Unaffiliated Investigator Agreement

Please Note: This document is valid for one year from the date of IRB approval.

Unaffiliated Investigator's Name: _____Institution_____

Title of the Research Protocol: _____

IBC, or IRB ID# _____

How is the Research funded?_____

Specify Scope of Research Activities to be performed by Unaffiliated Investigator: _____

_____

Unaffiliated Investigator's Research Activities will include: (Baystate Supervisor to initial all that apply)

____Access to Baystate patients' or research participants' Personal Health Information

____Access to Baystate's Electronic Health Record

____Communications with Baystate patients or participants

____Direct contact with Baystate patients or participants

____Obtaining consent from Baystate patients or participants

____Access bench space in the Baystate Research Facility

____ Require access to Baystate data

☐ Yes–Baystate to provide or send data

*(explanation below)

____*Other (see below)

____Access to Baystate employees' personal identifiers

____Need for a Baystate email address

____Communications with Baystate employees as research subjects

____Direct contact with Baystate employees as research subjects

____Obtaining consent from Baystate employees as research subjects

____ Require direct contact with Baystate patients or participant

____Could this collaboration result in the creation of new intellectual property

☐ Yes new intellectual property may be created (e.g. new methods, software, datasets, tools, inventions). May require an Intellectual Property Agreement

*Provide data requirement explanation (examples: extracts, data files, de-identified or limited data sets) – these options require a data use agreement

_____

_____

*Provide other explanation

_____

_____

How many hours per month will the Unaffiliated Investigator be required to be present on a BH campus:_____

Explain why the study cannot contract to have a person affiliated with Baystate perform these Research Activities:

_____

_____

Overview:

(1) If working in human research, the above-named Unaffiliated Investigator (UI) understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in (1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; (2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 if applicable to this study; (3) the FDA regulations relating to Good Clinical Practice and Clinical Trials if applicable to this study; (4) the FWA (FWA 00004355); (5) the NIH Human Subjects Policies if applicable to this study, and (6) the relevant institutional policies and procedures for the protection of human subjects.

(2) The UI 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 in which the UI participates under this Agreement.

(3) The UI will abide by all determinations of the Institutional Biosafety Committee (IBC), and/or Institutional Review Board (IRB) and will accept the final authority and decisions of the committee, including, but not limited to, directives to terminate participation in designated research activities.

(4) The UI will comply with all institutional requirements for participation in research including CITI training, Conflict of Interest disclosures, and any other educational training or requirement of the Institution, and/or the approving committee prior to participating in research activities covered under this Agreement.

(5) The UI will at all times remain within the approved Scope of Research Activities as specified above.

Supervision:

(1) _____ (Supervisor), who is affiliated with Baystate Health, Inc. ("BH") through employment or Medical Staff membership at an entity affiliated with BH, has agreed to serve as the UI's Supervisor for purposes of the UI's research activities pursuant to this Agreement.

(2) The Supervisor shall ensure that (a) the UI abides by the terms and conditions of all BH and Office of Research policies, including, without limitation, Unaffiliated Investigators (Policy); (b) patient care and patients' rights are not compromised because of the UI's actions or presence; (c) patients or their representatives have been informed that the individual is a UI and have given consent if the protocol involves contact with patients or their representatives; and (d) the submission and approvals relevant to the research protocols have been obtained, where required, from the Institutional Biosafety Committee (IBC) and IRB.

(3) The Supervisor shall report immediately to the Office of Research Leadership designee any violations of or deviations from the Policy by the UI of which the Supervisor becomes aware.

(4) The Supervisor will ensure the UI's access to electronic systems, badge access to facilities and Baystate belongings are returned at the conclusion of their work. This includes but is not limited to notification to I&T when the UI's access to Baystate applications is no longer required. The Supervisor will ensure the UI has returned any keys, badge and other Baystate items. Finally, the Supervisor will ensure the appropriate committee is notified, utilizing IRBNet, when the UI's work on the project concludes.

