

# Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is “None”, please specify “None” as your response. “Not applicable” is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-231-2825.

1. **Grantee Institution:** Thomas Jefferson University
2. **Reporting Period (start and end date of grant award period):** 1/1/2011 – 12/31/2014
3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Theodore F. Taraschi, PhD
4. **Grant Contact Person’s Telephone Number:** 215-955-3900
5. **Grant SAP Number:** 4100054872
6. **Project Number and Title of Research Project:** 3: Increasing Colorectal Cancer (CRC) Screening in Primary Care among African Americans
7. **Start and End Date of Research Project:** 1/11/11 – 12/31/14
8. **Name of Principal Investigator for the Research Project:** Ronald Myers, PhD
9. **Research Project Expenses.**

9(A) Please provide the total amount of health research grant funds spent on this project for the entire duration of the grant, including indirect costs and any interest earned that was spent:

\$ 777,460.35

9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name, First Name	Position Title	% of Effort on Project	Cost
Sendecki, Jocelyn	Biostatistician	10% Yr 1; 14% Yr 2	\$19,802.74
Romoff, Selma	Survey Interviewer	100%	\$8,888.27
Swan, Heidi	Research Assistant	10%	\$7,394.97
Njoku, Anuli	Patient Navigator	50%	\$32,289.34
Sifri, Randa	Co-Investigator	5%	\$20,462.58
Burgh, Desiree	Patient Navigator	50%	\$74,094.92
Cocroft, James	Program Analyst	24% Yr1; 28% Yr2; 10% Yr3; 10% Yr4	\$58,605.84
Myers, Ron	PI	5%	\$51,808.15
Wolf, Thomas	Research Coordinator	20% Yr1; 20% Yr2; 41% Yr3; 50% Yr5	\$75,705.56
Daskalaki, Constantine	Biostatistician	5%	\$18,725.44
Dennis, Marie	Research Associate	23% Yr1; 60% Yr2	\$24,213.76
DiCarlo, Melissa	Project Manager	50% Yr1; 40% Yr2; 20% Yr3; 20% Yr4	\$76,636.44

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name, First Name	Position Title	% of Effort on Project
None		

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost
None		

**10. Co-funding of Research Project during Health Research Grant Award Period.** Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes   X        No \_\_\_\_\_

If yes, please indicate the source and amount of other funds:

This project was an extension of an existing project funded by the American Cancer Society, grant number RSGT-08-017-01-CPPB.

## 11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes  X  No \_\_\_\_\_

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert “not funded” in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds awarded:
Increasing CRC Screening among Hispanic Primary Care Patients	<input type="checkbox"/> NIH <input checked="" type="checkbox"/> Other federal (specify: <u>PCORI</u> ) <input type="checkbox"/> Nonfederal source (specify:_)	August 2013	\$1,750,433	\$1,750,433
Increasing Adherence and Reducing Disparity in Colorectal Cancer Screening	<input type="checkbox"/> NIH <input checked="" type="checkbox"/> Other federal (specify: <u>ACS</u> ) <input type="checkbox"/> Nonfederal source (specify:_)	October 2013	\$1,879,314	Not Funded

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes  X  No \_\_\_\_\_

If yes, please describe your plans:

Work is currently under way on a Patient Centered Outcomes Research Institute (PCORI) Engagement Award Proposal to be submitted in July 2015.

**12. Future of Research Project.** What are the future plans for this research project?

The planned PCORI Engagement Award proposal aims to build a learning community of physicians, patients, insurers, hospital administrators, and community organizations to determine best practices for increasing colon and lung cancer screening among populations experiencing disparities.

**13. New Investigator Training and Development.** Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male				
Female				
Unknown				
<b>Total</b>				

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic				
Unknown				
<b>Total</b>				

	Undergraduate	Masters	Pre-doc	Post-doc
White				
Black				
Asian				
Other				
Unknown				
<b>Total</b>				

**14. Recruitment of Out-of-State Researchers.** Did you bring researchers into Pennsylvania to carry out this research project?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please list the name and degree of each researcher and his/her previous affiliation:

**15. Impact on Research Capacity and Quality.** Did the health research project enhance the quality and/or capacity of research at your institution?

Yes  No

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

This research has led to a study on colorectal cancer screening with Hispanic primary care patients in the Lehigh Valley Health Network. That project was funded by the Patient Centered Outcomes Research Institute (AD-1306-01882).

**16. Collaboration, business and community involvement.**

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes  No

If yes, please describe the collaborations:

This research was conducted with the assistance of Albert Einstein Health Care Network to accrue additional patients. As mentioned above, this collaboration has led to a research project on colorectal cancer screening with Hispanic primary care patients in the Lehigh Valley Health Network. That project was funded by the Patient Centered Outcomes Research Institute (AD-1306-01882).

16(B) Did the research project result in commercial development of any research products?

