

**Evaluation of an Intervention to Increase Colorectal Cancer Screening
in Primary Care Clinics**

(OMB no. 0920-0769, exp. date 3/31/2011)

Change Request and Justification

August 31, 2009

Summary

We are requesting non-substantive changes to an approved study (approved in March 2008). The study scope, purpose, burden, protocol, methodology, and planned analyses remain unchanged from the original application.

The proposed changes relate to minor changes in the language and structure of the patient, clinic support staff and clinician post-intervention surveys; post-intervention letters to patients, clinic support staff, and clinicians; and survey reminder postcards for clinic support staff and clinicians. These changes are the result of corrected text for improved readability and flow of the post-intervention surveys, changes to screening recommendations, and changes to the systems at the participating sites. The proposed changes will not result in a change in the approved burden estimate.

The proposed changes to the post-intervention surveys and letters are identical in content and scope to the changes approved April 24, 2009, for the pre-intervention surveys and letters.

The proposed changes are described in more detail below.

Justification for Proposed Changes

Post Intervention Surveys for Patients, Clinic Support Staff and Clinicians

The original surveys that were submitted included procedures that were, at the time of submission to OMB, approved for screening for colorectal cancer. However, as of, October 2008, the United States Preventive Services Task Force (USPSTF) no longer includes one previously included screening modality, double contrast barium enema, as an approved or recommended screening option. Additionally, the latest recommendations no longer include the use of flexible sigmoidoscopy as a stand-alone option, rather it is, optimally, to be used in conjunction with fecal occult blood testing. However, some physicians will continue to use these modalities without regard to the current screening recommendations. To reflect the changes in the USPSTF recommendations, we have reduced the number of items pertaining to double contrast barium enema and flexible sigmoidoscopy, but we have not eliminated all items to ensure that we document current clinical practices.

Additionally, the original surveys were submitted after intensive literature reviews and reviews by clinicians and clinic support staff and patients. However, in the time since the submission to

OMB for original approval, additional review revealed ways to increase readability and flow of the surveys. The information collected remains the same, however, minor changes to wording and item order necessitate the submission of this OMB change request. Finally, the survey has been formatted for professional printing and the appearance of the survey has changed.

Post-Intervention Survey Letters to Patients

The Institutional Review Boards of both HFHS and ABQ HP (Lovelace) required slightly different human subjects protection language for their respective sites.

ABQ HP (Lovelace) IRB now requires a HIPPA authorization to be completed by patients. HFHS IRB does not require this form. The ABQ HP (Lovelace) letters contain the IRB approved language.

Both HFHS IRB and ABQ HP (Lovelace) now require that potential participants be given an opportunity to opt-out of further contact. This language is now included on patient post-intervention survey letter.

All letters will be printed on site specific letterhead.

Post-Intervention Survey Letters to Clinic Support Staff and Clinicians

The previously submitted letters contained placeholder information which has been modified. If participants have any questions about the study, they will be asked to call the Study Coordinators at the respective sites, and not Battelle. Participants will also be given the telephone number to the site IRB.

All letters will be printed on site specific letterhead.

Clinic Support Staff and Clinician Survey Reminder Postcards

The postcards sent as reminders to participants 1-2 weeks after the initial survey mailing have been updated with the correct contact person and phone number. In the original application, we had a placeholder name and number. Also, postcards for each study site (HFHS or ABQ HP (Lovelace)) will display the logo for the appropriate site.

Documents

Two types of documents are attached to this Change Request.

- Documents that have been formatted to facilitate review and identification of proposed changes. These documents include the keyword “**Changes**” in the filename. In these documents, text that has been removed is indicated by ~~strikeout~~. Text that has been added

or revised is indicated by *italics*.

- Clean copies of the revised attachments. These documents include the keyword “**Revised**” in the filename, and are intended to replace the previously approved versions.

<u>Key to Documents and Attachments</u>		
<u>Reference Document</u>	<u>Changes Document</u>	<u>Revision Document</u>
<i>(see original Information Collection Request)</i>	<i>(formatted to facilitate OMB review and rapid identification of proposed changes)</i>	<i>(clean copy of revised attachment to be used in data collection)</i>
Attachment 4b, Patient Post-Intervention Survey	Attachment 4b_Changes_Patient_Post-Intervention_Survey	Attachment 4b_Revised_Patient_Post-Intervention_Survey
Attachment 4c, Clinic Support Staff Post-Intervention Survey	Attachment 4c_Changes_Clinic_Support_Staff_Post-Intervention_Survey	Attachment 4c_Revised_Clinic_Support_Staff_Post-Intervention_Survey
Attachment 4d, Clinician Post-Intervention Survey	Attachment 4d_Changes_Clinician_Post-Intervention_Survey	Attachment 4d_Revised_Clinician_Post-Intervention_Survey
Attachment 5, Post-Intervention <u>Patient</u> Survey Cover Letter	Attachment 5_Changes_Post_Patient_Survey_Cover_Letter	Attachment 5_Revised_Post_Patient_Survey_Cover_Letter
Attachment 5, Post-Intervention <u>Clinic Support Staff</u> Survey Cover Letter	Attachment 5_Changes_Post_Clinic_Support_Staff_Cover_Letter	Attachment 5_Revised_Post_Clinic_Support_Staff_Cover_Letter
Attachment 5, Post-Intervention <u>Clinician</u> Survey Cover Letter	Attachment 5_Changes_Post_Clinician_Cover_Letter	Attachment 5_Revised_Post_Clinician_Cover_Letter
Attachment 6, Reminder Postcard for Clinic Staff	Attachment 6_Changes_Reminder_Postcard_Clinic_Staff	Attachment 6_Revised_Reminder_Postcard_Clinic_Staff
Attachment 6, Reminder Postcard for Clinicians	Attachment 6_Changes_Reminder_Postcard_Clinicians	Attachment 6_Revised_Reminder_Postcard_Clinicians