1.0 Purpose
The purpose of this SOP is to describe the required elements for informed consent documents.

2.0 Policy
It is the policy of the IRB that the IRB shall ensure that informed consent is documented in accordance with and to the extent required by Health and Human Services 45 CFR §46.116, unless documentation is waived by the IRB as provided in Health and Human Services 45 CFR §46.109(c) and §46.117.

2.1 Introduction
The IRB shall require that information given to participants as part of informed consent is in accordance with Health and Human Services regulations at 45 CFR §46.116. The IRB may require that information, in addition to that required by regulations, be given to participants when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of participants in accordance with Health and Human Services 45 CFR 46.§109(b). The IRB has authority to observe or have a third party observe the consent process and/or the conduct of research [45 CFR §46.109(e)]. Guidelines through the use of a template are available to assist all investigators to meet requirements of the federal regulations and IRB (available through the HRPP website, http://research/orr/forms.shtml).

2.2 Investigator Responsibilities
The investigator has a legal and ethical obligation to ensure that the prospective research participant has sufficient knowledge and comprehension of the elements of informed consent, meaning that the prospective research participant must be able to make an informed decision whether or not to participate in research. Obtaining informed consent should be seen as a communication process of explanation and not as an act of signing a form. As part of the process of obtaining informed consent, each element of consent should be explained carefully and simply to the prospective participant. In addition, the investigator should assess periodically the prospective participant’s comprehension by asking appropriate questions. Ultimately, the investigator bears full responsibility for obtaining valid informed consent from the participant.

Investigators should be sensitive to the possible needs of an interpreter or translator for participants who do not speak English as a first language or who are hearing impaired.

2.3 Mail/Telephone Surveys
Mailed surveys that are completely anonymous can meet the informed consent requirement in one of two ways: a) they can be sent out with an accompanying cover letter and an informed consent form, or b) they can be sent out with an accompanying informed consent form but written in a cover letter format. If the second option is
chosen, the return of the survey implies consent, which can be approved if the IRB grants an exemption determination or waives the requirement for documentation of the consent process. The letter would have to include notification of use of data, assurance of confidentiality, and phone numbers to contact in case of questions about participant’s rights.

Some anonymous telephone interviews with adults can be handled in a similar way. It is preferred for the participant to receive a copy of the informed consent letter or form before the interview; however, in situations when that is not possible, information typically given on an informed consent form (notification of use of the data, assurance of confidentiality, phone numbers to contact in case of questions, etc.) can be included in an oral script that is read to participants to obtain oral consent. Oral scripts must be submitted to the IRB for review and approval before the study is conducted.

### 2.4 Required Elements for Informed Consent Documents

The following are the required elements that must be present in all consent documents.

The consent form must be:

**A.** Approved by the IRB and include the elements of informed consent required by Health and Human Services 45 CFR §46.117 and 46.117(b)(1);

**B.** Signed by the participant or the participant’s legally authorized representative [Health and Human Services 45 CFR §46.117(a)]; unless the IRB has waived the requirement for document of the consent process in, which case a cover letter may be used as an informed consent document; and

**C.** A copy must be given to the participant or legally authorized representative [Health and Human Services 45 CFR §46.117(a)].

The agreement, written or oral, entered into by the participant, may not include language through which the participant is made to waive, or to appear to waive, any legal rights, or to release the investigator, the sponsor, UNL, or its agents from liability for negligence.

Informed consent should be appropriate to the research and participant population being studied.

