BC 10.400 - Unaffiliated Investigators

I. POLICY:

The Office of Research may permit individuals who otherwise lack a formal affiliation with Baystate Health, Inc., including its affiliates as defined in the Baystate Health, Inc. corporate bylaws (together, and each individually, "BH"), to participate in research activities conducted at or under the auspices of BH subject to the terms of this Policy.

II. PURPOSE:

To ensure that individuals who otherwise lack a formal affiliation with BH are permitted to participate as appropriate in research activities at or under the auspices of BH only under circumstances that do not interfere with patient safety and in a manner consistent with the rules, regulations, bylaws, policies, procedures, and practices of BH and its affiliated medical staffs ("BH Policies") and relevant law.

III. SCOPE:

All individuals who otherwise lack a formal affiliation with BH and desire to participate in research activities at or under the auspices of BH as a UI.

IV. DEFINITION:

An *Unaffiliated Investigator* ("UI") is an individual who is not employed by BH, is not a member of a BH Medical Staff or Associate Professional, is not a student enrolled in an academic program affiliated with BH, is not a party to a contract directly between BH and the individual, or who otherwise lacks a formal affiliation with BH, who has been approved to participate in research without salary, stipend, or other compensation from BH, subject to the terms of this Policy.

V. PROCEDURE:

All UIs must comply with the following conditions:

A. General Conditions:

1. Individuals seeking to participate in research activities at or under the auspices of BH as a UI shall submit a request for approval of UI status to the Office of Research.
2. Each such request shall include all information that the Office of Research may determine relevant, including, at a minimum, a description of the research activities in which the individual wishes to participate as a UI, including identification of specific research protocols; and the name of an individual affiliated with BH through employment or Medical Staff membership who agrees to serve as the individual's Supervisor for purposes of research activities as a UI and to ensure that the UI abides by all BH and Office of Research policies, including this Policy, and relevant law related to the UI's activities at or under the auspices of BH.
3. The Supervisor must ensure that the submissions and approvals relevant to the research protocols have been obtained, where required, from the Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) before the UI may participate in any research activities at or under the auspices of BH.
4. A student, resident, or fellow may not serve as a Supervisor, even if the student, resident, or fellow holds a full license to practice medicine and is a member of a BH-affiliated Medical Staff.
5. The Chief Research Officer ("CRO"), in consultation with the Department Chair or Service Line Director, or designee or others as deemed appropriate, shall determine whether a request for UI

status shall be granted or denied and shall notify the individual seeking UI status of their decision.

6. If the request for UI status is granted, an *Agreement for Unaffiliated Investigator Research* (Attachment "A") must be executed by the UI, Supervisor, Department Chair and/or Service Line Director or designee, and Chief Research Officer ("CRO") or designee. The UI may not engage in any research activities at or under the auspices of BH until such agreement has been executed.

B. <u>Before starting the research, the UI must:</u>

1. Read the BH Confidentiality Policy and sign a Statement of Confidentiality.
2. Obtain clearance from BH Employee Health Service if the UI will have direct patient contact or otherwise be present in clinical areas at BH, or if they will be present on BH premises for more than eight (8) hours total during the time the UI participates in research under this Agreement.
3. Complete the current online orientation training required of all BH employees.
4. Cooperate in BH's obtaining a criminal background file review.
5. Provide verifications and references, if requested.
6. Obtain an identification badge from BH Security.
7. Obtain a CN login number.
8. Execute the *Agreement for Unaffiliated Investigator Research*.
9. Obtain approvals relevant to the research protocols, where required, from the IACUC, IBC and IRB.

C. <u>Responsibilities of the Unaffiliated Investigator</u>:

At all times during the research experience, the UI shall:

1. Comply with all BH, BMC, and Office of Research policies.
2. Wear the identification badge visibly above the waist at all times while on the premises of any BH facility.
3. Remain within the scope of approved activities.
4. Refrain from unsupervised interactions with patients or patient families until such time as the Supervisor attests in writing to the CRO that (1) the Supervisor has directly observed the UI's interactions with patients and/or families as required for the approved protocol(s); (2) the UI has demonstrated consistently appropriate behavior, integrity, and professionalism in interacting with patients and families; and (3) the UI is fully competent in executing study procedures for the approved protocol(s) to interact independently with patients and/or patient families.
5. Refrain from participating in or performing any direct patient care or clinical or laboratory procedures.

D. <u>Responsibilities of the Supervisor</u>:

At all times during the research, the Supervisor shall:

1. Oversee and be responsible for the UI's activities and ensure compliance with all BH, BMC, and Office of Research policies.
2. Ensure that the UI complies with all terms and conditions in this Policy.
3. Ensure that patient care and patients' rights are not compromised because of the UI's actions or presence.
4. Ensure that patients or their representatives have been informed that the person is a UI and have given consent if the protocol involves contact with patients or their representatives.
5. Ensure that the submissions and approvals relevant to the research protocols have been obtained, where required, from the IACUC, IBC and IRB.

6. Report immediately to the CRO or designee any violations of or deviations from this Policy by the UI of which the Supervisor becomes aware.

E. Upon Completion of the Research Affiliation:

1. The UI must complete the exit process including returning the identification badge.
2. The CRO may request a report from the UI and/or Supervisor at the conclusion of the UI's research activities.

F. Intellectual Property:

1. All intellectual property derived from the UI's BH research will be subject to the BH Intellectual Property Policy as may be amended from time to time.
2. Authorship of research manuscripts, abstracts, books, book chapters, and presentations derived from the UI's BH research must include the following acknowledgement of the affiliation "Unaffiliated Investigator, Department of _____, University of Massachusetts Chan Medical School - Baystate and Baystate Health, Springfield MA." If the research was funded with a BH internal grant, authors must list this affiliation first.
3. All research manuscripts, abstracts, books, book chapters, and presentations relating to the UI's BH research activities must be submitted to the CRO or designee for approval prior to submission.

G. Foreign Nationals:

1. Foreign nationals participating in research activities at BH must enter the United States on a valid visa and maintain appropriate visa status for the duration of such activities. A copy of a valid visa must be provided to the Office of Research. The Office of Research does not sponsor or otherwise assist UIs in the process of obtaining a visa.

H. Retention of Documents:1. Final signed agreements are maintained by the Office of Research.

2. All other documents are maintained by the Student Education Coordinator, Healthcare Education Office.

APPROVALS:

		Date
Approved:	BH Policy Management Committee	9/20/2022
Policy Owner (department name)	Director of Healthcare Research Compliance/Chief Research Compliance Officer	
Originating (if new) Revising Department/Author/Title:		
Reviewers:	Jennifer Pacheco, Director of Healthcare Research	
Replaces		
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