To approve research, the IRB must determine that all of the following criteria are satisfied:

<table>
<thead>
<tr>
<th>Science</th>
<th>Is the scholarly or scientific design adequate (If &quot;No the research cannot be approved)?</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Is the selection of participants equitable taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria, and the recruitment procedures (If &quot;No the research cannot be approved)?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>2.</td>
<td>When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, are additional safeguards included in the study to protect the rights and welfare of these participants (If &quot;No the research cannot be approved)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>3.</td>
<td>Does the process for obtaining consent incorporate all of the following (If &quot;No&quot; indicate the items that must be addressed before approval is granted): a. The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative. b. Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and to read any consent document before it is signed. c. Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence. d. The information that is given to the participant or the representative shall be in a language understandable to the participant or the representative.</td>
<td>Yes/No/NA a/b/c/d</td>
</tr>
<tr>
<td>4.</td>
<td>When appropriate, are there adequate provisions to protect the privacy of participants (If &quot;No the research cannot be approved)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>5.</td>
<td>When appropriate, are there adequate provisions to maintain the confidentiality of data (If &quot;No the research cannot be approved)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>6.</td>
<td>Are risks to subjects minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (If &quot;No the research cannot be approved)?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>7.</td>
<td>Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result (If &quot;No the research cannot be approved)?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>8.</td>
<td>When appropriate, does the research plan make adequate provision for monitoring the data collected to ensure the safety of participants and integrity of the data (If &quot;No the research cannot be approved)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>9.</td>
<td>If this is a multi-site research study, is the management of information that might be relevant to the protection of participants adequate (If &quot;No the research cannot be approved)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>10.</td>
<td>Is the following information provided as part of the interaction with the participant and in the documentation of the consent process, unless waived or altered: (If &quot;No&quot; to any of the research cannot be approved)</td>
<td>Yes/No/NA</td>
</tr>
</tbody>
</table>

### 3a. When the long form of documentation is used: (If "No" the research cannot be approved)
- The participant or the participant's legally authorized representative will sign the consent document.
- A copy of the consent document will be given to the person signing the consent document.

### 3b. When the short form of documentation is used: (If "No" the research cannot be approved)
- The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.
- A written summary embodies the basic and appropriate additional elements of disclosure.
- There will be a witness to the oral presentation and will sign short form and a copy of the summary.
- For participants who do not speak English, the witness will be conversant in both English and the language of the participant.
- The participant or the participant's legally authorized representative will sign the consent document.
- The person actually obtaining consent will sign a copy of the summary.
- A copy of the summary and the short form will be given to the participant or the representative.

### 3c. If a waiver or alteration of the consent process (including the use of deception), or a waiver of written documentation of consent is requested, does the study qualify for the waiver as delineated in the Determinations for Consent Waivers in Research (If "No" the waiver cannot be granted)?

### 10a. A statement that the study involves research, and an explanation of the purposes of the research.

### 10b. The expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

### 10c. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

### 10d. A description of any reasonably foreseeable risks or discomforts to the participant.

### 10e. A description of any benefits to the subject or to others which may reasonably be expected from the research.

### 10f. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.

### 10g. An explanation of whom to contact for answers to pertinent questions, concerns, or complaints about the
Additional Comments and items to be addressed:

22b. If less than one year, specify time period:

22a. Based on the level of risk to subjects, can approval be granted for the maximum time period of one year?

22b. If less than one year, specify time period:

Additional Considerations for Continuing Review:

11. Are all of the appropriate additional/optimal elements provided in the consent process and in the documentation of the consent process, unless waived or altered? (If “no” indicate the element(s) that must be added before approval is granted)

a. A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable.

b. A statement that if the participant is or may become pregnant the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable.

c. Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.

d. Any additional costs to the participant that may result from participation in the research.

e. The consequences of a participant’s decision to withdraw from the research.

f. Procedures for orderly termination of participation by the participant.

g. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.

h. The approximate number of participants involved in the study.

i. The amount and schedule of all payments to the participant.

