



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

February 26, 2015

Partners HealthCare System ("Partners") maintains a high standard of system security in the operation of its clinical, administrative, and other information systems used by itself and its affiliated hospitals and organizations to support clinical care and clinical research.

Partners has adopted a diversified range of access protocols, software solutions, technical safeguards, policies, monitoring and other systems and controls that are designed to maintain, as appropriate, the privacy, confidentiality, integrity and security of electronic clinical and research data.

These systems and controls are designed for compliance with applicable laws as well as with industry standards set by leading academic medical institutions. With respect to 21 CFR Part 11 specifically, it is Partners' understanding that FDA does not apply the Part 11 regulations to electronic health record systems ("EHRs") and does not intend to evaluate EHRs' compliance with Part 11's requirements, even when EHRs contain data relevant to clinical research. Upon request, Partners will provide FDA, research sponsors, or other appropriate parties with information and documentation regarding Partners' specific information systems and controls applicable to its EHRs that maintain data relevant to clinical research.

Sincerely,

A handwritten signature in black ink, appearing to read "JK", with a long horizontal line extending to the right.

Jigar Kadakia
Chief Information Security and Privacy Officer
Partners HealthCare