

Principal Investigator Notification:

From: Mayo Clinic IRB
To: William Hooten
Cc: Jason Egginton
William Hooten
Molly Jeffery
Jaime Long
Jessica McCoy
Oluwaseyitan Oloyede
Jennifer Ridgeway
Leah Springer
Kathleen Yost

Re: **IRB Modification #:** Mod21-012561-13

Title: A Mixed Methods Research Design to Identify Factors Influencing Prescriber Decision-Making about Pain Management and Opioid Prescribing

IRB#: 21-012561

Modification Approval Date: 2/10/2023

The above referenced modification was reviewed by expedited review procedures. The modification includes: Revisions to study protocol to change study design, increase number of focus groups, and add remuneration. The Reviewer determines that this modification does not alter the previous determination, and it continues to be EXEMPT under 45 CFR 46.104, Category 2. The Reviewer noted the revised protocol reflecting the modification. Further modifications to the study design or procedures must continue to be submitted to the IRB to determine whether the study remains exempt.

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