

**POLICY FOR DETERMINING WHEN IRB APPROVAL IS NEEDED
BY VA IRB, BUMC IRB OR BOTH IRBS.**

Based on the OHRP guidance on engagement in research
<http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>
specifically the paragraph describing what constitute “employee or agent”:

For purposes of this document, an institution’s *employees or agents* refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

General Considerations:

- a. Authorization Agreements between the VA and BU are not possible
- b. In some cases IRB review by both institutions will be required (e.g. when both institutions are determined to be engaged in human subjects research, when BU is engaged in research and some research activities are taking place at the VA).
- c. There may be instances, based on the OHRP guidance, when only one institution is actually “engaged” in the research. If that can be determined then it may only be necessary to have IRB review by *one* institution’s IRB.
- d. However, at the VA, under certain circumstances they require **VA IRB review** even if, according to the OHRP guidance, the VA is not engaged in research. Some examples are
 - If VA patients/subjects are directly recruited, enrolled, randomized, consented into research (even if all investigators are from BU) the VA still requires VA IRB review
 - If BU investigators wish to obtain research data ABOUT VA patients from VA records then VA IRB review is required

BU and the VA agree that:

- A. If a BU faculty/staff person has a VA appointment (dual appointment) but has a project where all the research is at BU and the research *has no connection to the VA* (no VA subjects, no VA investigators, no VA funding). **This only requires BUMC IRB approval.** (BU faculty is acting *only* as an “employee or agent” of BU for this study.)
 - ❖ Under some circumstances, depending on the employment arrangement, the person with the joint VA/BU appointment may need to provide documentation that, for this project, he/she will be (1) acting on behalf of the BU; (2) exercising BU authority or responsibility; and (3) performing BU designated activities
- B. If a VA faculty/staff person has a BU appointment (dual appointment) but has a project where all of the research is being done at the VA *with no connection to BU* (primary funding is NOT through BU, no other BU investigators, BU is not otherwise engaged per OHRP guidance) – **only requires VA IRB Approval** because this person is acting as an employee/agent *only* of the VA.
 - ❖ Under some circumstances, depending on the employment arrangement, the person with the joint VA/BU appointment may need to provide documentation that , for this project he/she will be (1) acting on behalf of the VA; (2) exercising VA authority or responsibility; and (3) performing VA designated activities

- C. **IRB review by both institutions.** Where there is any direct Federal funding awarded to BU (BU is prime awardee) then BU is engaged in the research and BUMC IRB approval is required even if all research activities are taking place at the VA. Likewise, if any direct Federal funding is awarded to the VA (VA or its research foundation is prime awardee) then the VA is engaged in the research and VA IRB approval is required (even if all research activities are at BU).
- D. If a BU employee is subcontracted **through an agreement** to work on a RESEARCH project or multiple research projects at the VA – and the **agreement specifies** that, while working on this/these specific project(s) the BU employee will be (1) acting on behalf of the VA; (2) exercising VA authority or responsibility; and (3) performing VA designated activities –**then BU will not be engaged in research and BU/BMC IRB approval will not be required.** (assuming that BU is not recipient of a direct Federal award for the project).
- E. If a VA employee is subcontracted **through an agreement** to work on a RESEARCH project or multiple research projects at BU – and the agreement specifies that, while working on this/these specific project(s) the VA employee will be (1) acting on behalf of the BU; (2) exercising BU authority or responsibility; and (3) performing BU designated activities –**then the VA will not be engaged in research and VA IRB approval will not be required.** (assuming that VA is not recipient of a direct Federal award for the project).
- F. Trainees- for BU trainees conducting research at the VA, all research activities are at the VA (no direct federal awards to BU), if there is an “agreement” that says that, while working on this project the trainee will be (1) acting on behalf of the VA; (2) exercising VA authority or responsibility; and (3) performing VA designated activities – **then BU/BMC is not engaged and BU/BMC IRB review is not required**
- G. For situations where a third institution is the primary awardee of direct Federal funding, BU is a sub-awardee and the VA is then a sub-awardee of BU and human subjects research activities are taking place at the VA but no human subjects research activities are being conducted at BU or by BU investigators: According to the “engagement guidance” BU investigators/BU are not engaged. IRB approval is needed from the primary awardee institution and the VA. **BUMC IRB review is NOT required.**

Who is responsible for signatory person for these “agreements”?

- A. **For the VA-** all these “agreements” should go through
- Terence M. Keane, Ph.D. at VA Boston
 - Benjamin Cipolloni, M.D. at the Edith Norse Rogers VA in Bedford, MA.
- B. **For BU/BMC-** Thomas Moore M.D.

BUMC Process for making the determination (BUMC is engaged in the research)

1. BU PI submits IRB protocol via INSPIR

- a. VA person is listed as a co-investigator /research staff on INSPiR protocol
- b. PI attaches a document to the INSPiR protocol verifying that the VA person is conducting research SOLELY as an agent of BUMC
- c. PI attaches a copy of the “agreement” (for D,E, F, G, H above)
- d. As part of its review, the IRB will send a correspondence to Dr. Moore indicating that the VA “investigators” are engaged on behalf of BU and therefore only BUMC IRB review is needed
- e. Dr. Moore will confirm with Dr. Keane
- f. Documentation by Drs. Moore and Keane will be attached to the BUMC INSPiR protocol

VA Boston Process for making determination (VA Boston is engaged in research).

- 1. VA PI submits protocol for initial review to the R&D Coordinator.
 - a. BU Faculty member is listed as a co-investigator/research staff.
 - b. PI states in cover letter to R&D and IRB that faculty who are exclusively funded by BU are involved in the study solely as an agent of VA (e.g., as a WOC on an IPA).
 - c. Cover letter states the agreement (for D, E, F, G, and H, when applicable) suggesting that all involved are acting exclusively on behalf of VA.
 - d. The IRB co-chairs through the IRB coordinator will inform the ACOS-Research that all investigators are engaged on behalf of VA and that only VA IRB is needed.
 - e. The ACOS-Research will communicate this to Dr. Moore who will confirm this to the ACOS-Research who will inform the IRB Coordinator of this confirmation.
 - f. This confirmation will remain in the permanent study files.

What should be the format for “the agreements” referenced in D,E, F, G, H above)

- A. The “agreement language” can be added to agreement templates already in place (MOU agreements)
- B. The “agreement” could be a simple “stand alone” with the OHRP language, signed by the study PI
- H. The agreement language includes the statement that, for this project, [Name & title] , while working on [xxx project with IRB protocol number], this person will be (1) acting on behalf of the [specify VA or BU]; (2) exercising [specify VA or BU] authority or responsibility; and (3) performing [specify VA or BU] designated activities