

February 28, 2023

EXEMPTION DETERMINATION

Determination Date: 2/2/2023

Investigator: Jennifer Miller
Type of Review: Initial Study
Title of Study: EXEMPT: A positive deviance approach for representing women, older adults and patients identifying as racial and ethnic minorities in oncology research

IRB Protocol ID: 2000033803
Submission ID: 2000033803
Documents:

- COVID Supplement, Category: Other;
- Demographic Survey, Category: Study questionnaires, measures, focus groups/interview questions;
- Exemption Form , Category: IRB Protocol;
- Interview Guide, Category: Study questionnaires, measures, focus groups/interview questions;
- Recruitment Email , Category: Recruitment Materials;
- Updated Consent Forms Clean, Category: Consent Form;

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- This research was deemed exempt under Exempt Category 45 CFR 46.104(d)(2)(ii).
 - The protocol does not require annual IRB review.
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See the next page for important reminders.

IMPORTANT REMINDERS:

- Exempt research does not require additional IRB oversight except in cases where the study is to be modified in a way that would change the applicability of the exempt status.
- Should you wish to modify the study in way that affects the applicability of the exemption determination, a new protocol must be submitted for the IRB review. See IRB Guidance document 100 GD 9: Guidance on Exemption from IRB Review for examples.
- Information that requires prompt reporting to the IRB must be done so within 5 days of the PI becoming aware of the event (see Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events). This includes potential serious noncompliance, continuing noncompliance, and unanticipated problems to subjects or others.
- In conducting this activity, you should refer to and follow the Investigator Manual (HRP-103) as applicable, which can be found in the IRB Library within the IRB system.

Please keep this letter with your copy of the protocol documents.