

**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.

Usted está invitado a participar en este estudio de investigación. La información en este formulario tiene como propósito ayudarle a decidir si desea o no participar. Si usted tiene cualquier pregunta, por favor hágala.

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.

Si usted está embarazada, alimentando a un infante, o planea embarazarse durante este estudio, no podrá ser parte del mismo.

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.

Es posible que otros efectos secundarios raros que no se describen en este formulario de consentimiento, puedan ocurrir. Es también posible que usted pueda tener un efecto secundario que no ha ocurrido antes.

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.

Usted podría no recibir ningún beneficio por participar en este estudio de investigación.

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.

No se espera que usted obtenga ningún beneficio por participar en este estudio de investigación.

What are the possible benefits to other people?

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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.

En vez de participar en este estudio de investigación, usted puede elegir no participar.

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:

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

No tiene ningún costo para usted participar en este estudio de investigación.

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:

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

No le pagarán por participar en este estudio de investigación.

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.

El patrocinador de la investigación es [nombre del patrocinador]. El Centro Médico de la Universidad de Nebraska, o el Centro Médico de Nebraska, recibe el dinero del patrocinador para conducir este estudio.

[or] [o]

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].

El patrocinador de la investigación es [nombre del patrocinador]. El Centro Médico de la Universidad de Nebraska, o el Centro Médico de Nebraska, recibe el dinero del patrocinador para conducir este estudio. El investigador recibe un pago pequeño del patrocinador el cual se utiliza para... [por ejemplo, propósitos educativos].

For studies supported by extramural or intramural research grants:

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.

Esta investigación está siendo pagada con fondos subvencionados por [nombre de la agencia]. El Centro Médico de la Universidad de Nebraska, o el Centro Médico de Nebraska recibe el dinero de [nombre de la agencia] para conducir este estudio

[or] [o]

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].

Esta investigación está siendo pagada con fondos subvencionados por [nombre de la agencia]. El Centro Médico de la Universidad de Nebraska, o el Centro Médico de Nebraska recibe el dinero de [nombre de la agencia] para conducir este estudio. El investigador recibe un pago pequeño de [nombre de la agencia] el cual se utiliza para... [por ejemplo, propósitos educativos].

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.

El Centro Médico de la Universidad de Nebraska recibe dinero para proporcionar ayuda administrativa para los estudios de [nombre del grupo cooperativo]. No se proporciona ningún dinero específicamente para la conducción de este estudio.

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].

Esta investigación está siendo pagada por... [por ejemplo, el Departamento de Medicina Interna, Sección de Oncología del Centro Médico de la Universidad de Nebraska].

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.

Si usted se lesiona o tiene un problema médico como resultado de participar en este estudio, debe comunicarse inmediatamente con una de las personas listadas al final de este formulario de consentimiento.

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.

Si usted se lesiona o tiene un problema médico como resultado directo de participar en este estudio, debe comunicarse inmediatamente con una de las personas listadas al final de este formulario de consentimiento. Tratamiento médico de emergencia inmediata por esta lesión estará disponible en el Centro Médico de Nebraska. Sin embargo, es la política de UNMC, de los Médicos de UNMC, y del Centro Médico de Nebraska (**agregue la UNO si aplica**), no pagar por cualquier tratamiento requerido. El convenir con esto no significa que usted ha renunciado a ninguno de sus derechos legales.

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.

Usted o su compañía de seguro médico necesitará pagar cualquier costo. Los costos por cualquier otro problema médico no relacionado a este estudio de investigación, son también su responsabilidad. No hay planes de proporcionar pago por cosas como salarios, incapacidad o malestares. El convenir con esto no significa que usted ha renunciado a ninguno de sus derechos legales.

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.

Si usted se lesiona o tiene un problema médico como resultado directo de participar en este estudio, debe comunicarse inmediatamente con una de las personas listadas al final de este formulario de consentimiento. Tratamiento médico de emergencia inmediata por esta lesión estará disponible en el Centro Médico de Nebraska. Sin embargo, es la política de UNMC, de los Médicos de UNMC, y del Centro Médico de Nebraska (**agregue la UNO si aplica**), no pagar por cualquier tratamiento requerido. El convenir con esto no significa que usted ha renunciado a ninguno de sus derechos legales.

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.

Es la política de UNMC, los Médicos de UNMC y el Centro Médico de Nebraska, no proporcionar ninguna remuneración adicional. El convenir con esto no significa que usted ha renunciado a ninguno de sus derechos legales.

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-ray.

Usted tiene derechos con respecto a la privacidad de su información médica obtenida antes y durante esta investigación. Esta información médica, llamada "Información Médica Protegida" (PHI, por si siglas en inglés), puede incluir típicamente, dependiendo de la naturaleza de la investigación, información demográfica (como su dirección y fecha de nacimiento), los resultados de exámenes físicos, los análisis de sangre, las radiografías.

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.

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Al firmar este formulario de consentimiento usted está permitiendo que el equipo de investigación tenga acceso a su PHI. El equipo de investigación incluye a los investigadores listados en este formulario de consentimiento y a otro personal involucrado en este estudio específico de UNMC y el Centro Médico de Nebraska.

Required*

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

Su PHI será utilizada solamente para el(los) propósito (s) descrito(s) en la sección "¿Cuál es la razón de hacer este estudio de investigación?"

Required*

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.

Su PHI será compartida, como sea necesario, con la Junta de Revisión Institucional (IRB por sus siglas en inglés) y con cualquier persona o agencia requerida por la ley. Usted también está permitiendo que el equipo de investigación comparta su PHI con otras personas o grupos listados abajo. Todas estas personas o grupos están obligados a proteger su PHI.

