CommonSpirit Health Research Institute
Institutional Review Board
(CSHRI IRB) IRB Application

Last edited by: C. J. Newton
Last edited on: October 21, 2022
PI Name: Angie Longing, MHSM, BSN

☑ Exemption ☐ Expedited ☐ Full Board
☐ Treatment Use ☐ Emergency Use ☐ Not Research
☐ Ceding

[Jump to Instructions]

[1955028-2] The Effect of a Shared Governance Model on Perceptions of Professional Control and Governance

I. Principal Investigator or Treating Physician

Name: Angie Longing
Degree(s)/ Title: MHSM, BSN
Phone: [redacted]
Email: angie.longing[redacted]
Dept: Nursing Administration
Facility: Arkansas (Little Rock) - St. Vincent Infirmary Medical Center
Mailing Address: angie.longing[redacted]

Is the PI a student/trainee/resident/fellow? ☐ Yes ☑ No
Primary Contact? ☐ Yes ☑ No
CSHRI-employed Clinical Project Manager submitting to CSHRI IRB? ☐ Yes ☑ No
CSHRI-Employed Name:
Financial Conflict of Interest? ☐ Yes ☑ No

II. Project Mentor N/A ☑

Name:
Degree(s)/ Title:
Phone:
Email:
Dept:
Facility:
Mailing Address:
Financial Conflict of Interest? ☐ Yes ☐ No

III. Primary Contact N/A ☐

Name: C.J. Newton
Degree(s)/ Title: MSN, RN
Phone: [redacted]
Email: cjnewton[redacted]
Dept: Nursing Administration
Facility: Arkansas (Little Rock) - St. Vincent Infirmary Medical Center

Mailing Address: cjnewton[redacted]

Financial Conflict of Interest? ☐ Yes ☑ No

IV. Additional Personnel N/A ☐

Please complete this section for each Additional Personnel.

Name: Pamela Ashcraft **Degree(s)/ Title:** PhD, RN, PHCNS-BC

Phone: [redacted] **Email:** pama[redacted]

Dept: Nursing Administration **Facility:** Arkansas (Little Rock) - St. Vincent Infirmary Medical Center

Role: Co/Sub Investigator

Mailing Address: pama[redacted]

Will this person conduct the informed consent process? ☐ Yes ☑ No

Will this person have a financial conflict of interest? ☐ Yes ☑ No

---

Name: C. J. Newton **Degree(s)/ Title:** MSN, RN, NE-BC

Phone: [redacted] **Email:** cjnewton[redacted]

Dept: Nursing Administration **Facility:** Arkansas (Little Rock) - St. Vincent Infirmary Medical Center

Role: Research Coordinator

Mailing Address: cjnewton[redacted]

Will this person conduct the informed consent process? ☐ Yes ☑ No

Will this person have a financial conflict of interest? ☐ Yes ☑ No

---

Name: Laura McAnally **Degree(s)/ Title:** BSN, RN, RN-BC, Magnet Program Director

Phone: [redacted] **Email:** laura.mcanally[redacted]

Dept: Nursing **Facility:** Arkansas (Hot Springs) - CHI St. Vincent Hot Springs

Role: Co/Sub Investigator

Mailing Address: laura.mcanally[redacted]

Will this person conduct the informed consent process? ☐ Yes ☑ No

Will this person have a financial conflict of interest? ☐ Yes ☑ No

---

Name: Teresa Lambert **Degree(s)/ Title:** MBA, BSN, RN, Chief Nursing Office

Phone: [redacted] **Email:** teresa.lambert[redacted]

Dept: Nursing **Facility:** Arkansas (Hot Springs) - CHI St. Vincent Hot Springs

Role: Co/Sub Investigator

Mailing Address: teresa.lambert[redacted]

Will this person conduct the informed consent process? ☐ Yes ☑ No

Will this person have a financial conflict of interest? ☐ Yes ☑ No

---

Name: Allison Fitts **Degree(s)/ Title:** RN, CMSRN, Clinical Nurse

Phone:[redacted] **Email:** Allison.Fitts[redacted]

Dept: Nursing **Facility:** Arkansas (Hot Springs) - CHI St. Vincent Hot Springs

Role: Co/Sub Investigator

Mailing Address: Allison.Fitts@[redacted]

Will this person conduct the informed consent process? ☐ Yes ☑ No

Will this person have a financial conflict of interest? ☐ Yes ☑ No

---

V. Location Information

Affiliated Locations:

