

Exhibit A  
Commitment Statement for Investigators

As an investigator at NEWTON WELLESLEY HOSPITAL (“HOSPITAL”), I, \_\_\_\_\_, would like to participate in research for which review and continuing oversight is provided by the IRB of Partners HealthCare System (Partners) as provided in the IRB Authorization Agreement dated \_\_\_\_\_ between PARTNERS and HOSPITAL. I understand that one of the conditions of my participation in such research is my acknowledgement and acceptance through this Commitment Statement of my responsibilities under the Agreement and applicable laws, regulations, ethical guidelines, and other policies and principles, as described herein.

A. Overview

1. I acknowledge that I have read the Agreement, HOSPITAL’s OHRP-approved Federalwide Assurance, the Federal Research Regulations, the applicable requirements under HIPAA, the Belmont Report, the Partners Confidentiality Policy, and the Partners Responsible Conduct of Human Studies. I understand and hereby accept my responsibilities for satisfying the intent and procedures in these documents, for fully complying with them, and for protecting the rights and welfare of human research subjects involved in research conducted under the Agreement.

2. I will comply with other federal, state, or local laws or regulations as they may relate to research covered by the Agreement.

3. I will abide by determinations of the PARTNERS IRBs and will accept the final authority and decisions of that IRB. I will further abide by other policies, procedures, and decisions of PARTNERS and HOSPITAL as they may apply.

B. Reporting

1. I will report promptly to the PARTNERS IRB(s) proposed changes in research activities under the Agreement. The changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.

2. I will report immediately to the PARTNERS IRB(s) any injuries to subjects (including but not limited to deaths or illnesses) or unanticipated problems involving risks to subjects or others.

C. Other Responsibilities

1. A designated Principal Investigator will assume overall administrative responsibility for all aspects of each study approved under the Agreement.

2. I will attend any required training and educational sessions provided by HOSPITAL before conducting any research under the Agreement. I will attend other educational and training sessions that HOSPITAL deems appropriate and will be responsible for reviewing updated information from PARTNERS, HOSPITAL, and the PARTNERS IRB(s) regarding the conduct of research under the Agreement.

3. I understand that the PARTNERS IRB(s) has documents and procedures that it regularly uses in conducting research, and I agree to use such documents and procedures, unless both HOSPITAL and the PARTNERS IRB(s) specifically agree otherwise before the PARTNERS IRB(s) reviews and approves the research.

4. I will seek, document, and maintain records of informed consent and HIPAA authorization from each prospective subject or his or her legally authorized representative as required by applicable federal regulations.

5. I acknowledge and agree to cooperate in the PARTNERS IRB's responsibility for initial and continuing IRB reviews and approvals, record keeping, reporting, and certification. I will timely provide all necessary information for progress reports used in the PARTNERS IRB's continuing review process.

6. I will provide the PARTNERS IRB(s) and HOSPITAL with all information that they deem appropriate to assist them in carrying out their responsibilities under the Agreement, including but not limited to my name, the study in which I am participating, the name of the PI for the study, and the start and end dates of the study.

7. I will communicate constructively with representatives of PARTNERS and HOSPITAL, other investigators, and human subjects as a means of maintaining a high level of awareness regarding the protection of the rights and welfare of the subjects.

8. If I conduct research under an investigational new drug or device subject to FDA regulations, I will comply with all investigator (or investigator-sponsor, if appropriate) responsibilities described in 21 CFR Parts 312 and 812 or successor provisions.

9. I will not accrue subjects on studies under the Agreement prior to approval of the study and without certification of IRB review and approval. Provision of any emergency medical care without prior full board review is permitted under applicable federal regulations. However, research data may not be used from such interventions.

10. I will not participate in convened discussion or voting of the PARTNERS IRBs except by invited attendance to provide information to it upon request.

11. I will cooperate with any inquiry by the PARTNERS IRBs into research compliance in a study in which I participate under the Agreement, including but not limited to providing research records and related information and meeting with PARTNERS research representatives upon request. In the event the PARTNERS IRB(s) deems me to have failed to comply with the Agreement, I agree to take action(s) that the PARTNERS IRBs, PARTNERS, and HOSPITAL deem appropriate, including but not limited to termination of my participation in designated research activities.

12. I acknowledge receipt of and compliance with existing federal policies and guidance concerning notification of sero-positivity, counseling, and confidentiality, where HIV research activities are concerned.

I understand that it is my personal responsibility to abide by the Federal Research Regulations, the HIPAA regulations, IRB policies, and this Commitment Statement and the Agreement, and that in the event of serious or continuing noncompliance with any of these requirements, the PARTNERS IRB(s) will report such noncompliance to OHRP, other federal departments or agencies that sponsor the research or have jurisdiction over it, such as the FDA, the sponsor of the research, and institutional officials as appropriate. I understand that my primary responsibility is to the well-being of research subjects and that their interests take precedence to the research.

Investigator Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Phone: \_\_\_\_\_

Receipt of signed Commitment Statement acknowledged by:

NEWTON WELLESLEY HOSPITAL

By: \_\_\_\_\_

Date of receipt: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_