

# 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:** American College of Radiology
2. **Reporting Period (start and end date of grant award period):** 1/1/2009 – 12/31/2012
3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Marcia Fogle, RN, CCRC
4. **Grant Contact Person’s Telephone Number:** 215-940-8898
5. **Grant SAP Number:** 4100047624
6. **Project Number and Title of Research Project:** 4 - Assessment of Methods to Increase Latino Enrollment into Cancer Clinical Trials
7. **Start and End Date of Research Project:** 1/1/2009 – 12/31/2012
8. **Name of Principal Investigator for the Research Project:** Deborah Watkins-Bruner, RN, PhD
9. **Research Project Expenses.**

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

\$ 185,625.84

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	Position Title	% of Effort on Project	Cost
Bruner	PI	4% All Yrs	\$72,683.96
Stine	Senior Director RTOG	3% Yr 2; 2% Yr3;1% Yr 4	\$6,660.59
Boparai	Project Manager RTOG	5% Yr 4	\$5,099.21
Bruner	Male undergrad	10% Yrs 3-4	\$3,000.00
Reardon	Pre-doc	14% Yr 3	\$7,000.00
Fogle	Project Manager	5% Yr 3; 4% Yr 4	\$9,752.74

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

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:
None	<input type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify: _____) <input type="checkbox"/> Nonfederal source (specify: _)		\$	\$

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:

We will be submitting a PCORI grant on cultural competency training 2013.

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

We will be submitting a PCORI grant on cultural competency training 2013.

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

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

	Undergraduate	Masters	Pre-doc	Post-doc
Male	1			
Female			1	
Unknown				
<b>Total</b>	<b>1</b>		<b>1</b>	

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic	1		1	
Unknown				
<b>Total</b>	<b>1</b>		<b>1</b>	

	Undergraduate	Masters	Pre-doc	Post-doc
White	1		1	
Black				
Asian				
Other				
Unknown				
<b>Total</b>	<b>1</b>		<b>1</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:

ePharmasolutions and Alchemedia.

These two companies, from Pennsylvania, were funded to assist with the development and implementation of Cultural Diversity training. The training was then presented at a Radiation Therapy Oncology Group (RTOG) Annual meeting for all appropriate

attendees. The training was videotaped and posted to the RTOG website, in order to allow access to all RTOG Members.

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

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 application’s strategic plan). 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.**

*Assessment of Methods to Increase Latino and African American Enrollment into Cancer Clinical Trials* – (NOTE: SCOPE AMENDED FROM ORIGINAL SUBMISSION TO INCLUDE AFRICAN AMERICAN POPULATION AND AIMS MODIFIED AND APPROVED 2011)

Despite national initiatives to increase the enrollment of racial and ethnic minorities into cancer clinical trials, participation by Latinos and African Americans remains low. The Radiation Therapy Oncology Group (RTOG), which conducts cancer clinical trials involving radiotherapy, will develop and evaluate evidence-based, culturally and linguistically appropriate patient education materials and investigator training programs to increase the enrollment of Latinos and African Americans into cancer clinical trials in Pennsylvania and nationally. We will also use cartographic modeling techniques to perform a gap analysis and geo-targeting through identification of current RTOG sites, their Latino and African American population density compared to non-RTOG sites, and the distance of Latino and African American trial participants from the site.