Additional Considerations for Continuing Review and Amendments

14. Based on study results to date, in comparison to those originally anticipated the relationship of benefits to risks is:

a. More Favorable

b. Unchanged

c. Less Favorable

15. Is there any information that has arisen that might reasonably affect the willingness of participants to continue to take part in the research and if so, will it be provided to those participants or should it be provided to them?

a. There are no significant new findings to notify participants about.

b. Findings have already been appropriately communicated to participants.

c. Findings exist but should not or cannot be communicated to participants.

d. Findings need to be communicated to participants. The protocol contains an appropriate plan for doing so.

e. Findings need to be communicated to participants. An appropriate plan for doing so must be submitted before approval can be recommended. (If “e” the research cannot be approved until addressed)

Additional Considerations for Amendments

16. Do any amendments/modifications represent “minor” modifications? (If “No” the renewal must reviewed by the full board).

17. Is the amendment/modification addressing an apparent immediate hazard to a research subject or study personnel? (If “Yes” the change represents a response to a Serious Event/Problem (SEP) and these changes must be accompanied by a SEP report).

18. Do all materials (e.g. protocol, informed consent documents, etc.) appropriately incorporate the proposed amendments/modifications? (If “No” the amendment cannot be approved as proposed).

Final Determinations

19. Rate the overall level of risk involved with this project: (If greater than minimal expedited review can not be used except to approve minor amendments or in specific cases).

20. The research should be:

1. Approved “as is”

2. Approved once specified changes are made

3. Reconsidered for approval once changes are made

4. Referred to the full board for determination

5. Disapproved

21. This study meets the criteria for expedited review under category(s): 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8a / 8b / 8c / 9 NA

22a. Based on the level of risk to subjects, can approval be granted for the maximum time period of one year?

22b. If less than one year, specify time period:

Additional Comments and items to be addressed:
**Guidelines for Review**

1. **Is the selection of participants equitable?**
   - Is the choice of participants appropriate for the question being asked?
   - Selection of the proposed study population(s) may not be solely based on their easy availability, compromised position, or susceptibility to manipulation.
   - If used, are inclusion and exclusion criteria clearly specified and appropriate?
   - Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research protocol? The research may not unduly involve individuals from populations unlikely to benefit from any subsequent beneficial applications of the research.
   - If the study is restricted to individual groups (children, vulnerable populations, gender) is this appropriate for this study and does the project description include proper procedures for protection of these participants?
   - If the study excludes individual groups (children, vulnerable populations, gender) is this appropriate for this study or is the prospect of a significant benefit being withheld by not allowing participation to be as broad as possible across various populations?
   - Are vulnerable populations specifically targeted for inclusion only when needed to answer the scientific hypothesis posed?

2. **Are methods of recruitment and participant selection (location, timing, personnel, screening, etc.) and their associated materials specified in the project description, appropriate for the study and non-coercive?**
   - Are recruitment materials and the methods for recruiting potential participants appropriate?
   - Are the location and timing of the recruitment process described and acceptable?
   - Is the individual performing the recruitment identified and appropriate for the process?
   - If necessary, are there acceptable methods for screening participants before recruitment?
   - If screening is used, is the process defined in the protocol and appropriate?

3. **Is compensation handled appropriately, non-coercive and adequate to avoid significant out-of-pocket expenses for participants unless this is justified?**
   - Is the amount or type of compensation or reimbursement reasonable?
   - Is there a reasonable plan to compensate persons who withdraw from the study before completion?
   - Are there adequate provisions to avoid out-of-pocket expenses by the research participant, or is there sufficient justification to allow participants to pay?
   - If children or adolescents are involved, is there a specification of who receives the compensation, and is this appropriate?

4. **When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, are additional safeguards included in the study to protect the rights and welfare of these participants?**
   - Are safeguards for vulnerable populations described, appropriate for the study and adequate for protecting the participants?
   - Is a specific vulnerable population the target of this study? Is this justified?
   - Is the inclusion of individuals from vulnerable populations who are not the specific target of the study justified? Have federal regulatory requirements been met?
   - If a vulnerable population is involved, are appropriate additional procedures and safeguards described and acceptable to address risks unique to that population?
   - Vulnerable subject populations are identified and adequately protected, and additional safeguards are provided where needed to protect subjects’ rights and welfare and minimize coercion or undue influence.
   - The informed consent process takes into account the potential compromised status of subjects in vulnerable populations.

