OO19 – The organization's policies, procedures, charters or bylaws designating that at least one nurse must be a voting member of the governing body responsible for the protection of human research participants, and that at least one nurse votes on nursing-related protocols.

The purpose of the UVA Institutional Review Board for Health Sciences Research (IRB-HSR) is to review all research involving human subjects; to ensure the research complies with institutional policies and state, local and federal laws; and to safeguard the rights and welfare of research subjects.
Several Nursing representatives participate in UVA IRB-HSR processes, both in leadership and supportive staff roles, to ensure that the nursing profession has a strong voice in research at UVA, well-positioned to promote the *ANA Code of Ethics for Nurses* Section 3.3 principles of patient advocacy, informed consent, data privacy and robust review of ethical research methodology.[1]
For a description of the processes of the UVA IRB-HSR, see Exhibits OO19.a and OO19.b, with key excerpts summarized below.

- Exhibit OO19.a: UVA IRB Standard Operating Procedures. The Vice-Chair of the UVA IRB-HSR is a Registered Nurse and represents Nursing on all protocol votes.
    - Page 10, "The chair designates the vice chair to review and approve all expedited reviews."
    - Page 11, "By virtue of appointment, all vice chairs are designated by the chair to review and approve research."
    - Pages 11-12, "The IRB-HSR will consist of members of various professions, including at least one scientist, one nonscientist and one member who is not otherwise affiliated with the institution ... One of the scientist members will always include a registered nurse."
    - All appointed IRB-HSR members have a vote. Page 12, "If both the alternate and the member attend a meeting, only one of these two may vote. In these cases, the minutes reflect who is in attendance as a voting member."
- Exhibit OO19.b: UVA IRB-HSR Members' Guide outlines detailed expectations of all members for reviewing, commenting on and voting on protocols. The Vice-Chair (an RN) reviews and votes on all protocols. Selected excerpts below highlight key elements of Exhibit OO19.b regarding voting principles.
    - Page 7 specifies that appointed scientific members of the IRB have a vote (Exhibit OO19.a above requires that at least one of the scientific members is an RN).

[1]The American Nurses Association. (2001). Section 3.3. Protection of participants in research. *ANA Code of Ethics for Nurses, with Interpretive Statements.* (retrieved online: http://www.nursingworld.org/MainMenuCategories/EthicsStandards/CodeofEthicsforNurses/Code-of-Ethics.pdf).

- Page 3 outlines the differing roles of the IRB administrative staff and the IRB itself, clearly indicating that only board members vote: “The IRB, not the professional staff, makes final decisions regarding a research project that has been submitted for consideration.”
- Page 6 allows for other RNs to provide nonvoting consultant expertise: “On occasion, additional individuals with expertise in a particular field may be invited to a meeting to provide consultation on specific protocols; such individuals are not included in the quorum nor do they have voting rights.”
- Pages 5-6 summarize the parameters for the level of protocol review: Full Board, Expedited (which Exhibit OO19.a designates as the responsibility of the Vice-chair, an RN) or Exempt. “While the default is review by the full board at a scheduled meeting, certain minimal risk projects may be eligible for expedited review or may be exempt from review requirements. Only the IRB can make the determination that the research meets exempt criteria, meets expedited criteria or will require approval of the full board.”
- Pages 9-10 require a quorum consisting of a majority of the IRB to be present in order to vote; full-time board members are expected to attend each meeting, and their active participation is recorded in the minutes and in reviewer comments they are expected to submit (Pages 13,15). Failure to fulfill these expectations will result in termination of their IRB appointment.
- Page 35 describes the general process to conduct the vote.

The IRB-HSR respects the professional perspective that RNs bring to the roles of IRB voting member and Principal Investigator (PI), especially noting when those PIs are not full-time researchers but rather clinical nurses whose protocols are developed through the PNSO Nursing Research Program. Figures 1, 2 and 3 below are drawn from the IRB-HSR Administrative Pre-Review Checklists / Approval Comment Forms.

- Figure 1, the Checklist for New “Full Board” Protocols and Full Board 5-Year Updates, requires an RN IRB member to vote on protocols from the PNSO Nursing Research Program, in which RNs serve as the Principal Investigators.
- Figure 2, the Checklist for New “Expedited” Protocols and Expedited 5-Year Updates, requires either the IRB Vice-Chair (an RN, as described above), or an IRB RN member-designee, to review the expedited PNSO protocol and sign the assurance form.
- Figure 3, the Checklist for “Modifications,” reinforces the same expectations above, that an RN vote on full board protocol modifications or sign the assurance form for expedited protocol modifications.