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

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

De ser un estudio multi-institucional donde la PHI se compartirá con otros investigadores, agregue: investigadores en (nombre de las instituciones) involucrados en este estudio;

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

your health insurance company;

Si UNMC/ o el Centro Médico de Nebraska esperan que terceras partes paguen por procedimientos clínicos realizados durante el curso de la investigación, agregue:

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su compañía de seguro de salud;

if the research involves patients with cancer add:

the Eppley Cancer Center Scientific Review Committee (SRC);

el Comité de Revisión Científica del Centro de Cáncer Eppley (SRC);

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

the Food and Drug Administration (FDA);

la Administración de Drogas y Alimentos;

Required* if the research is sponsored, add:

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

[if applicable] [name of CRO] which has been hired by the sponsor to coordinate the study; and

[if applicable] [name of cooperative group]; and

[if applicable] a Data and Safety Monitoring Committee (DSMC).

However, this organization does not [or these organizations do not] have the same obligation to protect your PHI.

Su PHI puede ser también compartido con [nombre del patrocinador], quien patrocina esta investigación y proporciona fondos a UNMC/CENTRO MÉDICO DE NEBRASKA para conducir esta investigación; y

[si aplica] [nombre de la CRO] que ha sido contratada por el patrocinador para coordinar el estudio; y

[si aplica] [nombre del grupo cooperativo]; y

[si aplica] el Comité de Datos y Monitoreo de Seguridad (DSMC).

Sin embargo, esta organización no [o estas organizaciones no] tiene(n) la misma obligación de proteger su PHI.

Required*

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

Usted nos está autorizando a utilizar y a divulgar su PHI mientras se esté

conduciendo el estudio de investigación.

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

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

o mientras el patrocinador necesite obtener la aprobación de la FDA

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

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

Actualmente no existe un plan para terminar este estudio, por lo tanto su información puede ser guardada y utilizada indefinidamente.

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

Information obtained in the course of the research that will not be shared with you is:

[insert details of the information to be withheld].

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.

La información obtenida en el curso de la investigación que no será compartida con usted es:

[Inserte los detalles de la información que se retendrá].

Firmando esta autorización, usted está renunciando temporalmente a su derecho de ver la información relacionada a la investigación mientras se esté conduciendo la misma. Usted podrá ver esta información si así lo desea, después de que se complete la investigación.

Required*

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.

Usted puede cancelar su autorización para obtener más datos de su PHI para el

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uso en esta investigación en cualquier momento, comunicándose por escrito con el investigador principal.
Sin embargo, la PHI que se incluye en los datos de la investigación obtenida hasta la fecha puede ser utilizada todavía. Si usted cancela esta autorización, no podrá participar más en esta investigación.

Required*

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.

Los resultados de pruebas clínicas y terapia realizada como parte de esta investigación se pueden incluir en su expediente médico. La información de este estudio puede ser publicada en revistas científicas o presentada en reuniones científicas, pero su identidad será mantenida estrictamente confidencial.

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:

Usted tiene derechos como sujeto de investigación. Estos derechos se han explicado en esta forma del consentimiento y en *Los Derechos de los Participantes de Investigación* que le han entregado. Si usted tiene alguna pregunta referente a sus derechos o quejas sobre la investigación, hable con el investigador o llame a la Junta de Revisión Institucional (IRB) al:

- Teléfono (402) 559-6463
- Correo electrónico: IRBORA@unmc.edu
- Dirección: 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:

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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.

Usted puede decidir no participar en este estudio de investigación. El decidir no estar en este estudio de investigación no afectará su cuidado médico, o su relación con el investigador, con el Centro Médico de la Universidad del Nebraska, o con el Centro Médico de Nebraska. Su médico estará aún a su cuidado, y usted no perderá ningún beneficio a los cuales tenga derecho.

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.

Usted puede dejar de participar en este estudio de investigación ("retirarse") en cualquier momento antes, durante, o después de que el tratamiento haya comenzado. Su médico estará aún a su cuidado aunque usted no pueda conseguir el tratamiento de la investigación. El decidir retirarse no afectará de otra manera su cuidado o su relación con el investigador, con el Centro Médico de la Universidad de Nebraska, o con el Centro Médico de Nebraska. Usted no perderá ningún beneficio a los cuales tenga derecho.

Para su seguridad, hable por favor con el equipo de investigación antes de suspender cualquier tratamiento de la investigación. Ellos le aconsejarán cómo suspender el tratamiento de la manera más segura posible. Si usted se retira, se le puede pedir que se someta a algunas pruebas adicionales. Usted NO tiene que estar de acuerdo con someterse a estas pruebas.

A usted se le puede sacar del estudio si usted no sigue las instrucciones del investigador o del equipo de investigación. Usted también puede ser sacado del estudio si:

[incluya otros casos que sean apropiados]

Si el equipo de investigación recibe alguna información nueva durante este estudio de investigación que pueda afectar su decisión de seguir participando en el estudio, usted será informado en seguida.

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:

Usted está libremente tomando una decisión de participar en este estudio de investigación. Su firma en este formulario significa que (1) ha leído y entendido este formulario de consentimiento, (2) se le ha explicado el formulario de consentimiento, (3) le han contestado sus preguntas y (4) ha decidido participar en este estudio de investigación.

Si usted tiene alguna pregunta durante el estudio, debe hablar con uno de los investigadores listados a continuación. Le entregarán una copia de este formulario para guardar.

Firma del Sujeto

Fecha

Hora

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:

Mi firma certifica que todos los elementos del consentimiento informado descritos en este formulario le han sido explicados completamente al sujeto. A mi juicio, el participante posee la capacidad legal para dar consentimiento informado para participar en esta investigación y está voluntariamente y a sabiendas dando consentimiento para participar.

Firma de la persona que obtiene consentimiento:

Fecha:

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.