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Office of Research and Development (ORD) and Office of Nursing Services (ONS) Guidance: VA Facility Participation in the 2021 Press-Ganey Research Study:

RN National Database of Nursing Quality Indicators RN Survey

DATE: July 26, 2021

This is a new guidance document. For questions on the content within this guidance, email ORD through FIND Pro.

Scope: This guidance document provides specific requirements that must be followed by VA Facilities participating in the Press-Ganey Research Study: RN National Database of Nursing Quality Indicators (NDNQI) RN Survey. For purposes of this guidance, the study will be called the RN Survey research study. This joint guidance, issued by both the VHA Office of Research and Development (ORD) and Office of Nursing Services (ONS), provides information to VA Facility nursing leadership, VA Facility Human Research Protection Programs and Research Development (R&D) Committees, Institutional Review Boards (IRBs), and VA Facility information systems security officers (ISSOs) and privacy officers (POs) on the review and approval of this research study.

Background: Many VA Facilities voluntarily conduct the National Database of Nursing Quality Indicators as an optional quality improvement activity contracted through Press Ganey Associates. The NDNQI is a unit-level nursing quality measurement product offered to client health care facilities primarily in the United States by Press Ganey. This quality assurance product, commonly referred to as the Press Ganey/NDNQI, collects data from nursing units in client health care facilities. The NDNQI is not a research study.

The Press Ganey/NDNQI offers to its clients an additional data collection activity called the RN Survey. The RN Survey is a human subjects research study collecting data from direct care registered nurses (RNs) evaluating RN job satisfaction and the nursing work environment. ORD has evaluated the study and determined that it is an exempt study as described in the federal human subject regulations at 38§16.104(d)(2) requiring a limited Institutional Review Board (IRB) review. Press-Ganey has also confirmed that the RN Survey study has been determined to be an exempt study from the Advarra IRB. While any VA Facility without a research program can conduct the Press-Ganey NDNQI data collection if a contract is executed between the VA Facility and Press Ganey, only VA Facilities with research programs can conduct the RN Survey. Any RN who completes the NDNQI RN Survey is a research subject To assist VA Facilities wishing to participate in the RN Survey and address humans subjects protection issues, ONS and ORD coordinated on national enterprise mechanisms designed to facilitate conducting the RN Survey by participating VA Facilities. This guidance document addresses a variety of issues to assist VA facilities wishing to participate in the RN Survey research study divided into the following sections:

A. VA Facility Requirements to Conduct the RN Survey research study

1. VA Facilities who have already begun conducting the RN Survey research study or plan to conduct the survey prior to September 1, 2021
   a. Local IRB approval
   b. VA Facility R&D Committee approval
   c. ISSO and PO reviews

2. VA Facilities planning to conduct the RN Survey study on or after September 1, 2021
   a. Central or Local IRB approval
   b. VA Facility R&D Committee approval
   c. ISSO and PO reviews

B. Additional Agreement and Review Topics Related to the RN Survey research study
   a. Organizational Assessment Committee (OAC) Review approval:
   b. Office of Management and Budget (OMB) approval for RN Survey research study data collection tool

C. Required Notifications to ONS and ORD for all VA Facilities participating in the RN Survey research study

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A. VA Facility Requirements to Conduct the RN Survey research study

In order for your VA Facility to conduct the RN Survey research study, the following must occur based upon whether or not your VA Facility (a) has already began conduct of the RN Survey research study or is planning to conduct the survey **prior to September 1, 2021**, or (b) is planning to conduct the RN Survey research study **on or after September 1, 2021**.

1. VA Facilities who have already begun conducting the RN Survey research study or plan to conduct the survey prior to September 1, 2021.

   For VA Facilities who plan to conduct the RN Survey research study prior to September 1, 2021, local IRB approval for the required limited IRB review and R&D Committee approvals are required unless your VA Facility wishes to rely upon the VA Central IRB for limited IRB approval. The anticipated date of VA Central IRB approval for the limited IRB review is late August or early September dependent upon receipt of required materials for application submission.

If your VA Facility placed a temporary hold on the RN Survey research study, ORD and ONS recommend that the study proceed with the required research approvals. If your VA Facility began conducting the RN Survey research study and placed a temporary hold pending limited IRB approval and R&D Committee approval are pending, your VA Facility can choose to use its own local IRB to conduct the limited IRB review with approval or wait until the VA Central IRB conducts its approval. Please note that R&D Committee final approval cannot be obtained until after the limited IRB approval has been obtained.

a. Local IRB approval:

The primary IRB of Record for the VA Facility (either the VA Facility's internal IRB or university-affiliated IRB) will conduct the limited IRB review and provide approval unless your VA Facility wishes to delay until the VA Central IRB's review and approval. A limited IRB review can be done by expedited procedures (does not require review at a convened IRB meeting).

If your IRB approved the RN Survey research study as a non-exempt human subjects study, there is no requirement to convert the study to an exempt study. ORD will grant a single IRB exception allowing use of more than one IRB to approve the research study if more than two or more VA Facilities approved the study as a non-exempt study.

b. VA Facility R&D Committee approval:

The VA Facility's R&D Committee must approve the RN Survey research study prior to initiation of the research, including ACOS/R&D notification to the investigator, in writing, when the research project can be initiated. As an exempt study, designated review is permitted to be used for R&D Committee approval as described in VHA Directive 1200.01, Paragraph 9.e.(4).

