



Beth Israel Deaconess
Medical Center



A major teaching
hospital of Harvard
Medical School

FROM: John Halamka, MD
CIO, CareGroup Information Systems
330 Brookline Ave
Boston, MA, 02215

To Whom It May Concern:

Thank you for your inquiring regarding Beth Israel Deaconess Medical Center's ("BIDMC") compliance with Section 21 of the United States Code of Federal Regulations, Part 11.

BIDMC represents that each of the Information Systems ("Systems") over which BIDMC IS has control shall be used in compliance with BIDMC's relevant Standard Operating Procedures ("SOP"), of which such SOPs may be made available to Sponsor for review. Some examples of BIDMC's control over the Systems include:

- (i) regular back-up of data;
- (ii) storage of back-up media in a secure location;
- (iii) a contingency plan exists in case any such System is unavailable;
- (iv) a full audit trail can be established, allowing the tracking of entries/deletions into/from the System by date, time, identity of person making entry/deletion, reason for entry/deletion and other standard parameters;
- (v) a reasonable level of security, including specifically that System access is restricted, that all users have a unique user identification and password, and that the use of each System can be monitored through a full audit trail; and
- (vi) appropriate training is given to System users on a documented basis including regarding the Procedures.

Our main Clinical Care electronic medical record system (also known as CCC) was reviewed by Baxter, Inc and certified to be 21 CFR Part 11 compliant in June of 2002.

Sincerely,

A handwritten signature in black ink, appearing to read "John Halamka".

John Halamka, M.D.
CIO, CareGroup