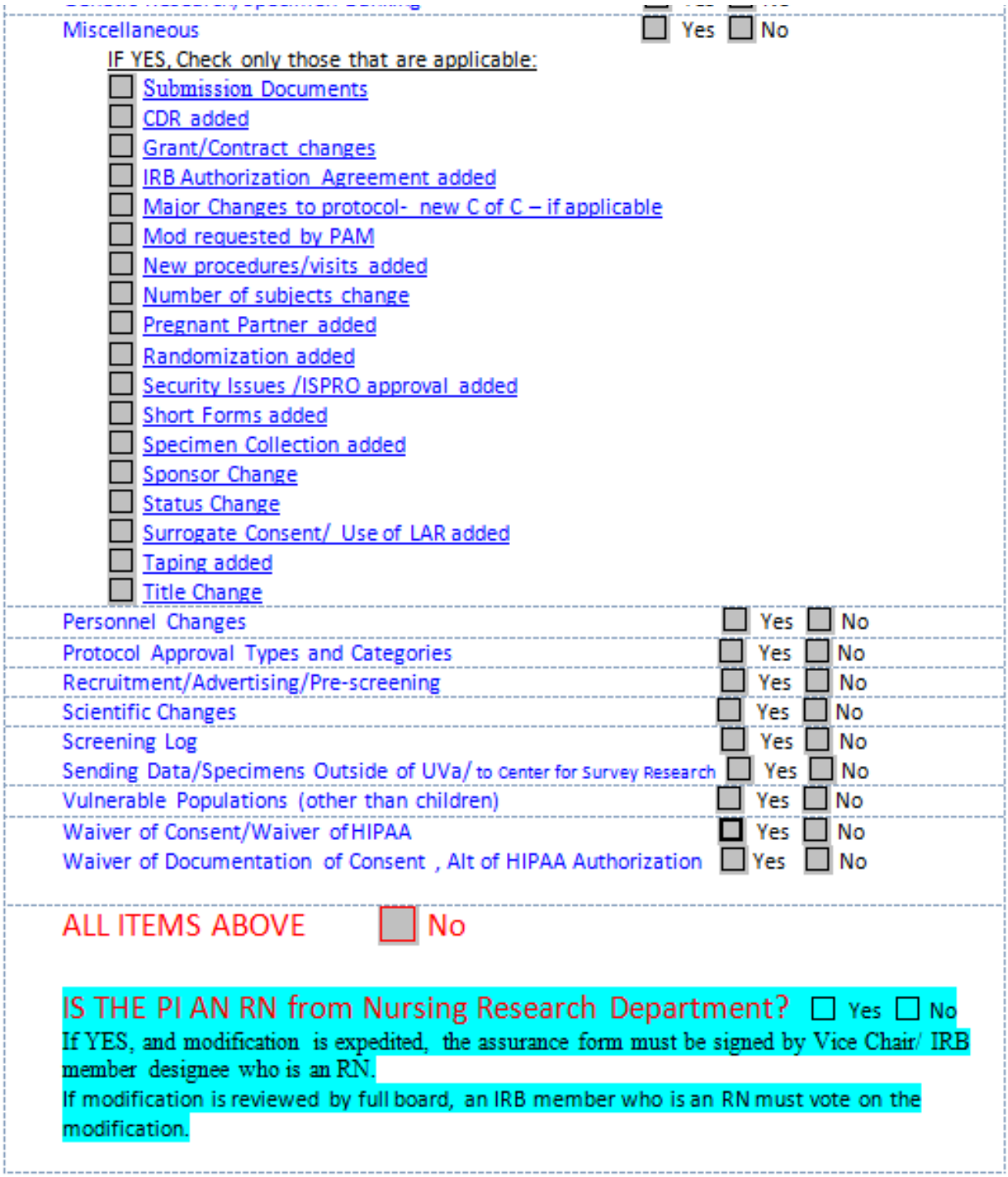
OO19 Figure 1. Excerpt from IRB-HSR's Full Board Protocols Checklist

ADDITIONAL APPROVALS/REVIEWS ☐ NONE *If any of the approval items below are applicable- they should be checked below and on the regulatory page of IRB Online.*	
Cancer Center Protocol Review Committee (PRC)	☐ NA ☐ Pending Approval ☐ On file
Radiation Safety Review/HIRE Review	☐ NA ☐ Pending Approval ☐ On file If "On file" is checked, will Template D wording for a radiation dose of >50mSv/year be used? ☐ Yes ☐ No *If YES, add the following wording into the receipt event:* This protocol will deliver a radiation dose >50 mSv/year. The radiology representative on the IRB must review this protocol to determine a risk-benefit analysis.
Institutional Biosafety Committee (IBC)	☐ NA ☐ Pending Approval ☐ On file
Information Security, Policy & Records Office (ISPRO)	☐ NA ☐ Pending Approval ☐ On file
SOM CTO-**PI of Multi-site**	☐ NA ☐ Pending Approval ☐ On file
SOM CTO-**Need for IND/IDE**	☐ NA ☐ Pending Review ☐ On file
SOM CTO **IND/IDE held by Outside PI**	☐ NA ☐ Pending Approval ☐ On file
SOM CTO **UVa PI of IND/IDE**	☐ NA ☐ Pending Approval ☐ On file
SOM CTO-Outside academic investigator serving as Sponsor (overarching sponsor protocol requires review)	☐ NA ☐ Pending Approval ☐ On file
Outside IRB approval	☐ NA ☐ Pending Approval ☐ On file
New Medical Device Form	☐ NA ☐ Pending Application ☐ On file
ESCRO committee: viable embryos/embryonic stem cells	☐ NA ☐ Pending Approval ☐ On file
SOM Issues (If PI is in SOM and FDA approval section,-3 or more questions NO-refer)	☐ NA ☐ Referred to IRB Chair and Wasserman *No response needed*
ISPRO	☐ NA ☐ Pending Approval ☐ On file
PI is an RN from the Nursing Research Department	☐ Yes ☐ No If Yes, an IRB member who is an RN must vote on the protocol.