*Background:* Clinical trials provide evidence that is formulated into recommendations for practice guidelines, but without improvements in recruitment it is an ongoing concern that patients enrolled in trials may not be similar to those treated in routine practice. There is some evidence that clinical trials have a positive effect on patient outcomes and therefore, for reasons of social justice, all cancer patients should have access to the high-quality care, surveillance and availability of the latest treatments put forth in clinical trials. The Latino population is the fastest growing minority population in the United States (U.S.) and in Pennsylvania. According to the U. S. Census Bureau, Latinos account for approximately 15% of the population, while African Americans account for 13%. Cancer ranks as the second leading cause of death among Latinos (24%) and African Americans (23%) in the U.S., second only to heart disease. Although the percentage of Latinos and African Americans in the U.S. continues to rise, enrollment in cancer clinical trials for these populations does not mirror their representation in the general population. Latinos and African Americans constitute a much lower percentage of clinical trial participants at only about 3.1% and 9.2%, respectively (Murthy et al, 2004). However, with equal access, Latinos appear to have similar clinical trials participation rates as Whites (Murthy et al 2004). A recent study documented a significant positive correlation between clinical trials awareness/knowledge and willingness to participate among all races/ethnicities. However, reduced clinical trials awareness was seen among Latinos and African Americans (Lara et al 2005), suggesting that interventions to increase awareness and knowledge of clinical trials may increase Latino and African American accrual. This project will leverage the resources of the Philadelphia-based RTOG to develop and evaluate methods including training programs and materials to increase the enrollment of Latinos and African Americans into cancer clinical trials in Pennsylvania and nationally. RTOG will use its network of Pennsylvania facilities, and its national resources to develop, monitor, and evaluate culturally

and linguistically appropriate patient recruitment techniques and materials as well as investigator and research cultural competence and recruitment training and will test these methods for improvements in Latino and African American recruitment.

*Research Objectives:*

**1)** The RTOG will develop and evaluate evidence-based, culturally and linguistically appropriate education and awareness programs and recruitment materials to increase the enrollment of Latinos and African Americans into cancer clinical trials in Pennsylvania and nationally. We will identify approximately 4 RTOG clinical trials to target and evaluate. **2)** We will develop and assess cultural competency training for RTOG investigators and research staff. **3)** We will also use cartographic modeling techniques to perform a gap analysis and geo-targeting through identification of current RTOG sites, their Latino and African American population density compared to non-RTOG sites, and the distance of Latino and African American trial participants from the site. This will help us strategically identify sites to recruit into the RTOG that will facilitate access to state-of-the-art cancer clinical trials as well as implementation of recruitment strategies utilizing geo-targeting technology.

*Methods:*

**1)** The RTOG will develop and evaluate evidence-based, culturally and linguistically appropriate education and awareness programs and recruitment materials to increase the enrollment of Latinos and African Americans into cancer clinical trials in Pennsylvania and nationally.

i. Identify RTOG member facilities in Pennsylvania and nationally with high density Latino and African American populations through the RTOG database. There may be as many as 100/284 RTOG U.S. institutions that will be targeted for this study.

ii. In consultation with our RTOG investigators and patient advocates, identify up to four RTOG randomized clinical trials for disease sites with a high incidence in the Latino and African American community. One trial may be a developing cervical cancer protocol (if open within the timeframe of this proposal). Latina's experience a disproportionate burden from cervical cancer. Other trials will likely include head and neck, prostate, and lung trials. Set study-specific, disease-specific target goals for Latino and African American recruitment.

iii. For the protocols identified, use certified Spanish translators who will do back-forth translations of the informed consents and the study specific and general clinical trials and radiation therapy patient materials.

- Materials will be developed by our investigators and our in house marketing staff with input from patient advocates.
- Culturally appropriate Spanish language patient information brochures, posters, and Spanish translations of patient consent forms for RTOG's larger randomized trials will be developed and provided to enrolling facilities.
- We will also compile a resource list of existing Spanish language clinical trial information (i.e. National Cancer Institute developed resources) and will draw on national oncology associations (American Society for Therapeutic Radiology and Oncology, American Society of Clinical

Oncology) patient education materials for the Latino and African American communities.

- We will distribute print versions of study-specific materials to identified member institutions and publish electronic versions on the RTOG Web site.

