

# 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 717-783-2548.

1. **Grantee Institution:** Thomas Jefferson University
2. **Reporting Period (start and end date of grant award period):** 01/01/2010 – 12/31/2013
3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Joy Soleiman, MPA
4. **Grant Contact Person’s Telephone Number:** 215-955-5684
5. **Grant SAP Number:** 4100050910
6. **Project Number and Title of Research Project:** 4 - Tailored Preference Intervention and Colon Cancer Screening in Primary Care
7. **Start and End Date of Research Project:** 01/01/2010 - 06/30/2013
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:

\$ 474,055.92

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
Myers, Ronald	Principal Investigator	5% Yrs, 1,2,3,4	35,002
Andrel Senddecki, J	Biostatistician	50%, Yr 1, 10% Yr.2&3	45,557
Keith, Scott	Co-investigator	7% Yrs. 1, 2, 3	16,723
Sifri, Randa	Co-investigator	5% Yrs. 2&3	12,118
Hyslop, Theresa	Co-investigator	5% Yrs. 1,2,3	17,716
Cocroft, James	Program Analyst	30% Yrs 2 &3	35,489
Wolf, Thomas	Research Manager	30% Yrs. 2,3,4	30,189
Keintz, Martha	Research Associate	50% Yr.1	48,500
Daskalakis, C	Biostatistician	5%, Yrs. 2&3	11,006
Dennis, Marie	Research Analyst	20% Year 2&3	19,076
DiCarlo, Melissa	Project Manager	20% Yr2, 30% Yr.3	24,633

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	Cost
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 \_\_\_\_\_ No X \_\_\_\_\_

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

### 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 to be awarded:
Increasing CRC Screening among Hispanic Primary Care Patients (funded)	<input type="checkbox"/> NIH <input checked="" type="checkbox"/> Other federal (specify: <u>PCORI</u> ) <input type="checkbox"/> Nonfederal source (specify: <u>  </u> )	August 2013	\$1,737,687	\$TBD
Increasing Adherence and Reducing Disparity in Colorectal Cancer Screening (pending)	<input type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify: <u>      </u> ) × Nonfederal source (specify: <u>ACS</u> )	October 2013	\$1,879,314	\$TBD

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:

Given findings from the current study, that those who receive only tailored materials are less likely to screen, we have chosen to further refine a tailored navigation approach. This approach involves the assessment of participant screening test preference (stool blood testing versus colonoscopy), provides access to both tests, and includes telephone navigation to perform the preferred test. We have recently submitted new research grants exploring this idea to both the Patient Centered Outcomes Research Institute (PCORI) and the American Cancer Society (ACS). We have received funding from PCORI, while the ACS grant is still pending a decision.

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

Findings from the current study suggest that providing access to all available screening tests generates higher screening rates than limiting access to CRC screening tests on the basis of an expression of test preference reported during a telephone survey. Going forward, we plan to determine why screening rates were higher in the former group than the latter group.

**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  X

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

**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  X  No \_\_\_\_\_

If yes, please describe the collaborations:

This research was conducted in collaboration with the Albert Einstein Health Care Network in order to accrue additional patients. In addition, this collaboration has since been extended into further research proposals. Specifically, a new research grant application on CRC screening among white and African American patients served by the Albert Einstein Healthcare Network has been submitted to the American Cancer Society.

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

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

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

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

As a result of this study, we established a patient and stakeholder advisory committee with the Albert Einstein Healthcare Network to guide future research on CRC screening.

## **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**

Colorectal cancer (CRC) screening can reduce CRC incidence and significantly lower CRC mortality by detecting and removing polyps at an early stage of disease. Unfortunately, screening is underused by African Americans. This project will be a cohort study ancillary to an IRB-approved investigation of African Americans who are 50 to 75 years of age.

This project assigned 282 consenting participants to receive a mailed intervention that was based on the individual's preferred CRC screening test, ascertained from a baseline survey. This approach is referred to as a "tailored preference intervention" (TPI). Participants in the TPI group, who preferred stool blood testing, were mailed a stool blood test kit; while those who preferred colonoscopy or who preferred both tests evenly, were mailed instructions for

scheduling a colonoscopy. A screening reminder was sent to participants 45 days after randomization. An endpoint survey and endpoint chart audits were completed six months following study group assignment.

