

**Executive Committee Supporting the
Collaborative IRB**

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POLICY:

This policy illustrates that the protection of human subjects is a shared responsibility that requires open lines of communication among institutions, including NU, UIC, and the JBVAMC. This policy outlines the operation of the Executive Committee Supporting the Collaborative IRB (EC) in coordinating the communication regarding human subjects protection related to the Collaborative IRB (UIC IRB#4).

- I. The EC facilitates communication among the IRB Chair or appropriate Board member designee and UIC OPRS with JBVAMC and/or NU staff, departments and faculty in accordance with the executed MOUs or IAAs between JBVAMC, UIC and NU.
- II. The EC is made up of the following members:
 - A. UIC Vice Chancellor for Research;
 - B. UIC HPA;
 - C. Collaborative IRB Chair and Vice Chair;
 - D. JBVAMC HPA;
 - E. JBVAMC COS;
 - F. JBVAMC ACOS for R&D (Chair of the Executive Committee);
 - G. NU Vice President for Research; and
 - H. NU HPA.
- III. To assist with scheduling, up to three individuals may be appointed by members who are not HPAs to attend the EC meeting on their behalf. HPAs must attend either via tele/videoconference or in person and may not appoint a designee.
- IV. Legal representation is available from the appropriate entity's legal counsel on an *ad hoc* basis.
- V. The EC does not have the authority to supersede the determinations of the Collaborative IRB, including those related to suspension or termination of research and any of the prompt reporting obligations to the investigator, appropriate institutional officials, and the Department of Agency Head. Also, the EC does not have the authority to approve or disapprove research reviewed by the collaborative IRB or supersede the determination of the IRB.

VI. The EC has authority to review policies and procedures, draft new, or revise existing, policies and procedures, and delegate such responsibilities to the appropriate individuals.

VII. The EC may make recommendations regarding allocation of resources to the Collaborative IRB, to the Collaborative IRB Chair, and to the UIC OPRS.

VIII. At the discretion of the Collaborative IRB Chair and/or the Collaborative IRB, the EC assists the IRB in the review of allegations of non-compliance, including undue influence per the UIC HSPP policy [*Undue Influence of IRB Members and OPRS Staff*](#). The appropriate members on the EC coordinate the investigations with their respective institutions as necessary and as directed by the Collaborative IRB Chair and/or Collaborative IRB.

IX. The EC submits a report of its findings and recommendations for corrective actions regarding non-compliance, including undue influence, when appropriate, to the Collaborative IRB and other parties as required by UIC policy and procedures.

PROCEDURE:

I. Meeting Frequency

- A. The EC meets at minimum on a quarterly basis to address matters within the scope of their role with the Collaborative IRB.