2) RTOG will develop a Latino and African American Cultural Competency and Recruitment Training Program (CCRTP) for physician investigators and clinical research associates (CRAs) who have primary contact with cancer patients and are located at facilities in geographic regions with Latino and African American populations. Up to 100 health professionals will have access to in person training and an additional 200 (at least 2 per 100 sites) will have access through distribution of a video of a training session. In person training will be conducted at an RTOG semiannual meeting that is open to new and experienced RAs and investigators.

i. To develop the training we will draw on the work of Leininger (1991) and others and will employ the Cultural Competency Model that includes: (a) cultural diversity, (b) cultural awareness, (c) cultural sensitivity, and (d) cultural competence behaviors (Schim, Doorenbos, & Borse. 2005). Guided by this model, we will partner with a nationally recognized patient recruitment firm to develop a Latino and African American Recruitment Training Program for physicians and clinical research associates (CRAs) who have primary contact with cancer patients. The training program will instruct health professionals in the barriers, myths, beliefs, and norms within the Latino and African American cultures that may impede clinical trial enrollment and provide strategies for overcoming these barriers. There are few tools to direct the development of Latino and African American specific training programs and fewer tools for assessment. As one part of the training program, we will modify the Lay Advocate Communication Assessment Tool (LACAT) developed specifically through Latina focus groups to improve communications about clinical trials (Larkey et al 2007). While this tool was created for lay advocate communication among Latinas, the communication strategies elicited in this tool apply across Latino and African American populations. Research has demonstrated the importance of storytelling in the recruitment of African American populations to clinical research (Banks-Wallace, Enyart & Johnson, 2004). It has also demonstrated that an ethnic focus and discussion of the health of future generations is also important (Unson et al., 2001). As such, this tool contains information useful in determining communication strategies across different minority populations. The strategies and tools were developed for the lay public but common sense dictates that these factors would be important for health care professionals to learn and to address as well.

*Lay Advocate Communication Assessment Tool (LACAT)(Larkey et al 2007)*

Subscale	Items
Tells Own Story	1 tell my own story in my own words. 1 share my personal experiences
Describes Benefits	1 let them know about the benefits of getting involved in (the study),
Expresses Caring	1 find out what they are concerned about and suggest (the study) as
Future Generations' Health	something that might help them with their concerns.
Repeating	1 try to let them know that I care about them and their health.
Ethnic Focus	1 communicate that I'm concerned about the women I talk to.

Role-playing and brainstorming sessions will be used to augment and reinforce techniques presented. Video recordings of the training sessions were made available on the RTOG website [www.rtog.org](http://www.rtog.org) for subsequent reinforcement of course material and for physicians and CRAs unable to attend in person.

ii. Pre- and post-training session evaluations were conducted using a modified Cultural Competence Assessment (CCA) tool, a 26-item instrument designed to measure cultural diversity experience, awareness and sensitivity, and competence behaviors. The item score is a simple count of the number of patients seen over the past 12 months, with higher numbers indicating greater diversity of experience. The combined subscale (CAS) for cultural awareness (knowledge) and sensitivity (attitude) is based on a 5-point, Likert-like response set ranging from strongly agree to strongly disagree and scaled from 1-7, with 7 indicating the answer demonstrating the highest cultural awareness or sensitivity and 1 indicating the answer demonstrating the least cultural awareness or sensitivity. If a respondent indicates “no opinion”, the item is not included. The subscale for cultural competence behavior (CCB) has response categories of “always, very often, somewhat often, often, sometimes, few times, and never”, which are scaled from 1-7. Items with a response of “not sure” are not scored. The items are summed for each subscale score; higher scores indicate higher levels of knowledge and more positive attitudes, and greater self-reported frequency of competence behaviors (Schim, Doorenbos, & Borse, 2005). Cultural diversity experience in the original scale was assessed with a single item on which respondents identify whether they have cared for people of various cultural groups in the past 12 months. The instrument has been shown to be valid and reliable. ([Schim, Doorenbos, Miller, & Benkert, 2003](#); [Doorenbos, Schim, Benkert, & Borse, 2005](#)).

