REQUEST FOR AMENDMENT APPROVAL

If any significant changes occur to the initial protocol reviewed by the ERB, the ERB should be informed and asked for approval. A review may be initiated on the amended protocol if warranted. This form should be duly filled out and submitted together with the amended protocol.

PROTOCOL ID:

PROTOCOL TITLE:

PI NAME:

MEDICAL DIRECTOR NAME:

EXPECTED STUDY PERIOD:

Please provide the information in the table below (indicate if not applicable)

<table>
<thead>
<tr>
<th>Changes</th>
<th>Justifications</th>
<th>Implications of the changes</th>
<th>Page number in amended protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>On study participants</td>
<td>On study outcomes</td>
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</table>

4. Has the amended protocol been submitted to or approved by National/ Local Ethics Review Committee(s)?
   If not yet submitted, please indicate when and to which committee the protocol will be submitted. Please furnish the ERB a copy of the local ethics board approval.