**REQUESTING PERMISSION TO TREAT** **PREVIOUSLY ENROLLED SUBJECTS**

**DURING A LAPSE IN IRB APPROVAL**

**IRB #**:  **Principal Investigator**:

**Study Title**:

1) Explain why continuing to treat already enrolled subjects during the lapse is in the **best interest** **of the subject**:

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| ***Response*:** |

2) Identify the specific activities for which approval is sought:

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| ***Response***: |

3) Confirm that approval for continuation\* is in the process of being obtained:

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| ***Response***: |

4) Provide a brief explanation of why the lapse occurred:

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| ***Response***: |

5) Provide a brief explanation for preventing subsequent lapses:

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| ***Response***: |

6) Confirm that all study team members are aware that no new subjects are to be enrolled during the lapse:

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| ***Response***: |

**Signature of PI and Date\*\*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*or, after the revised version of 45 CFR 46 takes effect, a modification to extend the expected completion date of an expedited project if continuing review is not required

**\*\***If submitted by e-mail directly from PI, or as attachment in iRIS with the submission signed by the PI, signature and date on this form are not required.

**DIRECTION TO IRB STAFF:** If not done within IRIS through the submission process, the email, form and decision of Chair, are to be converted to PDF file and uploaded to the Review Board Internal Documents section of the study.