**D.** Informed consent shall include the following elements:

1. A statement that the study involves research [Health and Human Services 45 CFR §46.116(a)(1)];

2. An explanation of the purposes of the research [Health and Human Services 45 CFR §46.116(a)(1)];

3. The expected duration of the participant’s participation in the research [Health and Human Services 45 CFR §46.116(a)(1)];

4. A description of the procedures to be followed [Health and Human Services 45 CFR §46.116(a)(1)];
5. Identification of any procedures, which are experimental [Health and Human Services 45 CFR §46.116(a)(1)];

6. A description of any reasonably foreseeable risks or discomforts to the participants [Health and Human Services 45 CFR §46.116(a)(2)];

7. A description of any benefits to the participant or to others which may reasonably be expected from the research [Health and Human Services 45 CFR §46.116(a)(3)];

8. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant [Health and Human Services 45 CFR §46.116(a)(4)];

9. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained [Health and Human Services 45 CFR §46.116(a)(5)];

10. For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs; whether any medical treatments are available if injury occurs; and, if so, what they consist of, or where further information can be obtained [Health and Human Services 45 CFR §46.116(a)(6)];

11. An explanation of whom to contact for answers to pertinent questions about the research and who to contact in the event of a research related injury to the participant. [Health and Human Services 45 CFR §46.116(a)(7)]. A contact phone number for the PI and the Supervising Investigator must be provided;

12. A statement of whom to contact concerning questions about research participants rights, for example, “Please contact the University of Nebraska-Lincoln Institutional Review Board at (402) 472-6965 for the following reasons:
   • you wish to talk to someone other than the research staff to obtain answers to questions about your rights as a research participant
   • to voice concerns or complaints about the research
   • to provide input concerning the research process
   • in the event the study staff could not be reached,” [Health and Human Services 45 CFR §46.116(a)(7)]; and

13. A statement that participation is voluntary that refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled: for example “Participation in this study is voluntary. You can refuse to participate or withdraw at any time without harming your relationship with the researchers or the University of Nebraska-Lincoln, (include any other agency/institution you are working with), or in any other way receive a penalty or loss of benefits to which you are otherwise entitled.” [Health and Human Services 45 CFR §46.116(a)(8)].
14. If appropriate to the research, indicate whether the informed consent process provides the following 6 additional elements of information 45 §CFR 46.116(b):

a) That some risks to subjects may be unforeseeable.
b) Outlines the circumstances where a subject’s participation may be terminated by PI without regard to subject’s consent.
c) Whether there are any costs for which subjects will be responsible.
d) The consequences of a subject’s decision to withdraw (safety issues).
e) That new and significant findings, which may affect subject’s willingness to continue, will be disclosed.
f) The approximate number of subjects involved in the research at the institution and nationally.

The IRB requires that information in addition to that required by Health and Human Services 45 CFR §46 be given to research participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of participants (Health and Human Services 45 CFR 109):

i) The age of participants (under 19 require parental informed consent in Nebraska except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).

ii) Where research takes place.

iii) When individuals with decisional impairments are potential research participants, the IRB may require the investigator to use techniques that would confirm that individuals did understand the consent process.

iv) A statement about why the participant was selected.

v) The IRB may require the consent process be monitored or observed when individuals with decisional impairments are involved.

vi) The IRB may require waiting periods prior to consenting.

vii) The IRB may require an advocate or ombudsman oversee the consent process for individuals with decisional impairments.

viii) The IRB may require procedural changes or additional protections for individuals with decisional impairments.

ix) A statement that if the participant was or became pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which were currently unforeseeable.

x) Procedures for the orderly termination of participation by the participant.
2.5 Documentation of Consent Process
The consent process must be appropriately documented in accordance with Health and Human Services regulations at 45 CFR §46.117. (see HRPP policy # 9.002):

A. The participant must initial the bottom of each page of the consent, or the consent form should say page __ of ___ and formally provide their full signature, and date, at the end of the consent.

B. For studies involving greater than minimal risk, a witness must also provide signature and date.

C. The investigator’s name and phone number must be listed at the end of the consent form.

2.6 Signed informed consent can be obtained by the following methods.

A. Participant physically signs a piece of paper or an electronic form using a stylus. This could be returned hardcopy, via fax, or via email.

B. For on-line studies, a signature can be:
   1. Checking a box to indicate the person agrees to participate. The on-line consent form should state: By clicking this box, you are providing your electronic signature and you are agreeing to participate in this research.
   2. The person types their name on the on-line form.

