Criteria for Approval Tool for IRB Reviewers

Principal Investigator: 

Protocol Title: 

Review Process: □ Convened □ Expedited

Review Type: □ New □ Continuing □ Modification

Scientific and Scholarly Validity

Necessary Resources

Risk-Benefit Ratio

• Physical, psychological, social, legal, and economic risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
  o Would an alternative scientific design reduce the likelihood or magnitude of harm but still answer the scientific question?
  o Would alternative procedures reduce the likelihood or magnitude of harm but still answer the scientific question?
  o Would an alternative participant population reduce the likelihood or magnitude of harm but still answer the scientific question?
  o Would the use of fewer procedures answer the scientific question?
  o Would the enrollment of fewer participants answer the scientific question?
  o Are the research staff members qualified to conduct the procedures?
  o Does the investigator have adequate numbers of qualified staff?
  o Does the investigator have adequate facilities to conduct the research?
  o Does the investigator have a process to ensure that persons assisting with the research are adequately informed about the protocol and their research-related duties and functions?
  o Are medical or psychological resources available that participants might require as a consequence of the research?

• Physical, psychological, social, legal, and economic risks to participants are minimized, when appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
  o Are procedures that will answer the scientific question being done anyway?
  o If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm?

• Under the criterion “risk to subjects are reasonable in relationship to the anticipated benefits, if any, and the importance of the knowledge reasonably expected to result”, does the investigator have:
  o Access to a population that would allow recruitment of the necessary number of participants?
  o Sufficient time to conduct and complete the research?

• Physical, psychological, social, legal, and economic 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.
  o Does the investigator have access to a population that will allow recruitment of the necessary number of participants?
  o Does the investigator have sufficient time to conduct and complete the research?
  o Is the research feasible?
  o Is the research likely to answer its proposed question?
  o Does the knowledge expected to result have importance?
Devices (IDE, HDE)
• If the research involves devices, is the storage, control, and dispensing of the investigational device appropriate so that it will only be used by authorized investigators and on subjects?

Eligibility for Initial Expedited Review
• The research involves no more than minimal risk.
• The research is not classified research.
• The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
• The research falls into one or more of the seven categories allowing initial review using the expedited procedure.

Data Safety Monitoring
• The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. (Not applicable if the research involves no more than minimal risk.)
  o Who will monitor the data?
  o What data will be monitored?
  o How frequently will data be monitored?
  o What analyses will be performed on the data?
  o What decision rules (e.g., stopping rules) will be considered?
  o Will unexpected harms be detected promptly?
  o Will an increased frequency or severity of unexpected harms be detected promptly?
  o Will the protocol be stopped once benefits are proven to outweigh harms?
  o Will the protocol be stopped once harms are proven to outweigh benefits?

Vulnerable Populations
• Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence. (Not applicable if the research does not involves participants likely to be vulnerable to coercion or undue influence.)

Equitable Participant Selection
• Selection of participants is equitable.
  o The purpose of the research.
  o The setting in which the research will be conducted.
  o The involvement of populations vulnerable to coercion or undue influence.
  o Inclusion and exclusion criteria.
  o Recruitment and payment methods.

Participants' Privacy
• There are adequate provisions to protect the privacy of participants.
  o Will participants have an expectation of privacy?
  o Will participants think that the information sought is any of the researcher’s business?
  o Will participants be comfortable in the research setting?
  o Will participants be comfortable with the research procedures?
Confidentiality

- There are adequate provisions to maintain the confidentiality of the data.
  - Will confidentiality be pledged?
  - Are there legal/ethical requirements?
  - Will data release cause risk of harm?
  - Are appropriate techniques being used to protect confidentiality?
    - Inter-file linkage.
    - Error inoculation.
    - Statistical strategies.
    - Top coding.
    - Restricted public use data.
    - Restricted access, enclaves, archives.
    - Certificates of Confidentiality.
    - Ethical editing of qualitative descriptions.
    - Data brokering.

Consent Process

- The investigator will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative.
  - Has the investigator indicated whether consent will be obtained from the participant, from a legally authorized representative, or both?
  - If a legally authorized representative will be used, do the individuals meet the regulatory definition?
  - Will the participants or legally authorized representatives appreciate the implications of decision?
  - Will the participants or legally authorized representatives be able to decide?
  - Will the participants or legally authorized representatives be able to communicate a decision?
- The circumstances of consent provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate.
  - How much time will be devoted to the consent discussion?
  - How much time will be allowed for a decision?
  - The circumstances of consent minimize the possibility of coercion or undue influence.
  - Is there a power differential?
  - Are there communication issues?
  - Are there issues regarding the capacity to make a decision?
  - Are there excessive motivating factors?
  - Is the recruitment process acceptable?
  - Are advertisements acceptable?
  - Are payment arrangements acceptable?
- The information that will be given to the participant or the legally authorized representative will be in language understandable to the participant or the representative.
  - What language do the participants or legally authorized representatives speak?
  - Can the research team communicate in understandable language to the participants or legally authorized representatives?
  - Will written information be in the language understandable to the participants or legally authorized representatives?
- No information will be provided to the participant or the legally authorized representative that waives or appears to waive any of the participant’s legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
  - Is the information factual (e.g., the policy, plan, expectation, or law)?
  - Does the information avoid stating an outcome (e.g., something will or will not happen)?
- All required elements of disclosure will be provided to participants.
Consent Process

