numbers in the upper right corner and a participant's initial blank in the lower right corner.

The following should be considered when developing the consent form:

1. The informed consent form must be written in the second person. When combined with conditional language, utilization of the second person personalizes the consent form and reflects the existence of voluntary decision making on the part of the prospective subject.

2. The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the prospective subject focus on each individual element of consent thereby increasing the validity of the consent process.

3. The consent form must be written in simple enough language so that it is readily understood by the least educated of the subjects to be utilized. Normally the highest level of language in the consent form should equate to an eighth grade standard. Medical and scientific terms should be avoided when possible. If medical jargon is used, the lay terms should be used first and then the medical term included in parentheses.

### Title of this Research Study

*List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.*

## Invitation

*Invite the prospective subject to participate in the study using the following standard invitation to participate:*

> You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

## Why are you being asked to be in this research study?

*Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section (eg "You are being asked to be in this study because you are over 50 years old and have diabetes and heart disease").*

*If pregnant or breastfeeding women are excluded from this study (section II.4.d of application) include the following standard statement:*

> If you are pregnant, nursing an infant, or plan to become pregnant during this study, you may not be in this study.

## What is the reason for doing this research study?

*This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential subject understand why the research is being done (eg, "Adults with diabetes are at high risk for developing heart and blood vessel disease. Treating the diabetes may reduce the risk of heart attacks. This research is trying to see which of two medicines is most effective in reducing blood sugar and the risk of heart attacks.") This information should be provided in simplistic language without reference to the subject.*

*This section should also describe the FDA approval status of all tests articles (ie, drugs, devices or biologics which are being evaluated in this research).*

## What will be done during this research study?

*Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability*

## What are the possible risks of being in this research study?

*Identify each intervention with a subheading and then state the associated risk(s) using simplistic language (section II.13 of application). The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Provide incidence data if available and appropriate.*

*If the study involves use of drugs, refer to the IRB Policy on Contraception, and include standard contraception language as indicated.*

*Conclude with the following standard clause:*

> It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

*Alternately, if there are no known risks this should be stated.*

**What are the possible benefits to you?**

*If direct subject benefits can reasonably be anticipated as a result of participating in the protocol (section II.16 of application), then describe these possible benefits. Conclude with the following standard clause:*

> You may not get any benefit from being in this research study.

*If direct subject benefits are NOT anticipated, then use the following standard clause:*

> You are not expected to get any benefit from being in this research study.

**What are the possible benefits to other people?**

*State the possible benefits to society in terms of advancement of medical knowledge and/or ultimate possible therapeutic benefit to future patients.*

**What are the alternatives to being in this research study?**

*Describe, in reasonable detail, available therapeutic alternatives the patient may have available. Specifically, address therapeutic alternatives available to the subject in the non-research context, and whether any of the therapeutic interventions in the study would be available to the prospective subject if they did not elect to participate in the study. (See section II.18 of the Application)*

*Alternately, use the following standard clause if applicable:*

> Instead of being in this research study you can choose not to participate.

**What will being in this research study cost you?**

*This section should state the financial obligations the subject will incur as a result of participating in the study, and whether any financial obligations will be increased as a result of procedures performed solely for research purposes (section II.20 of application).*

*If there are no financial obligations to the subject then use the following standard clause:*

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| There is no cost to you to be in this research study. |

**Will you be paid for being in this research study?**

*If the subject will receive compensation for participating in the research, state the amount of compensation and conditions for payment (section II.21 of application). A prorated payment system should be used when appropriate. If no compensation is provided, then use the following standard clause:*

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| You will not be paid to be in this research study. |

**Who is paying for this research?**

*For commercial studies:*

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| The sponsor of the research is [name of sponsor]. The University of Nebraska Medical Center, or the Nebraska Medical Center receives money from the sponsor to conduct this study.<br><br>[or]<br><br>The sponsor of the research is [name of sponsor]. The University of Nebraska Medical Center, or the Nebraska Medical Center receives money from the sponsor to conduct this study. The investigator receives a small payment from the sponsor which is used for … [for example, educational purposes]. |

*For studies supported by extramural or intramural research grants:*

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| This research is being paid for by grant funds from [name of granting agency]. The University of Nebraska Medical Center, or the Nebraska Medical Center receives money from [name of granting agency] to conduct this study.<br><br>[or]<br><br>This research is being paid for by grant funds from [name of granting agency]. The University of Nebraska Medical Center, or the Nebraska Medical Center receives money from [name of granting agency] to conduct this study. The investigator receives a small payment from [the granting agency] which is used for … [for example, educational purposes]. |

*For NIH funded cooperative group studies:*

The University of Nebraska Medical Center receives money to provide administrative support for the [name of cooperative group] studies. No money is provided specifically for the conduct of this study.

*For unfunded studies, include as applicable:*

This research is being paid for by … [for example, the Department of Internal Medicine, Section of Oncology of the University of Nebraska Medical Center].

*If none of these templates are appropriate, please contact the IRB Office prior to submission of the consent forms.*

**What should you do if you are injured or have a medical problem during this research study?**

*Your estimation of risk determines what additional information you will include in this section regarding emergency care.*

*For studies classified as minimal risk, use the following standard clause:*

If you are injured or have a medical problem as a result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

*For studies conducted at UNMC or UNO classified as greater than minimal risk which are NOT commercially sponsored, use the following standard clause.*

If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Immediate emergency medical treatment for this injury will be available at the Nebraska Medical Center. However, it is the policy of UNMC, UNMC Physicians, and The Nebraska Medical Center **(add UNO if applicable)** not to pay for any required treatment. Agreeing to this does not mean you have given up any of your legal rights.