5. **If pregnant women are to be included, does the study meet the requirements for the involvement of Pregnant Women, Human Fetuses, Neonates, or Fetal Materials in research as delineated in the Determinations for Inclusion of Pregnant Women, Fetuses and Neonates in Research? (If “No” or “NA” these subjects cannot be included)**
   - All studies involving Pregnant Women, Human Fetuses, Neonates, or Fetal Materials must meet the criteria in the Determinations for Inclusion of Pregnant Women, Fetuses and Neonates in Research.

6. **If prisoners are to be included, does the study meet the requirements for the involvement of Prisoners in research as delineated in the Determinations for Inclusion of Prisoners in Research? (If “No” or “NA” prisoners cannot be included)**
   - All studies involving Prisoners must meet the criteria in the Determinations for Inclusion of Prisoners in Research.

7. **If Children are to be included, does the study meet the requirements for the involvement of Children in research as delineated in the Determinations for Inclusion of Children in Research? (If “No” or “NA” children cannot be included)**
   - All studies involving Children must meet the criteria in the Determinations for Inclusion of Children in Research.
3. Does the process for obtaining consent incorporate all of the following (If "No" indicate the items that must be addressed before approval is granted):
   a. The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
   b. Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and to read any consent document before it is signed.
   c. Consent will be sought under circumstances that minimize the possibility of coercion or undue influence.
   d. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.

A. Is the consent process (written, oral, implied, waived) described, appropriate and adequate given the level of risk?
   • Are the individuals presenting information to and obtaining consent from the subject appropriate?
   • Is the location and manner of obtaining consent appropriate?
   • Who will provide consent or permission? Will consent be sought from each prospective participant or their legal representative? Where surrogates/legally authorized representatives will consent, the required additional safeguards are in place, including VAMC requirements where needed.
   • When will consent be obtained? Will there be a sufficient time period allowing participants to consider their options between presenting information to the subject and obtaining consent?
   • Does the consent process minimize the possibility of coercion or undue influence?

B. If participants are unable to give consent (e.g., children or mentally incompetent), is the permission/assent process described and the associated documentation provided and appropriate?
   a. When children are involved the requirements for the inclusion of children must be met. This includes specifics on the adequacy of the parental permission/assent processes. (see UB IRB Guide/Evaluation for the Inclusion of Children in Research).
   b. When other participants are unable to give consent, the guidelines for children should be used to ensure that the participants are adequately protected (see UB IRB Guide/Evaluation for Inclusion of Children in Research).
   c. Are assent procedures described and appropriate?
   d. Is an appropriate person asked to give permission?
   e. Are permission procedures described and appropriate?

3a. When the long form of documentation is used: (If "No" the research can not be approved)
   • The participant or the participant’s legally authorized representative will sign the consent document.
   • A copy of the consent document will be given to the person signing the consent document.

3b. When the short form of documentation is used: (If "No" the research can not be approved)
   • The consent document states that the elements of disclosure required by regulations had been presented orally to the participant or the participant’s legally authorized representative.
   • A written summary embodies the basic and appropriate additional elements of disclosure.
   • There will be a witness to the oral presentation who will sign the short form and a copy of the summary.
   • For participants who do not speak English, the witness is conversant in both English and the language of the participant.
   • The participant or the participant’s legally authorized representative will sign the consent document.
   • The person actually obtaining consent will sign a copy of the summary.
   • A copy of the summary and the short form will be given to the participant or the representative.

3c. If a waiver or alteration of the consent process (including the use of deception), or a waiver of written documentation of consent is requested, does the study qualify for the waiver as delineated in the Determinations for Consent Waivers in Research (If "No" the waiver cannot be granted)?
   A. If a waiver or alteration of the consent process (including the use of deception), or a waiver of written documentation of consent is requested, does the study qualify for the waiver as delineated in the UB IRB Guide/Evaluation for Waiver or Alteration of Consent and Waiver of Signed Documentation of Informed Consent in Research and is the waiver adequately justified in the project description?
B. If deception is employed or students are the primary participants is the procedure adequately described, an appropriate debriefing provided to minimize risks and educate participants, and has the deception and/or use of this participant group been adequately justified

