

**APRNet Unaffiliated Investigator Agreement**

Name of Institution with Federalwide Assurance: Yale University (“Yale”)

Applicable FWA #: FWA 00002571

Unaffiliated Investigator’s (“Investigator”) Name and Address:

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Research covered by this Agreement:

APRNet protocols approved by Yale IRB #3, Fed. Reg. No. 00000596 , at Yale School of Nursing (“IRB #3”)

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(1) By his or her signature below, the Investigator certifies that he or she has reviewed: (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; (b) The U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46; (c) The Federalwide Assurance (FWA) referenced above; and (d) Yale University’s and Yale IRB #3’s policies and procedures for the protection of human subjects in research. The Investigator further certifies that he or she has taken either the NIH or Yale training in human subjects protections. The Investigator understands, and hereby accepts the responsibility to comply with, the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement. The Investigator agrees to comply with all other applicable national, state, or local laws and regulations. The Investigator will complete any educational training required by Yale and/or IRB #3 prior to initiating research covered by this Agreement. The Investigator acknowledges that he or she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.

(2) The Investigator acknowledges IRB #3’s responsibility for initial and continuing review, record keeping, reporting, and certification, and agrees to cooperate with the IRB in fulfilling that responsibility, including but not limited to by timely providing all documents and information requested by IRB #3. The Investigator will not enroll subjects in research under this Agreement prior to review and approval of the research by IRB #3. The Investigator will obtain, document, and maintain records of informed consent from each subject or the subjects legally authorized representative as required under DHHS and FDA regulations and as stipulated by IRB #3. The Investigator will abide by all applicable determinations of IRB #3 and Yale and will accept the final authority and decisions of IRB #3, including but not limited to directives to terminate participation in designated research activities.

(3) The Investigator will report promptly to IRB #3 any proposed changes in the research conducted under this Agreement and will not initiate any changes in the research without prior review and approval by IRB #3, except when necessary to eliminate apparent immediate hazards to subjects. The Investigator will report immediately to IRB #3 any unanticipated problems involving risks to subjects or others in research covered under this Agreement. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law. Data and information obtained as a result of emergency medical care may not, however, be used as part of federally-supported or –conducted research.

(4) This Agreement authorizes the Investigator to rely on the Yale IRB with respect to protocols put forward by the APRNet, a research network established by the Yale School of Nursing. The Investigator may conduct research only with respect to those APRNet protocols that have been reviewed and approved Yale IRB #3, as evidenced by an approval notice from that IRB. This Agreement does not preclude the Investigator from taking part in human subjects research not covered by the Agreement. The Investigator understands, however, that he or she may not rely on the Yale IRB with respect to any research not covered by this Agreement or by a similar agreement with Yale.

(5) By his or her signature below, the Investigator certifies that he or she is a certified Advanced Practice Registered Nurse, authorized by applicable state law to conduct research with respect to his or her patients, including with respect to patients' medical records. If the Investigator employed by another individual or an entity with the primary patient relationship, this Agreement must be endorsed by that individual and is ineffective without such an endorsement. The Investigator agrees to give Yale prompt written notice of any change in his or her employment status, in his or her patient relationship status, or of any other matter affecting his or her authority to conduct research under this Agreement.

(6) This Agreement may be terminated by Yale or by Investigator, with or without cause, upon 30 days prior written notice, or in any lesser period of time (including forthwith), if required to protect the safety of human subjects.

**Investigator Signature:** \_\_\_\_\_ Date \_\_\_\_\_

Name: \_\_\_\_\_ Degree(s) \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Phone: \_\_\_\_\_

E-mail: \_\_\_\_\_

Fax: \_\_\_\_\_

**Yale Institutional Official** \_\_\_\_\_ Date \_\_\_\_\_  
(or designee)

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

\_\_\_\_\_ E-mail: \_\_\_\_\_

Fax: \_\_\_\_\_

**Investigator employer signature (if required)** \_\_\_\_\_

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Address: \_\_\_\_\_ Phone \_\_\_\_\_

\_\_\_\_\_ E-mail \_\_\_\_\_

Fax \_\_\_\_\_