- Additional elements of consent disclosure, if appropriate, will be provided to participants. For example:
  - A statement that the particular treatment or procedure might involve risks to the participant, which were currently unforeseeable. For example, applicable if the research involves unapproved drugs or devices or involves procedures whose risk profile is not well known.
  - 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. For example, applicable if the research includes pregnant women or women of child bearing potential and involves procedures in the drugs or devices whose risk profile in pregnancy is not well known.
  - Anticipated circumstances under which the participant’s participation might be terminated by the investigator without regard to the participant’s consent. For example, applicable if there are circumstances under which the participant’s participation might be terminated by the investigator without regard to the participant’s consent.
  - Any additional costs to the participant that might result from participation in the research. For example, applicable if the participant might experience any additional costs.
  - The consequences of a participant’s decision to withdraw from the research. For example, applicable if there are adverse consequences to withdraw.
  - Procedures for orderly termination of participation by the participant. For example, applicable if the protocol describes procedures for orderly termination.
  - A statement that significant new findings developed during the course of the research which might relate to the participant’s willingness to continue participation would be provided to the participant. For example, applicable if such new findings are likely to occur during the course of the study.
  - The approximate number of participants involved in the study. For example, applicable if this information might be relevant to a participant’s decision to take part in the research.

- The investigator will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative.
  - Has the investigator indicated whether consent will be obtained from the participant, from a legally authorized representative, or both?
  - If a legally authorized representative will be used, do the individuals meet the regulatory definition?
  - Will the participants or legally authorized representatives appreciate the implications of decision?
  - Will the participants or legally authorized representatives be able to decide?
  - Will the participants or legally authorized representatives be able to communicate a decision?

- The circumstances of consent provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate.
  - How much time will be devoted to the consent discussion?
  - How much time will be allowed for a decision?
  - The circumstances of consent minimize the possibility of coercion or undue influence.
  - Is there a power differential?
  - Are there communication issues?
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Consent Process

- No information will be provided to the participant or the legally authorized representative that waives or appears to waive any of the participant’s legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
  - Is the information factual (e.g., the policy, plan, expectation, or law)?
  - Does the information avoid stating an outcome (e.g., something will or will not happen)?

Documenting Consent

- For the long form of consent documentation:
  - The consent document embodies the basic and appropriate additional elements of disclosure. (See Elements of Informed Consent Disclosure)
  - The participant or the participant’s legally authorized representative will sign and date the consent document.
  - A copy of the signed and dated consent document will be given to the person signing the consent document.
  - The investigator will give either the participant or the legally authorized representative adequate opportunity to read the consent document before it is signed.

- For the short form of consent documentation:
  - 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.
  - 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 and date the consent document.
  - The witness will sign both the short form and a copy of the summary.
  - The person actually obtaining consent will sign a copy of the summary.
  - A copy of the signed and dated short form will be given to the participant or the representative.
  - A copy of the summary will be given to the participant or the representative.

Multi-site Studies

- Is the investigator is the lead investigator of a multi-site study or is UAB the lead site in a multi-site study?
  - If yes, is the plan for the management of information obtained in multi-site research that might be relevant to the protection of participants adequate to protect participants?

Renewal Period (Expedited/Convened)

- Should the approval period be one year or more frequent?

Continuing Review

- Is the consent document accurate and complete?
- Does the protocol need verification from sources other than the investigators that no material changes had occurred since previous IRB review?
- Will any significant new findings that might relate to subjects’ willingness to continue participation be provided to them?
Eligibility for Continuing Expedited Review

- The research involves no more than minimal risk (does not apply to category (8)(b)).
- The research is not classified research.
- The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal (does not apply to category (8)(b))
- The research falls into one or more of the nine categories allowing continuing review using the expedited procedure.

 Modifications

- Will any significant new findings that might relate to participants’ willingness to continue participation be provided to them?
Elements of Consent

- Version Date
- Page Numbers
- Initials
- Explanation Of Procedures
- Risks & Discomforts
- Childbearing Discussed
- Benefits
- Alternatives
- Confidentiality
- MSO Compliance Billing
- UAB
- TCHA
- Medical Records Language
- Withdrawal
- New Findings with Heading
- Costs of Research
- Costs of Standard Medical Care

Payment for Participation
UAB Injury Statement
Sponsor Injury Statement
Sponsor Verification
Name & Number (Research/Injury)
Name & Number (Participant’s Rights)
Legal Rights
Specimen Storage/Signature Lines
Signatures (Part/Witness/PI)
LAR Needed
Assent of Child/Waiver of Assent
Assent Not Applicable
HIPAA

Notes:

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