



Brandeis University

Committee for Protection of Human Subjects

Investigator's Assurance

Your signature below indicates that the information provided in this application is correct and that you agree to comply with all federal, state and institutional policies and procedures designed to protect human subjects in research. Your signature also acknowledges your understanding of your responsibilities, as a research investigator as noted below and in Brandeis University's Multiple Project Assurance of Compliance (<http://www.brandeis.edu/osp/>). Contact the BCPHS Office with questions related to the Code of Federal Regulations (45 CFR 46) or your responsibilities as an investigator.

A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Brandeis University Multiple Project Assurance.

B. Research investigators who intend to involve human research subjects will submit a protocol to the BCPHS to determine compliance with applicable Federal regulations or provisions of this Assurance.

C. Research investigators are responsible for providing a copy of the BCPHS-approved and signed informed consent document to each subject at the time of consent, unless the BCPHS has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the Office of Sponsored Programs.

D. Research investigators will promptly report proposed changes in previously approved human subject research activities to the BCPHS. The proposed changes will not be initiated without BCPHS review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

E. Research investigators are responsible for reporting progress of approved research to the Office of Sponsored Programs, as often as and in the manner prescribed by the BCPHS on the basis of risks to subjects, but not less than once per year.

F. Research investigators will promptly (within 5 days) report to the BCPHS any injuries or other unanticipated problems involving risks to subjects or others.

G. No research investigator who is obligated by the provisions of this Assurance, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior BCPHS approval. A physician may provide emergency medical care to a patient without prior BCPHS review and approval, to the extent permitted by law, however, such activities will not be counted as research nor the data used in support of research.

H. Research investigators will advise the BCPHS, Office of Sponsored Programs and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OHRP-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

Name of Investigator: _____

Project Title: _____

Signature: _____ Date: _____