- ☐ CHI National Office
- ☑ Arkansas (Little Rock) - St. Vincent Infirmary Medical Center
- ☐ Iowa (Des Moines) - Mercy Medical Center
- ☐ Kentucky - Flaget Healthcare
- ☐ Kentucky (Louisville) - Jewish Hospital and St. Mary's Healthcare
- ☐ Kentucky (Lexington) - Saint Joseph Health System
- ☐ Nebraska (Omaha) - Alegent Creighton Health
- ☐ Nebraska (Lincoln) - Nebraska Heart Institute
- ☐ Nebraska (Lincoln) - St. Elizabeth's
- ☐ Nebraska (Kearney) - Good Samaritan
- ☐ Oregon (Roseburg) - Mercy Medical Center
- ☐ Pennsylvania (Reading) - St. Joseph Regional Health Network
- ☐ Tennessee (Chattanooga) - Memorial Health Care System
- ☐ Texas (Bryan) - St. Joseph Health System
- ☐ Texas (Lufkin) - Memorial Health System
- ☐ Texas (Houston) - St. Luke's Health
- ☐ Washington (Tacoma) - Franciscan Health System
- ☐ Mercy Medical Center Redding
- ☐ Mercy General Hospital
- ☐ Mercy San Juan Medical Center
- ☐ Mercy Hospital of Folsom
- ☐ Methodist Hospital of Sacramento
- ☐ Woodland Memorial Hospital
- ☐ Dominican Hospital
- ☐ St. John's Regional Medical Center
- ☐ St. John's Pleasant Valley Hospital

- ☐ St. Joseph's Medical Center of Stockton
- ☐ St. Mary's Medical Center
- ☐ California Hospital Medical Center - Los Angeles
- ☐ Sequoia Hospital
- ☐ Mercy Hospital
- ☐ Bakersfield Memorial Hospital
- ☐ Mercy Medical Center
- ☐ Arroyo Grande Community Hospital
- ☐ Mercy Gilbert Medical Center
- ☐ Community Hospital of San Bernardino
- ☐ Mercy Medical Center Mt. Shasta
- ☐ Oak Valley Hospital
- ☐ St. Rose Dominican Hospital - San Martin
- ☐ St. Joseph's Behavioral Health Center
- ☐ Dignity Health Medical Foundation - Mercy Cancer Center - Carmichael
- ☐ Dignity Health Medical Foundation - Mercy Cancer Center - Rocklin
- ☑ Other - list sites below
- ☐ Nebraska (Grand Island) - St. Francis Medical Center
- ☐ Texas (Houston) - Texas Heart Institute
- ☐ Iowa - Wheaton Franciscan Healthcare
- ☐ Pacific Central Coast Health Center, Inc.
- ☐ Northridge Hospital Medical Center
- ☐ St. Rose Dominican Hospital - Rose de Lima
- ☐ Sierra Nevada Memorial-Miners Hospital
- ☐ St. Bernardine Medical Center
- ☐ Glendale Memorial Hospital and Health Center
- ☐ Dignity Health Medical Foundation
- ☐ Saint Francis Memorial Hospital
- ☐ French Hospital Medical Center
- ☐ Mark Twain St. Joseph's Hospital
- ☐ Mercy Southwest Hospital
- ☐ St. Elizabeth Community Hospital
- ☐ St. Rose Dominican Hospital - Siena
- ☐ Dignity Health Medical Foundation - Rocklin
- ☐ Dignity Health Medical Foundation - Mercy Cancer Center - Elk Grove
- ☐ Mercy Oncology Center - Redding
- ☐ CIRI Cooperative Group Network
- ☐ North Dakota - St. Alexius Health
- ☐ Centura - list site(s) below

If "Centura" or "Other" was selected:

Other/Centura Performance Site: Arkansas (Hot Springs) - CHI St. Vincent Hot Springs

VI. Data Security Risk Assessment and Mitigation:

Disclosed Information:

No protected health information (PHI) will be used, accessed or disclosed for this project. Employee names and email addresses will be used for communications throughout this project, which are publicly available in the CommonSpirit Health directory.

The following demographic data will be collected:

Sex/Gender

Age

Current Role

Current Unit

Highest educational degree

Employment status

Number of years employed

Number of years in present position

Overall satisfaction with professional practice within the organization

How will you obtain the protected health information that will be used at any point in the study?