**3)** We will conduct a gap analysis of current RTOG sites with high density Latino and African American populations and areas of the State of Pennsylvania and the country with high density populations where we do not have RTOG sites. This will help us strategically identify sites to recruit into the RTOG that will facilitate Latino and African American access to state-of-the-art cancer clinical trials.

i. Using cartographic modeling techniques to do a gap analysis to assist with the identification of current RTOG sites with high density Latino and African American populations and areas of the State of Pennsylvania and the country with high density populations where we do not have RTOG sites. This will help us strategically identify sites to recruit into the RTOG that will facilitate Latino and African American access to state-of-the-art cancer clinical trials. We will also use cartographic modeling to identify RTOG site Latino and African American accrual by participant zip code in order to analyze accrual rates based on the participant's distance from the site. This will facilitate the implementation of recruitment strategies utilizing geo-targeting technology. We sub-contracted with the University of Pennsylvania Cartographic Modeling Lab (CML) which specializes in Geographic Information Systems (GIS) and spatial research. The CML helps create information systems and online mapping applications with the special expertise in working with administrative records.

**Results:** Aim 1 was part of the development process for aim 2. The results of Aim 1 and 2 are presented together, followed by the results of Aim 3. The CCRTP focused on training physicians and CRAs, who have primary contact with cancer patients, to incorporate strategies to overcome barriers to enrolling Latino and African American patients. Materials were distributed, of culturally appropriate recruitment and education materials. These materials included Spanish translated consent forms, for clinical trials of disease sites that have a high incidence of Latino populations, as well as National Cancer Institute (NCI) developed, culturally appropriate general informational pamphlets, regarding clinical trials for Latino and African American populations. Additionally, 3 - 4 RTOG clinical trials focusing on disease sites with high incidence in Latino and/or African American populations were chosen in order to develop study-specific recruitment and education materials.

#### *The Cultural Competency Assessment (CCA) Tool*

Scores from the CCA were used to assess cultural competency pre and post CCRTP training. For this study, the CCA was modified for use by clinical research associates and physician investigators as it relates to their interactions with Latino and African American cancer patients considering radiation therapy clinical trials. Instead of referring to clinical practice in general, the tool was adapted to apply specifically to the research setting. The new tool was evaluated for face and content validity by subject matter experts. The tool was adapted as necessary based on subject matter expert review.

#### *Statistical Analysis*

Participant demographic information was analyzed using standard descriptive statistics. Pre- and post-training competency evaluation was assessed for significant changes in Likert scale item responses using the 2-sided Wilcoxon-Mann-Whitney test with an overall significance level of 0.05. An analysis was performed after collapsing the survey responses into 3 or 4 items. The table below depicts how survey items were collapsed.

Very competent	Competent
Somewhat competent	
Neither competent nor incompetent	Neither competent nor incompetent
Somewhat incompetent	Incompetent
Very incompetent	
Very comfortable	Comfortable
Somewhat comfortable	
Neither comfortable nor uncomfortable	Neither comfortable nor uncomfortable
Somewhat uncomfortable	Uncomfortable
Very uncomfortable	
Strongly agree	Agree
Agree	
Somewhat agree	
Neutral	Neutral
Somewhat disagree	Disagree
Disagree	
Strongly disagree	
No opinion	No opinion
Always	Always
Very often	
Somewhat often	
Often	Often
Sometimes	Never
Few times	
Never	
Not sure/no response	Not sure/no response

### Minority Accrual

Pre- and post-training minority accrual rates encompassed accrual to any RTOG study and any RTOG-endorsed study. Accrual within one year of the cultural competency training was used to determine pre-training accrual rates and accrual up to one year post cultural competency training was used for the post-training accrual rates. Minorities in this context consisted of Hispanic/Latino, Black/African American and American Indian/Alaskan Native.

Rates were analyzed using standard descriptive statistics. To ensure that relative increase in minority enrollment was not masked by overall declines in clinical trial enrollment, enrollment as a percentage of total RTOG enrollments was analyzed in a similar fashion. Comparisons between minority accrual rates for pre- and post-training were performed via paired t-tests in subsets consisting of sites who participated in training and those who did not participate in

training. Sites with no total accrual were excluded from the analysis. Pearson's correlation coefficient was used to determine correlations between baseline cultural competency scores and pre-training minority accrual, as well as post training cultural competency scores and post training minority accrual.

