Expired Study Continuation Request Form

DIRECTIONS FOR USE OF THIS TEMPLATE:

- Replace bracketed items on the title page, such as “[Insert Date]” with the requested information.
- Delete all directions written in italics, such as this section. Instructions in red font should be replaced or deleted.
- Complete as applicable for your project and then delete the template guidelines.
- Submit the completed form to the following individuals:

  **Non-VA Studies:**
  - Gerald.Treiman@va.gov
  - Ann.Johnson@hsc.utah.edu

  **VA Studies:**
  - Gerald.Treiman@va.gov
  - Ann.Johnson@hsc.utah.edu
  - John.Hoidal@va.gov
  - Laurence.Meyer@va.gov
  - Caroline.KallesPhinney@va.gov
  - Holly.Cannon@va.gov
  - Ruben.Harnandez5@va.gov
  - Suzanne.Plumb@va.gov

  This form CANNOT be used to re-open a study that was closed due to expiration. If you wish to re-open a closed study, you must submit a new study application to the IRB.

[Insert Date]

The following study has expired IRB approval and research-related activities have been halted:

**IRB Number:** <<Insert IRB Number>>

**Study Title:** <<Insert Study Title>>

This study involves procedures that if stopped could harm the currently enrolled research participants. The procedures that must continue during the expiration period are:

<table>
<thead>
<tr>
<th>Procedure Description</th>
<th>Risks to Participants If Procedure is Halted</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;&lt;List each procedure&gt;&gt;</td>
<td>&lt;&lt;List associated risks to participants if procedure is stopped during expiration period&gt;&gt;</td>
</tr>
</tbody>
</table>

<<Describe the procedures and risks to participants if procedures are halted>>. Currently, <<insert total number of enrolled participants enrolled at Utah>> are enrolled in this study at Utah. Of these, <<insert number of participants who will require treatment during the expiration period>> will require some or all of the procedures described above. The next procedure is scheduled <<insert date of first procedure that will occur during the expiration period>>.
This is a request to continue research-related activity for these participants in order to avoid jeopardizing the safety or well-being of the participants. Research-related procedures for these participants will **not** resume until the IRB gives notice that an exception can be made or full IRB approval is obtained.

**FOR VA STUDIES ONLY:**
*Delete this section if this study does not enroll VA participants*

This study involves VA participants. The following VA participants may be harmed if research activities are stopped: **Enter as many rows as needed for the study.**

<table>
<thead>
<tr>
<th>Participant Initials</th>
<th>Enrollment Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

Thank you,
[Insert PI Name]
[Insert PI contact information]