MAYO CLINIC

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Heidi Lindroth
CC: Hannah Friesen
Kathleen Leistikow
Heidi Lindroth

Re: **IRB Application #:** 22-010825
Title: Worldwide delirium prevalence study March 15th, 2023

IRB Approval Date: 11/16/2022
IRB Expiration Date:

The above referenced application was reviewed by expedited review procedures and is determined to be exempt from the requirement for IRB approval (45 CFR 46.104d, Category 2). Continued IRB review of this study is not required as it is currently written. However, any modifications to the study design or procedures must be submitted to the IRB to determine whether the study continues to be exempt.

The Reviewer reviewed the Conflict of Interest (COI) Review Board determination related to Heidi Lindroth. The Reviewer accepted the COI Review Board determination of no conflict of interest.

The recruitment email and WDAD questionnaire were reviewed and noted.

As protected health information is not being requested from subjects, HIPAA authorization is not required in accordance with 45 CFR 160.103.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and major protocol violations/deviations within 5 working days of becoming aware of the occurrence.
4) Compliance with applicable regulations for the protection of human subjects and with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer