

**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

March 24, 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 pre-intervention surveys, letters to participants, patient intervention materials (colorectal cancer fact sheet and patient appointment reminder cards), and survey reminder postcards. These changes are the result of corrected text for improved readability and flow of the patient 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.

In addition, we are including the final forms of the clinician training sessions that will be used at both sites, Henry Ford Health System (HFHS) and Albuquerque Health Partners/Lovelace (ABQ HP/Lovelace). In the original submission, a draft of the clinician training sessions were provided. All of these documents are provided so that the final forms of all documents are on file for this study.

The proposed changes are described in more detail below.

Justification for Proposed Changes

Patient Pre Intervention Survey

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.

Letters to Participants

The Institutional Review Boards of both HFHS and ABQ HP (Lovelace) required slightly different human subjects protection language for their respective sites. Additionally, HFHS will allow patients to be contacted up to three times before nonresponse is considered a passive refusal to participate. However, ABQ HP (Lovelace) only allows participants to be contacted twice before nonresponse is considered a passive refusal to participate. In our original application, we proposed that each site would attempt to contact participants three times. The numbers of letters in our application now complies with the IRB requirements at both sites.

The patient intervention mailing originally included a letter from the medical center about colorectal cancer, information about colorectal cancer screening, a checklist for completing colorectal cancer screening tests, and frequently asked questions (FAQs) about completing colorectal cancer screening tests. We are no longer including the checklist and the FAQs. These items will be made available to patients in the clinics and will be available for clinicians and clinic support staff to use during their discussions with patients about colorectal cancer screening.

Finally, HFHS IRB requires that potential participants be given an opportunity to opt-out of further contact. This language is now included on the first mailing for the patient pre-intervention survey.

Patient Intervention Materials

The patient intervention materials (colorectal cancer fact sheet and patient appointment reminder cards) were revised to increase the font size to facilitate easier reading, conform to the latest USPSTF recommendations for colorectal cancer screening and provide greater clarity.

Colorectal Cancer Fact Sheet

Minor modifications were made to the colorectal cancer fact sheet. For example, on the fact sheet, the option of flexible sigmoidoscopy is no longer presented as a stand alone option. Guidelines now state the flexible sigmoidoscopy is best in combination with a fecal occult blood test (FOBT). Additionally, on the fact sheet, materials have been slightly modified to accurately represent where colonoscopy procedures are performed for each site. For example, HFHS now performs colonoscopies in specialty clinics. Further, for the screening test options, we no longer provide a listing of advantages and disadvantages for each screening test, rather we now present, "Important Points to Consider". Finally, the materials with the logos of individual sites were also created. The colorectal cancer fact sheet with the HFHS logo is presented. Identical materials with the ABQ HP (Lovelace) logo will be sent to participants in the ABQ HP (Lovelace) clinics.

Patient Appointment Reminder Cards

Minor modifications were made to the reminder cards. On the original reminder card, Step 2 asked the participant to make a decision with his or her doctor about the appropriate screening test and to make the arrangements to get a screening test. In the revision, we have made making the screening test decision and making the arrangements to get the screening test two distinct steps. We have eliminated Step 4 from the original reminder card that asked the participant to ask his or her doctor if there were any additional tests the participant might need. Finally, we have revised the text under, “After Your Doctor’s Appointment” to state more clearly what screening test for colorectal cancer has been selected by the participant.

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 and not all of the logos of all participating organizations.

Modules for Curriculum Training Sessions

The slides that were included in the original OMB package were an outline version of the clinician and clinic support staff curriculum training session. We have now included the final version of the slides for both sites. The time allotted for the training sessions has been shortened slightly. We have also updated the slides to conform to the latest USPSTF recommendations for colorectal cancer screening (published October 2008). These slides, as proposed in the original OMB package for this study, will be delivered via a PowerPoint presentation. The components of the slides remain the same as proposed in the original OMB package. Participants will review the latest statistics, evidence, and CRC screening guidelines, participate in exercises to enhance skills to begin conversations about CRC screening with their patients, and develop skills in motivational interviewing and reflective listening. In a second session, participants will identify and develop office surveillance and reminder systems that will increase or facilitate identification of patients eligible for CRC screening and patient tracking and follow-up after CRC screening.

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.

Key to Documents and Attachments

<p><u>Reference Document</u></p> <p><i>(see original Information Collection Request)</i></p>	<p><u>Changes Document</u></p> <p><i>(formatted to facilitate OMB review and rapid identification of proposed changes)</i></p>	<p><u>Revision Document</u></p> <p><i>(clean copy of revised attachment to be used in data collection)</i></p>
<p>Attachment 4a, Patient Pre-Intervention Survey</p>	<p>Attachment 4a_Changes_Patient_Pre-Intervention_Survey</p>	<p>Attachment 4a_Revised_Patient_Pre-Intervention_Survey</p>
<p>Attachment 5, Patient Intervention Materials Cover Letter</p>	<p>Attachment 5_Changes_Patient Intervention Materials Cover Letters</p>	<p>Attachment 5_Revised_Patient Intervention Materials Cover Letters</p>
<p>Attachment 6, Reminder Postcard-Patient</p>	<p>Attachment 6_Changes_Reminder_Postcard-Patient</p>	<p>Attachment 6_Revised_Reminder Postcard-Patient</p>
<p>Attachment 7, Training Curriculum Summary</p>	<p>NOTE: There is no "Changes" document for Attachment 7 as this attachment was originally an summary outline of the proposed training curriculum.</p>	<p>Attachment 7_Revised_Training Curriculum</p>
<p>Attachment 8, Patient Focused Intervention</p>	<p>NOTE: There are no "Changes" documents for Attachments 8a and 8b since they are .pdf files. The information presented in the patient focused intervention has been reduced as discussed in the change request narrative.</p>	<p>Attachment 8a_Revised_Patient Focused Intervention</p>
<p>Attachment 8, Patient Focused Intervention</p>	<p>See above</p>	<p>Attachment 8b_Revised_Patient Focused Intervention</p>