## **Results**

### *Pre- and Post- Training Competency Evaluation*

Sixty seven participants took part in the first RTOG face-to-face CCRTP at a semi-annual meeting in Philadelphia. Participant characteristics are presented in Table 1. At baseline, 68% of participants had prior diversity training with the majority of training being from an employer sponsored program (59%) [Table 2]. Compliance with pre and post CCA evaluations is presented in Table 3. Data from all 67 participants, n=66 at baseline and n=42 at follow-up was used to assess the cultural diversity knowledge and attitudes of participants at baseline and follow-up. Several survey items were found to be significant. There were statistically significant improvements ( $p<0.05$ ) between baseline and follow-up in cultural attitudes for consideration of the following:

- Race as an important factor in influencing a person's culture;
- Need to assess patient preferences related to clinical trial participation;
- Whether a person may identify with more than one cultural group;
- Consideration of culture when evaluating a patient for clinical trial participation.

In regards to assessing cultural needs, the following CCA items were significant improvements between baseline and follow up scores for:

- Seeking information on cultural needs;
- Having access to a variety of resources that would help research staff to learn about people from different cultures;
- Removing obstacles to clinical trial participation for people of different cultures;
- Assessing patient language preferences.

**Table 1**  
**Baseline Characteristics**  
**All Patients**

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Age (years)	(n=65)
Median	42
Min - Max	23 - 64
Q1 - Q3	34 - 53
Gender	(n=65)
Female	60 ( 92.3%)
Male	5 ( 7.7%)
Education	(n=66)
Associate degree	7 ( 10.6%)
Bachelor's degree	30 ( 45.5%)
Diploma	2 ( 3.0%)
Graduate or professional degree	25 ( 37.9%)
High school or GED	2 ( 3.0%)
Current Role	(n=66)
Clinical Research Associate	29 ( 43.9%)
Clinical Research Nurse	33 ( 50.0%)
Other (Specify)	2 ( 3.0%)
Physician Investigator	2 ( 3.0%)

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Q1 = first quartile; Q3 = third quartile.

**Table 2**  
**Cultural Diversity Training**  
**All Patients**

	Baseline	P-value <sup>†</sup>
Diversity training	(n=65)	
No	21 ( 32.3%)	
Yes	44 ( 67.7%)	
Diversity training type	(n=44)	
Covered in college course	13 ( 29.6%)	
Professional conference	15 ( 34.1%)	
Employer sponsored program	26 ( 59.1%)	
Continuing education	18 ( 40.9%)	
Other	5 ( 11.4%)	

**Table 3**  
**Completion of Surveys**  
**(n=67)**

Completion Status	
Baseline only	25 ( 37.3%)
Follow-up only	1 ( 1.5%)
Baseline and Follow-up	41 ( 61.2%)

