PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

ClinicalTrials.gov Registration and Reporting Designation Letter

The clinical trial entitled:
Click to type Protocol Title

(the "Trial") has been identified as a study for which registration and reporting of results is required on ClinicalTrials.gov. This document serves as notice that Click to type Partners Institution has designated the Principal Investigator, Click to type PI Name , of the Trial as the "Responsible Party" for the purposes of registering the Trial with the ClinicalTrials.gov registry and for reporting results and adverse events to that registry. As the Responsible Party, you are responsible for registering this clinical trial and submitting accurate results and adverse events relating to this clinical trial on ClinicalTrials.gov, as required by the Food and Drug Administration Amendments Act (FDAAA).

To assist in fulfilling responsibilities to register and report data on ClinicalTrials.gov, Partners Human Research Affairs has made the following resources available:

Partners Clinical Trials Registration Information
http://healthcare.partners.org/phsirb/investigatorctregistration.htm

Generally speaking, requirements include:

- □ Registration of the study on ClinicalTrials.gov.
- □ Updates every 6 months as required by ClinicalTrials.gov.
- □ Submission of results and adverse events to ClinicalTrials.gov within 12 months of either the estimated primary outcome completion date (as documented in your ClinicalTrials.gov registration) or the actual date of primary outcome completion endpoint, whichever is sooner.
- □ Notification to ClinicalTrials.gov within 30 days of study completion.

My signature below acknowledges that I, Click to type PI Name have been designated as the "Responsible Party" by Click to type Partners Institution and assures that I meet the following statutory requirements:

1) I am responsible for conducting the Trial.
2) I have access to and control over the data from the Trial.
3) I have the right to publish the results of the Trial.
4) I have the ability to meet all of the requirements under FDAAA for the submission of clinical trial information.

PI Signature: _____ Date: _____