

Change Request for CDC Prostate Cancer Screening Decision Aid Randomized Controlled Trial

We are proposing a change that would allow the methods of the study to be more aligned with the clinical practice at the participating clinics. This change would raise the study exclusion to a PSA level equal to or greater than 4 ng/mL. Physicians at the participating clinics agree that patients with PSA scores equal to or greater than 4 ng/mL are clinically differently than those below 4 ng/mL; these two groups of patients would receive different treatments. The current study exclusion of a PSA level greater than 3 ng/mL, which was selected based on published guidelines and is different from how physicians at these clinics treat patients.

This change will not affect the currently approved burden estimate because the same number of respondents would complete the patient eligibility screener.

Table A12A: Estimated Annualized Burden (Hours)

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|------------------------|------------------------------|--------------------|---------------------------------|--|--------------------|
| Primary care providers | Provider survey | 40 | 1 | 10/60 | 7 |
| Men ages 55-69 | Patient eligibility screener | 900 | 1 | 8/60 | 120 |
| Men ages 55-69 | Pre-exposure survey | 900 | 1 | 20/60 | 300 |
| Men ages 55-69 | Post-exposure survey | 900 | 1 | 20/60 | 300 |
| Men ages 55-69 | Usability survey | 300 | 1 | 18/60 | 90 |
| Men ages 55-69 | User experience interview | 30 | 1 | 20/60 | 10 |
| Men ages 55-69 | Post-clinic survey | 900 | 1 | 20/60 | 300 |
| Clinic coordinators | Clinic coordinator interview | 4 | 1 | 30/60 | 2 |
| | | | | Total | 1,129 |