Yes  No

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes  No

If yes, please describe involvement with community groups that resulted from the research project:

## 17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant agreement). Summarize the progress made in achieving these goals, objectives and aims for the period that the project was funded (i.e., from project start date through end date). Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

**There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha ( $\alpha$ ) and beta ( $\beta$ ) should not print as boxes (□) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.**

### Project Overview

This project built on an American Cancer Society (ACS)-funded randomized, controlled study (RSGT-08-017-01-CPPB) of behavioral interventions intended to boost colorectal cancer (CRC) screening among African American patients in primary care practices affiliated with Thomas Jefferson University (TJU) and the Albert Einstein Health Network (AEHN) in Philadelphia. The ACS-funded study was designed to assess screening at six months after randomization. We extended the screening observation period for participants from 6 to 12 months per patient. The additional time allowed for the complete ascertainment of CRC screening use and specific screening procedures (e.g., colonoscopy screening). In this project, we also developed and pilot tested new patient recruitment procedures. Additionally, patient navigation telephone calls were recorded for analysis in order to identify barriers to and facilitators of successful navigation. Focus groups were conducted with study participants who screened (one group for women and

one group for men), and those who did not screen (one group for women and one group for men), within the 12-month observation period. Two additional focus groups with Hispanic patients were conducted to learn what factors influenced response to intervention in this population group. A thorough intervention cost-effectiveness analysis was completed. Finally, we translated intervention materials into Spanish to broaden the reach of intervention contacts. Results of these analyses will support the design of an enhanced CRC screening intervention system.

### List Project Goals/Specific Aims

Primary specific aims of the project were:

1. Assess the effects of the intervention on CRC screening rates at 12 months after exposure to study interventions,
2. Assess the performance of different types of CRC screening tests (e.g., colonoscopy and stool blood testing)

Secondary aims are:

3. Identify mediators and moderators of CRC screening among study participants.
4. Process data on modified participant recruitment procedures.
5. Identify barriers to and facilitators of patient navigation.
5. Examine focus group responses to study interventions that have been delivered and those that are planned.
6. Conduct a cost analysis of study interventions.

### Methods

#### Measurement of primary outcomes

Consenting participants in the originating project who completed a baseline telephone survey were randomly assigned either to a standard intervention (SI) Group or a tailored navigation intervention (TNI) Group. The SI Group received a generic mailed CRC screening intervention that includes a mailed informational booklet, a stool blood test (SBT) kit, and instructions for scheduling a screening colonoscopy, and a reminder. The TNI Group received a preference-based intervention (a mailed informational booklet and either an SBT kit or colonoscopy screening instructions based on preference assessed on the baseline survey), telephone navigation through performance of the preferred screening test, and a reminder. Six months following randomization, an endpoint survey was conducted. Twelve months after randomization, patient medical records were reviewed to collect outcomes data on overall CRC screening and performance of different CRC screening tests.

CRC screening was defined as the performance of any recommended screening test (stool blood test, colonoscopy, flexible sigmoidoscopy, or double contrast barium enema) during the 12 months (365 days) following the randomization date. Tests identified either through the endpoint survey or the endpoint medical records review were counted, as long as there was an associated date (at least month and year) which fell within the 12-month window. The two study groups were compared with respect to CRC screening in a logistic regression model that included study group, wave, practice, age, and gender.

### Identification of mediators and moderators

We attempted to identify mediating variables, which are defined as variables that are in the causal pathway between intervention and screening. We investigated a global Preventive Health Model (PHM) measure, as well as its five subscales, as potential mediators. In terms of moderator analyses, interactions between study group and several participant attributes on 12 month screening were investigated. Additional analyses were conducted on the five PHM subscales, as well as a global PHM measure.

### Modified recruitment process

For this project, an additional approach to patient recruitment within the office was developed and implemented. A brief slide presentation was shown on waiting room televisions as a part of the AEHN Healthy Advice Channel. This presentation briefly described the study and directed interested patients to the reception desk. Interested patients were then given an educational booklet and a registration card to be completed and returned to project personnel. Following registration, a study research assistant then planned to contact respondents to assess eligibility, obtain consent for participation, and administer the baseline survey.

### Navigation Call Analysis

Recorded navigation calls were transcribed and coded. Using grounded theory and MaxQDA software, 50 intermediate codes were reduced to 5 factors that were hypothesized as screening predictors. The final codes were then analyzed using SPSS. Independent-samples t-tests compared screening (Yes/No) with our 5 final factors.

### Focus Groups

Two focus groups were completed with African Americans who participated in the larger study. Focus groups included both men and women and were divided based on screening status. Both focus groups were transcribed and analyzed, resulting in a complete report from each group. Additionally, we conducted two focus groups with Hispanic patients from Lehigh Valley Health Care Network primary care practices. Similarly, focus groups were audio recorded for transcription and analysis.