C. For email consent procedures, a signature can be:
   1. The informed consent is included as an attachment to the email. The participant prints the form, signs the form, scans it, and emails the signed document back to the researcher.
   2. The consent information is included in the body of the email or as an attachment to the email. The person responds to the email indicating they agree to participate.

If these methods are not used, a waiver of consent signature must be requested. The waiver is not required if the proposed research can be classified as Exempt.

Depending on the nature of the research, the risks involved, and the characteristics of the Potential participants, the IRB may require one signature process over another.

2.7 Observation of the Consent Process
A. The IRB can observe the consent process where it determines that such observation will meaningfully contribute to the reduction of risk to the research participant. For example, situations with vulnerable populations where observation of the consent might minimize coercion or undue influence, or situations involving non-compliance with the consent process.

B. If the IRB decides that the consent should be observed, the investigator would be notified before such observation. The PI will be consulted collegially so that appropriate arrangements can be made for the observation to take place in a manner that is as unobtrusive as possible. HRPP staff would conduct the observation.
Administrative Approval:

Julia Torquati, Ph.D.
IRB Chair

Regina Werum, Ph.D.
Associate Vice Chancellor for Research
1.0 Purpose
The purpose of this SOP is to describe development of the informed consent document.

2.0 Policy
It is the policy of the IRB that the informed consent document will be developed in accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Stationery
All consent documents including email and web-based consent documents must be printed on UNL letterhead.

2.2 Specific Layout Instructions
All consent/assent documents should be submitted suitable for reproduction and easy readability by potential participants.

Lines requiring the participant, witness, or PI signatures should not be placed on a separate page without the presence of any of the preceding language required in that section of the informed consent.

Each page of the consent/assent document must include:
A. The IRB protocol number in the upper right corner as labeled by the IRB (“IRB # _____”), date of approval of current consent form, and “valid until” date. Commonly, there are many versions or amendments to the original consent throughout the course of a study. This requirement will help the investigator and IRB track the most current version of the consent/assent documents.

B. Page numbers (“Page _ of _”) at the bottom of each page. or

C. “Participant’s Initials _____” at the bottom of each page.

2.3 Identification of Type of Consent and Assent
To easily identify the type of consent/assent document, one of the following labels should be placed at the top of the first page:

A. Adult Consent: Utilized when enrolling competent adults (in Nebraska defined as individuals 19 years of age or older and individuals under 19 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).
B. **Parent or Legal Guardian Consent:** Utilized when enrolling children (in Nebraska defined as individuals under 19 years of age except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research) in a research study.
   1. *Youth Assent:* To be used for children aged 13-18 years
   2. *Child Assent:* To be used for children aged 7-12 years

C. **Proxy, Legally Authorized Representative, or Durable Power of Attorney Consent:** Utilized when enrolling decisionally impaired adults.
   1. *Adult Assent:* Used when enrolling decisionally impaired adults.

D. **Screening Consent:** Used to obtain participant consent to allow study-related screening tests for potential enrollment in a study. Full study consent will follow.

E. **Addendum Consent:** Commonly used to obtain additional consent from participants for auxiliary studies (e.g., tissue banking). Also may be used to inform currently enrolled participants of new information pertaining to the research.

2.4 **Identification of Study Personnel**
The PIs and Supervising Investigators, if any, listed in the IRB Application must be listed on the last page of the informed consent/assent document in accordance with Health and Human Services regulations at 45 CFR §46.111(a) (4) and §46.116(a) (7).

The following subheadings must be used (as appropriate):
A. Principal Investigator
B. Supervising Investigators

A contact phone number for the PI and the Supervising Investigator must be provided.

2.5 **General Style of Consent Documents**
The informed consent form should be written in the second person throughout (e.g., you are invited to participate; you will be assigned, etc.). When combined with conditional language and the invitation to participate, utilization of the second person communicates that the investigator believes there is a choice to be made by the prospective participant. Utilization of the first person may be interpreted as presumption of participant consent before consent has been legally obtained.