## **LIST PROJECT GOALS/SPECIFIC AIMS**

The primary objective of this project was to assess the difference between the project Tailored Preference Intervention (TPI) group and the ACS ongoing study Standard Intervention (SI) group.

The primary aim of the project was to determine if screening in the project TPI Group was higher than screening in the SI Group in the ongoing study.

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

We were able to complete the primary objective and primary aim of this project. However, it is important to note that enrollment was lower than initially planned. While the initial target for enrollment was 427, the decision to suspend recruitment at 282 participants based on the result of an interim analysis, which showed that screening adherence in the TPI Group, was lower than that observed in the SI Group. Furthermore, we projected that additional recruitment was not likely to result in a screening rate in the TPI Group that would be significantly higher than that observed in the SI Group.

## **METHODS**

### Measurement of Predictor and Outcome Variables

The primary endpoint of the study was participant screening utilization in the six-month period after enrollment. This outcome is a dichotomous variable based on data obtained from the endpoint chart audit and from the endpoint survey. We computed the proportion of participants who screened and the corresponding 95% confidence interval for the TPI Group participants. Screening test use included any CRC screening tests (stool blood testing (SBT), colonoscopy, flexible sigmoidoscopy, and barium enema x-ray) that were performed during a 6-month observation period after randomization. We classified participants as having screened if there were a report of screening in their chart or if they self-reported a screening test and a screening date on the endpoint survey.

Changes in screening decision stage (SDS) constituted a secondary outcome for the study. The baseline and endpoint surveys contained items determining whether participants had 1) decided against, 2) never heard of, 3) were not considering, 4) undecided about, 5) decided to do each screening test, or, if they had completed a screening test at endpoint, 6) screened. The CRC screening test with the highest SDS (i.e. the closest to screening) was assigned as the participant's preferred test and that stage was the participant's overall SDS. Participant SDS was computed at both baseline and endpoint. Change in SDS was dichotomized as "forward change" if a participant moved closer to screening at endpoint, and "no forward change", if the participant reported the same SDS at both baseline and endpoint, or if the participant reported a lower SDS at endpoint as compared to baseline.

Demographic characteristics, including age, gender, education, and marital status, were measured on the baseline survey. Fourteen items forming five Preventive Health Model (PHM) constructs were also measured at baseline and at endpoint. Change in PHM variables was another secondary outcome. Each item was measured on a 5-point Likert scale, and the items forming each PHM scale were averaged to obtain the scale score. These PHM scales included Salience and Coherence (3 items), Perceived Susceptibility (3 items), Screening Response Efficacy (2 items), Worries and Concerns (2 items), and Social Support and Influence (4 items), as well as a global PHM scale constructed from all 14 items. Analyses of the TPI effect was adjusted for demographic variables and PHM scale scores at baseline.

### Data Analysis

All analyses followed the intent-to-treat principle, and participants who did not complete an endpoint survey were excluded from the analyses of secondary outcomes. We used logistic regression to analyze CRC screening and the baseline-to-endpoint change in CRC decision stage. A Generalized Estimating Equations approach was employed to account for potential within-practice clustering, but yielded almost identical results to the ordinary logistic model. The results of the logistic model are therefore presented. We also used linear regression for the analyses of the baseline-to-endpoint change in PHM variables. The final models controlled for study wave, practice, and all participant baseline characteristics.

## **RESULTS**

### Study Population

Accrual to the study was accomplished in 17 separate cohorts. The SI and TPI groups were composed of 380 and 282 participants respectively. Endpoint surveys were completed for 68% of the SI Group and 71% of the TPI Group. Endpoint Chart Audits were carried out for both study groups. Participant demographic and attitudinal characteristics are summarized in Table 1.