### Cost-Effectiveness Analysis

To examine the cost effectiveness of the TNI versus SI, overall cost was divided among participants and per person cost will be compared. Overall cost divided among participants was reported previously. Currently, data for per person cost were analyzed. Per person cost accounted for both fixed and differentiated costs for each enrolled participant. Data points included, but are not limited to, the cost of introduction mailing and completion of the baseline telephone call, mailing of intervention materials and completion of navigation. Data sources included staff time logs, study invoices, participant call logs, the study tracking database and the current market price of supplies. Personnel costs for each activity were divided between the intervention arms by number of patients in each group and number of patients involved in each activity, while supplies for each participant were individually determined. Activity cost/completion differed based on study arm and the active participation of the patient.

The baseline survey cost was estimated at 33 percent of recorded time, eliminating the time required for research and including time to introduce the study, assess eligibility and ask

questions about test preference. Where baseline survey time was missing, 33 percent of the average was applied. Baseline survey costs were only included for the TNI Group, which required eliciting preference to condition a preference-based mailing. SI Group participants received a generic mailing that could be sent to members of a practice without a baseline survey.

Personnel costs were computed by time of each activity (assembling mailings, completing navigation calls etc.), by adjusted salary per minute using the base salary for each position, to calculate the adjusted salary per minute. Activity costs were determined using staff time logs and recorded start and end times of telephone calls. Supplies included questionnaires, printing costs, envelopes, paper, postage, cell phone use and other resources used to enroll participants and produce intervention materials. Costs were calculated by quantifying the materials for each activity and pricing according to current market rates. Professionally printed materials were accounted from project invoices.

## Results

### Primary Outcomes

Table 1 summarizes the main study results regarding CRC screening within 12 months from randomization. The TNI group had significantly higher screening than the SI group. Furthermore, the TNI group had higher rates of both stool blood test and colonoscopy than the SI group.

### Mediators and Moderators

We found that baseline-to-endpoint changes in PHM global measure as well as its five subscales were small and did not differ significantly between the TNI and SI groups (Table 2). Therefore, we conclude that differences in screening rates between the study groups are not due to the study groups' differential impact on the PHM scales.

In terms of moderator analyses, Table 3 displays results concerning interactions between study group and several participant attributes on 12 month screening. Here we present the odds ratio for TNI vs SI within the levels of the potential moderator variables. None of the predictor variables showed a significant interaction.

For the global PHM score as well as the individual PHM subscales, the contrast between TNI and SI was somewhat stronger among participants with less favorable attitudes toward screening (low susceptibility, low salience, low response efficacy, high worries, low social support and influence). The only subscale that had an appreciable impact on the relationship between the intervention and screening was response efficacy. At 12 months, the effect of TNI vs. SI was greater for participants with lower response efficacy (OR = 3.91) than those with higher response efficacy (OR = 1.51). Thus, TNI tended to have a greater, marginally significant ( $p=0.06$ ) effect among those with lower response efficacy than those with higher response efficacy.

### Modified Recruitment Process

Unfortunately, newly developed recruitment methods did not yield any new participants. The study was completed with traditional recruitment methods of a mailed introduction letter and a

follow-up call from study personnel.

### Navigation Call Analysis

A total of 24 recorded navigation calls were transcribed and coded. Patients who screened exhibited more “positive behaviors” (were organized, felt screening was salient, paid attention on the call) ( $M=10.6, SD=7.5$ ) than those who did not ( $M=6, SD=4.8$ );  $t=-1.8, p=.085$ ). Screeners also had more “positive interactions with the navigator,” (she ‘used “I” language,’ ‘praised the patient,’ and ‘used empathy’) ( $M=19.9, SD=12.2$ ) than those who did not ( $M=11.1, SD=9.8$ );  $t=-1.9, p=.07$ ). Patient “negatives,” which included ‘perceived obstacles,’ ‘anxieties about screening,’ or ‘inattention on the phone’, did not predict screening. Navigators did not engage in negative behavior, such as making inferences, providing too much information without checking, or rushing a patient. Patients with more family or personal history of cancer ( $M=.75, SD=.75$ ) were also more likely to screen than those with less ( $M=.17, SD=.39$ ;  $t=-2.38, p=.03$ ). It was concluded that even though patients may have obstacles to screening, navigation that emphasizes the elicited positive factors can help patients decide to screen.

### Focus Groups

Two focus groups completed with African Americans offered insight into intervention delivery within the project. Those who did screen stated that the navigator call was very important to the process of their screening. Additionally, her persistence and flexibility made the participants more receptive to her call. One thing suggested by the participants was that there is a closer tie between the navigator and the primary care physician, specifically with an update on screening status at the end of the navigation process. With those who did not screen, it was determined that materials should be more positive, focusing on the “Good News” of prevention, not the fear of cancer. Most importantly, participants stated that while the navigation call was helpful, giving the navigator the ability to schedule a colonoscopy may have given them what they needed to complete screening.

