Mass General Brigham IRB
Mass General Brigham
399 Revolution Drive, Suite 710
Somerville, MA 02145
Tel: 857-282-1900
Fax: 857-282-5693

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:

Mass General Brigham IRB
Mass General Brigham
399 Revolution Drive, Suite 710
Somerville, MA 02145
Tel: 857-282-1900
Fax: 857-282-5693

(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