

**INSTITUTIONAL REVIEW BOARD (IRB)
AUTHORIZATION AGREEMENT**

Name of Institution(s) Providing IRB Review:

BRIGHAM & WOMEN'S HOSPITAL (BWH) - Federalwide Assurance (FWA) # 484
MASSACHUSETTS GENERAL HOSPITAL (MGH) - Federalwide Assurance (FWA) #3136

Name of Institution Relying on the Designated IRB:

NEWTON WELLESLEY HOSPITAL ("HOSPITAL") - Federalwide Assurance (FWA) # 799

Terms of Agreement

1. The Officials signing below agree that HOSPITAL may rely on the BWH and/or MGH IRBs (hereafter referred to as the "PARTNERS IRB(s)") registered with OHRP for review and continuing oversight of its human subject research as described herein.
 - a) A Principal Investigator (PI) at HOSPITAL, MGH, or BWH must submit an initial written request for review of a study to HOSPITAL and to the PARTNERS IRB. Determinations of eligibility for review will be made case-by-case. At a minimum, for a study to be eligible for review by the PARTNERS IRB(s) under this Agreement, it must involve collaboration between investigators within PARTNERS and investigators at HOSPITAL.
 - b) The PARTNERS IRB(s) and HOSPITAL each reserves the right to decline any request by a PI to include a study under this Agreement, but they must do so in writing to the PI and to the other party, as applicable.
2. The review and continuing oversight performed by the PARTNERS IRB(s) will meet the human subjects protection requirements of HOSPITAL's OHRP-approved FWA. HOSPITAL will notify the PARTNERS IRB(s) if the FWA is no longer effective or in good standing for any reason.
3. HOSPITAL reserves the right at any time to assert its jurisdiction over the review of a study and to require its concurrent review of the study, but must do so in writing to the PI and to the applicable PARTNERS IRB. In this event, the more stringent requirements of the two IRBs' reviews will govern.
4. This Agreement does not require the PARTNERS IRB(s) to allow representatives of HOSPITAL to attend its meetings or otherwise accept comments or influence from HOSPITAL representatives in the review of study, except to the extent necessary to ensure sufficient knowledge of the local research context.
5. The PARTNERS IRB(s) will notify HOSPITAL officials specified herein and the responsible HOSPITAL PI in writing of its decision to approve or disapprove any study accepted for review under this Agreement or of modifications required to secure approval of the study, as well as subsequent IRB-reviewed and approved changes in the research activity, namely, by sending copies to such officials of the review notification letters it sends to investigators. Relevant minutes of IRB meetings at PARTNERS will be made available to HOSPITAL upon written request.
6. HOSPITAL will accept the decisions and requirements of the PARTNERS IRB(s) with respect to the studies conducted under this Agreement. HOSPITAL also will ensure that its investigators cooperate in the PARTNERS IRB's continuing review process.

7. HOSPITAL remains responsible for its own compliance, and for ensuring compliance by its investigators (including, but not limited to, physicians, research nurses, coordinators, data managers, or other members of the research team), with the determinations of the PARTNERS IRB(s); with the terms of HOSPITAL's OHRP-approved Assurance; with 21 CFR Parts 50, 54, 56, 312, and 812 and 45 CFR Part 46 (collectively, the "Federal Research Regulations"), HIPAA and its regulations, and all other applicable legal requirements; with the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and other applicable ethical principles; and with the PARTNERS Confidentiality Policy, the Responsible Conduct of Human Studies, and PARTNERS' and BWH's/MGH's other institutional policies, procedures, and documents for conducting research as applicable. In addition, and without limiting the foregoing, any agreement that HOSPITAL may enter with a corporate sponsor in connection with a study included in this Agreement shall comply with PARTNERS' and MGH's/BWH's policies governing such agreements, including but not limited to, policies on indemnification from the sponsor, freedom to publish, and ownership of records and data. Copies of the PARTNERS' and MGH's/BWH's policies, procedures, and documents referenced herein are available upon request to HOSPITAL and its investigators. HOSPITAL is responsible for educating and training its investigators to perform research involving human subjects covered by this Agreement.

Without limiting any of the foregoing, HOSPITAL will require its investigators to sign the Commitment Statement for Investigators attached at Exhibit A and incorporated by reference herein before they may conduct research under this Agreement. Copies of signed Commitment Statements shall be provided to the PARTNERS IRBs upon request.