In the two focus groups among Hispanics, participants reviewed study informational booklet and study letters written in English and Spanish. Participants acknowledged the importance of cancer in the Hispanic community and the value of participation in screening research. In terms of encouraging recruitment to the proposed study, focus group participants highlighted the importance of primary care provider sponsorship of the intervention. They also noted the importance of screening-related costs as a potential barrier to participation and adherence. In addition, the focus groups supported using multiple communication channels to contact participants and recommended that the research staff should use a local telephone number, rather than an unknown telephone exchange to place calls. Focus group participants were very supportive of the plan to provide navigator assistance in scheduling colonoscopy screening and the proposed strategy of delivering feedback to providers about each participant’s screening plan and status. Finally, participants pointed out that formation of a Hispanic community advisory committee to ensure that the voice of the community would be represented in project planning and implementation.

## Cost-Effectiveness Analysis

### *Intervention Costs*

The base case costs per eligible patient for the Standard Intervention (SI) Group and Tailored Navigation Intervention (TNI) Group were \$123.00 dollars and \$419.42 per person, respectively (see Table 4). Within the SI study arm, approximately 55 percent of the intervention cost was accounted for by personnel and 45 percent of the cost was for supplies. In the TNI study arm, approximately 92 percent of intervention cost was for personnel and only 7 percent for supplies. The TNI Group cost included time for completion of a portion of the baseline survey that is necessary for tailoring mailings, production of the tailored mailings, training and time required for completing navigation calls, and any follow-up calls needed to address patient barriers. The TNI Group incurred a lower supplies cost, because FIT kits were not mailed to all participants.

### *Cost-Effectiveness*

We completed estimates of the intervention cost effectiveness moving from less resource intensive SI to a more resource intensive TNI. Since the purpose of the economic evaluation was estimation and not hypothesis testing, we used the point estimates as the “best” available estimates of program effects and costs. At 12 months following randomization, approximately 32 percent of the SI subjects were screened, compared with 43 percent in the TNI Group. The cost per additional person screened (ICER) was \$2630.17, when comparing the TNI Group with the SI Group. These costs were sensitive to investigator time and salary and navigator time. Adjusting investigator salaries to levels paid to administrators and primary care physicians likely to be implementing these interventions in the “real world” yields lower cost estimates for both interventions. Additionally, navigator time was expressed as a range, as time logs reported a much higher navigation effort than noted in previous studies. When comparing SI and TNI, the ICER increased by 18 percent when higher values were applied and decreased by 18 percent when lower values were applied. However, even with the low estimate, the cost per additional person screened was \$2,158 when comparing TNI with SI.

### Other

Finally, we have produced study materials in Spanish

### Publication

Study results have been published but did not cite the Pennsylvania Department of Health as a funding source; therefore the following article may not be listed in Question 20 of this report:

Ronald E. Myers, PhD, Randa Sifri, MD, Constantine Daskalakis, PhD, Melissa DiCarlo, MS, MPH, Praveen Ramakrishnan Geethakumari, MD, James Cocroft, MA, Christopher Minnick, MSW, Nancy Brisbon, MD, Sally W. Vernon, PhD; *Increasing Colon Cancer Screening in Primary Care among African Americans*; Journal of the National Cancer Institute (2014) 106(12).

Table 1. CRC screening (N = 761)

SCREENING	SI	TNI	TNI vs. SI		
	(N = 379)	(N = 382)	OR	(95% CI)	P
	<i>n</i> (%)	<i>n</i> (%)			
<b>Any screening within 12 months</b>	122 (32)	166 (43)	1.67	(1.23, 2.27)	0.001
<b>SBT within 12 months</b>	70 (18)	88 (23)			
<b>CX within 12 months</b>	52 (14)	78 (20)			

OR: odds ratio (for screening, this was adjusted for study wave and practice, and participant age, and sex; for forward change in decision stage, this was adjusted for study wave and practice, and participant age, sex, education, marital status, baseline global PHM score, baseline decision stage, and baseline preferred test). CI: confidence interval. SBT: stool blood test. CX: colonoscopy.

Table 2. Baseline-to-endpoint change in PHM scales (N = 517\*).