**Table 1.** Summary of participant baseline characteristics (N=661)

	SI (N = 379)		TPI (N = 282)	
Study site, n (%)				
Jefferson	236	(62)	125	(44)
Einstein	143	(38)	157	(56)
Age (years), n (%)				
50-59	255	(67)	208	(74)
60+	124	(33)	74	(26)
Sex, n (%)				
Female	243	(64)	189	(67)
Male	136	(36)	93	(33)
Education, n (%)				
High school or less	227	(60)	175	(62)
Greater than high school	151	(40)	106	(38)
Marital status, n (%)				
Married (or living as married)	110	(29)	82	(29)
Single/divorced/widowed	269	(71)	197	(71)
Global PHM scale, n (%)				
Low (1.0-3.0)	33	(9)	12	(4)
High (3.1-5.0)	346	(91)	269	(96)
Perceived susceptibility, n (%)				
Low (1.0-3.0)	277	(75)	197	(72)
High (3.1-5.0)	94	(25)	77	(28)
Screening salience, n (%)				
Low (1.0-3.0)	11	(3)	4	(1)
High (3.1-5.0)	367	(97)	278	(99)
Screening response efficacy, n (%)				
Low (1.0-3.0)	49	(14)	31	(12)
High (3.1-5.0)	311	(86)	238	(88)
Worries and concerns, n (%)				
Low (1.0-3.0)	205	(56)	161	(58)
High (3.1-5.0)	164	(44)	115	(42)
Social support & influence, n (%)				
Low (1.0-3.0)	46	(12)	29	(11)
High (3.1-5.0)	326	(88)	247	(89)
Screening decision stage, n (%)				
Decided against / never heard of	7	(2)	3	(1)
Not considering / undecided	36	(10)	42	(15)
Decided to do	336	(89)	237	(84)
Preferred screening test, n (%)				
Stool blood test	66	(17)	40	(14)
Equal preference	220	(58)	169	(60)
Colonoscopy	93	(25)	73	(26)

Counts may not sum to each group's total because of occasional missing data.

### Intervention Impact on CRC Screening

Table 2 displays the primary study results regarding CRC screening. The SI Group had higher overall screening rate than the TPI Group. That is, 24 percent of the SI Group had a screening test, while 19% for the TPI Group screened. Controlling for demographic and attitudinal factors, the TPI Group had roughly half the odds of screening, compared with the SI group (OR=0.52, 95% CI=0.28-0.96, p=0.038). This effect may be due to the fact that the SI Group was provided access to the SBT and Colonoscopy, as compared to the TPI group which was given access to the one test that the individual reported as being preferred.

**Table 2.** CRC screening within 6 months (N = 661).

	SI	TPI	TPI vs SI	
	(N=379) n (%)	(N=282) n (%)	OR (95% CI)	P-value
Any screening	90 (24)	54 (19)	0.52 (0.28, 0.96)	0.038
SBT screening	58 (15)	12 (4)		
CX screening	32 (8)	42 (15)		

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

### Intervention Impact on Change in SDS

Baseline to endpoint changes in SDS are shown in Table 3. Although the TPI Group displayed greater forward SDS change than the SI Group (34% to 28% respectively), the difference was not statistically significant (OR=1.44, 95% CI=0.71-2.92, p=0.316).

**Table 3.** Baseline-to-endpoint forward change in CRC decision stage (N = 459).

	SI	TPI	TPI vs SI	
	(N=259) n (%)	(N=200) n (%)	OR (95% CI)	P-value
Any forward change:	72 (28)	68 (34)	1.44 (0.71,2.92)	0.316

OR: odds ratio (adjusted for study wave and practice, and participant age, sex, education, marital status, baseline global PHM scale, baseline decision stage, and baseline preferred screening test). CI: confidence interval.

