

“Healthcare Professional Interviews:
Risk Processing for Newly Promoted Prescription Drugs”
(OMB Control Number 0910-0695)

January 23, 2020

The Food and Drug Administration is submitting this nonmaterial/non-substantive request to make minor modifications to our approved project, *Healthcare Professional Interviews: Risk Processing for Newly Promoted Prescription Drugs* (#0910-0695). We conducted pilot testing in order to assess the materials and procedures and have been fielding sessions for the main study. We are now proposing minor modifications to these materials and procedures based on difficulty with recruiting enough participants to complete data collection. There is no change to the burden hours for this project.

The proposed changes are outlined below:

1. We will recruit from various hospitals and ambulatory care centers in DC metro area with the potential to expand to the full mid-Atlantic region and may also recruit from healthcare professional conferences and meetings. Recruitment-related language was updated to allow for maximum flexibility.
2. Data collection will be extended through the spring of 2020.
3. The screener will now have an online survey completion option in addition to the approved phone screening.
4. The exclusion criteria based on recent focus group or interview research participation will be reduced from three months to one month.