No protected health information (PHI) will be used, accessed or disclosed for this project. Email addresses and names will be obtained from a standard nursing distribution list normally used for business purposes.

Which identifiers will you have possession of at any point in the study?

- [x] Name of individual or family members
- [ ] Address
- [ ] All elements (except years) of dates related to an individual
- [ ] Telephone numbers
- [ ] Fax number
- [x] Email address
- [ ] Social Security Number
- [ ] Medical record number
- [ ] Health plan beneficiary number
- [ ] Account number
- [ ] Certificate or license number
- [ ] Any vehicle or other device serial number
- [ ] Web URL
- [ ] Internet Protocol (IP) Address
- [ ] Finger or voice print
- [ ] Photographic image
- [ ] Any other characteristic that could uniquely identify the individual
- [ ] None

If you selected "Social Security Number", please provide justification to include, use or disclose the social security number.

How will you maintain the data/PHI?

All study data will be stored on a secure CHI St. Vincent AR owned server for a minimum of 5 years. Only the members of the research team will have access to the study data.

How will you transfer, transmit, transport data/PHI?

Data will be collected electronically through Qualtrics and exported to SPSS for data analysis by research team member Pamela Ashcraft. No PHI is being collected for this study.

How will you remove the HIPAA identifiers?

For study purposes email addresses, IP addresses, and names are not being collected. The Qualtrics survey is completely anonymous.

Upon completion of the survey, participants will have the voluntary option to provide an email address to be entered into a random drawing for a prize valued at no more than $25.

Participants will be directed to a separate link to collect email addresses for the drawing. This assures anonymity of the survey responses. Once the drawing has been completed, this data will be destroyed.

Who will see the PHI at the research site?

No PHI is being collected for this study. Investigator and research team members will have access to email addresses.

Who will see the PHI other than the research site?

- ☐ Institutional Review Boards
- ☐ Institutional research oversight/quality assurance/compliance personnel
- ☐ Sponsor of the research and sponsor's representatives (Laboratory, CRO, specimen repository)
- ☐ Regulatory agencies from other countries
- ☐ Student's mentor at their school/college/ university
- ☐ Other:
- ☐ Federal and state regulators
- ☐ Researchers at other institutions who are collaborating on the study
- ☐ Sponsor monitors or auditors
- ☐ Data Safety Monitoring Board
- ☐ NIH, NCI

How will you store or destroy the dataset and any identifying information after the study is complete?

After five years, the electronic data will be permanently deleted/erased from the server.

Are there additional details related to data security for your study that have not been captured in an earlier question?

All study data will be stored on a secure CHI St. Vincent AR owned server for a minimum of 5 years. Only the members of the research team will have access to the study data.

No medical records will be reviewed for this study.

Employees will access the online survey via a hyperlink included in the email distribution. The online survey will be administered using Qualtrics. Responses will not be linked to specific employees. Demographic questions do not include any participant identifiers. Only members of the research team will have access to the data, which will be stored on a secure CHI St. Vincent AR server.

No personally identifying data will be collected.

VII. Type of Review Requested:

- ☐ Determination of Not Human Subject Research
- ☑ Determination of Exemption
- ☐ Expedited and Limited IRB Review
- ☐ Convened IRB
- ☐ CSHRI IRB to cede to another IRB OR another IRB to cede to CSHIRB
- ☐ Treatment Use including Single Patient Use
- ☐ Emergency Use

VIII. Project Summary

Project Summary:

Background: Catholic Health Initiatives St. Vincent Infirmary (CHI SVI) previously had a Nursing Shared Governance Model in place. This Model has not been functioning or active for the last 3 years. With the COVID pandemic and the changes in the current health care climate, many nurses have left the organization and/or profession. As many hospitals around the country are seeing staffing shortages, we are looking at processes that were happening pre-pandemic that engaged clinical nurses and provided a high perception of professional control. The hospital is working to create a new model that will be more sustainable with plans to implement the program in the third quarter of 2022. The goal of the new implementation is to increase professional control and governance of the clinical coworkers.

Catholic Health Initiatives St. Vincent Hot Springs (CHI SVHS) implemented an interprofessional shared governance model in 2017, as this is best practice for creating a healthy work environment for nurses and other healthcare professionals in the acute care setting. As the hospital continues to strive toward excellence, the goal is to continually increase professional control and governance of the clinical employees.