Any modifications/amendments in the RN Survey study must be approved by the VA Facility's R&D Committee prior to initiation of the modification/amendment. If the modification/amendment impacts the limited IRB review, the R&D Committee is responsible for ensuring the reviewing IRB of Record reviews the modification/amendment. If the IRB approved the RN Survey research study as a non-exempt human subjects study, any modification/amendments must be approved by the IRB prior to initiation of the modification/amendment.

c. ISSO and PO reviews:

The VA Facility's ISSO and PO will be responsible for completion of all required ISSO and PO review prior to R&D Committee approval if local IRB approval is obtained for the limited IRB review. Please follow your local procedures for submission through the VA Innovation and Research Review System (VAIRRS) of all required documents.

If the VA Central IRB is used for approval of the limited IRB review, centralized ISSO and PO reviews will be done. The Study Chair/PI will make a copy of the approval to all participating sites using the VA Central IRB upon request by email or will give access for the study approval and approved documents through the "Share" function to all participating sites in VAIRRS.

2. VA Facilities planning to conduct the RN Survey research study on or after September 1, 2021,

For VA Facilities planning to conduct the RN Survey research study on or after September 1, 2021, ORD and ONS are recommending use of the VA Central IRB to conduct the limited IRB review with central ISSO and PO reviews unless your local IRB has already conducted the limited IRB review or approved it as a non-exempt humans subjects study. .

a. IRB approval:

The VA Central IRB will conduct the limited IRB review and provide approval for the RN Survey research study. The Study Chair/Principal Investigator (PI) will be Dr. Sheila Sullivan, Director of Research Evidence-Based Practice (EBP) & Analytics; ONS. The Study Chair/PI will obtain approval for the master protocol/application of the RN Survey research study from the VA Central IRB.

While local site applications are not required for submission to the VA Central IRB, all participating sites using the VA Central IRB to conduct the limited IRB review will submit their names to Dr. Sullivan with the name of the VA Facility's Principal Investigator. The Study Chair/PI will make a copy of the approval to all participating sites using the VA Central IRB upon request by email or will give access for the study approval and approved documents through the "Share" function to all participating sites in VAIRRS.

b. VA Facility R&D Committee approval:

The VA Facility's R&D Committee must approve the RN Survey research study prior to initiation of the research, including ACOS/R&D notification to the investigator, in writing, when the research project can be initiated. As an exempt study, designated review is permitted to be used for R&D Committee approval as described in VHA Directive 1200.01, Paragraph 9.e.(4).

Any modifications/amendments in the RN Survey study must be approved by the VA Facility's R&D Committee prior to initiation of the amendment. If the modification/amendment impacts the limited IRB review, the Study Chair/PI will submit the modification/amendment to the VA Central IRB for approval The VA Central IRB will notify the participating site investigators of amendment/modification approval for subsequent approval by the R&D Committee.

c. ISSO and PO reviews:

Central ISSO and PO reviews will be done for any VA Facility using the VA Central IRB to conduct the limited IRB review for the RN Survey research study, including any reviews of modifications/amendments requiring ISSO and PO reviews. Participating VA sites will not submit a VA Form 10-250. However, any participating site using the VA Central IRB to conduct the limited IRB review must also submit the Enterprise Research Data Security Plan (ERDSP) by uploading it into VAIRRS.

No other materials will be required to be submitted to the VA Central IRB using VAIRRS by participating sites unless specifically requested by the individuals or groups completing the central ISSO and PO reviews.

The Study Chair/PI will make a copy of the approval to all participating sites using the VA Central IRB upon request by email or will give access for the study approval and approved documents through the "Share" function to all participating sites in VAIRRS.

B. Additional Agreement and Reviews Topics Related to the RN Survey research study

a. Organizational Assessment Committee (OAC) Review approval:

VA Facilities are not required to obtain OAC approval if your site has already begun the RN Survey research study or National approval will be obtained by ONS from OAC.

b. Office of Management and Budget (OMB) approval for RN Survey research study data collection tool:

VA employees (RNs) are the prospective subjects asked to participate in the RN Survey research study. Surveys involving VA employees are not subject to the Paperwork Reduction Act (PRA). OMB approval is not required.

C. Required Notifications to ONS and ORD for all VA Facilities Participating in the RN Survey research study

a. ONS and ORD Notification of VA Facilities conducting the NDNQI and/or NDNQI RN Survey research study:

To facilitate communication and coordination for all VA Facilities participating in the RN Survey research study, ONS and ORD are requesting notification if your VA Facility has elected to conduct the RN Survey research study and/or the NDNQI.

Please send your notification to the following individuals:

- For ONS: Dr. Sheila Sullivan at Sheila.sullivan2@va.gov
- For ORD: Dr. Karen Jeans at c.karen.jeans@va.gov

b. Questions to Press-Ganey about the NDNQI RN Survey research study:

If there are questions related to the RN Survey research study requiring a response by Press Ganey, ONS requests that these questions be sent to the Study Chair/PI if it is related to study procedures. If the question is specific to the site, such as a local contract question, there is no need to contact ONS.