- As deception is an alteration of the consent process, does the research meet with federal guidelines (As outlined in the Reviewer Guide for Consent waivers) for granting this waiver and is the waiver adequately justified in the project description?
- If participants are actively deceived in any way, is the deception described in the protocol and is the justification acceptable?
- If deception is used, does the protocol provide for a Debriefing Statement?
- If used, does the Debriefing Statement adequately describe and justify the use of deception and seek to minimize the potential costs to the participant of the deception?
- Does the debriefing statement include at least two references for use as educational materials?
- Generally, the employment of deception by an investigator(s) for the purpose of securing subject participation and/or to prevent potentially biased reporting of data/information by the subject is permissible provided all of the following conditions exist:
  a. Deception is necessary due to the lack of alternative procedures for data collection not involving deception.
  b. The deceptive procedures will not place subjects at significant financial, physical, legal, psychological, or social risk.
  c. The data collection/experiment will be followed by careful debriefing sessions whereby the subjects are fully informed of the nature and purpose of the deception or in rare instances where revealing the deception increases risk, the IRB has documented the need to waive debriefing.
  d. The procedures for deception meet the guidelines established by the discipline of the investigator through its professional code of ethics.

4. When appropriate, are there adequate provisions to **protect the privacy** of participants (If “No” the research cannot be approved)?

   A. Are adequate provisions described to protect the privacy of the research participants?

   - Privacy protection measures are adequate
   - If privacy is to be invaded, does the importance of the research justify the intrusion and any provision for informing the subject of the invasion of privacy?
   - Does any combination of data present the risk of subject identification?
   - Does the research will involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy?
   - Will subject identifiers be destroyed as soon as possible?
   - Any data to be retained in subject’s medical or other records is described and justified.
   - If investigators want to review existing records to select subjects for the project, how will this be accomplished?
   - Will access to the data be limited and how/to whom?

5. When appropriate, are there adequate provisions to **maintain the confidentiality of data** (If “No” the research cannot be approved)?

   A. Are adequate provisions described to assure the confidentiality of the research participants including storage, coding procedures, destruction of and methods of dealing with identifiable records (tapes, pictures, etc.)?

   - Are there alternatives to the proposed method of doing the research that would yield the same quality of results but lower the risks to confidentiality?
   - Are there adequate plans to store and code identifiable data to protect confidentiality?
   - Are the use of identifiers or links to identifiers necessary or could the data can be collected anonymously?
   - If identifiers or links to identifiers are used, are these adequately protected?
   - If audio or videotapes are produced, is the disposition of the tapes described adequately?
   - Will the data will be stored in a secure area and will electronic files will be coded or encrypted?
   - Disclosures to subjects about confidentiality are adequate and that the confidentiality of identifiable data will be maintained in accordance with agreement between investigators and participants.
   - Should documentation of consent be waived in order to protect subject confidentiality?
   - Should a Certificate of Confidentiality be considered to protect the identity of subjects from subpoena (in research where information obtained about subjects might interest law enforcement or other government agencies)?

6. Are risks to subjects minimized: (i) By using procedures which are consistent with **sound research design** and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (If “No” the research cannot be approved)?

   A. Are all reasonable physical, psychological, social, legal, employment or other risks to participants identified, minimized with appropriate safeguards and stated in both the project description and the consent forms?

   - Are risks (including physical, psychological, social, legal, or economic risks) adequately and consistently described and in both the protocol and the consent procedures?
   - Are risks appropriately minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?
   - Have the potential risks to subjects associated with the research, been distinguished from the risks of therapies the subjects would receive even if not participating in the research?

   B. Have potential adverse events and the minimization of their effects on participants been adequately and consistently considered and described in the project description and consent forms?

   - Are procedures for dealing with potential injury/illness due to research adequately described and appropriate for the range of adverse events that could occur?
UB SBSIRB Reviewer Guide/Evaluation for Protocols, Renewals and Amendments

7. **Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result (If “No” the research cannot be approved)***

A. **Is the purpose of the study clearly described, justified relative to risk and achievable given the scientific design?**
   - Are the objectives or hypotheses clearly specified and likely to be accomplished within the stated time period?
   - Are adequate background, preliminary data, and references provided/cited to justify the research?
   - Is there appropriate scientific justification for proceeding with this research study?
   - Is the scientific design described adequate to achieve the stated objective?
   - Is the rationale for the proposed number of participants provided and reasonable?