	<b>SI</b>	<b>TNI</b>	<b>TNI vs. SI</b>	
	<i>mean (sd)</i>	<i>mean (sd)</i>	<i>mean diff (95% CI)</i>	<i>P</i>
<b>Global PHM scale</b>				
Baseline	3.9 (0.6)	3.9 (0.5)		
Endpoint	3.8 (0.6)	3.8 (0.6)		
Baseline-to-endpoint change	-0.1 (0.6)	0.0 (0.5)	0.0 (-0.1, 0.1)	0.489
<b>Perceived susceptibility</b>				
Baseline	2.6 (1.1)	2.5 (1.1)		
Endpoint	2.5 (1.2)	2.5 (1.2)		
Baseline-to-endpoint change	-0.1 (1.3)	0.0 (1.2)	0.1 (-0.1, 0.2)	0.580
<b>Screening salience</b>				
Baseline	4.8 (0.5)	4.8 (0.5)		
Endpoint	4.8 (0.5)	4.9 (0.4)		
Baseline-to-endpoint change	0.0 (0.5)	0.0 (0.6)	0.1 (0.0, 0.1)	0.088
<b>Screening response efficacy</b>				
Baseline	4.4 (0.8)	4.5 (0.7)		
Endpoint	4.6 (0.8)	4.5 (0.8)		
Baseline-to-endpoint change	0.1 (0.9)	0.0 (0.8)	0.0 (-0.1, 0.1)	0.943
<b>Worries and concerns</b>				
Baseline	3.0 (1.4)	2.8 (1.4)		
Endpoint	2.7 (1.4)	2.6 (1.4)		
Baseline-to-endpoint change	-0.3 (1.4)	-0.2 (1.4)	-0.1 (-0.3, 0.2)	0.602
<b>Social support and influence</b>				
Baseline	4.2 (0.9)	4.3 (0.8)		
Endpoint	4.2 (0.8)	4.2 (0.8)		
Baseline-to-endpoint change	-0.1 (0.9)	-0.1 (0.9)	0.0 (-0.1, 0.2)	0.469
<b>Religiosity/fatalism</b>				
Baseline	2.5 (1.1)	2.5 (1.0)		
Endpoint	2.5 (1.1)	2.5 (1.1)		
Baseline-to-endpoint change	0.0 (1.1)	0.0 (1.0)	0.0 (-0.2, 0.2)	0.902

Mean diff: mean difference (adjusted for study wave and practice, participant age, sex, education, marital status, baseline decision stage, baseline preferred test, and the baseline value of each outcome). CI: confidence interval.

(\*) N = 517 for global PHM scale, 499 for susceptibility, 516 for salience, 485 for response efficacy, 499 for worries and concerns, 504 for social support and influence, and 488 for religiosity/fatalism.

Table 3. Effects of the intervention (TNI versus SI) on CRC screening at 12 months, within categories of various participant characteristics.

	Screening (%)		TNI vs SI		Interaction <i>P</i> -value
	<i>SI</i>	<i>TNI</i>	<i>OR</i>	(95% <i>CI</i> )	
<b>Age x Study group</b>					0.405
50-59	29%	40%	1.53	(1.05, 2.22)	
60+	38%	55%	2.05	(1.15, 3.66)	
<b>Sex x Study group</b>					0.533
Female	34%	46%	1.78	(1.23, 2.58)	
Male	29%	37%	1.43	(0.80, 2.54)	
<b>Education x Study group</b>					0.548
High school or less	31%	40%	1.54	(1.02, 2.32)	
Greater than high school	34%	48%	1.87	(1.15, 3.02)	
<b>Marital status x Study group</b>					0.310
Married (or living as married)	37%	45%	1.32	(0.76, 2.29)	
Single/divorced/widowed	30%	43%	1.86	(1.28, 2.73)	
<b>Global PHM scale x Study group</b>					0.507
Low (1.0-3.0)	30%	48%	2.43	(0.77, 7.73)	
High (3.1-5.0)	32%	43%	1.62	(1.17, 2.24)	
<b>Screening decision stage x Study group</b>					0.547
Decided against to undecided	16%	31%	2.30	(0.77, 6.80)	
Decided to do	34%	45%	1.62	(1.17, 2.24)	
<b>Preferred screening test x Study group</b>					0.344
Stool blood test	30%	53%	1.48	(0.98, 2.24)	
Equal preference	33%	41%	2.77	(1.31, 5.87)	
Colonoscopy	31%	42%	1.53	(0.82, 2.86)	

OR: adjusted odds ratio for TNI versus SI (simultaneously adjusted for all variables shown plus study wave and practice). CI: confidence interval.

Table 4. Cost of the Interventions

Activity	SI (n=380)	TNI (n=384)
	Cost (\$)	Cost (\$)
Identify Target Population	16,057.86	16,226.89
Training & Planning Mtgs.	2,185.56	14,056.42
MI and Navigation Training	NA	6,675.71
Focus Groups	4,348.00	\$4,393.76
Brochure Development	528.10	530.63
Baseline Survey	NA	25,955.83
SI Intervention Mailing	11,484.79	NA
SI Reminder Mailing	1,351.37	NA
TNI Intervention Mailing	NA	4,384.14
TNI Intervention Call	NA	48,583.40
TNI Reminder	NA	1,396.68
Total Direct Cost	35,952.68	123,891.06
Overhead *	10,783.58	33,694.19
Total Cost	46,738.49	161,058.38
Cost per person	123.00	419.42

Table 5: Incremental Cost-effectiveness (intervention cost per additional subject screened)

Intervention	Cost (\$)*	Incremental Cost (\$)	Effect; % screened	Incremental effectiveness (%)	Cost-effectiveness ratio ICER (\$)	Incremental cost-effectiveness ratio ICER (\$)
SI	123.00	123.00	32.18	--	382.13	--
TNI	419.42	296.42	43.45	11.27	965.29	2630.17

**18. Extent of Clinical Activities Initiated and Completed.** Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be “No.”