II. Administrative Matters

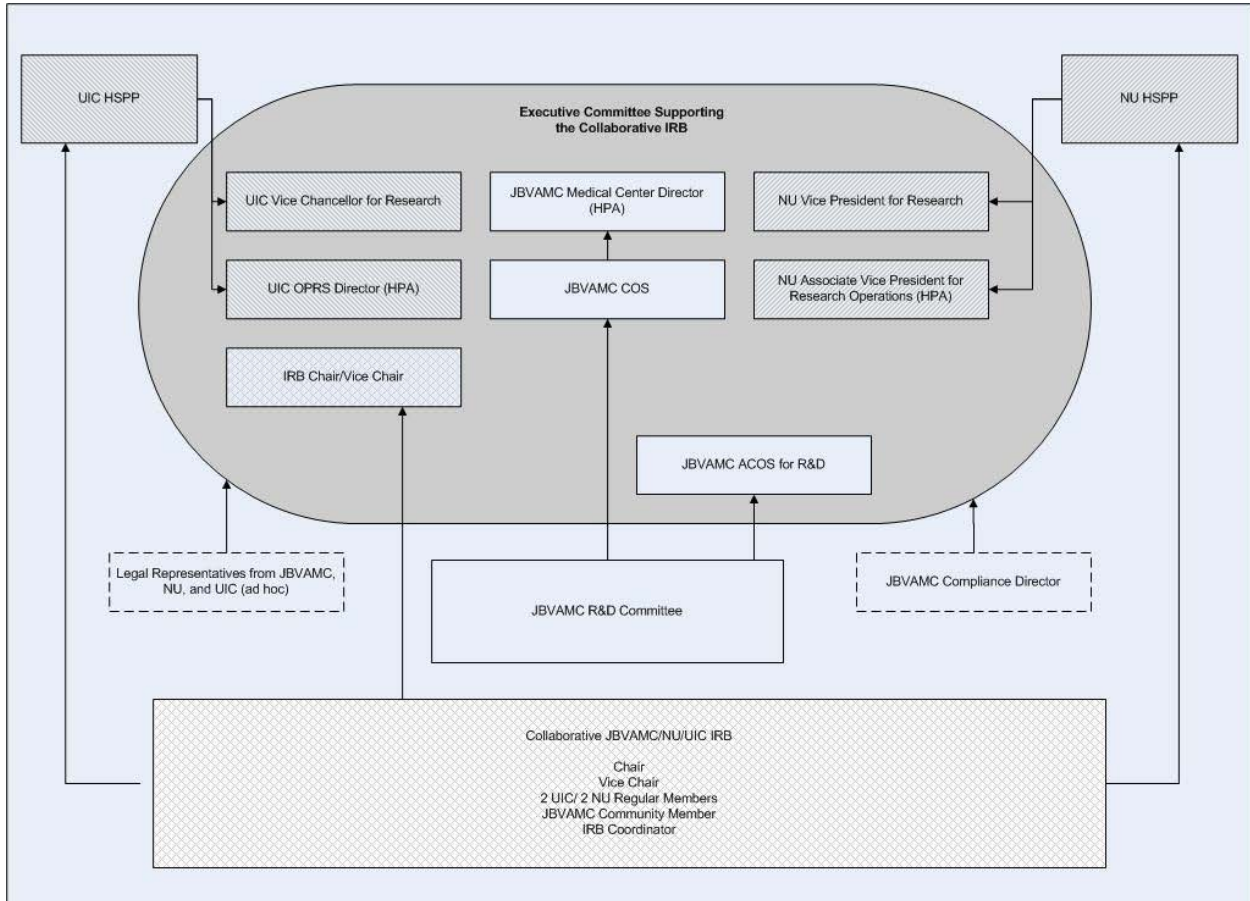
- A. The UIC HPA will designate a staff member to provide administrative assistance for each meeting.
- B. The designated staff member will provide the following:
 - 1. In advance of the meeting:
 - a) Schedule meeting dates, update members, communicate with NU OPRS, UIC OPRS, and JBVAMC regarding meeting agendas.
 - 2. At the meeting:
 - a) Draft minutes of the key matters discussed; and
 - b) Distribute documents to members.
 - 3. After the meeting:
 - a) Finalize meeting minutes;
 - b) Email meeting minutes to all members; and
 - c) Generate correspondence to the IRB or respective institution

III. Quorum

- A. To attain quorum, the HPAs from each institution must be in attendance (in person or via tele/video conference).
- B. Quorum for all meetings is a majority of members or their designees (up to three maximum per meeting).
- C. Members may participate via tele/video conference.

- D. No individual on the EC may participate in the review of an issue who has a real or perceived conflict of interest with the matter under consideration.

IV. Diagram of the EC:



REFERENCES:

[VHA Handbook 1200.1](#), [VHA Handbook 1200.05](#)

Generally.

[21 CFR 56.109\(a\)](#), [21 CFR 56.109\(e\)](#), [21 CFR 56.112](#), [21 CFR 56.109\(e\)](#), [21 CFR 56.112](#), [21 CFR 56.113](#)

[38 CFR 16.109\(a\)](#), [38 CFR 16.109\(c\)](#), [38 CFR 16.112](#), [38 CFR 16.113](#)

[45 CFR 46.109\(a\)](#), [45 CFR 46.109\(e\)](#), [45 CFR 46.112](#), [45 CFR 46.113](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 04/03/09	1.0, 05/19/08	Revised UIC and NU HPA to reflect position changes.
1.2, 06/09/10	1.1, 04/03/09	Included a clause that allows up to three designees per EC meeting for individuals who are not HPAs. Included a reference to an IAA, as the MOUs between the various NU legal entities and UIC have not yet been executed. Deleted reference to titles for HPAs, leaving only "UIC HPA; JBVAMC HPA; NU HPA."