B. **Does research procedure information (including qualifications of study personnel, differentiation between research and standard care) adequately ensure participants’ safety and well being?**
   - Are the rationale and details of the research procedures including frequency and duration of participation adequately described and acceptable?
   - If standard interventions are involved, is there a clear differentiation between research/experimental procedures and standard methods of care and evaluation?
   - Are the individuals performing the procedures appropriately trained for performing procedures?
   - Are the facilities and resources available adequate to ensure participants safety and well being?
   - Are data collection/recording methods adequately explained?
   - When exclusionary criteria are necessary, are the procedures sufficient to prevent the enrollment of excluded subjects?
   - Is placebo appropriately utilized in this research?

C. **Are benefits adequately identified, evaluated, and maximized and is the risk/benefit ratio acceptable for proceeding with this research?**
   - Are Benefits well described?
   - Are the Risks reasonable in relation to potential benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result?
   - The IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
   - The IRB should not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

8. **When appropriate, does the research plan make adequate provision for monitoring the data collected to ensure the safety of participants and integrity of the data (If “No” the research cannot be approved)?**

A. **Are data analysis procedures adequate to ensure participant safety and achieve the scientific goal of the study?**
   - Are plans for data/statistical analysis defined, justified and adequate?
   - If warranted, specific stopping rules or triggers used to determine when the study should be stopped or altered are explained and sufficiently detailed.
   - Procedures for monitoring safety data are adequate to ensure the safety of participants (Required for greater than minimal risk research). These procedures may include:
     - The type of data or events that will be monitored
     - The frequency of review.
     - The individual(s) responsible for monitoring the plan and reporting any unanticipated problems involving risk to subjects or others/adverse events
     - The time frame for and responsible party to whom reports of unanticipated problems involving risks to subjects or others/adverse events are made.
     - What safety information will be collected, including serious adverse events.
     - How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
     - The frequency of data collection, including when safety data collection starts.
     - The frequency or periodicity of review of cumulative safety data.
     - The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the Sponsor.
     - For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB or EC needs to carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed.
     - If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring;
     - Provisions for the oversight of safety data (e.g., by a data monitoring committee).
     - Conditions that trigger an immediate suspension of the research, if applicable.

9. **If this is a multi-site research study, is the management of information that might be relevant to the protection of participants adequate (If "No" the research cannot be approved)?**
   - When UB is the coordinating center or the prime grant holder provisions for communicating risks and material protocol changes between sites are adequate.
   - Procedures for communicating the outcome of DSMP reviews to the IRB, the study sponsor, and others are adequate.

10. **Is the following information provided as part of the interaction with the participant and in the documentation of the consent process, unless waived or altered: (If “No” to any the research cannot be approved)**
A statement that the study involves research, and an explanation of the purposes of the research.

- Statement that the study involves research.
- Purpose of research stated in lay language.

The expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

- Expected duration of subject participation.
- The approximate number of subjects involved in the study (optional).
- Study design described that is appropriate to the level of disclosure justified by the protocol.
- Study procedures or treatments are described and experimental procedures identified.
- Statement that significant new findings will be disclosed (If applicable).

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

- For clinical trials, disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

A description of any reasonably foreseeable risks or discomforts to the participant.

- Risks or discomforts without disclaimers or waivers.
- An accurate and fair description of any reasonably foreseeable risks and discomforts to the subject.
- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable (Optional).

A description of any benefits to the subject or to others which may reasonably be expected from the research.

A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- A statement describing the possibility that the overseeing agencies such as OHRP the Food and Drug Administration and/or the Pharmaceutical Co. may inspect the records where applicable.
- Checks offs for identifiable information (tapes, pictures, quotes) are included and appropriate

An explanation of whom to contact for answers to pertinent questions, concerns, or complaints about the research (Researcher/faculty sponsor contact information). An explanation of whom to contact for answers to pertinent questions about the research participant’s rights and someone independent of the research team for problems, concerns, questions, information, or input (IRB contact information). An explanation of whom to contact in the event of a research-related injury to the participant.

- Information for researcher & faculty sponsor contact for questions about the research.
- Information for IRB contact for purpose of rights as a participant in research.
- Information for research related injury contact.

A statement that participation is voluntary, that the participant may discontinue participation at any time or refuse to participate and that these choices will involve no penalty or loss of benefits to which the participant is otherwise entitled.

Voluntary nature with no penalties or loss of benefits, withdrawal/termination methods and consequences.