### Intervention Impact on Perceptions about CRC Screening

Table 4 summarizes the means and standard deviations of the changes in the PHM scales for both of the study groups, as well as the mean differences between the groups. Baseline-to-

endpoint changes in these outcomes were very small and differences between the study groups were mostly not statistically significant. The only significant difference between the SI and TPI groups was observed for the Salience and Coherence scale. Specifically, the TPI Group was more likely than the SI Group to exhibit a positive change in this measure. (p=0.004)

**Table 4.** Baseline-to-endpoint change in PHM scales

	SI	TPI	TPI vs SI	
	Mean (sd) change	Mean (sd) change	Mean difference (95% CI)	p-value
Global PHM	-0.1 (0.6)	-0.1 (0.5)	0.1 (-0.0, 0.2)	0.147
Susceptibility	-0.1 (1.3)	-0.3 (1.4)	0.1 (-0.3, 0.4)	0.710
Salience & coherence	0.0 (0.5)	0.1 (0.6)	0.2 (0.1, 0.3)	0.004
Response efficacy	0.1 (0.9)	0.1 (0.9)	0.1 (-0.1, 0.3)	0.369
Worries & concerns	-0.3 (1.4)	-0.4 (1.6)	0.2 (-0.1, 0.6)	0.214
Social support & influence	-0.1 (0.9)	-0.2 (0.8)	0.1 (-0.1, 0.3)	0.559

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

**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?

Yes  
 No

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

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?

12 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?

427 Number of subjects originally targeted to be included in the study

282 Number of subjects enrolled in the study

**Note:**

While the initial target for enrollment was 427 for the TPI Group, the decision to suspend recruitment at 282 participants based on the results of an interim analysis, which showed that screening adherence in the TPI Group was lower than that observed in the SI Group. Furthermore, we projected that additional recruitment was not likely to result in a screening adherence rate in the TPI Group that would be significantly higher than that observed in the SI Group.

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

**Gender:**

93 Males

189 Females

       Unknown

**Ethnicity:**

0 Latinos or Hispanics

282 Not Latinos or Hispanics

       Unknown

**Race:**

       American Indian or Alaska Native

       Asian

282 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.)

Participants were members of practices within Philadelphia County however, since this study was completed over the phone, participants also may have lived in Montgomery, Bucks and Delaware 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:

The study team will develop, write and submit an article to peer-reviewed journal that focuses on the comparison of the TPI Group to the SI Group.

**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.

Findings from the study suggest that there was no significant difference in overall adherence between participants who were provided access only to preferred screening tests (SBT or colonoscopy), as was done for persons in the TPI Group, and participants who were provided access to both SBT and colonoscopy screening, as was the case for individuals in the SI Group. Surprisingly, participant perceived salience and coherence of screening was significantly higher in the TPI Group than the SI Group.

**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.

Findings from the study suggest that providing patients access to SBT and colonoscopy screening via mail (SI) had a positive and significantly greater impact on CRC screening than limiting access to either SBT or colonoscopy screening via mail on the basis of preference elicited using a telephone survey (TPI). As a result, it is likely that an SI screening program

will identify more patients with colorectal adenomas and with early, curable CRC than a TPI screening program.

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

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 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. Please limit to 1-2 pages.

<b>BIOGRAPHICAL SKETCH</b>			
<b>NAME</b> RONALD E. MYERS, Ph.D.		<b>POSITION TITLE</b> Professor and Director, Division of Population Science Department of Medicine, Kimmel Cancer Center, Thomas Jefferson University	
eRA Commons User Name REM103			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	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.