OO19 Figure 2. Excerpt from IRB-HSR's Expedited Protocols Checklist

ADDITIONAL APPROVALS/REVIEWS ☐ NONE **If any of the items below are applicable- they should be checked below and on regulatory page of IRB Online.**	
Cancer Center Protocol Review Committee (PRC)	☐ NA ☐ Pending Approval ☐ On file
Institutional Biosafety Committee (IBC)	☐ NA ☐ Pending Approval ☐ On file
SOM CTO-**PI of Multi-site**	☐ NA ☐ Pending Approval ☐ On file
SOM CTO **Need for IND/IDE**	☐ NA ☐ Pending Review ☐ On file
Outside IRB approval	☐ NA ☐ Pending Approval ☐ On file
New Medical Device Form	☐ NA ☐ Pending Application ☐ On File
Information Security, Policy & Records Office (ISPRO)	☐ NA ☐ Pending Approval ☐ On file
SOM Issues:If PI is in SOM and *FDA approval section, 3 or more questions NO-refer*	☐ NA ☐ Referred to IRB Chair and Steve Wasserman *No response required*
ISPRO	☐ NA ☐ Pending Approval ☐ On file
PI is an RN from the Nursing Research Department	☐ Yes ☐ No If YES, assurance form must be signed by Vice Chair/ IRB member designee who is an RN.

OO19 Figure 3. Excerpt from IRB-HSR's Modified Protocols Checklist



Miscellaneous ☐ Yes ☐ No

IF YES, Check only those that are applicable:

- ☐ Submission Documents
- ☐ CDR added
- ☐ Grant/Contract changes
- ☐ IRB Authorization Agreement added
- ☐ Major Changes to protocol- new C of C – if applicable
- ☐ Mod requested by PAM
- ☐ New procedures/visits added
- ☐ Number of subjects change
- ☐ Pregnant Partner added
- ☐ Randomization added
- ☐ Security Issues /ISPRO approval added
- ☐ Short Forms added
- ☐ Specimen Collection added
- ☐ Sponsor Change
- ☐ Status Change
- ☐ Surrogate Consent/ Use of LAR added
- ☐ Taping added
- ☐ Title Change

Personnel Changes	☐ Yes ☐ No
Protocol Approval Types and Categories	☐ Yes ☐ No
Recruitment/Advertising/Pre-screening	☐ Yes ☐ No
Scientific Changes	☐ Yes ☐ No
Screening Log	☐ Yes ☐ No
Sending Data/Specimens Outside of UVa/ to Center for Survey Research	☐ Yes ☐ No
Vulnerable Populations (other than children)	☐ Yes ☐ No
Waiver of Consent/Waiver of HIPAA	☐ Yes ☐ No
Waiver of Documentation of Consent , Alt of HIPAA Authorization	☐ Yes ☐ No

ALL ITEMS ABOVE ☐ No

IS THE PI AN RN from Nursing Research Department? ☐ Yes ☐ No

If YES, and modification is expedited, the assurance form must be signed by Vice Chair/ IRB member designee who is an RN.

If modification is reviewed by full board, an IRB member who is an RN must vote on the modification.

Table 1 below depicts the members of the IRB-HSR staff; six of the 13 are RNs, including the leadership roles of Vice-Chair, Director and Associate Director.

OO19 Table 1. UVA IRB-HSR Staff

Name	Title	Focus Areas
Richard Stevenson, MD	Chair	• Subject Safety Concerns
Lynn Noland, PhD, RN	Vice-Chair	• Subject Safety Concerns
Susie Hoffman, BSN, RN, CIP	Director	• Policy Issues • Template Issues
Karen Mimms, RN, CIP	Associate Director	• Advertisements • Adverse Events • Protocol/Grant Continuations • Protocol Violations • Unanticipated Problems • Closures
Eileen Sembrowich, BS, BA, CCRP, CIP	Assistant Director	• Pre-review of Full Board Submissions
Margaret Ball, BSN, CCRP, CIP	Compliance Coordinator	• New Protocol Development
Helena Estes Johnson, RN, CIP	Compliance Coordinator	• Continuations and Expedited Protocols • Closures
Medard Ng, PhD, CIP	PRC-IRB-HSR Compliance Coordinator	• Modifications and CIRB Submissions
Terry Ryan, BSN, BS, RN	Compliance Coordinator	• New Full Board Submissions • New Grant Submissions • Exempt Applications
Blaise Spinelli, BA	Compliance Coordinator	• Expedited Protocols
Jean Gaare Eby, ScD	IRB Educator	• Education

Name	Title	Focus Areas
Rob Banks	Office Administrator	• Personnel changes • CITI Training Records
Florence Thoms	Administrative Assistant	• General Information