CHI SVI

Aim: The purpose of this study is to examine employee perceptions of professional control and governance prior to and following the implementation of a revised shared governance model.

CHI SVHS

The purpose of the study for this site is to examine current employee perceptions of professional governance and control and revise the shared governance model, if necessary, after examining the results to increase clinical employees? perception of professional control and governance.

Design: The study will use a longitudinal, quasi-experimental design. The *Index of Professional Governance 3.0* (IPG) survey tool (Hess, 2017) will be used to measure professional governance on a continuum range from traditional to shared to self-governance.

IX. Ceding - CSHRI IRB

N/A ☑

Please complete this section for each non CSH-affiliated institution/site.

Name of Institution/ Site:

OHRP IRB Registration Number:

IRB's FWA#:

Investigator's Name:

IRB Contact Person:

Investigator's Phone:

Investigator's Email:

Research Activities Performed:

- ☐ Recruiting Subjects
- ☐ Consenting Subjects
- ☐ Performing research interventions with subjects
- ☐ Analysis of identifiable data
- ☐ Analysis of only de-identified data
- ☐ Other

If "Other" was selected:

Flow PHI:

PHI Protection:

X. Ceding - Other IRB N/A ☑

Name of Other IRB:

OHRP IRB Registration Number:

IRB's FWA#:

IRB Contact Person Information:

Contact Name: **Contact Title:**

Contact Phone: **Contact Email:**

Contact Mailing Address:

Why would it be appropriate for CSHRI IRB to cede to an outside IRB for this study?

What research activities will take place at CommonSpirit Health facilities?

What research activities will the CSH investigative team perform?

- ☐ Recruiting Subjects
- ☐ Seeking consent from Subjects
- ☐ Performing research interventions with subjects
- ☐ Analysis of identifiable data
- ☐ Analysis of only de-identified data
- ☐ Other

If "Other" was selected:

Other Research Activity Performed:

Risks Associated with Research:

Flow PHI:

PHI Protection:

CSHRI Investigator Responsibility: ☐ Yes ☐ No

XI. Treatment Use N/A ☑

Investigational Agent (FDA Approved)? ☐ Yes ☐ No

Treatment Use Apparatuses ☐ Drug ☐ Device

XII. Treatment Use - Drug N/A ☑

Name:

Manufacturer Name:

IND Number

Person for IND:

Number of Patients:

Serious Diagnosis of Patient(s):

Explanation for Satisfactory Drug/Therapy:

Safety for Patient(s)/Population:

XIII. Treatment Use - Device N/A ☑

Name:

Manufacturer Name:

IND Number:

Population Size: ☐ Single Patient ☐ More than one patient

If more than one patient, what is this estimated number of patients?

Significant Risk: ☐ Yes ☐ No

FDA Approved: ☐ Amended IDE ☐ New IDE

Serious Diagnosis of Patient(s):

Explanation for Satisfactory Drug/Therapy:

Safety for Patient(s)/Population:

XIV. Determination of Exemption

N/A ☐

Category:

- ☐ Category 1
- ☑ Category 2
- ☐ Category 3
- ☐ Category 4
- ☐ Category 5
- ☐ Category 6
- ☐ Category 7
- ☐ Category 8

Exemption Category 1 Explanation:

Exemption Category 2 and 3 Criteria:

- ☑ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ☑ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

Exemption Category 2 or 3 - Proposed Details :

We will utilize a longitudinal, quasi-experimental design.

The Index of Professional Governance (IPG) measures the perceptions of governance of healthcare personnel.

The IPG measures professional governance on a continuum ranging from traditional governance to shared governance to self-governance. *Professional governance* is a multidimensional concept that encompasses the structure and process through which professionals control their professional practice and influence the organizational context in which it occurs. Higher aggregate scores indicate that the professionals, as a group, believe that they have more influence over professional practice and governance decisions in their organization.

Managers and administrators dominate control and influence of governance-related decisions in traditionally governed organizations. When a shared governance model is implemented, a left-to-right shift usually occurs on the governance continuum, allocating more control and influence to staff. Shared governance is a management innovation that legitimizes staff members? decision-making control over their professional practice, while extending their influence to administrative areas previously controlled by management. The lowest cutoff score for shared governance is 101 (IPNG 3.0).

