



AMERICAN INSTITUTES FOR RESEARCH®

IRB Determination

Institutional Review Board
American Institutes for Research
1000 Thomas Jefferson Street, NW
Washington, DC 20007
IRB00000436 FWA00003952

B&P Number: 87414
Project number:
Project/Proposal title: Patient/Provider Messagin
Program: Practice Area w/ Strategy
Project Director: Hanno Petras
IRB Reviewer: Coretta J. Mallery

1. Type of Review:

Initial review

2. Is the activity a systematic investigation designed to contribute to generalizable knowledge? [45 CFR 46.102(d)]

Yes

3. Does the activity involve living individuals about whom the investigator conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information?

Yes

4. Is this activity eligible for expedited IRB review, as authorized by 45 CFR 46.110 and 21 CFR 56.110?

Yes

5. Does the project meet any of the exemption categories (45 CFR 46.101)?

Yes

6. After reviewing this submission, the Institutional Review Board (or member signing below) has determined the following:

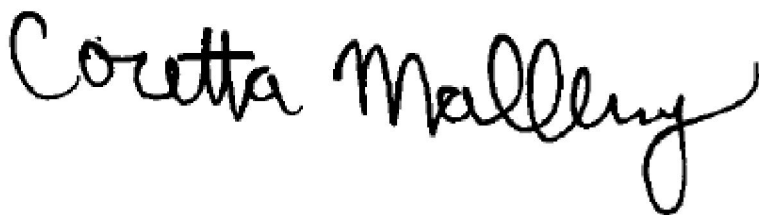
Determination of Exemption: the project is exempt from further IRB review because it meets one of the six exemption categories defined in 45 CFR §46.101(b). This research meets the following exemption category: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human

subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

7. Determination:

On the basis of this review, the IRB has determined that the activity is exempt. The activity involves an online survey focused on a) clinicians' beliefs, attitudes, and cultural frames informing alcohol use, b) clinicians' view of providing interventions within clinical visits and perceptions of self-efficacy to administer SBI and counsel patients, c) perceptions of/agreement with the National Center on Birth Defects and Developmental Disabilities (NCBDDD) guidelines regarding alcohol abstinence, and d) perceptions of issue relevance of alcohol consumption during pregnancy and FASD in relationship to other patient risk factors; Clinician telephone interviews into above described issues and to establish areas to avoid or target with message framing; and Face-to-face interviews with women to explore women's beliefs, cultural norms, and attitudes about alcohol and pregnancy as well as their perceptions about discussing their alcohol use with their healthcare provider. Therefore, according to 45 CFR §46.101(2)(b), the activity is exempt and IRB oversight does not apply.

8. IRB Signature(s):

A handwritten signature in black ink that reads "Coretta Mallery". The signature is written in a cursive, flowing style.

Coretta J. Mallery, IRB Representative

04/10/2018

Please keep in mind that any material changes made to the study or the study procedures require the submission of an updated IRB package.