Other Responsibilities:

(1) The UI acknowledges and agrees to cooperate in the, IBC and/or IRB's responsibility for compliance with all relevant federal and state regulations and the standards and policies of the IBC, IRB and Baystate Health, including without limitation initial and continuing review, record keeping, reporting, and certification for the research referenced above. The UI will provide all information requested by the IBC, IRB, HRPP, Office of Research Leadership or Chief Research Compliance Officer in a timely fashion.

(2) For human research, the UI will allow the HRPP, IRB and/or Research Integrity Officer access to research records for the purposes of routine or for-cause review as described within the HRPP Standard Operating Procedures manual.

(3) For bench or animal research, the UI will allow the Baystate Research Facility staff and/or Research Integrity Officer access to research records for the purposes of routine or for-cause review as described within the BRF Policies and Procedures.

(4) The UI will not participate in research activities under this Agreement prior to the review and approval of the relevant protocols by the IBC, and the IRB, as applicable. The UI will notify the Office of Research Leadership promptly of any proposed changes in the UI's research activities under this Agreement. The UI will not initiate changes in his or her research activities without prior approval of the Office of Research Leadershipor designee, and receipt of any required IRB review and approval.

(5) The UI shall cooperate in all background file reviews requested by BH and provide verification of references, if requested; obtain such clearance from the BH Employee Health Service as is required under the Policy; complete the required orientation training; obtain and wear visibly a BH identification badge; and obtain a CN login number.

(6) The UI will protect the privacy of subjects and the confidentiality of their information and hereby affirms and acknowledges having received and read the BH Confidentiality Policy and having signed a Statement of Confidentiality.

(7) The UI agrees to complete the exit process required by the Office of Research Leadership agrees to comply with any requests by the Office of Research Leadership for a report at the conclusion of the UI's research activities.

(8) The UI agrees to comply with the BH Intellectual Property Policy, as may be amended from time to time, and to include the appropriate acknowledgement of the UI's status at BH, as required by the Policy. All research manuscripts, abstracts, books, book chapters, and presentations will include acknowledgement of the contributions of Baystate Health, UMass Chan Medical School-Baystate and its faculty, including authorship where appropriate. The UI understands and agrees that all research presentations and manuscripts relating to the UI's BH research activities must be submitted to the Office of Research Leadership or designee for approval prior to submission.

(9) This agreement does not obligate any of the above-mentioned research Committees to accept any research protocol submitted by the UI.

Failure to comply with the terms of this Agreement or the regulations and policies applicable to this research project may result in sanctions up to and including termination of this Agreement and any research privileges held by the UI at this institution.

Before routing for signatures ensure that the following information is included:

☐ Completed Form
☐ Unaffiliated Investigator's CV is attached.
☐ Abstract, copy of the protocol, and consent form (if applicable) are attached.
☐ Confirmation from IRB that the Unaffiliated Investigator is a named Staff Member of the IRB Protocol if applicable
☐ UIA request matches the IRB Protocol
☐ All Applicable CITI training certifications
☐ Is a reliance agreement between the two entities needed and if so, is there one executed? If so, attach.

☐ If there is an intention for data use or data transfer, ensure that the IRB protocol covers this?
If yes to above, is a DUA in place? If so, please provide.

☐ Is there a possibility of generating Intellectual Property? If so, a separate agreement may also be needed

Unaffiliated Investigator:

Signature: _____ Date _____

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

Address: _____ Phone #: _____

_____

Supervisor:

Signature: _____ Date _____

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

Address: _____ Phone #: _____

_____

Person to Whom Supervisor Reports (e.g. Department Chair or Service Line Director):

Signature: _____ Date _____

Name: _____ Title: _____
(*Last*) (*First*) *(Middle Initial)*

Address: _____ Phone #: _____

_____

Office of Research Leadership

Signature: _____ Date _____

Name: _____ Title: _____
(*Last*) (*First*) *(Middle Initial)*

Address: _____ Phone #: _____

_____