Date: Tuesday, November 22, 2022 5:18:06 AM Print Close

Application Type
ID: 22-010825

For help selecting the application type, use the **IRB Wizard.** If you need assistance, submit a **ServiceNow ticket** or call the Research Service Center at 507-266-4000.

1. * **Select one:**
   Exempt

Title and Personnel

1. * **Full title:**
   Worldwide delirium prevalence study March 15th, 2023

2. Sponsor Protocol ID:

3. **Principal Investigator:**
   Students, fellows, residents, supplemental consultants, emeritus staff, and RTP personnel may not serve as PI or co-PI on new applications submitted to the IRB, unless approval has been received. Please review the Eligibility as Principal Investigator Policy for additional information and instructions to request approval.

   Heidi Lindroth

Personnel:

	Last Name	MI	First Name	Location	Role	Edit	Consent	Notify	IRB Member	Disclosure Filed	Curr Discl	Positive Disclosure	COI Determination
View	Friesen	Emilie	Hannah	Mayo Clinic in Rochester, MN	Other Study Staff	yes	yes	yes	No	Yes	Yes	No	
View	Leistikow	Rae	Kathleen	Mayo Clinic in Rochester, MN	Other Study Staff	yes	yes	yes	No	Yes	Yes	No	
View	Lindroth	Lynne	Heidi	Mayo Clinic in Rochester, MN	Principal Investigator	yes	yes	yes	No	Yes	Yes	Yes	No conflict

Research Plan

1. * **In simple (lay) language, describe the question(s) the research is designed to answer:**
To assess the delirium practice and organizational characteristics in wards and units caring for pediatric and adult institutionalized patients.

2. **Attach the research protocol here:**
Proposal_WDAD-2023-09-12.pdf(0.01)

Link to protocol templates

If this is a sponsor written protocol, and Mayo or other institution(s) covered by this application will conduct only a portion of the research activity, explain in the "Research Locations" section, question 2.

3. * **Is this an investigator-initiated protocol or sponsor-initiated protocol?**

- ○ Sponsor
- ● **Investigator**

Exempt Research

* **To qualify for exempt status, the research must be limited to activities in the following categories.**
Select the category(ies) that apply to the research:

1. ☐ Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

2. ☑ Research only including interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

   Will this research involve children?
   ○ Yes ● **No**

   Which of the following apply?
   - ☑ The Information obtained will be 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.

     Describe how the information will be coded or de-identified:
     Study participants will only be asked to provide name of city, where the hospital is located and the name of ward or unit where they are employed. No personal identifiers will be collected.

   - ☐ 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.

   - ☐ Neither of the above

3. ☐ Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects through verbal or written responses (including data entry) or audiovisual recording.

4. ☐ Secondary research use of identifiable private information or identifiable biospecimens for which consent is not required **(e.g. medical records review)**

5. ☐ Research and demonstration projects conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve or otherwise examine public benefit or service programs.

6. ☐ Taste and food quality evaluation and consumer acceptance studies.

Funding/Other Support

1. * **Select all sources of funding or other support. Other support includes material goods, such as drugs or devices, equipment, supplies, etc., provided to conduct the research:**

- ☐ Industry/Commercial Entity
- ☐ Federal
  (Federal funding may involve support from NIH, NCI, and other government agencies and includes Career Development Awards (K Awards), and Training Grants)
  NIH Grant & Funding Activity Codes
- ☐ External Foundations
- ☐ Institutional Funding (e.g. Mayo Clinic or other institution covered by this application)
- ☑ **No funding/support required**

If no specific funding/support is required, explain:

This study has no funding

2. * **Department of Defense (DoD) involvement in your research (check all that apply):**

- ☐ The research is funded by a component of DoD, and the investigator or institution is primary awardee.
- ☐ The research involves cooperation, collaboration, or other type of agreement with a component of DoD.
- ☐ The research uses property, facilities or assets of a component of DoD.
- ☐ The subject population will intentionally include personnel (military and/or civilian) from a component of DoD, or data or specimens from DoD personnel.
- ☑ **None of the above.**

3. * **Will subjects receive payment (remuneration) for taking part in the research, or be offered reimbursement for expenses related to taking part in the research?**

○ Yes ● **No**

If non-monetary incentives will be offered to subjects, mark this question 'No', and attach a description of the incentives in 'Contact Materials (After Enrollment)'.

4. * **Do you have a related budget or funding proposal (pending or active) in the Grants and Contracts (GnC) module?**

○ Yes ● **No**

Explain and/or attach budget/funding documentation:
No Budget or funding is needed

Attach other budget documentation:

Name	Version	Date Created	Date Modified

There are no items to display

Research Locations

1.

