Please refer to this checklist as necessary when reviewing amendments and revision.

If the amendment proposes changes that impact risks and benefits:

<table>
<thead>
<tr>
<th>Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.</th>
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</thead>
<tbody>
<tr>
<td>Risks are minimized by using procedures which are consistent with sound research design and which do not expose subjects to unnecessary risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.</td>
</tr>
<tr>
<td>Where the investigator conducting the research under review is seeking funding from the federal government or other extramural funding agency, the IRB may depend on the rigorous review by the agency’s peer review process.</td>
</tr>
<tr>
<td>Determine that the importance of the scientific question is sufficient to merit inclusion of human subjects.</td>
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<th>Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.</th>
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<tr>
<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.</td>
</tr>
<tr>
<td>• Consider physical, psychological, social, legal, and economic risks. Are the risks and benefits adequately described?</td>
</tr>
<tr>
<td>• Does the investigator have access to a population that will allow recruitment of the necessary number of participants?</td>
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<tr>
<td>• Does the investigator have sufficient time to conduct and complete the research?</td>
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<tr>
<td>• Is the research and timeline for completion feasible?</td>
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<tr>
<td>• Does the knowledge expected to result have importance?</td>
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<tr>
<td>• Are there adequate plans to notify the subjects about the research results (clinical issues, suicidal, referrals)?</td>
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<th>Adequate Resources.</th>
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<tr>
<td>• Will the investigator have access to a population that will allow recruitment of the required number of subjects?</td>
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<tr>
<td>• Will the investigator have adequate numbers of qualified staff?</td>
</tr>
<tr>
<td>• Will the investigator have adequate facilities?</td>
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<tr>
<td>• Availability of medical or psychological resources that participants might need as a consequence of the research?</td>
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<tr>
<td>• Sufficient time to conduct and complete the research?</td>
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If the amendment proposes changes that impact eligibility/exclusion or recruitment procedures:

<table>
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<th>Selection of participants is equitable.</th>
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<tr>
<td>The IRB should also take into account:</td>
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<tr>
<td>• The purposes of the research.</td>
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<tr>
<td>• The setting in which the research would be conducted.</td>
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<tr>
<td>• Whether prospective participants would be vulnerable to coercion or undue influence.</td>
</tr>
<tr>
<td>• The inclusion/exclusion criteria.</td>
</tr>
<tr>
<td>• Participant recruitment and enrollment procedures.</td>
</tr>
<tr>
<td>• The influence of payments to participant</td>
</tr>
<tr>
<td>Who will be enrolled? Pregnant women? Children? Prisoners? Decisionally impaired? Economically or educationally disadvantaged persons? Are these subjects appropriate for the protocol? What is the rationale for inclusion/exclusion?</td>
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<tr>
<th>Recruitment procedures are appropriate</th>
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<tr>
<td>• Are the setting, location and timing of recruitment appropriate for the research being conducted?</td>
</tr>
<tr>
<td>• Are recruitment methods well defined and appropriate for the population?</td>
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</table>
- Are all recruitment materials non coercive, and easily understood?

If Amendment proposes changes that impact how the research and data are collected, analyzed or monitored:

**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.)*

- Does the protocol adequately specify:
  - Who will monitor the data?
  - What data will be monitored?
  - How frequently will data be monitored?
  - What analyses will be performed on the data?
  - What decision rules (e.g., stopping rules) will be considered?
- Is there a plan to promptly detect unexpected harms or an increase in frequency or severity of harms?
- Is there an adequate plan to stop the protocol if benefits are proven to outweigh harms or harms are proven to outweigh benefits?

If Amendment proposes changes that impact respect for privacy and maintenance of confidentiality:

**There are adequate provisions to protect the privacy of participants.**

- Will participants have an expectation of privacy?
- Will participants think that the information sought is by the investigator is appropriate?
- Will participants be comfortable in the research setting?
- Are there adequate provisions to consider and assure the privacy of the subject?

**There are adequate provisions to maintain the confidentiality of the data.**

- Are there adequate provisions to protect the confidentiality of the data?
- Are there legal/ethical requirements to breach confidentiality and is this well described and addressed?
- Will data release cause risk of harm?
- Are appropriate techniques being used to protect confidentiality (storage, coding, use of identifiers)?
- Does the protocol and consent specify where the data and consent form will be stored?

If the amendment proposes changes that impact involvement of vulnerable subjects:

- Have additional safeguards been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence?
- If the research involves other vulnerable populations, do additional safeguards remain appropriate?

If the Amendment proposes changes that impact informed consent:

**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?
- Are steps taken to help the participants or representatives understand the facts?
- Are adequate steps taken to help the participants or representatives understand the research and associated ramifications?
- Does the investigator adequately address how he/she will determine that a subject understands the research prior to providing consent/assent?
The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.

- Is adequate time devoted to the consent discussion and decision making process?
- Do the circumstances of consent minimize the possibility of coercion or undue influence?
- Have all issues regarding the capacity to make a decision been addressed?

The circumstances of consent minimize the possibility of coercion or undue influence.

- Are consent procedures well defined?
- Are there excessive motivating factors?
- Are the timing, location and setting of obtaining consent acceptable?
- Are payment arrangements acceptable?
- If study procedures are not complete or a subject withdraws is there any pro-rating of compensation?

The information that will be given to the participant or the representative will be in language understandable to the participant or the representative.

- What language do the participants or representatives speak?
- Can the research team communicate in understandable language to the participants or representatives?
- Will written information be in the language understandable to the participants or representatives?

No information will be provided to the participant or the 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.

All required and appropriate additional disclosures will be provided to the participant or the participant’s Representative. The consent document embodies the basic and appropriate additional elements of disclosure.

The participant or the participant's legally authorized representative will sign (and date for FDA-regulated research) the consent document.
A copy of the consent document will be given to the person signing the consent document.
The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

If the Amendment proposes a new or changes a alteration or waiver of consent process:

One of the criteria must be met:

- The consent form would be the only record linking the subject with the research, and a potential risk would be a breach in confidentiality. In such case, each subject should be asked if they want documentation and their wishes would govern (cannot apply to FDA regulated research); or,
- Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

And the following apply to both sets of waiver criteria

- If informed consent documentation is waived, consider whether subjects should be provided with a written statement regarding the research?
- If written statement is required, is the statement appropriate and can it be approved?

If the Amendment involves a new or change in waiver of written documentation, the following criteria need to be met:

- The research involves no more than minimal risk to the subjects;
- The waiver/alternation will not adversely affect the rights and welfare of the subjects;
• The research could not practicably be carried out without the waiver or alteration, and
• When appropriate, the subject will be provided with pertinent information after participation.
• The research is not FDA-regulated.

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<th>If the Amendment involves a new or change to a short form of consent:</th>
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• 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 for FDA-regulated research) 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 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.

<table>
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<th>Other considerations for amendments and revisions:</th>
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• If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?