



Mass General Brigham IRB
Mass General Brigham
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Notification of IRB Review

Protocol #: 2021P002615

Date: October 05, 2021 [Reissued October 19, 2021]

To: Sarpatwari, Ameet, Ph.D, JD
BWH
Mass General Brigham > BWH > Medicine > Pharmacoepidemiology

From: Mass General Brigham IRB
399 Revolution Drive, Suite 710
Somerville, MA 02145

Title of Protocol: Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Physician Interviews on Experiences with REMS Programs

Version/Number: Detailed Protocol-V1

Version Date: 09/08/2021

Sponsor/Funding/Support : Proposal Title: Risk evaluation and mitigation strategy (REMS) programs to promote appropriate medication use and knowledge

Principal Investigator: Sarpatwari, Ameet

Immediate Sponsor: Food & Drug Administration (Contracts)

Award Number: 75F40120C00044

Fund #: 123748

IRB Review Type: Expedited

IRB Approval Date: 10/05/2021

Next Review: Exempt Check In

IRB Expiration Date: **10/05/2024**

IRB Review Action: Exempt

The IRB has determined that this project meets the criteria for exemption 45 CFR 46.104(d)(#).

EXEMPTION (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least ONE of the following criteria is met:



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(i) 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;

(ii) 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; or

ANCILLARY COMMITTEES

1. Nursing (BWH) : Approved

2. MCA (MGB) : Review not needed

As Principal Investigator, you are responsible for the following:

1. Ensuring that this project is conducted in compliance with the exemption determination.
2. Ensuring that all study staff have completed the required human research education requirements through the Collaborative Institutional Training Initiative (CITI).
3. Submission of significant proposed changes to this project to ensure that the project continues to meet the criteria for exemption.
4. Submission of Exempt Check-In as required by institutional policy.

Questions related to this project may be directed to IRB@partners.org

cc:

Ameet Sarpatwari, Ph.D, JD, Principal Investigator, Pharmacoepidemiology, Medicine