* **Select the Mayo location(s) where subject interactions and/or interventions will be conducted.**
(Examples: recruitment, research visits/examinations, specimen collection.)
This is intended to define locations at which interested individuals may enroll and take part in the research.
For medical record review or archived specimen studies, mark only the location(s) where the research activity is occurring. (This may differ from the locations where data or samples originated)

- Mayo Clinic in Rochester, MN
- Mayo Clinic in Florida
- Mayo Clinic in Arizona
- Mayo Clinic Health System in Eau Claire
- Mayo Clinic Health System in Mankato

2. **Click ADD to specify location(s) listed above that will conduct only a portion of the subject interactions/interventions, or will conduct modified or additional interactions/interventions at that location.**
(Examples: research phases/cohorts/ procedures limited to specific locations, additional use of radiation at a select location.)

Location	Description

There are no items to display

3. **Add other Mayo Clinic location(s) (not included in question 1) conducting research activities that do not involve subject interactions/interventions.**
(Examples: analysis of information/specimens, regulatory/administrative reporting.)

Location	Research Activities to be Conducted	Other

There are no items to display

4. * **Is this a multi-center trial for which a location covered by this application will serve as a coordinating/lead center?**
○ Yes ● **No**

5. * **Will research staff covered by this application conduct the research at a location for which Mayo Clinic IRB is not the IRB of record?**
○ Yes ● **No**

6. **Check this box if the application includes request(s) for the Mayo Clinic IRB to serve as the IRB of record for a Relying Organization(s).**
☐

7. * **Will a local physician or other provider/medical center ("local provider") perform subject interventions or procedures for the purpose of this research, without participating as a research location?**
○ Yes ● **No**

Subject Population

1.

* **Specify the maximum number of subjects to be accrued at the location(s) covered by this application.**
500

For retrospective data or biospecimens review, "Subjects" refers to the number of individuals whose information or biospecimens will be reviewed.

2.

* **Will additional individuals be screened in order to reach the maximum accrual specified above?**
● **Yes** ○ No

Indicate the total number of individuals to be screened. (This number will be higher than the number in question 1 above).
1000

3.

* **Will there be any interaction or intervention with the research subjects? Interaction may occur in person or remotely, such as by mailed surveys or phone calls.**

○ Yes ● **No**

Describe how you will access the information or biospecimens:

> Clinical data related to delirium assessments and policies will be accessed retrospectively by clinical partners. Clinical data includes the instrument used (CAMICU, DTS, bCAM), # of assessments administered at 0800 and 2000 on 3/15/22, outcome of assessment (positive, negative, unable to assess), delirium-related policies, education, and care plans in place at the institution/location of focus. No PHI will be collected.

4.

* **Age range of subjects**

Minimum Age:

18 **years**

Maximum Age (if applicable):

100 **years**

5.

* **Protected research populations – check all populations expected to be included:**

☐	Pregnant women, fetuses or neonates	Subpart B

- ☐ Prisoners — Subpart C
- ☐ Children — Subpart D
- ☐ Adults lacking capacity to consent
- ☑ **None of the above**

Confidentiality

1. * **Describe measures that will be used to maintain confidentiality of subjects' information and/or biospecimens.**

   Since this study will not collect any patients' personal data, we do not expect any ethical problems or challenges. Similar, data of the partner-clinicians will not be published, and we do not expect any serious challenges with data protection.
   Nevertheless, participating clinicians have to prove their national and local policies for ethics and data protection. We will inform each participant about this need.
   All participants will be informed about the voluntary approach on the first page of the survey. They will be informed about data protection. They will be informed that participation means consent.

2. * **Is the research covered by a Certificate of Confidentiality (CoC)?**
   ○ Yes ● **No**

   NIH Certificate of Confidentiality resources

Protected Health Information (HIPAA)

Studies utilizing identifiable private health information (PHI) or coded PHI (with ability to link to specific subjects) require HIPAA authorization or Waiver of HIPAA authorization. (**Example: Medical Chart Reviews**)

1. * **Indicate how HIPAA authorization will or will not be obtained for this research: (check all that apply)**

   Health Insurance Portability and Accountability Act (HIPAA)
   Informed Consent and the Research Subject

   - ☐ Waiver of HIPAA authorization requested.
   - ☐ HIPAA authorization will be obtained using a standalone HIPAA form.
   - ☑ **HIPAA authorization does not apply because no protected health information is being recorded or used.**
   - ☐ HIPAA authorization is not required because the research involves receipt of a limited data set from an external party with a data use agreement in place.

   If multiple boxes are selected, explain how each applies to the research:

2. * **Will information and/or specimens be shared with an external party?**
   ○ Yes
   ● **No**

Supporting Documents

1. **Attach supporting documents:**

Name	Version	Date Created	Date Modified
Ethics Approval	0.01	10/20/2022 4:38 PM	10/20/2022 4:38 PM

You have reached the end of the IRB portion of the application.

Complete the questions on the following pages to provide information required for Mayo Clinic's Research Systems and Research Resources.

Your application **IS NOT SUBMITTED** until you press the Submit button on the next page.
Submission to the IRB may only be done by the Principal Investigator.
Click 'Continue' to submit the application for review.