You or your insurance company will need to pay for any costs. The costs for any other medical problems unrelated to this research study are also your responsibility. There are no plans to provide payment for things like lost wages, disability or discomfort. Agreeing to this does not mean you have given up any of your legal rights.

*For studies conducted at UNMC or UNO classified as greater than minimal risk which ARE commercially sponsored, use the following (3) clauses in order:*

If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Immediate emergency medical treatment for this injury will be available at the Nebraska Medical Center. However, it is the policy of UNMC, UNMC Physicians, and The Nebraska Medical Center **(add UNO if applicable)** not to pay for any required treatment. Agreeing to this does not mean you have given up any of your legal rights.

Insert the commercial sponsor language, clearly stating the extent and limitations of the compensation

It is the policy of UNMC, UNMC Physicians and the Nebraska Medical Center not to provide any additional compensation. Agreeing to this does not mean you have given up any of your legal rights.

**How will information about you be protected?**

*Starred (*) items must be included. Indented items (with italicized instructions for the investigator) may also need to be included depending upon the nature of the study (e.g. cancer study; FDA-regulated; sponsored, etc).*

*Investigators should review carefully their study protocols and ensure that all required items of the HIPAA authorization are included in the consent document in clear, simplified language and in the exact sequence described.*

Required*

You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called "protected health information" (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures, as well as your medical history.

Required*

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC and the Nebraska Medical Center.

Required*

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| Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?" |

Required*

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| Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. You are also allowing the research team to share your PHI with other people or groups listed below. All of these persons or groups listed below are obligated to protect your PHI. |

*if multi-institution study where PHI will be shared with other researchers, add*:

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| researchers at (name of institutions) involved in this study; |

*if UNMC/The Nebraska Medical Center is expecting third party payers to pay for clinical procedures performed in the course of the research add:*

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| your health insurance company; |

*if the research involves patients with cancer add:*

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| the Eppley Cancer Center Scientific Review Committee (SRC); |

*if the research involves an FDA-regulated drug, device or biologic add*

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| the Food and Drug Administration (FDA); |

Required* if the research is sponsored, add:

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| Your PHI may also be shared with [Name of sponsor], which sponsors this research and provides funds to UNMC/The Nebraska Medical Center to conduct this research; and<br><br>[if applicable] [name of CRO] which has been hired by the sponsor to coordinate the study; and<br><br>[if applicable] [name of cooperative group]; and<br><br>[if applicable] a Data and Safety Monitoring Committee (DSMC).<br>However, this organization does not [*or* these organizations do not] have the same obligation to protect your PHI. |

Required*

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| You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. |

*if the research involves an FDA-regulated drug, device or biologic add:*

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| or for as long as the sponsor needs to obtain approval from the FDA. |

*OR if the research is without a foreseeable end-point (i.e., banking or registry studies) add instead:*

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| There is currently no plan to end this study, so your information may be kept and used indefinitely. |

*if information is withheld from the subject (see IRB Application section II.28) add:*

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| Information obtained in the course of the research that will not be shared with you is:<br><br>[insert details of the information to be withheld].<br><br>By signing this authorization, you are temporarily giving up your right to see this research related information while the research is going on. You will be able to see this information if you wish after the research is completed. |

Required*

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| You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research. |

Required*

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| The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential. |

**What are your rights as a research subject?**

*Use the following standard clause:*

You have rights as a research subject. These rights have been explained in this consent form and in *The Rights of Research Subjects* that you have been given. If you have any questions concerning your rights or complaints about the research, talk to the investigator or contact the Institutional Review Board (IRB) by:

- telephone (402) 559-6463.
- Email: IRBORA@unmc.edu
- Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830

**What will happen if you decide not to be in this research study?**

*Use the following standard clause:*

You can decide not to be in this research study. Deciding not to be in this research study will not affect your medical care or your relationship with the investigator, the University of Nebraska Medical Center or the Nebraska Medical Center. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

**What will happen if you decide to stop participating once you start?**

*Use the following standard clause:*

You can stop being in this research study ("withdraw") at any time before, during, or after the treatment begins. Your doctor will still take care of you though you may not be able to get the research treatment. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator, the University of Nebraska Medical Center, or the Nebraska Medical Center. You will not lose any benefits to which you are entitled.

For your safety, please talk to the research team before you stop any research treatments. They will advise you how to stop the treatment most safely. If you withdraw you may be asked to undergo some additional tests. You do NOT have to agree to do these tests.

You may be taken off the study if you don't follow instructions of the investigator or the research team. You may also be taken off the study if:

*[include other cases as appropriate]*

If the research team gets any new information during this research study that may affect whether you would want to continue being in the study you will be informed promptly.

**Documentation of informed consent**

*Use the following standard clause:*

You are freely making a decision whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study.

If you have any questions during the study, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Subject: Date: Time:

*For all studies include the following certification clause:*

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent: Date:

**Authorized Study Personnel**

*List by name those personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Principal Investigator, Secondary Investigator(s), Participating Physicians and Participating Health Care Personnel. Include day phone numbers for all listed individuals. For greater than minimal risk studies, include night/home phone numbers and/or other direct contact mechanism. List other study personnel and contact information as appropriate.*