8. HOSPITAL will promptly report to the PARTNERS IRBs and to PARTNERS any noncompliance by HOSPITAL or its investigators with the determinations, documents, laws, and policies listed in Section 7 in connection with the research activities conducted under this Agreement of which HOSPITAL is aware. HOSPITAL also will ensure that its investigators immediately report to the PARTNERS IRBs any injuries to subjects or unanticipated problems involving risks to subjects or others in the research activities conducted under this Agreement of which the investigators are aware, and promptly report any proposed changes in such research activities; such changes shall not be initiated without the PARTNERS IRB's review and approval except where necessary to eliminate apparent immediate hazards to the subjects.
9. In turn, the PARTNERS IRB(s) will notify HOSPITAL in writing of serious or continuing non-compliance by HOSPITAL or its investigators discovered by PARTNERS, any suspension or termination of IRB approval, injury to subjects or unanticipated problems involving risks to subjects or others discovered by PARTNERS.
10. HOSPITAL will cooperate with and use best efforts to ensure its investigators' cooperation with any inquiry by the PARTNERS IRBs into research compliance in a study conducted under this Agreement. Such cooperation will include, but is not limited to, providing research records and related information, meeting with PARTNERS research representatives upon request, and helping to carry out remedial action if reasonably indicated. Such remedial action may include termination of participation by HOSPITAL or its investigators in designated research activities. HOSPITAL also may take further action where appropriate to deter and remedy such deficiencies.
11. HOSPITAL will instruct its investigators to maintain records of all human subjects research and related activities conducted under this Agreement for at least six years, and longer if required by law,

after completion of the research. Upon reasonable request, HOSPITAL shall provide a copy of such records to the PARTNERS IRB(s), and to others if legally required.

12. This Agreement shall become effective on the last date signed below and shall continue for successive one year periods, provided that the parties' FWAs remain in good standing and provided that the Agreement is not earlier terminated as provided below.
13. Either PARTNERS or HOSPITAL may terminate this Agreement (i) without cause upon 30 days prior written notice to the other party or (ii) upon 14 days prior written notice to the other party in the event of a breach by the other party that is not cured to the reasonable satisfaction of the non-breaching party within said 14-day notice period. In the event of any termination, the parties will ensure that OHRP is notified and will work together to determine effect of such termination on any research being conducted under the Agreement at the time of termination.
14. All communications, reports and notices shall be delivered by hand, by facsimile, or by first-class mail, postage prepaid and addressed as follows:

If to Partners: P. Pearl O'Rourke, M.D.
Director of Human Research Affairs
Partners HealthCare System, Inc.
Research Management
50 Staniford Street – Suite 1001
Boston, MA 02114
Tel: (617) 724-2731

With copy to: Elizabeth L. Hohmann, M.D., Director and Chair
Partners Human Research Committee
Research Management – 10 BPW
Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

If to HOSPITAL: Hope M. Violette
Manager, Office of Research
Newton-Wellesley Hospital
2014 Washington Street
Allen Riddle Room 117
Newton, MA 02462


With copy to: Frederick Millham, M.D., Chair
Human Research and Investigation Committee
Newton-Wellesley Hospital
2014 Washington Street
Newton, MA 02462

15. Miscellaneous: This Agreement has been executed and delivered in and shall be construed and enforced in accordance with the laws of the Commonwealth of Massachusetts. This Agreement may be amended only by a written agreement signed by the parties. If any provision of this Agreement shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions of this agreement shall not be affected thereby. This Agreement is not

assignable in whole or in part, and any attempt to do so shall be void. This Agreement supercedes the previous Agreement the parties had for HOSPITAL to rely on PARTNERS IRBs for IRB review.

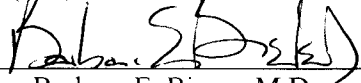
This document must be kept on file at each institution and provided to OHRP upon request.

EXECUTED BY AUTHORIZED SIGNATORY OFFICIALS


Name: P. Pearl O'Rourke, M.D.
Institutional Title: Director of Human Research Affairs
Date: 12-10-03

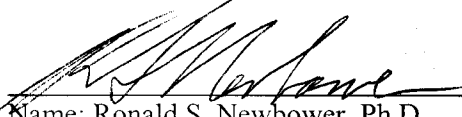
Partners HealthCare System, Inc.

Research Management
50 Staniford Street – Suite 1001
Boston, MA 02114
Tel: (617) 724-2731


Name: Barbara E. Bierer, M.D.
Institutional Title: Senior Vice President for Research
Date: 12/11/03

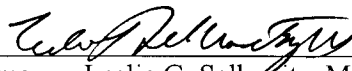
Brigham & Women's Hospital

Research Management
75 Francis Street – 10 BPW
Boston, MA 02115
Tel. of BWH IRB: (617) 525-3170
Fax of BWH IRB: (617) 232-9216


Name: Ronald S. Newbower, Ph.D.
Institutional Title: Senior Vice President for Research & Technology
Vice President for Research Management
Partners HealthCare System, Inc.
Date: 12/11/03

Massachusetts General Hospital

Research Management
50 Staniford Street - Suite 1001
Boston, MA 02114
Tel. of MGH IRB: (617) 726-3494
Fax of MGH IRB: (617) 724-1919


Name: Leslie G. Selbovitz, M.D.
Institutional Title: Senior Vice President of Medical Affairs
Hospital: Newton-Wellesley Hospital
Date: December 9, 2003

Newton-Wellesley Hospital

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Newton, MA 02462
Tel.: (617) 243-5987
Fax: (617) 243-5006