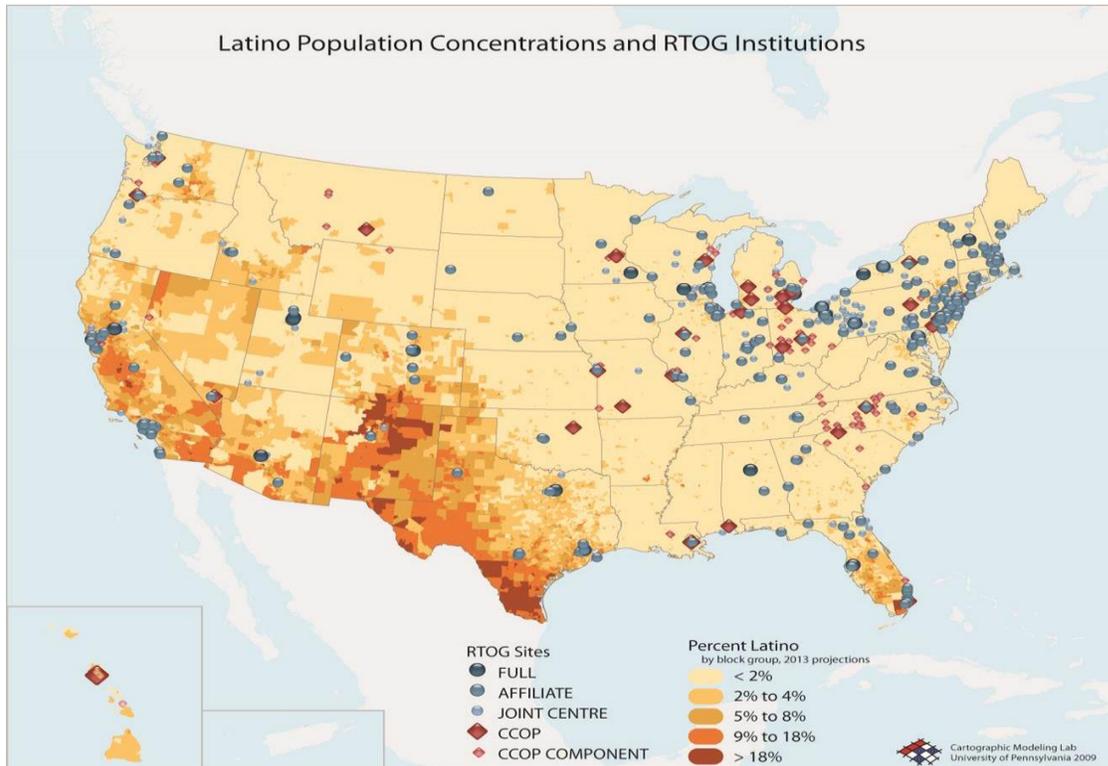
*Conclusions from Aims 1&2: We have developed a theory driven CCRTP that was tailored to cancer clinical trials research recruitment. The CCA was adapted for pre- and posttest evaluation and preliminary results of the CCRTP show improvement at 3 months post training on the CCA regarding cultural attitudes and assessing cultural needs. CCA psychometric analysis including factor analysis, and the pre- and post-training minority accrual rates are in analysis.*