2.6 **Parental, Legal Guardian, Proxy, and Durable Power of Attorney Consent Documents**
Proxy consent documents should reflect that it is the minor, or other vulnerable participant, who is the participant in the study. The individual giving consent (parent or legally authorized representative) is providing permission to allow the participant to participate in the study.

2.7 **Adult, Youth, and Child Assent Documents**
Assent documents should reflect the age, maturity and cognitive ability of the decisionally impaired adults, youth, and children that will be the participants of the trial.
For further information about:
A. Parental/legal guardian consent and youth/child assent, see HRPP policy # 9.002.

B. Proxy/DP consent and adult assent, see HRPP policy # 9.002.

2.8 Readability
The consent form must be written in simple enough language so that it is readily understood by the least educated of the participants to be involved. Generally, the level of language in the adult consent document should be around an eighth grade standard. Youth and child assent documents should be written in an age-appropriate style.

Medical and scientific terms should be avoided where possible. If medical jargon is used the lay terms should be used first and then the medical term included in parentheses.

Common units of measure should be used appropriate to the procedure or content.

It is recommended that the language consist of short, concise sentences arranged in relatively short simple paragraphs. Headers should be used to separate sections of the document for easier reading, particularly when describing what will happen during the study. Generally, abbreviations should not be used in the consent document that is, all words should be spelled out. The IRB may approve limited use of abbreviations where appropriate, as long as the acronym is spelled out the first time it is used.

2.9 Length
There are no restrictions on the length of the informed consent/assent documents. The informed consent form should be lengthy enough to explain the elements of consent adequately, but not so lengthy or detailed as to lose the attention of the participant or to cause confusion.

2.10 Format
A. Exempt Research: If the research is exempt, but requires written informed consent (e.g., an educational study requiring parental consent), a narrative consent form format may be used at the discretion of the investigator. In the narrative consent form, all necessary elements of consent should be present on the consent form, but the elements need not be identified by subheadings.

B. Research Involving Minimal Risk or Greater: If the research involves procedures, which are minimal risk or greater, the legalistic consent document format must be used (see HRPP policy # 3.004 for a definition of minimal risk). The IRB has developed an informed consent document template that is designed to provide investigators guidance in the development of this form. The template is available on the HRPP website (http://research/orr/forms.shtml).

2.11 Exculpatory Language
The consent document must not contain any exculpatory language through which the participant or the participant’s representative is made to waive, or appear to waive, any of the participant’s legal rights. Additionally the consent document must not release, or appear to release, the research investigator, the sponsor, the Institution, or its agents from liability for negligence.
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<td>Kimberly Andrews Espy, Ph.D.</td>
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<td>Associate Vice Chancellor for Research</td>
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1.0 Purpose
The purpose of this SOP is to describe the guidelines governing telephone consent.

2.0 Policy
It is the policy of the IRB that telephone consent will be gained in accordance with the regulations at Health and Human Services 45 CFR §46.

2.1 Introduction
Whenever possible, consent should be obtained in person by an authorized investigator. However, the IRB recognizes that an alternative informed consent process may, at times, be necessary for the safety of the participant. Therefore, under extenuating circumstances, when it is in the best interests of the participant, the IRB may approve an alternative informed consent process(es) via telephone. IRB approval of a telephone consent process for nonexempt research requires a waiver of the requirement for written documentation of consent. The consent discussion needs to include all required elements of consent disclosure unless the IRB approves a waiver or alteration of the consent process.

2.2 IRB Requirements for Use of a Telephone Consent Process
The IRB will review the proposed method of consent based upon the nature of the study, the risk level, participant population needs and/or significance of the treatment related change. The proposed method of consent must be fully explained and justified in the IRB application (Section 7) or in the Description of Proposed Changes section of the Request for Change in Protocol Form.

