**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:* | *VA Studies:* |
| *Mark.Eliason@hsc.utah.edu**Richard.Lemons@imail2.org**Ann.Johnson@hsc.utah.edu* | *Mark.Eliason@hsc.utah.edu**Richard.Lemons@imail2.org**Ann.Johnson@hsc.utah.edu**Caroline.Phinney@va.gov**Holly.Cannon@va.gov**Ruben.Harnandez5@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:

|  |  |
| --- | --- |
| **Procedure Description** | **Risks to Participants if Procedure is Halted** |
| <<List each procedure>> | <<List associated risks to participants if procedure is stopped during expiration period.>> |

Currently, *<<insert total number of 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.*

|  |  |
| --- | --- |
| **Participant Initials** | **Enrollment Date** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

Thank you,

[Insert PI Name]
[Insert PI contact information]