##### **Honors**

1988	National Cancer Institute New Investigator Award
2004	American Cancer Society Cancer Control Award

**C. Selected Publications** (in chronological order from 60+ peer-reviewed publications)

1. Myers RE. Decision Counseling in Cancer Prevention and Control. *Health Psychology* 24(4) (Supplement):S71-S77, 2005.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.* 52(3-4):262-264, 2011.
7. Leader A, Daskalakis C, Braddock C, Kunkel E, Cocroft J, Bereknyci 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, Manne SL, Wilford 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*. 32(1):25-31, 2011; Epub Sep 7.
9. [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.
2. Gomella LG, Liu XS, Trabulsi, EJ, Kelly WKK, Myers RE, Showalter T., Dicker A., Wender R. Screening for Prostate Cancer: the Current Evidence and Guidelines Controversy. *Canadian J. Urology* 18(5): 5875-5883, 2011
3. Leader A, Daskalakis C, Braddock C, Kunkel E, Cocroft J, Bereknyci S, Riggio J, Capkin M, Myers RE. Measuring Informed Decision Making about Prostate Cancer Screening in Primary Care. *Medical Decision Making*. Mar-Apr;32(2):327-36, 2012. Epub 2011 Jun 17.
4. 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.
5. Feldstein AC, Perrin N, Liles EG, Smith DH, Rosales AG, Schneider JL, Lafata JE, Myers RE, Mosen DM, Glasgow RE. Primary Care Colorectal Cancer Screening Recommendation Patterns: Associated Factors and Screening Outcomes. *Society for Medical Decision Making* 32:198-208, 2012.
6. 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.

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**BIOGRAPHICAL SKETCH.**

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NAME Randa Sifri, MD		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**

**Professional Experience**

**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

**Committees:**

American Cancer Society, Pennsylvania Division:

**1995** Primary Care Work Group, Chairperson

**1997-present** Cancer Prevention and Control Lecturer

**2009-2010** Board of Directors, Pennsylvania Division

**2009-2010** Colorectal Cancer Task Force

**1996-present** Preventive Health Advisory Committee, PA Independence Blue Cross

Thomas Jefferson University Committees:

**2001-present** Population Science Group, Thomas Jefferson University

**2001-2006** Kimmel Cancer Center Internal Advisory Committee

**2003-2006** Tobacco Project III Committee

**2006-2008** Kimmel Cancer Center Minority Report Committee

**2010-2011** University Research Advisory Committee

**2010-present** Student Promotions Committee

**2002-2010** Pennsylvania Cancer Control Consortium (PAC3)

**2002-2007** Research Sub-Committee

**2003-2010** Early Detection and Screening Committee

**2005-present** National Colorectal Cancer Roundtable

**2005-present** Professional Education and Practice Task Group **B. SELECTED B.**

## **B. PEER-REVIEWED PUBLICATIONS**

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

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

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

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

Sifri R, Wender R, Lieberman D, Potter M, Peterson K, Weber TK, Smith R. Developing a Quality Screening Colonoscopy Referral System in Primary Care Practice: a Report from the National Colorectal Cancer Roundtable. *CA Cancer J Clin* 2010; 60(1):40-9

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

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.

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.

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.

Sarfaty M, Myers RE, Harris DM, Borsky AE, Sifri R, Cocroft J, Stello B, Johnson M. Variation in Colorectal Cancer-Screening Steps in Primary Care: Basis for Practice Improvement. *Am J Med Qual.* 2012; 27(6):458-66.

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.

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.

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.

Lairson D, DiCarlo M, Deshmuk A, Bittner-Fagan H, Sifri R, Katurakes N, Cocroft J, Sendecki 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.

Ahnen D, Wade S, Jones W, Sifri R, Silveiras J, Greenamyre J, Guiffre S, Axilbund J, Spiegel A, You Y. The Rising Incidence of Young-Onset Colorectal Cancer: A Call to Action. *Mayo Clin Proc.* 2013, in press.

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME <b>Constantine DASKALAKIS</b>	POSITION TITLE <b>Associate Professor</b>		
eRA COMMONS USER NAME (credential, e.g., agency login) <b>cdaskala</b>			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Massachusetts (Amherst, MA)	MS	1992	Epidemiology
Harvard University (Boston, MA)	ScD	1997	Biostatistics & Epidemiology

### A. Positions and Honors

#### Positions and Employment

1987-1991	Research Assistant, Department of Biostatistics & Epidemiology, University of Massachusetts
1992-1996	Research Assistant, Department of Epidemiology, Harvard University
1993-1996	Teaching Fellow, Department of Biostatistics, Harvard University
1997-2000	Research Fellow, Department of Biostatistics, Harvard University
2000-2008	Assistant Professor, Division of Biostatistics, Department of Pharmacology & Experimental Therapeutics, Thomas Jefferson University
2008-present	<b>Associate Professor</b> , Division of Biostatistics, Department of Pharmacology & Experimental Therapeutics, Thomas Jefferson University
2013-present	<b>Director</b> , Student Summer Research Program, Jefferson Medical College