- A statement regarding voluntary participation, (e.g. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled).
- The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (Optional).
- Anticipated circumstances under which a participant's participation may be terminated by the researcher or staff and policies relating termination to compensation (Optional).

For research involving more than minimal risk:

An explanation as to whether any compensation is available if injury occurs.

Compensation, Costs to the participants, Medical treatment for injuries available and further information (req. if > minimal risk)

- The amount of compensation, and whether payment will be made incrementally or paid in full upon completion.
- IF RISK IS GREATER THAN MINIMAL, an explanation as to whether any compensation or treatments are available if injury occurs and, if so, what they are or where further information may be obtained.

The informed consent does not include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights.

The informed consent does not release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

- Exculpatory language or other language indicating a waiver of rights/liability may not be present

Where applicable, the consent process informs participants about data retention at the time of withdrawal (Required for Clinical Trials)
Investigators should generally inform participants as a part of the consent process whether they intend to either:

i. Retain and analyze already collected data relating to the subject up to the time of subject withdrawal or the subject’s data from any analysis.

ii. Honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.

With regard to data retention when participants withdraw from a clinical trial the following procedures must be followed and the IRB will ensure as a part of its review that:

- When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
- A Researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant’s information.
- The Researcher must obtain the participant’s consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB or EC must approve the consent document.
- If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the Researcher must not access for purposes related to the study the participant’s medical record or other confidential records requiring the participant’s consent. However, a Researcher may review study data related to the participant collected prior to the participant’s withdrawal from the study, and may consult public records, such as those establishing survival status.

11. Are all of the appropriate additional optional elements provided in the consent process and in the documentation of the consent process, unless waived or altered? (If “no” indicate the element(s) that must be added before approval is granted)
   a. A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable.
   b. A statement that if the participant is or may become pregnant the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable.
   c. Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.
   d. Any additional costs to the participant that may result from participation in the research.
   e. The consequences of a participant’s decision to withdraw from the research.
   f. Procedures for orderly termination of participation by the participant.
   g. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.
   h. The approximate number of participants involved in the study.
   i. The amount and schedule of all payments to the participant.

Typically for the SBSIRB the following are applicable:

<table>
<thead>
<tr>
<th>Provided in most cases</th>
<th>Provided in cases where there is compensation offered or additional costs</th>
<th>Provided in most treatment protocols where applicable</th>
<th>Provided in cases where screening is utilized and some treatment protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>h, e, f</td>
<td>d, i</td>
<td>a, b, g</td>
<td>c</td>
</tr>
</tbody>
</table>

Should any additional optional elements be provided in the consent form?

- Identification of the sponsor in sponsor-initiated studies
- A disclosure statement if the Investigator is being directly compensated for conducting the study or has a significant financial conflict of interest
- If subjects are being followed for survival, the consent form must indicate the investigator’s intent to do so
- If blood samples will be drawn, information regarding the amount of blood that will be drawn
- If material such as tumor tissue, bone marrow, blood, etc. will be turned into a commercial product, subjects should also be informed that they may not benefit from the development of the commercial product
- The amount of compensation, and whether payment will be made incrementally or paid in full upon completion.
- Any additional costs to the subject that may result from participation in the research (When Applicable).
- When applicable, subjects should be informed that compensation of $600 or more paid to them within one calendar year is required to be reported to the IRS
- For student participants when course credit is offered as a form of compensation, alternatives to study participation are presented.

12. Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review (If “Yes” please indicate in your comments the reason for needing the verification and suggest a method for obtaining the verification so that it can occur before the renewal is approved)?

Projects requiring this verification may include:

- Complex projects involving unusual levels or types of risks to subjects, or
- Projects involving vulnerable populations, or
- Projects conducted by an investigator who previously failed to comply with IRB determinations, or
- Projects where the continuing review application or reports from other sources have indicated that changes may have occurred without IRB approval.

