

Human Research Protection Program Institutional Review Boards FWA00002571 25 Science Park – 3rd Fl., 150 Munson St. New Haven CT 06520-8327

Telephone: 203-785-4688 http://www.yale.edu/hrpp

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;

 This research was deemed exempt under Exempt Category 45 CFR 46.104(d)(2)(ii).

• The protocol does not require annual IRB review.

See the next page for important reminders.



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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.