#### Other Professional Activities

2001-2005	Reviewer, NCI grant review panels for the Small Grants Programs on Cancer Prevention and Cancer Epidemiology (R03 and R21)
2006	Reviewer, NIMH Special Emphasis Panel on Interventions for Youth – Anxiety and Mood Disorders (R01)
2007	Organizer, Symposium on “Analysis of outcomes measured through multiple imperfect sources”, annual meeting of the Society for Epidemiologic Research, Boston, MA
2008	Reviewer, NCI Special Emphasis Panel on Discovery and Development (P01)
2011	Reviewer, NCI Scientific Review Group for Population-based Research Optimizing Screening through Personalized Regimens and for associated Statistical Coordination Center (PROSPR, U54 and U01)
2010-present	Reviewer, NCI-F Manpower & Training Review Committee (K99/R00 and T32)
2010-present	Judge, Delaware Valley Science Fair (for high school students)
2000-present	Associate editor, American Journal of Epidemiology

2010-present Secretary/treasurer (2010-2011) and Chair-elect (2013), Section on Teaching Statistics in the Health Sciences, American Statistical Association

### **Awards**

1994 Robert B. Reed Prize of Biostatistics, Dept. of Biostatistics, Harvard School of Public Health

1995 Teaching Assistant of the Year Award, Harvard School of Public Health

### **B. Selected Peer-reviewed Publications** (Selected from 60+ peer-reviewed publications)

1. **Daskalakis C**, Laird NM, Murphy JM. Regression analysis of multiple-source longitudinal outcomes: A “Stirling County” depression study. *Am J Epidemiol* 2002;155(1):88-94. DOI 10.1093/aje/155.1.88
2. Kunkel EJS, Meyer B, **Daskalakis C**, Cocroft J, Jennings-Dozier K, Myers RE. Behaviors used by men to protect themselves against prostate cancer. *Cancer Epidemiol Biomarkers Prev* 2004;13(1):78-86. DOI 10.1158/1055-9965.EPI-010-3
3. Myers RM, **Daskalakis C**, Cocroft J, Kunkel EJS, Delmoor E, Liberatore M, Nydick RL. 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* 2005;97(8):1143-1154.
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* 2006;107(8 Suppl):1962-1970. DOI 10.1002/cncr.22149
5. Liberatore MJ, Nydick RL, **Daskalakis C**, Kunkel EJS, Cocroft J, Myers RE. Helping men decide about scheduling a prostate cancer screening exam. *Interfaces* 2009;39:209-217. DOI 10.1287/inte.1080.0395
6. Myers RE, **Daskalakis C**, Kunkel EJS, Cocroft JR, Riggio JM, Capkin M, Braddock CH. Mediated decision support in prostate cancer screening: A randomized controlled trial of decision counseling. *Patient Education and Counseling* 2011;83(2):24-246. DOI 10.1016/j.pec.2010.06.011
7. Bittner Fagan H, Myers R, **Daskalakis C**, Sifri R, Mainous AG, Wender R. Race/ethnicity, gender, weight status, and colorectal cancer screening. *Journal of Obesity* 2011, Article ID 314619, 6 pages. DOI 10.1155/2011/314619
8. Leader A, **Daskalakis C**, Braddock CH, Kunkel EJS, Cocroft JR, Berekyei S, Riggio JM, Capkin M, Myers RE. Measuring informed decision making about prostate cancer screening in primary care. *Medical Decision Making* 2012;32:327-336. DOI 10.1177/0272989X11410064
9. Myers RE, Bittner-Fagan H, **Daskalakis C**, Sifri R, Vernon SW, Cocroft J, DiCarlo M, Katurakes N, Andrel J. A randomized controlled trial of tailored navigation and standard intervention in colorectal cancer screening. *Cancer Epidemiol Biomarkers Prev* 2013;22(1):109-117. DOI: 10.1158/1055-9965.EPI-12-0701.