13. Is the consent document/process accurate and complete? (If “No” the research cannot be approved)
14. Based on study results to date, in comparison to those originally anticipated the relationship of benefits to risks is:
   a. More Favorable
   b. Unchanged
   c. Less Favorable (If “c” then full board review should be requested)

15. Is there any information that has arisen that might reasonably affect the willingness of participants to continue to take part in the research and if so, will it be provided to those participants or should it be provided to them?
   a. There are no significant new findings to notify participants about
   b. Findings have already been appropriately communicated to participants
   c. Findings exist but should not or cannot be communicated to participants
   d. Findings need to be communicated to participants. The protocol contains an appropriate plan for doing so.
   e. Findings need to be communicated to participants. An appropriate plan for doing so must be submitted before approval can be recommended. (If “e” the research cannot be approved until addressed)

16. Do any amendments/modifications represent “minor” modifications? (If “No” the renewal must reviewed by the full board)
   A minor amendment/modification is defined as a change that would not affect an assessment of the risk and benefits of the project nor substantially change the specific aims or design of the study. Examples of minor amendments/modifications may include:
   - An increase/decrease in proposed enrollment supported by a statistical justification
   - Changing the inclusion or exclusion criteria where risks do not increase
   - Alterations in payment or liberalization of payment schedule with proper justification
   - Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement
   - The addition/deletion of qualified investigators/research personnel or study sites
   A major amendment/modification is defined as any change which materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of major amendments/modifications may include:
   - Changing the inclusion or exclusion criteria such that it increases risk
   - Alterations in the dosage or route of administration of an administered drug
   - Extending substantially the duration of exposure to the test material or intervention
   - The deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations
   - A project change in response to an unanticipated problem or adverse events involving risks to subjects or others
   - Changes which, in the opinion of the IRB Chair or designee, do not meet the criteria or intent of a minor modification

17. Is the amendment/modification addressing an apparent immediate hazard to a research subject or study personnel? (If “Yes” the change represents a response to a Serious Event/Problem (SEP) and these changes must be accompanied by an SEP report)

Any proposed amendment/modification to an IRB-approved research protocol or consent document must be approved by the IRB prior to implementation. Any amendment/modification not prospectively approved by the IRB is considered a protocol violation and must be reported to the IRB. The only exception to this requirement is a change in procedure that may be necessary to eliminate an apparent immediate hazard to a research subject or study personnel.

18. Do all materials (e.g. protocol, informed consent documents, etc.) appropriately incorporate the proposed amendments/modifications? (If “No” the amendment cannot be approved as proposed)

19. Rate the overall level of risk involved with this project: (if greater than minimal expedited review can not be used except to approve minor amendments or in specific cases) No greater than minimal / Greater than minimal

   Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

20. The research should be:
   1. Approved “as is”
   2. Approved once specified changes are made
   3. Reconsidered for approval once changes are made
   4. Referred to the full board for determination
   5. Disapproved

   1. Approved “as is”
      a. Should be used only when all items are adequately addressed and no changes are requested
      b. May be used to indicate a recommendation for expedited or full board approval.
   2. Approved once specified changes are made
      a. There remain items to address or changes are requested but if your requests are adhered to the protocol will be approvable.
      b. May be used to indicate a recommendation for expedited or full board approval.
   3. Reconsidered for approval once changes are made
      a. There remain items to be addressed and the requested changes are substantive. Further review will be needed before a determination can be made.
      b. May be used for expedited or full board review.
   4. Referred to the full board for determination
      a. There remain items to be addressed and the requested changes are substantive. Further review by the full board will be needed before a determination can be made.
   5. Disapproved
      a. The recommendation is that the proposal cannot be approved in its present form.
      b. If this is the recommendation of an expedited reviewer, the protocol will be referred to the full board.
22a. Based on the level of risk to subjects, can approval be granted for the maximum time period of one year?

22b. If less than one year, specify time period:

Based on the level of risk to subjects, may approval be granted for the maximum time period of one year?

Examples of when the IRB might consider review more frequently than annually may include:

a) Experimental therapies in which the clear potential for significant adverse experiences have been identified at the time of review; or

b) Non-therapeutic projects based on risk information provided at the time of initial review; or
c) Projects in which new information provided during the duration of the study (including at the time of continuing review) indicates a high probability of significant adverse experiences not previously reported; or
d) Projects in which local or outside adverse experience reports create new concerns regarding the need for closer project scrutiny; or
e) Projects where the UB IRB has concerns with regard to previous or potential serious or continuing noncompliance; or
f) Other, as determined by the convened IRB.

In such cases, the IRB may consider granting approval for time periods less than one year, or for a limited number of subjects over a period not to exceed one year, or additional monitoring can be required.