

Yale University IRBs
Request for Permission to Serve as a Yale University
Collaborating Investigator
___ **Individual**
___ **Institutional**

Yale University, Federalwide Assurance No. 00002571

Name of Collaborating Investigator:

HIC Protocol # **Name of Yale Principal Investigator:**

Protocol Title:

Protocol Status: (Check one) **Approved** **Pending**

Provide a Brief Description of the Research Protocol Covered under this Request:

Describe the Role of the Collaborating Investigator in the Research:

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- (1) The above-named Investigator has reviewed and agrees to abide by: (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent: see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); (b) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46, and all Subparts (c) the U.S. Food and Drug Administration (FDA) regulations for the protection of human subjects at 21 CFR part 50; (d) the Yale University Federalwide Assurance (FWA) and the specific terms of the Yale University FWA; (e) the relevant Yale University policies and procedures for the protection of human subjects, and (f) *HIPAA at Yale, Researcher's Guide to HIPAA* (if applicable)

- (2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Request.
- (3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this Request, including, but not limited to, HIPAA's Privacy and Security Rules and the requirements governing the use and disclosure of Protected Health Information in research.
- (4) The Investigator will abide by all determinations of the Yale University Institutional Review Board (IRB) designated under the above-referenced FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
- (5) The Investigator will complete human subjects protection training and other applicable educational training required by Yale University and/or the IRB prior to initiating research covered under this Request.
- (6) The Investigator will report promptly to the Principal Investigator of this research and the IRB any proposed changes in the research conducted under this Request. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
- (7) The Investigator will report immediately to the Principal Investigator of this research and the IRB any unanticipated problems involving risks to subjects or others in research covered under this Request.
- (8) If the Investigator is involved in enrolling subjects, the Investigator will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA referenced above) and as consistent with the IRB approved protocol.
- (9) The Investigator acknowledges and agrees to cooperate in assisting the IRB in carrying out its responsibility for initial and continuing review, record keeping, reporting, auditing, monitoring and certification for the research referenced above.
- (10) The Investigator will provide all information requested by the IRB in a timely fashion.

- (11) The Investigator will not enroll subjects in research or otherwise initiate research activity under this Request prior to IRB review and approval of the proposed research and approval of this Request by Yale University.
- (12) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.
- (13) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
- (14) This Request does not preclude the Investigator from taking part in research not covered by this Request.
- (15) Copies of the Investigator Curriculum Vitae and professional license(s) [if applicable] are attached.

Collaborating Investigator Signature:

_____ Date _____

Name: _____ Degree(s): _____
(Last) (First) (Middle Initial)

Address: _____ phone #: _____

(City) (State/Province) (Zip/Country)

E-mail address: _____

Prepared by Yale University Institutional Review Board: Signature

_____ Date _____

Name Larson Jean H Degree(s): MBA
(Last) (First) (Middle Initial)

APPROVAL OF REQUEST:

Yale University

Institutional Signatory Official (or Designee) Signature:

_____ Date _____

Name: Mahoney Maurice J.; MD, JD.
(Last) (First) (Middle Initial)

Title: Executive Director

Address: Human Investigation Committee phone #: 203-785-4688
Yale School of Medicine
47 College Street, Suite 204
 New Haven, CT)6520
(City) (State/Province) (Zip/Country)

This Agreement is effective as of _____.