

## OO10c – NEW KNOWLEDGE, INNOVATIONS, AND IMPROVEMENTS

*Provide the policies, procedures, charters attestation, or bylaws (including Institutional Review Board [IRB]) that protect the rights of participants in human subject research and designates at least one nurse must be a voting member of the governing body responsible for the protection of human research participants.*

AND

*Provide a description and the organization's policies and procedures as part of a formal exempt determination process that effectively address the local setting and programs of research.*

OR

*Provide both of the following:*

- A letter signed and dated by the chair of the governing body responsible for the protection of human research participants that attests to this requirement.*
- A signed and dated attestation which states the organization has educated and trained appropriate staff to determine if the research is to be exempt from full IRB review. Include the exempt determinations are approved by the Human Research Protections Program governing body.*

### **IRB Attestation Letter**

OO10c.1	IRB Attestation Letter
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### **IRB Attestation Form**

OO10c.2	NYP Columbia IRB Attestation
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Human Research Protection Office  
Institutional Review Boards



May 18, 2022

FROM: Brenda Ruotolo  
AVP for Human Research Protection  
Human Research Protection Office  
Columbia University

ORGANIZATION: NewYork-Presbyterian Columbia University Irving Medical Center (CUIMC)

TO: American Nurses Credentialing Center  
Magnet Recognition Program®  
Silver Spring, MD 20910

SUBJECT: NURSE MEMBERSHIP ON THE CUIMC IRB

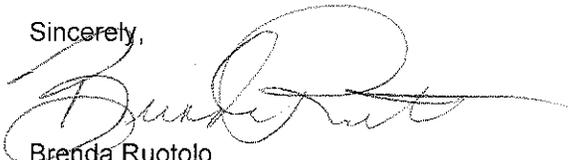
The CUIMC Human Research Protection Office has Institutional Review Board (IRB) policies, procedures, or bylaws designating consistent membership and involvement as a voting member by at least one nurse in the governing body responsible for the protection of human subjects. The vast majority of protocols from nurses are either exempt or eligible for an expedited review process, in accordance with applicable regulations. A nurse is a member of our IRB that is dedicated for expedited reviews with access to all assigned protocols and notes/minutes for the review thereof. In addition, those rare nurse-led protocols that require review by a convened IRB will go to a Board that is chaired by a nurse or includes a nurse member. Hence, our records indicate that the CUIMC IRB reviews of nurse-led protocols include either a nurse member or nurse alternate member with voting status.

The CUIMC IRB may also be asked to determine research to be exempt from IRB Review. Exempt determinations are made by the Human Research Protection Office. All relevant staff members are properly educated and trained.

If you have any questions, please contact:

Reynaldo R. Rivera, DNP, RN, NEA-BC, FAAN  
Director of Nursing Research and Innovation  
NewYork-Presbyterian Hospital  
Email: [RRR9001@nyp.org](mailto:RRR9001@nyp.org)  
Phone: 212-746-4088

Sincerely,



Brenda Ruotolo  
AVP for Human Research Protection

# 2023 Manual IRB Attestation

Date (within 48 months prior to document submission): February 2020 - 2024

From: (Applicant Organization) NewYork-Presbyterian Columbia Irving Medical Center

To: Magnet Recognition Program®

Subject: Institutional Review Board (IRB) Process

Please choose the attestation option(s) that represent(s) your organization's IRB process. If your organization uses both a full IRB Review and a Formal Exempt Determination process, please check and complete both attestation options as applicable. Refer to the 2023 Magnet Application Manual (0010) for more information.

## Select & Complete Section A: if your organization uses a full IRB Review

### Section A

Columbia University Institutional Review Board (IRB Name - applicant organization or external IRB) has policies, procedures, or bylaws designating consistent membership and involvement as a voting member by at least one nurse in the governing body responsible for the protection of human subjects. Our records indicate that the majority of our meetings have either a nurse member or nurse alternate member present and in voting status.

Sincerely,

Brenda L. Ruotolo

Executive IRB Chair (Printed Name)



Executive IRB Chair (Signature)

*Please note: an electronic transmission of this signed form constitutes an electronic signature.*

### Please direct all questions to:

Reynaldo R. Rivera, DNP, RN, NEA-BC, FAAN, FAONL

rrr9001@nyp.org

347-563-6263

Full Name

Email Address

Phone Number

## Select & Complete Section B: if your organization uses a Formal Exempt Determination process

### Section B

Columbia University IRB Staff (Name of organization staff member or group) has been educated and trained to determine if the research is to be exempt from full IRB Review. Exempt determinations comply with the Human Research Protections Program governing body.

Sincerely,

Bernadette Khan, DNP, RN, NEA-BC

Chief Nursing Officer (Printed Name)

Bernadette Khan

Bernadette Khan (Jan 8, 2024 11:45 EST)

Chief Nursing Officer (Signature)

*Please note: an electronic transmission of this signed form constitutes an electronic signature.*

### Please direct all questions to:

Reynaldo R. Rivera, DNP, RN, NEA-BC, FAAN, FAONL

rrr9001@nyp.org

347-563-6263

Full Name

Email Address

Phone Number