**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**CONTINUING REVIEW FORM**

**Please complete: CPHS# PI:**

**Study Title:**

* **Verify that the information on the basic information screens is accurate. You can access this by clicking on the View Study tab within the study.**
* **If you discover you need to request a modification at this time and have not selected "Modification and Continuing" Review, please submit a separate Modification after you complete this continuing review.**
* **Please note:** 
  + **All problems that require prompt reporting to the IRB should be reported to CPHS through the Reportable New Information tab. Problems that require reporting are outlined in the CPHS Memos found** [**here**](http://www.dartmouth.edu/~cphs/policies/)**.**
  + **The term "local" on this form refers to CPHS-reviewed sites.**

1. **If any of the following items were not checked in question #4 of the Continuing Review page in Rapport, or as appropriate, please provide information as requested below:**
   * Subjects experienced harm (expected or unexpected)

- Ata local site(s):  Yes  No or  Only at sites that do not include the local site(s)

Please explain why you have reported that subjects have experienced harm.

Local information: Has each incident been reported to the CPHS office, if appropriate?

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* + Subjects withdrew from the study

- Ata local site(s):  Yes  No

Local information: Provide the number of subjects who withdrew, a brief reason(s) for the withdrawal, and comment whether this number is higher than the projected rate of withdrawal.

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* + Unanticipated problems involving risks to subjects or others occurred

- Ata local site(s):  Yes  No

Please explain why you have reported unanticipated problems involving risks?

Local information: Has each incident been reported to the CPHS office, if appropriate?

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* + Multi-center trial reports:

Summarize the reports here, or upload to the **Continuing Review** page, question #5.

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* + Data safety monitoring reports:

Upload to the **Continuing Review** page, question #5.

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* + Regulatory actions that could affect safety and risk assessments:

Describe the regulatory actions that could affect safety and risk assessments.

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* + Other relevant information regarding this study, especially information about risks:

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* + In the opinion of the PI, have the risks or potential benefits changed?  Yes  No

If yes, please explain:

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1. **In reasonable detail, provide a synopsis of the study activities to date, both overall and at local sites. For example, is the study progressing as planned?** If no formal progress report is available, please discuss any available interim study results, whether enrollment goals have been met, reasons for funding changes, etc.

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1. **Please add a list of publications, abstracts, and or poster information from the past year, if any. If available, please upload documents to Rapport under the supporting documents tab in the Continuing Review.**

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**Optional: Use the space below to provide a list of specific items to be named on the Continuing Review letter:**

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