The following describes IRB requirements for the use of telephone consent for re-consent for significant changes or disclosure of significant additional risks and re-consent for minor changes or disclosure of additional minor risks.

2.3 Re-consent by Telephone for Significant Changes or Disclosure of Significant Additional Risks

With appropriate scientific rationale and justification, the IRB may approve a telephone consent procedure to allow participant to be notified of significant new risks.

A. The consent document (revised consent form or addendum) must be provided to the participant for review prior to the telephone consent process. It is preferred that this be done by mail; however, fax is acceptable when necessary. No research interventions can be conducted until a signed copy (fax or original) of the consent form has been received by the investigator. An extra copy must be provided for the participant to keep for their records.

B. A telephone call is scheduled. The minimum required participants in the consent process are:
1. The participant.
2. The investigator.

C. Each element of the consent document, which has been changed, must be explained to the participant, and the participant’s comprehension must be assessed. The participant must be given the opportunity to ask questions. It may be necessary to extend the process over several days and include other individuals such as the participant’s family members. The participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail. The participant must be re-consented in the presence of the investigator when he/she returns to research site for follow-up.

D. The alternative process of consent should be documented in the research record by indicating the reason for the alternative method used, and date.

2.4 Telephone Re-Consent for Minor Changes or Disclosure of Additional Minor Risks

With appropriate justification, the IRB, under certain circumstances, may approve a telephone consent procedure for participants to receive notification of a minor new risk.

A. The consent document (revised consent form or addendum) must be provided to the participant for review prior to the telephone consent process. It is preferred that this be done by mail; however, fax is acceptable when necessary. No research interventions can be conducted until a signed copy (fax or original) of the consent form has been received by the investigator. An extra copy must be provided for the participant to keep for his/her records.

B. A telephone call is scheduled. Minimum required participants in the consent process are:
   1. The participant.
   2. The investigator.

C. Each element of the consent document, which has been changed, must be explained to the participant, and the participant’s comprehension must be assessed. The participant must be given the opportunity to ask questions. The participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail. The alternative process of consent must be documented in the research record by indicating the reason for the alternative method used, date, time, and personnel involved in obtaining and documenting consent.
1.0 Purpose
The purpose of this standard operating procedure (SOP) is to describe the process of re-consent/assent of research participants.

2.0 Policy
It is the policy of the IRB that the process of re-consent/assent of research participants will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46.

The initial informed consent/assent document(s) signed by the participant at enrollment remains in effect for the duration of the participant’s participation in the study or until the IRB approves a change in the consent/assent document(s), which requires re-consent/assent of participants.

Informed consent/assent, however, is an ongoing process, not simply the document signed by the participant during enrollment in the research. In order to validate the voluntary nature of participation in research and exhibit respect for the individual, participants must be provided new information, which may affect their willingness to continue to participate in the research. Health and Human Services regulations at 45 CFR §46.116(b) (5), therefore, require investigators to inform participants of any important new information that is germane to the participant’s willingness to continue participating in the study.

Each year, during the continuing review process, original consent/assent document(s) are submitted for review. Upon IRB re-approval of the study, the consent/assent documents are stamped with the “date approved” and “valid until” dates. The IRB does not require re-consent of previously enrolled participants at this time, unless the IRB approves a request for change during the continuing review process or identifies new information, which requires re-consent of the participants

Commonly, minor information (e.g., changes in personnel or administrative changes in the consent document) is provided to participants through verbal exchanges between the investigator and participant, without undergoing a formal re-consent procedure. Minor information is unlikely to affect a participant’s willingness to continue participation in a study. However, significant new information, which requires re-consent/assent of participants must occur through use of IRB-approved, revised consent/assent document(s) or an addendum to the consent/assent form. For example, significant new information may include 1) changes in the duration of the study, or 2) major changes in the methods of the study.
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1.0 Purpose
The purpose of this SOP is to describe the guidelines governing the re-consent and the use of data in the absence of valid consent.