Procedures

CHI SVI

All nursing department employees will be invited to participate in the survey. An email/flyer will be sent to all nursing department employees using their CommonSpirit account. Follow-up reminders by email will be sent up to a maximum of twice weekly while the survey is open to encourage increased participation. In addition, investigators and nurse leaders will also encourage participation through sharing the same email/ flyer in shared governance council meetings, staff meetings, and rounds on nursing units.

CHI SVHS

All clinical employees will be invited to participate in the survey. An email will be sent to all clinical employees using their CommonSpirit account. Follow-up reminders by email will be sent as needed to encourage increased participation. In addition, investigators and nurse leaders will also encourage participation through flyers/announcements in shared governance council meetings, staff meetings, and rounds on nursing units.

Recruitment Plan

The recruitment email flyer will contain a link for the online Qualtrics survey (Appendix B). An informed consent cover letter (no signature required) will be provided on the first page of the online survey. Acknowledgement of the informed consent cover letter will be required to proceed to the survey.

Upon completion of the survey, participants will have the voluntary option to provide an email address to be entered into a random drawing for a prize valued at no more than $25. Prizes include a set of 2 backpacker chairs, 1 rapid rider tube float, 1 picnic basket/blanket set, and 1 self-inflating lounger or a gift card. Four individuals at CHI SVI and four individuals at CHI SVHS will be randomly selected to receive one of the gifts from the email addresses submitted. Participants will be directed to a separate link to collect email addresses for the drawing. This assures anonymity of the survey responses. Once the drawing has been completed, this data will be destroyed.

The survey will be available for a period of 6 weeks. In order to reach a 95% confidence interval and a 5% margin of error, 235 responses are needed. If that has not been reached in the 6-week time frame, the survey will remain open for an additional 4 weeks. If that minimum number has not been reached at the end of 10 weeks, the data will be analyzed using the total number received. Once the survey has closed, the data will be gathered, cleaned, and analyzed using the procedures outlined in section 8.0 of this document.

Exemption Category 2 - Children :

Children Involved in Research?	☐ Yes	☑ No
Children as Research Subjects?	☐ Yes	☑ No

Exemption Category 2 - Procedures for Privacy:

Employees will access the online survey via a hyperlink included in the email flyer distribution. The online survey will be administered using Qualtrics. Responses will not be linked to specific employees. Demographic questions do not include any participant identifiers. Only members of the research team will have access to the data, which will be stored on a secure CHI St. Vincent AR server. No personally identifying data will be collected. No IP Addresses will be collected.

Exemption Category 3 Criteria:

Benign Behavioral Interventions:

Deception? ☐ Yes ☐ No

Exclusion of Children? ☐ Yes ☐ No

This response is optional:
Authorized Deception of Subjects:

Exemption Category 4 Criteria:

- ☐ The identifiable private information or identifiable biospecimens are publicly available
- ☐ Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects and the investigator may not contact or re-identify the subjects.
- ☐ The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA.
- ☐ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

Exemption Category 5 Criteria:

Federal Website:

Exemption Category 7 Criteria - Broad Consent:

- ☐ Obtain Broad Consent

  Broad Consent Description:

- ☐ Obtain Waiver for Broad Consent

  - ☐ The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.
  - ☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
  - ☐ If the subjects or legally authorized representatives are member of a distinct cultural group or community in which signing forms is not the norm, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

  Tracking Declined Consent:

  Alternative for Documenting Broad Consent:

Exemption Category 8 Criteria - Broad Consent:

- ☐ Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained. (Please upload a copy of the broad consent form to your submission).
- ☐ There are adequate provisions for protecting the privacy of subjects and to maintain the confidentiality of data.

☐ The research to be conducted is within the scope of the original broad consent used to collect the data and/or tissue.

☐ The investigator does not plan to return individual research results to subjects.

Provisions for Protecting Privacy:

Does the research involve the following:

Prisoners? ☐ Yes ☑ No

Diminished Autonomy? ☐ Yes ☑ No

If you your research involves diminished autonomy, please describe what additional protections will be put in place for protecting individuals with diminished autonomy.

