**Dartmouth College and Dartmouth-Hitchcock Medical Center**

**Committee for the Protection of Human Subjects**

**Application to Defer Review to an External IRB**

Template v. 10/14/2013

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| **Investigator Responsibilities**When review by an external IRB is accepted, the local investigator is required to:* Notify the CPHS when the local PI has changed.
* Send the CPHS notifications from the reviewing IRB when study enrollment has been suspended or the study can be locally terminated.
* Send the CPHS any local serious adverse event (SAE) or unanticipated problems involving risks to subjects or others (UPR) reports. Because they will also need to be reported to the reviewing IRB, you may send SAEs or UPRs to the CPHS on the forms required by the reviewing IRB
* Meet PI responsibilities per the IRB Authorization Agreement, and comply with all requests from the reviewing IRB.
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**I. Study Information**

Local PI name and email:

Section: Department:

Local Co-Investigators:

Local Contact Person name and email:

Study Title:

Funding Source:

External IRB:

Participating sites under CPHS review:

Note: studies enrolling participants at the VA are not eligible for external IRB review.

[ ] Each key personnel has completed the CPHS education requirements.

 ([http://www.dartmouth.edu/cphs/tosubmit/education/index.html](http://www.dartmouth.edu/~cphs/tosubmit/education/index.html))

Please briefly describe the local PI’s role in this study:

 **II. Documentation**

Enclose the following documents:

 [ ] Protocol

[ ] Model Consent Form (*Note: if this study has already been approved by the external IRB, please submit the current, approved version)*

 [ ] Commercial or external IRB approval letter

 [ ] Minutes from the IRB meeting at which this study was initially approved (upon request)

[ ] Departmental Scientific review. *(If the study has already received scientific review, for example, by a cooperative group, local scientific review is not required.)*

**III. Conflict of Interest Review:**

*Dartmouth College, Dartmouth-Hitchcock Clinic, Mary Hitchcock Memorial Hospital, and the Hitchcock Foundation have adopted a policy on Conflict of Interest that applies to each study reviewed by the CPHS. Copies of the policy are available on the CPHS web site at* [*http://www.dartmouth.edu/cphs/policies/*](http://www.dartmouth.edu/~cphs/policies/)*.*

Does any key personnel have a significant financial relationship related to this research?

 [ ] Yes [ ] No

If yes, list the name of the individual(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has this individual(s) completed / updated an Annual Disclosure Form within the past year?

[ ] Yes [ ] No

If not yet completed, the individual must complete the CPHS disclosure form found at: [http://www.dartmouth.edu/cphs/tosubmit/forms/](http://www.dartmouth.edu/~cphs/tosubmit/forms/)

**IV. Future Notifications:**

To notify the CPHS that the local PI has changed, study enrollment has been suspended or the study can be terminated locally, please send an email to CPHS.Tasks@Dartmouth.edu. Be sure to reference the CPHS number and study title, and attach any relevant documentation.

**V. Signatures**

Electronic versions of this signed form are acceptable. Please e-mail to CPHS.Tasks@Dartmouth.edu.

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Investigator Signature Printed Name Date

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Department Chairperson or Designee Signature Printed Name Date

This signature certifies that I have reviewed this study and determined that we have adequate resources to conduct this research, and that the study has scientific merit.