Human Research Committee
Partners HealthCare System, Inc.
399 Revolution Drive, Suite 710
Somerville, MA 02145

Memorandum

TO: Collaborators and Sponsors

From: Rosalyn A. Gray, Director
Human Research Review and Compliance

Date: January 1, 2017

RE: The Spaulding Rehabilitation Hospital Corporation, Inc. (SRH) Human Subjects Research Statement of Compliance

The SRH operates in compliance with all applicable regulations and guidelines pertaining to human subjects research as listed below, and with the Federalwide Assurance (FWA) and Incorporated "Terms of the Federalwide Assurance for institutions within the United States" held by the SRH.

- Department of Health and Human Services (DHHS) 45 CFR Parts 46 and 164
- Food and Drug Administration (FDA) 21 CFR Parts 50 and 56
- International Conference on Harmonization (ICH) guidance relating to Good Clinical Practice (GCP), section 3(3.1-3.4) unless ICH guidelines conflict with FDA Regulations.

Federalwide Assurance (FWA)
The SRH FWA00000465 is approved and on file with the Office for Human Research Protections (OHRP). The current expiration date for the Spaulding Rehabilitation Hospital FWA is available from the OHRP IRBs and Assurance webpage http://ohrp.cit.nih.gov/search/.

PHS IRB Registration
The SRH relies primarily on the Partners HealthCare System, Inc. (PHS IORG0009015) IRBs for review and continuing oversight of human-subjects research. The PHS IRBs are registered with the Department of Health and Human Services (DHHS) as required by OHRP and FDA, and are designated in the SRH FWA. The current expiration dates for the PHS IRBs' registrations are available from the OHRP IRBs and Assurance webpage http://ohrp.cit.nih.gov/search/.

PHS IRBs: #IRB00010756; #IRB00010757; #IRB00010758; #IRB00010759; #IRB00010760; #IRB00010761; IRB00010762

SRH may also rely on other external IRBs registered with OHRP/FDA under reliance agreements executed between the SRH and the reviewing organization's IRB.

PHS IRB Membership
The PHS IRBs meet the IRB membership requirements in DHHS and FDA Code of Federal Regulations 45 CFR 46.107 and 21 CFR 56.107. As a matter of policy, PHS does not provide the IRB membership rosters to collaborators or sponsors. Any IRB Chair or member who has a conflict of interest with regard to a protocol under review will not participate in the deliberation or vote on that protocol except to provide information requested by the IRB.

PHS IRB Approval Letters
The PHS IRBs do not require the IRB Chairs or any other member of the IRB to sign approval letters. There is no regulatory requirement for such signatures. The documents reviewed and approved by the IRB are included in the approved submission available in Insight.

AAHRPP Accreditation
SRH is a component of the Partners HealthCare human research protection program, which has been fully accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP) since December 2004, and was most recently reaccredited for 5 years effective June 21, 2016.