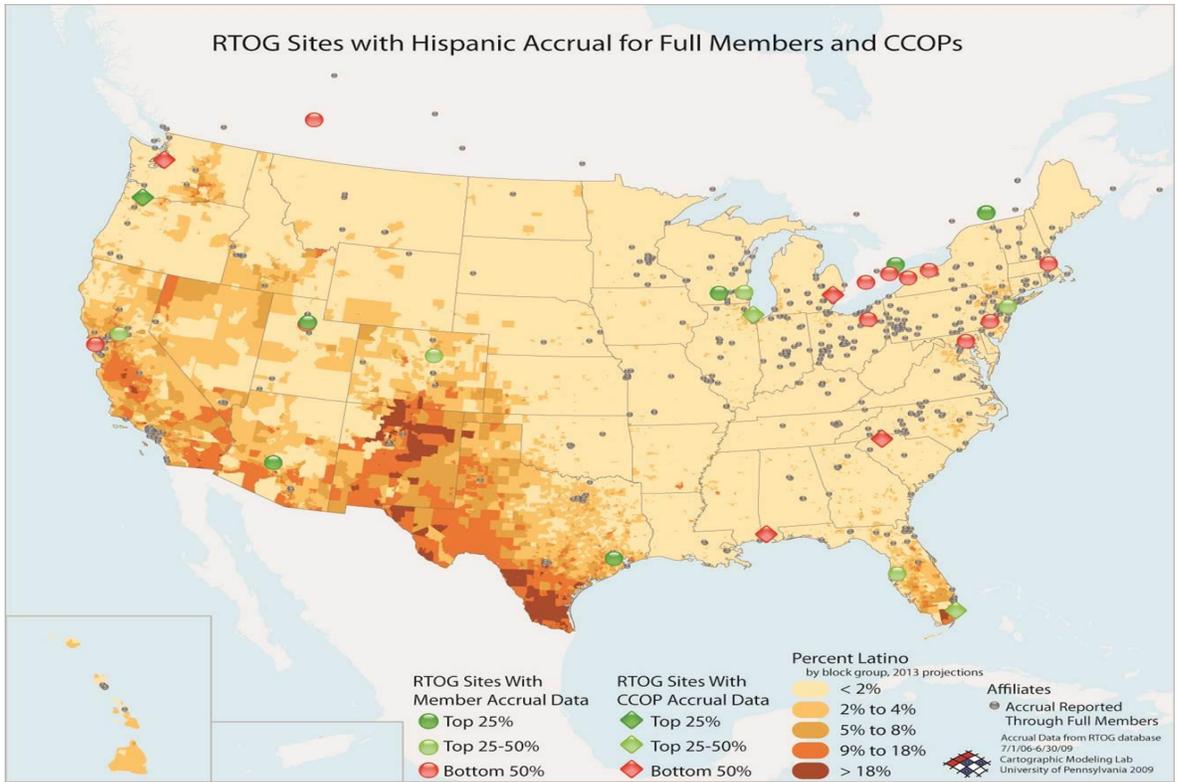
*Aim 3 was analyzed in 3 parts:*

Objective: We employed cartographic modeling techniques to perform a gap analysis through identification of current RTOG sites and their Latino population density compared to high density areas in the U.S. where we do not have RTOG sites. We also assessed Latino recruitment to clinical trials by geographic and RTOG member site locations.

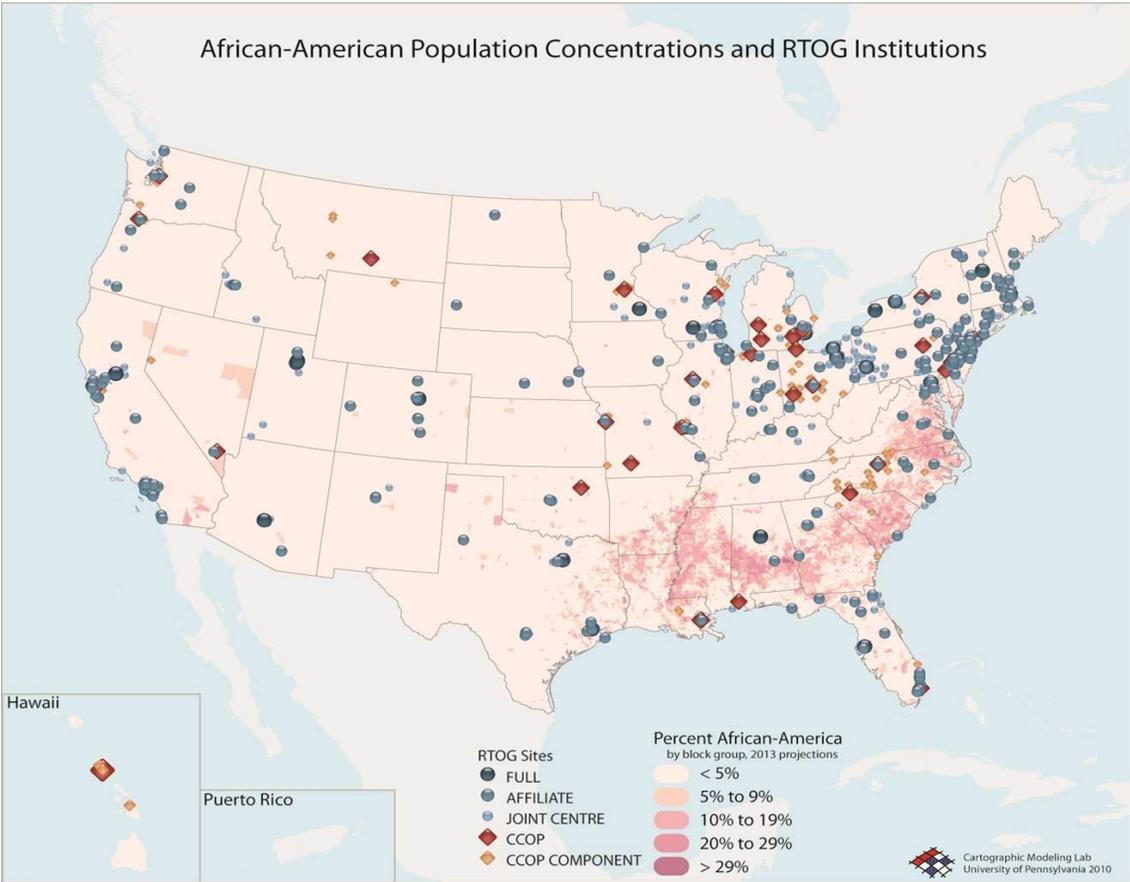
Methods: Geographic Information System (GIS), technology can be used to spatially analyze many different kinds of data relevant to clinical studies. Using ArcMap GIS 9.3 software maps were color-coded for Latino population density by county and RTOG members sites were designated with color-coding by quartile of overall Latino accrual to RTOG trials over the past 5 years. The 717 RTOG participating member sites were designated on the map with different symbols representing affiliation type.