Deception? ☐ Yes ☑ No

If deception will occur:

Reason for Deceiving Participants:

Authorized Deception? ☐ Yes ☐ No

Opportunity to Authorize Deception:

Procedures that Ensure Participants Are Debriefed:

XV. Expedited Review N/A ☑

Expedited Review Category:

☐ Category 1
☐ Category 2
☐ Category 3
☐ Category 4
☐ Category 5
☐ Category 6
☐ Category 7
☐ Category 8
☐ Category 9

XVI. Sponsor Sources N/A ☐

☑ None/Internal funding
☐ Federal
☐ Private (Industry, Foundations, Other)

Individuals Authorizing Use of Internal Funds:

IRB Fees:

CHI SVI previously had a nursing shared governance model in place. This model has not been functioning or active for the last three years. With the COVID pandemic and the changes in the current healthcare climate, many nurses have left the organization and/or profession. As many hospitals around the country are seeing staffing shortages,

we are looking at processes that were happening pre-pandemic that engaged clinical nurses and provided a high perception of professional control. The hospital is working to create a new model that will be more sustainable with plans to implement the program in the third quarter of 2022. The goal of the new implementation is to increase professional control and governance of the clinical coworkers.

CHI SVHS implemented an interprofessional shared governance model in 2017. As the hospital continues to strive toward excellence, the goal is to monitor the perceptions of the clinical employees and to revise the shared governance model, if necessary, to increase professional control and governance of the clinical employees.

Shared governance (SG), or shared decision making, is widely recognized as best practice for creating a healthy work environment for nurses and other healthcare professionals in the acute care setting. Shared governance empowers direct-care providers to make decisions regarding practice, aids in identifying areas for quality improvement, and provides a platform for research. Successful implementation of SG requires a paradigm shift within the organization. This paradigm shift often takes three to five years and requires a large investment of both time and resources. Porter-O?Grady, T (1996). More thoughts on shared governance. *Nursing Economic$, 14*(4), 254-255.

While the participants of this study may not personally benefit from participating in this study, the information gained from participant responses will serve as an ongoing evaluation of the professional work environment and shared governance model.

Federal Funding:

Funding/Sponsor Source:	PI of Contract/ Grant:	Contract/Grant #:	Contract/Grant Title:

Private (Industry, Foundations, Other):

Name: **Title:**

Company or Organization: **Mailing Address:**

Email: **Phone:**

Study #: **Site #:**

Insufficient Funding:

XVII. Participant Information N/A ☐

If applicable:

How will this project differ from the routine (standard of) care and normal clinic operations?

Not applicable.

Anticipated Number of Subjects: 1,500 (600 at CHI SVI and 900 at CHI SVHS)

Vulnerable Populations

- ☐ Pregnant Women, Fetuses, or Non-Viable Neonates
- ☐ Neonates
- ☐ Children
- ☐ Prisoners
- ☐ Individuals with Decisional/Cognitive Impairment
- ☐ Wards of the state
- ☑ Employees
- ☐ Economically disadvantaged
- ☐ None
- ☐ Other:

Inclusion Criteria:

CHI SVI

All employees in CHI St. Vincent Infirmary?s Nursing Department that provide clinical care, including nursing care, will be invited to participate.

CHI SVHS

Employees at CHI SVHS that provide clinical care, including nursing care, will be invited to participate.

Exclusion Criteria:

CHI SVI

Exclusion criteria would be any participant who does not identify as a nurse or as an employee of the nursing department. If any responses are received by participants who are not CHI SVI nursing department coworkers, their responses will be excluded.

CHI SVHS

If any responses are received by participants who are not a part of the targeted population at CHI SVHS, their responses will be excluded

Plan for Recruitment:

Recruitment will include emailing a flyer to all CHI St. Vincent AR identified employees using their CommonSpirit account. Additionally, investigators and nurse leaders will encourage participation through sharing the same flyer at shared governance council meetings, staff meetings, and rounding on the nursing units.

An informed consent cover letter (no signature required) (Appendix B) will be provided on the first page of the online survey. Acknowledgement of the informed consent cover letter will be required to proceed to the survey. By completing the survey, employee agrees to participate in the research study.

Emails (Appendix A) will be sent to all employees in the participant population; additional reminders will be sent by email as needed to encourage increased participation.

Flyers (Appendix A) to encourage participation will be used as handouts in meetings, and when rounding on the nursing units.

Only nurses/eligible employees will receive email invitations.

Potential Participants:

CHI SVI

All employees in CHI St. Vincent Infirmary?s Nursing Department that provide clinical care, including nursing care, will be invited to participate.

CHI SVHS

Employees at CHI SVHS that provide clinical care, including nursing care, will be invited to participate.