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

  X   Yes  
       No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

  X   Yes  
       No

**If “Yes” to either 18(A) or 18(B), items 18(C) – (F) must also be completed.** (Do NOT complete 18(C-F) if 18(A) and 18(B) are both “No.”)

18(C) How many hospital and health care professionals were involved in the research project?

  3   Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

 896  Number of subjects originally targeted to be included in the study  
 764  Number of subjects enrolled in the study

**Note:** Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached, the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:

 241  Males  
 523  Females  
       Unknown

Ethnicity:

  14  Latinos or Hispanics  
 750  Not Latinos or Hispanics  
       Unknown

Race:

- American Indian or Alaska Native  
 Asian  
 Blacks or African American  
 Native Hawaiian or Other Pacific Islander  
 White  
 Other, specify: \_\_\_\_\_  
 Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

Philadelphia County

**19. Human Embryonic Stem Cell Research.** Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?

- Yes  
 No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

- Yes  
 No

19(C) Please describe how this project involved human embryonic stem cells:

**20. Articles Submitted to Peer-Reviewed Publications.**

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication or paper submitted for publication, listed in the table, in a PDF version 5.0.5 (or greater) format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, and an abbreviated title of the

publication. For example, if you submit two publications for Smith (PI for Project 01), one publication for Zhang (PI for Project 03), and one publication for Bates (PI for Project 04), the filenames would be:

- Project 01 – Smith – Three cases of isolated
- Project 01 – Smith – Investigation of NEB1 deletions
- Project 03 – Zhang – Molecular profiling of aromatase
- Project 04 – Bates – Neonatal intensive care

If the publication is not available electronically, provide 5 paper copies of the publication.

**Note:** The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
1. None				<input type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input type="checkbox"/> Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes   X        No \_\_\_\_\_

If yes, please describe your plans:

Currently, 12-month screening data are being used in the preparation of a CRC screening adherence manuscript. Additionally, a cost-effectiveness paper is being prepared for submission.

**21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project.**

Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. **DO NOT DELETE THESE INSTRUCTIONS.** There is no limit to the length of your response.

We discovered that the tailored navigation intervention generated a significantly higher colorectal cancer screening rate among African American primary care patients than the mailed standard intervention. Application of this approach in practice has the potential to

increase screening among African Americans and reduce the screening disparity between whites and African Americans.

**22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment.** Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. **DO NOT DELETE THESE INSTRUCTIONS.** There is no limit to the length of your response.

At 12 months following randomization, 32 percent of the SI subjects were screened, compared with 43 percent in the TNI Group. The cost per additional person screened (ICER) was \$2630.17, when comparing the TNI Group to the SI Group. Adjusting study investigator salaries to levels normally paid to administrators and primary care physicians likely to be implementing these interventions in the “real world” yields lower cost estimates for both interventions.

**23. Inventions, Patents and Commercial Development Opportunities.**

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes \_\_\_\_\_ No  X

If “Yes” to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is “No.”)

- a. Title of Invention:
- b. Name of Inventor(s):
- c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):
- d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?  
Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, indicate date patent was filed:

- e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?  
Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, indicate number of patent, title and date issued:

Patent number:

Title of patent:

Date issued:

- f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, how many licenses were granted? \_\_\_\_\_

- g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes \_\_\_ No \_\_\_

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please describe your plans:

**24. Key Investigator Qualifications.** Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages.

## BIOGRAPHICAL SKETCH

NAME RONALD E. MYERS, Ph.D.	POSITION TITLE Professor and Director, Division of Population Science Department of Medicine, Kimmel Cancer Center, Thomas Jefferson University		
EDUCATION/TRAINING ( <i>Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.</i> )			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Shippensburg State U., Shippensburg, PA	B.S.	1968-1972	History, Social Science
Shippensburg State U., Shippensburg, PA	M.S.	1975-1977	Counseling Psychology
University of Pennsylvania, Philadelphia, PA	D.S.W.	1979-1983	Social Welfare
Fox Chase Cancer Center, Philadelphia, PA	Postdoctoral Training	1983-1985	Behavioral Epidemiology
University of Pennsylvania, Philadelphia, PA	Ph.D.	1981-1989	Sociology

### A. Positions and Honors

#### Positions

- 1972-1973 Vocational Rehabilitation Counselor, Department of Labor and Industry, Bureau of Vocational Rehabilitation, Commonwealth of Pennsylvania, Harrisburg, PA.
- 1973-1975 Language Instructor, United States Peace Corps, Gyeongsang National University, Republic of Korea.
- 1977-1979 Director of Refugee Resettlement, Diocese of Harrisburg, Harrisburg, PA.
- 1985-1987 Assistant Director, US HEALTHCHECK, Cancer Control and Continuing Education, Fox Chase Cancer Center, Philadelphia, PA.
- 1987-1988 Assistant Member, Division of Cancer Control, Fox Chase Cancer Center, Philadelphia, PA.
- 1988-1994 Associate Member, Division of Population Sciences, Fox Chase Cancer Center, Philadelphia, PA.
- 1994-2000 Associate Professor, Jefferson Medical College, Department of Medical Oncology and Department of Psychiatry and Human Behavior, Philadelphia, PA.
- 2001-Present Professor, Jefferson Medical College, Department of Medical Oncology and Department of Psychiatry and Human Behavior, Philadelphia, PA.

