The following instructions and examples are provided to assist in development of the Adult Consent Form for Emergency Treatment. 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 Treatment 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 patient to participate in the emergency treatment using the following standard invitation to participate:

The information in this form is meant to help you decide whether or not to undergo this treatment. If you have any questions, please ask.

Why are you being asked to undergo this treatment?

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 receiving treatment (section II.4.d of application) include the following standard statement:

If you are pregnant, nursing an infant, or plan to become pregnant during treatment, you may not eligible.

What is the reason for undergoing treatment?

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 treatment 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 treatment 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 treatment).

What will be done during the course of treatment?

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.

This section should include a brief description of the proposed therapy, as well as a description of the FDA status of the drugs utilized and a discussion of any standard therapies which will be discontinued. This section should also include a statement that no tests will be performed solely for research purposes, but that outcome and toxicity data may be collected and forwarded to the drug manufacturer as appropriate.)
What are the possible risks of undergoing treatment?

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 patient 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 undergoing treatment.

What are the alternatives to undergoing treatment?

Describe, in reasonable detail, available therapeutic alternatives the patient may have available, if any. The existence of other experimental therapies should also be mentioned here, including an offer to discuss these options. Specifically, address therapeutic alternatives available to the patient in the non-treatment context, and whether any of the therapeutic interventions would be available to the patient if they did not elect to undergo treatment. (See section II.18 of the Application)

Alternately, use the following standard clause if applicable:

The alternative to this treatment is to continue the current treatment (list current treatment being used).
What will this treatment cost you?

This section should state the financial obligations the patient will incur as a result of undergoing treatment, and whether any financial obligations will be increased as a result of procedures performed solely for treatment purposes (section II.20 of application).

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

There is no cost to you to receive this treatment.

Will you be paid for undergoing treatment?

If the patient will receive compensation for undergoing treatment, 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 undergo treatment.

What should you do if you are injured or have a medical problem during the course of treatment?

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

For studies classified as significant risk use the following standard clause:

Your safety is the major concern of every member of the treatment team. If you are injured or have a medical problem, 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.

If the study is not sponsored, the following clause must be added to the compensation statement:

You or your insurance company will need to pay for any costs. The costs for any other medical problems unrelated to this treatment 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.

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.
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 treatment. This medical information, called "protected health information" (PHI), includes 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. You have the right to limit the use and sharing of your PHI, and you have the right to see your medical records and know who else is seeing them.

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

Required*
Your PHI will be used only for the purpose(s) described in the section "What is the reason for undergoing treatment?"

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 treatment 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 treatment, add:

Physicians at (name of institutions) involved in this treatment;

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

Your health insurance company;

if the treatment involves patients with cancer add:

The Eppley Cancer Center Scientific Review Committee (SRC);

if the treatment involves an FDA-regulated drug, device or biologic add
The Food and Drug Administration (FDA);

Required* if the treatment is sponsored, add:

Your PHI may also be shared with [Name of sponsor], which sponsors this treatment and provides funds to UNMC/THE NEBRASKA MEDICAL CENTER to conduct this treatment; 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.

Required*

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

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

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

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

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

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

Information obtained in the course of the treatment 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 treatment-related information while the treatment is going on. You will be able to see this information, if you wish, after the treatment is completed.

Required*

You may cancel this authorization to use and share your PHI at any time by contacting the principal investigator in writing. If you cancel this authorization,
you may no longer participate in this treatment. If you cancel this authorization, use or sharing of future PHI will be stopped. The PHI which has already been collected may still be used.

**Required***

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

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

*Use the following standard clause:*

You can stop this treatment (“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 treatment. Deciding to withdraw will otherwise not affect your care or your relationship with the primary physician, 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 treatment team before you stop any 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 treatment if you don’t follow instructions of the physicians or the treatment team. You may also be taken off the treatment if:

*include other cases as appropriate*

If the treatment team gets any new information during the course of this treatment that may affect whether you would want to continue, you will be informed promptly.

Documentation of informed consent

*Use the following standard clause:*

You are freely making a decision whether to receive treatment. 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 receive treatment.
If you have any questions during the course of treatment, you should talk to one of the physicians listed below. You will be given a copy of this consent form to keep.

Signature of Patient:    Date:    Time:

For studies involving greater than minimal risk include the following witness certification clause:

My signature as witness certifies that the patient signed this consent form in my presence as their voluntary act and deed.

Signature of Witness:     Date:

For all studies include the following investigator certification clause:

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

Signature of Physician:    Date:

Authorized Personnel and Treatment Team

Identify all personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Primary Physician, Secondary Physician(s), Participating Physicians/Health Care Personnel, and Data/Administrative 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.