Participants Recruitment:

- ☐ Research personnel to speak directly with patient during an office visit
- ☐ Advertisement
- ☐ Telephone recruitment calls
- ☐ Other
- ☐ Patient gave permission for future research or future contact through a previous consent form
- ☑ Recruitment letters or flyers
- ☐ Not applicable

If "Other" was selected:

Additional Information on Recruitment:

None

XVIII. Project Information N/A ☑

Is this a clinical trial that meets the FDA's definition of "Applicable Clinical Trial" that is required by U.S. law to be registered on ClinicalTrials.gov?

- ☐ Yes
- ☐ No

Will drugs or biologics to be administered as a research procedure in the protocol?

- ☐ Yes
- ☐ No

Will you be collecting biological specimens to analyze as part of this protocol?

- ☐ Yes
- ☐ No

Will you be banking biological specimens for unspecified future research use?

- ☐ Yes
- ☐ No

Will you be banking data for unspecified future research use?

- ☐ Yes
- ☐ No

Which of the following informed consent/assent options apply to this study?

- ☐ Consent will be obtained from and documented (signed by) each subject
- ☐ Consenting non-English speaking subjects using fully translated consent forms.
- ☐ Consenting non-English speaking subjects using a short-form.
- ☐ Requesting a waiver or alteration of consent
- ☐ Requesting a waiver of documentation of consent

Participant Identification, Screening, Recruiting and Determining Eligibility:

- ☐ The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative
- ☐ The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens
- ☐ Not Applicable

Description for Oral/Written Consent:

XIX. Waiver of Documentation of Consent N/A ☑

Conditions for Waiver of Documentation of Consent:

- ☐ The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality
- ☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context
- ☐ The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

Explanation for Minimal Risk of Subjects:

Alternative Mechanism for Informed Consent:

To what portion(s) of this study does this waiver of documentation pertain?

XX. Waiver or Alteration of Consent N/A ☑

To what portion(s) of this study does this waiver or alteration pertain?

Explain why this research involves no more than minimal risk to the subjects:

Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects:

Explain why the research could not practicably be carried out without the waiver or alteration:

Provide rationale why the identifiers are required to conduct the research:

XXI. HIPAA Authorization

N/A ☐

Which method will you use to conform to HIPAA regulations?

- ☐ A signed HIPAA authorization (or combined consent and HIPAA authorization form)
- ☑ Requesting a waiver or alteration of HIPAA authorization
- ☐ Both a HIPAA waiver (e.g. for screening medical records) AND a combined consent and HIPAA authorization for prospective research

XXII. Off-Label/Investigational Drugs/Biologics

N/A ☑

Please complete this section for each off-label or investigational drug or biologic.

Trade Name: **Generic Name:**

IND/BB-IND#: **IND Holder:**

Status:

- ☐ FDA approved (Off-Label)
- ☐ IND
- ☐ Other:

If this is an FDA approved drug/biologic not being used in accordance with its approved indication, how does the use of this drug/biologic differ from the approved indication?

XXIII. FDA Approved Drugs/Biologics

N/A ☑

Please complete this section for each FDA approved drug or biologic.

Trade Name: **Generic Name:**

XXIV. Medical Devices

N/A ☑

Please complete this section for each medical device.

Device Name: **IDE Holder:**

IDE Number:

FDA Approved?	☐ Yes	☐ No	
Off-Label Use?	☐ Yes	☐ No	☐ Not FDA Approved
FDA Designation?	☐ A	☐ B	☐ N/A
Local Approval	☐ Yes	☐ No	☐ N/A
Approved by:			

Device Risk?

- ☐ Significant Risk
- ☐ Non-Significant Risk
- ☐ Not yet determined
- ☐ N/A

XXV. HIPAA Waiver Request

N/A ☐

Portion of Study: ☐ Entire study ☑ Identification and Recruitment ☐ Other: ☐ Telephone Consent

Covered Entities: All Nursing Department employees at CHI St. Vincent Infirmary and all clinical employees at CHI SVHS

Brief Description of PHI Used:

No protected health information (PHI) will be used, accessed or disclosed for this project. Employee names and email addresses will be used for communications throughout this project, which are publicly available in the CommonSpirit Health directory.
The following demographic data will be collected:
Sex/Gender
Age
Current Role
Current Unit
Highest educational degree
Employment status
Number of years employed
Number of years in present position
Overall satisfaction with professional practice within the organization

Brief Description of PHI Disclosed:

Data will be collected electronically through Qualtrics and exported to SPSS for data analysis by research team member Pamela Ashcraft. No PHI is being collected for this study.

