A Site Responsible Investigator with staff privileges must be listed for each Partners site where the research is being conducted.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name:  First Name, Middle Initial, Last Name, Degree(s) | | | | | | Partners user name: | |
|  | | | | | | | |
| Institution: | BWH | MGH | | | FH | | McLean |
|  | NSMC | NWH | | | PCHI | | SRH |
|  | Other, specify: | | | | | | |
|  | | |  | | | | |
| Dept/Service: | | | Division/Unit: | | | | |
|  | | |  | | | | |
| Address: | | | | | | | |
|  | | | | | | | |
| Tel: | | | | Fax: | | | |
|  | | | | | | | |
| E-Mail Address: | | | | | | | |

**PROTOCOL TITLE**

|  |
| --- |
|  |

**FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST**

|  |
| --- |
| Principal investigators and co-investigators must complete the Investigator Financial Disclosure Form and submit to the IRB in conjunction with the Human Subjects Research Application form when the research involves ANY of the following:  (1) for-profit sponsor or funding source;  (2) a marketed drug, device, or other technology, or a drug, device, or other technology in development; or  (3) a new technology, software or therapeutic approach. |

The Investigator Financial Disclosure Form is available on the [PHRC website](http://healthcare.partners.org/phsirb/Submission_Instructions/Investigator_Financial_Disclosure.08.12.doc).

**CERTIFICATIONS**

As a Site-Responsible Investigator on this protocol, I certify the following:

I have read and am familiar with the Hospital Assurance governing this research.

<http://healthcare.partners.org/phsirb/assure.htm>

I have completed Partners human-subject protection education requirements.

<http://healthcare.partners.org/phsirb/aboutciti.htm>

I have completed the applicable institutional credentialing processes, if any, required to conduct this research.

I understand the Harvard Faculty of Medicine and Partners conflict of interest rules that apply to individuals participating in clinical research and will at all times, during the course of this Research, be in compliance with those rules.

<http://hms.harvard.edu/about-hms/integrity-academic-medicine/hms-policy>

|  |  |
| --- | --- |
| If you have questions or concerns about potential conflicts of interest, contact the Partners Human Research Office at 617-424-4171. | |
| I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to comply with all applicable federal regulations and state laws, institutional policies and procedures, and the requirements and determinations of the Partners Human Research Committee with respect to this research. | |
|  |  |
| **SITE-RESPONSIBLE INVESTIGATOR** | **Date** |

**NOTE: When adding a Site-Responsible Investigator for Newton-Wellesley Hospital, North Shore Medical Center or Spaulding Rehabilitation Hospital, contact the NWH, NSMC, or SRH IRB to determine whether the local IRB will accept the Partners IRB review before you submit to the Partners IRB.**

**DEPARTMENT CHAIR SIGN-OFF**

|  |  |
| --- | --- |
| As Department Chair for the Site-Responsible Principal Investigator of this research. I have reviewed the research proposed and certify the following:   * The Site-Responsible Principal Investigator is qualified by training and experience to personally conduct and/or supervise the research described in the protocol. * The Site-Responsible Principal Investigator has completed all institutional credentialing requirements, if any, to conduct the research. * The Site-Responsible Principal Investigator has sufficient resources/facilities to carry out the research.   I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to assure compliance with all applicable federal regulations and state laws, institutional policies and procedures, and the requirements and determinations of the Partner Human Research Committee with respect to this research. | |
|  |  |
| **DEPARTMENT CHAIR**  Print/type name and department, then sign and date above | **Date** |

**NEWTON-WELLESLEY HOSPITAL, NORTH SHORE MEDICAL CENTER OR SPAULDING REHABILITATION HOSPITAL LOCAL IRB SIGN-OFF**

|  |  |
| --- | --- |
| As Chairperson of the local IRB, I certify the following:  I have reviewed the research plan described in the submission and have determined that the research may be reviewed by the Partners IRB on behalf of this site under the IRB Authorization Agreement we have executed with the Partners IRB. In my review, I specifically considered local site issues and (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data. | |
|  |  |
| **IRB CHAIR**  Print/type name and department, then sign and date above | **Date** |