### B. Selected peer-reviewed publications (in chronological order from 60+ peer-reviewed publications)

1. Liberatore MJ, Myers RE, Nydick RL, Steinberg M, Brown ER, Gay R, Powell T, Powell RL. Decision Counseling for Men Considering Prostate Cancer Screening. *Computers and Operations Research* 30:1421-1434, 2003.

2. Myers RE. Decision Counseling in Cancer Prevention and Control. *Health Psychology* 24(4) (Supplement):S71-S77, 2005.
3. Myers RE, Daskalakis C, Cocroft J, Kunkel JS, Delmoor E, Liberatore M, Nydick RL, Brown ER, Gay RN, Powell T, Lee Powell R. Preparing African-American Men in Community Primary Care Practices to Decide Whether or Not to Have Prostate Cancer Screening. *Journal of the National Medical Association* 97(8):1143-53, 2005.
4. Myers RE, Berry A, Bradley P, Cocroft J, Daskalakis C, Delmoor E, Fleisher L, Kasper-Keintz M, Witt D. Increasing Access to Clinical and Educational Studies. *Cancer* 107 S8:1962-1970, 2006.
5. Myers RE, Daskalakis C, Kunkel JS, Cocroft JR, Riggio JM, Capkin M, Braddock CH. Mediated Decision Support in Prostate Cancer Screening: A Randomized Controlled Trial of Decision Counseling. *Patient Education & Counseling*. 83(2):240-6, 2011. Epub 2010 Jul 8.
6. Vernon, Sally W, Bartholomew, Leona K. Bartholomew, McQueen A, Bettencourt JL, Greisinger A, Coan SP, Lairson D, Chan W, Hawley ST, Myers RE. A Randomized Controlled Trial of a Tailored Interactive Computer-Delivered Intervention to Promote Colorectal Cancer Screening: Sometimes More is Just the Same. *Annals of Behavioral Medicine*. 41(3):284-299, 2011.
7. Leader A, Daskalakis C, Braddock C, Kunkel E, Cocroft J, Berekenyei S, Riggio J, Capkin M, Myers RE. Measuring Informed Decision Making about Prostate Cancer Screening in Primary Care. *Medical Decision Making*. *Med Decis Making* epub, June, 2011.
8. Myers RE, Daskalakis C, Kunkel EJ, Cocroft JR, Riggio JM, Capkin M, Braddock CH 3rd. Mediated decision support in prostate cancer screening: a randomized controlled trial of decision counseling. *Patient Educ Couns*. 83(2):240-6, 2011. Epub 2010 Jul 8.
9. Hawley ST, McQueen A, Bartholomew LK, Greisinger AJ, Coan SP, Myers RE, et al. Preferences for Colorectal Cancer Screening Tests and Screening Test use in a Large Multispecialty Primary Care Practice. *Cancer* 118(10):2726-2734, 2012.
10. Myers RE, Bittner-Fagan H, Daskalakis C, Sifri R, Vernon SW, Cocroft J, DiCarlo M, Katurakes, Andrel J. A Randomized Controlled Trial of Tailored Navigation and Standard Intervention in Colorectal Cancer Screening. *Cancer Epidemiology, Biomarkers, & Prevention*. doi:10.1158/1055-9965.EPI-12-0701.
11. Weinberg D, Myers RE, Keenan E, Ruth K, Sifri R, Ziring B, Ross, E, Manne SL. Genetic and Environmental Risk Assessment and Colorectal Cancer Screening in an Average-Risk Population. *Annals of Internal Medicine*, 161:537-545, 2014.
12. Myers RE. Prostate Cancer Screening. *Psycho-Oncology*, 3<sup>rd</sup> Edition. Holland JC, Breitbart WS, Jacobsen PB, Lederberg MS, Loscalzo MJ, and McCorkle R. NY: Oxford University Press. (In Press).
13. Myers RE, Sifri S, Daskalakis C, DiCarlo M, Geethakaumari PR, Cocroft J, Minnick C, Brisbon N, Vernon SW. Increasing Colon Cancer Screening in Primary Care among African Americans. *Journal of the National Cancer Institute* (In Press).
14. Ritvo P, Myers RE, Paszat LF, Tinmouth JM, McColeman J, Mitchell B, Serenity M, Rabeneck L. Personal Navigation Increased Colorectal Cancer Screening Uptake. *Cancer Epidemiology Biomarkers & Prevention* (In Press).
15. Myers R, Lavu H, Keith SW, Kelly H, O'Rourke N, Cocroft J, Quinn A, Potluri V, Yeo C. Decision Counseling and Participation in a Pancreas Cancer Registry. *Journal of Registry Management*. (In Press).