2.0 Policy
It is the policy of the IRB that, in the absence of valid consent, re-consent and the use of data will adhere to the regulations at Health and Human Services 45 CFR §46.

The investigator has a legal and an ethical obligation to ensure that the prospective participant has sufficient knowledge and comprehension of the elements of informed consent prior to enrollment and during participation in research. This is accomplished through the initial and on-going process of informed consent.

If a participant enrolls and begins participation in a study without the presence of a valid informed consent document (e.g., the participant signed a wrong or outdated consent form), participant comprehension of the elements of informed consent and true informed decision making is called into question. The ethical principal of respect for persons demands that participants enter into research voluntarily and with adequate information.

If a participant enrolls in a study without valid informed consent, the principal investigator must immediately notify the IRB Chair and the participant and explain the situation. The PI should request that the participant re-consent to participate. If the participant agrees and the complete informed consent process is repeated, including signatures on the consent document and documentation of consent in the research record, data obtained during the period of invalid consent may be used with approval of the IRB.

If the participant refuses to consent, participation in the study must be halted immediately and the collected data cannot be used.

Administrative Approval:

Dan R. Hoyt, Ph.D.
IRB Chair

Kimberly Andrews Espy, Ph.D.
Associate Vice Chancellor for Research
1.0 Purpose
The purpose of this SOP is to describe the situations in which the IRB may waive or alter the informed consent process and/or waive consent documentation.

2.0 Policy
It is the policy of the IRB that all requests for waiver or alteration of the informed consent process or consent documentation must undergo appropriate IRB review, and when waivers or alterations are granted, they are given based on Health and Human Services regulatory criteria at 45 CFR §46.111(a) (4) and (5), 45 CFR §46.116(a) to (e), 45 CFR §46.117(a) to (c).

3.0 Waiver of Documentation of Informed Consent
The Board, for some or all participants, may waive the requirement that the participant or the participant’s representative sign a written consent document per 45 CFR §46.117(c) if it finds:

3.1 That only the record linking the participant and the research would be a potential harm to the participant resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern; or

3.2 That the research presents no more than the minimal risk of harm to the participants, and involves no procedure for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants a written statement regarding the research.

When the IRB considers waiving the requirement to obtain documentation of the consent process, the IRB should review a description of the information that will be provided to participants. When granting waivers of the requirement to obtain documentation of the consent process, the IRB should consider whether the investigator should provide participants with a written statement regarding the research.

4.0 Waiver or Alteration of Consent
The Board may waive the requirement for informed consent per 45 CFR §46.116(d) (or allow an alteration of some or all of the elements of informed consent) only if the Board finds that each of the following four elements are met. This is different than waiving the requirement of documentation of informed consent.

4.1 The research involves no more than minimal risk to participants; and
4.2 The waiver or alteration will not adversely affect the rights and welfare of the participants; and
4.3 The research could not practicably be carried out without waiver or alteration; and
Whenever appropriate the participants will be provided with additional pertinent information after participation (45 CFR 46.116(d)).

For research sponsored by the Department of Defense, the following guidelines will be followed:

5.1 The IRB may waive the consent process if the research participant(s) do not meet the definition of “experimental participant”

5.2 If the research participant meets the definition of “experimental participant,” the waiver of consent shall not be granted by the IRB unless approval is obtained from the Secretary of Defense.

5.3 “Experimental participant” as defined in Department of Defense Directive 3216.02 shall include:

A. An individual participating in an activity for research purposes where there is an intervention or interaction for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to a physical procedure, a drug, a manipulation of the subject or subject's environment, or the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include:

1. Activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense.

2. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.

3. Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews.

4. Activities exempt under 32 CFR 219 (reference (c)).

The investigator must complete the section requesting a waiver in the informed consent process portion of the new protocol submission form.

Administrative Approval:

William Thomas, Ph.D.                             Kimberly Andrews Espy, Ph.D.
IRB Chair                                         Associate Vice Chancellor for Research