List of PHI Sources:

No PHI is being collected for this study. Investigator and research team members will have access to email addresses.

Access to Identifiers:

No PHI is being collected for this study. Investigator and research team members will have access to email addresses.

Plan to Protect Identifiers:

Employees will access the online survey via a hyperlink included in the email flyer distribution. The online survey will be administered using Qualtrics. Responses will not be linked to specific employees. Demographic questions do not include any participant identifiers. Only members of the research team will have access to the data, which will be stored on a secure CHI St. Vincent AR server. No personally identifying data will be collected. No IP Addresses will be collected.

Identifiers Destroyed:

The data will be kept for a minimum of five years. After five years, the electronic data will be permanently deleted/erased from the server.

Waiver Justification:

Recruitment of subjects is dependent on the ability to provide an electronic link to the survey to participants. Without the ability to access email addresses or distribution list, recruitment will not be possible.

PHI Justification:

Recruitment of subjects is dependent on the ability to provide an electronic link to the survey to participants. Without the ability to access email addresses or distribution list, recruitment will not be possible.

PHI as Minimum Information:

No PHI is being collected for this study. Investigator and research team members will have access to email addresses. Email addresses will be accessed only for recruitment purposes. No IP Addresses will be collected.

Number of Records Accessed: ☐ Less than or equal to 50 ☑ Greater than 50

Principal Investigator/Treating Physician Attestation

Please note that the PI must sign this package. If the PI is a student, resident, trainee, or fellow, this package must <u>also</u> be signed by the mentor.
This application must be sent to the CSHRI IRB by the Principal Investigator only after the Principal Investigator has reviewed and determined that all information is accurate. The Principal Investigator assumes responsibility for ensuring that (please check all):

- I certify that the information provided in this application, and the accompanying materials, is complete and correct. All required materials have been uploaded as part of this submission.

- I certify that all known unanticipated problems (including those that are SAEs, involve potential or real loss of privacy/ confidentiality) have been reported to the CSHRI IRB.
- I certify that all personnel engaged in research activities on this project are listed on this application and that all personnel have completed Financial Conflict of Interest (FCOI) disclosures (your application will not move forward until this is completed).
- I certify that any change in investigator or study staff's Conflict of Interest status are accurately reported as required by CSH's Governance Policy No.1 and to the IRB.
- I certify that all personnel engaged in research activities are in compliance with the current CIRI Research Education Plan.
- I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and welfare of human subjects.
- I certify that the study will be conducted The Principal Investigator and study staff will conduct the study only as described in the application and accompanying protocol.
- Any changes to the protocol or research personnel will be submitted to the IRB for prospective approval, except when necessary to eliminate apparent immediate hazards to the subject(s).
- I agree to comply with all CSHRI IRB policies and procedures, including the CSH Research Data Security requirements as well as with all applicable federal, State, and local laws regarding the protection of human subjects in research.
- I will ensure that this study is performed by qualified personnel adhering to the study protocol, and will retain auditable records for all research activities including personnel trainings.
- I will only Access, Use, and Disclose PHI as described in this application.
- If changes in obtaining, storing, transmitting, transporting, destroying of PHI are needed, an amendment/modification form must be submitted for review and approval prior to implementation of the change.
- If the data is lost, stolen, or improperly used, accessed or disclosed in any way other than outlined in the study, I will notify the Privacy Officer immediately. This includes loss or theft of hardcopy, computer or mobile device containing PHI, faxing to wrong number, etc. I will also notify the IRB, as applicable, as this may constitute an Adverse Event per the Common Rule.
- I understand that if I do not abide by CSH Data Security requirements that I will be subject to possible disciplinary action, reporting to federal or state authorities, criminal prosecution, and/or civil penalties.

By clicking Next, you agree to the above statements.

HIPAA Attestation

The information listed in the waiver application is accurate and all research staff will comply with the HIPAA regulations and the waiver criteria. I assure that only the minimum amount of protected health information necessary to complete the study aims will be used and/or disclosed during the conduct of this research. I assure that PHI obtained as part of this research will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB.

INSTRUCTIONS TO RESEARCHERS

[top]

Now that you have completed this document, check your work, attach all appropriate documents, electronically sign and submit your work. If you have any questions, please refer to the guidelines in the IRBNet Forms and Templates Library.