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**BIOGRAPHICAL SKETCH.**

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NAME Sifri, Randa		POSITION TITLE Associate Professor	
EDUCATION			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Duke University	BA	12/83	Political Science
University of Cincinnati College of Medicine	MD	6/89	Medicine
Thomas Jefferson University	Residency	6/92	Family Medicine
Thomas Jefferson University	Fellowship	6/93	Family Medicine

**A. Positions and Honors**

**1993-1995:** Instructor, Department of Family Medicine, Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA

**1995-2006:** Clinical Assistant Professor, Department of Family Medicine, Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA

**2006-Present:** Associate Professor, Department of Family and Community Medicine, Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA

**2010-Present:** Director, Research Development, Department of Family and Community Medicine, Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA

**2012-Present:** Director, Faculty Development Research Fellowship, Department of Family and Community Medicine, Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA

**B. Selected Peer-Reviewed Publications**

1. Myers RE, Weinberg DS, Manne SL, Sifri R, Cocroft J, Kash K, Wilfond B. Genetic and Environmental Risk Assessment for Colorectal Cancer Risk in Primary Care Practice Settings: A Pilot Study. *Genet Med* 2007; 9(6):378-84
2. Myers, RE, Sifri R, Hyslop T, Rosenthal M, Vernon SW, Cocroft J, Wolf T, Andrel J, Wender R. A Randomized Controlled Trial of the Impact of Targeted and tailored Interventions on Colorectal Cancer Screening. *Cancer* 2007; 11(9):2083-91
3. Lairson DR, DiCarlo M, Myers RE, Wolf T, Cocroft J, Sifri R, Rosenthal M, Vernon SW, Wender R. Cost-effectiveness of Targeted and Tailored Interventions on Colorectal Cancer Screening Use. *Cancer* 2008; 112(4):779-88
4. Myers RE, Hyslop T, Sifri R, Bittner-Fagan H, Katurakes NC, Cocroft J, DiCarlo M, Wolf T. Tailored Navigation in Colorectal Cancer Screening. *Med Care* 2008; 46(9 Suppl 1):S123-31
5. Sifri R, Rosenthal M, Hyslop T, Andrel J, Wender R, Vernon S, Cocroft J, Myers R. Factors Associated with Colorectal Cancer Screening Decision Stage. *Prev Med* 2010; 51:329-31
6. Myers RE, Manne SL, Wilfond B, Sifri R, Ziring B, Wolf TA, Cocroft J, Ueland A, Petrich A, Swan H, DiCarlo M, Weinberg DS. A Randomized Trial of Genetic and

- Environmental Risk Assessment (GERA) for Colorectal Cancer Risk in Primary Care: Trial Design and Baseline Findings. *Contemp Clin Trials* 2011; 32(1): 25-31.
7. Siddiqui AA, Sifri R, Hyslop T, Andrel J, Rosenthal M, Vernon SW, Cocroft J, Myers RE. Race and Response to Colon Cancer Screening Interventions. *Prev Med* 2011; 52(3-4):262-4.
  8. Fagan HB, Myers RE, Daskalakis C, Sifri R, Mainous AG 3rd, Wender R. Race/Ethnicity, Gender, Weight Status, and Colorectal Cancer Screening. *J Obes*. 2011;2011:314619.
  9. Fagan HB, Sifri R, Wender R, Schumacher E, Reed JF. Weight Status and Perception of Colorectal Cancer Risk. *J Am Board Fam Med* 2012, Nov;25(6):792-7.
  10. Myer RE, Fagan HB, Daskalakis C, Sifri R, Vernon SW, Cocroft J, DiCarlo M, Katurakes NC, Andrel J. A Randomized Controlled Trial of Tailored Navigation and Standard Intervention in Colorectal Cancer Screening. *Cancer Epidemiol Biomarkers Prev*. 2013 22(1):109-17.
  11. Sarfaty M, Stello B, Johnson M, Sifri R, Borsky A, Myers RM. Colorectal Cancer Screening in the Framework of the Medical Home Model: Findings from Focus Groups and Interviews. *Am J Med Qual*. 2013 Sep-Oct;28(5):422-8.
  12. Lairson D, DiCarlo M, Deshmuk A, Bittner-Fagan H, Sifri R, Katurakes N, Cocroft J, Sendeki J, Swan H, Vernon S, Myers R. Cost-effectiveness of Standard vs. a Navigated Intervention on Colorectal Cancer Screening Use in Primary Care. *Cancer Epidemiol Biomarkers Prev*. 2013, in press.