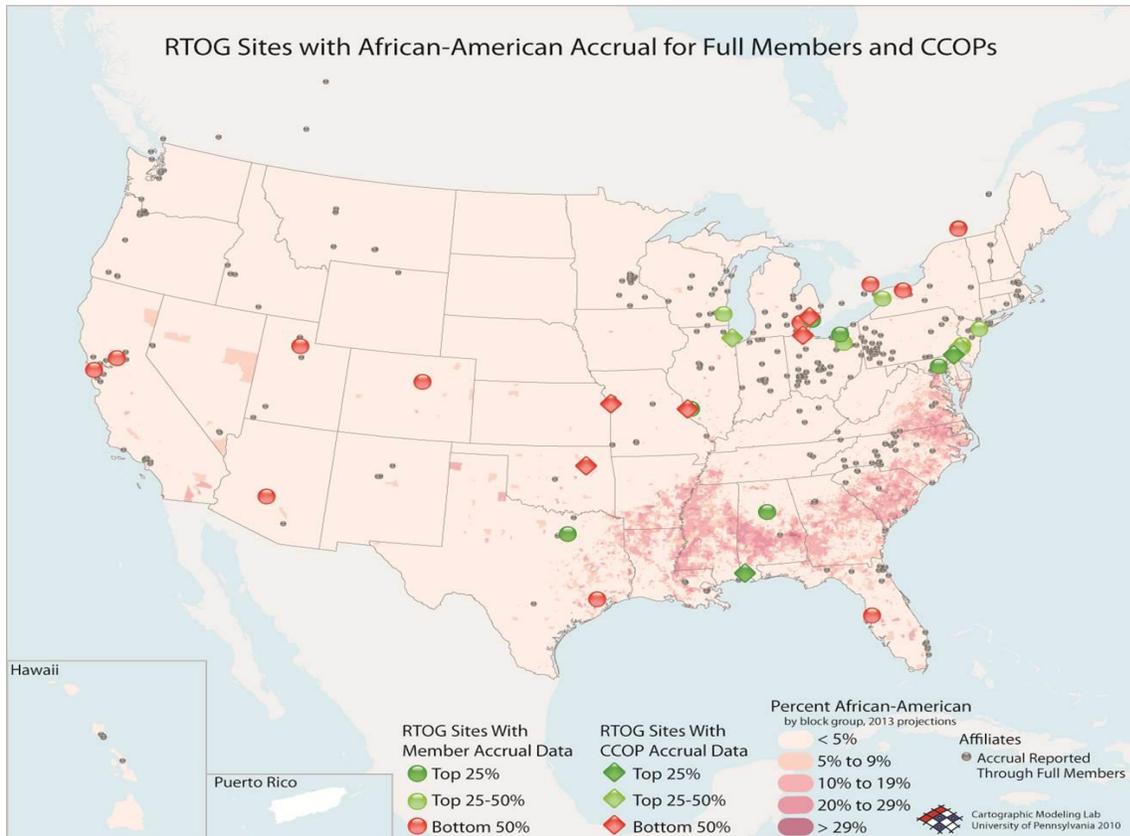
Results: GIS mapping clearly depicts a disconnect between Latino population density and RTOG member locations. In addition, mapping indicates that the highest Latino accruing sites to RTOG trials are not in high density geographic Latino population areas.





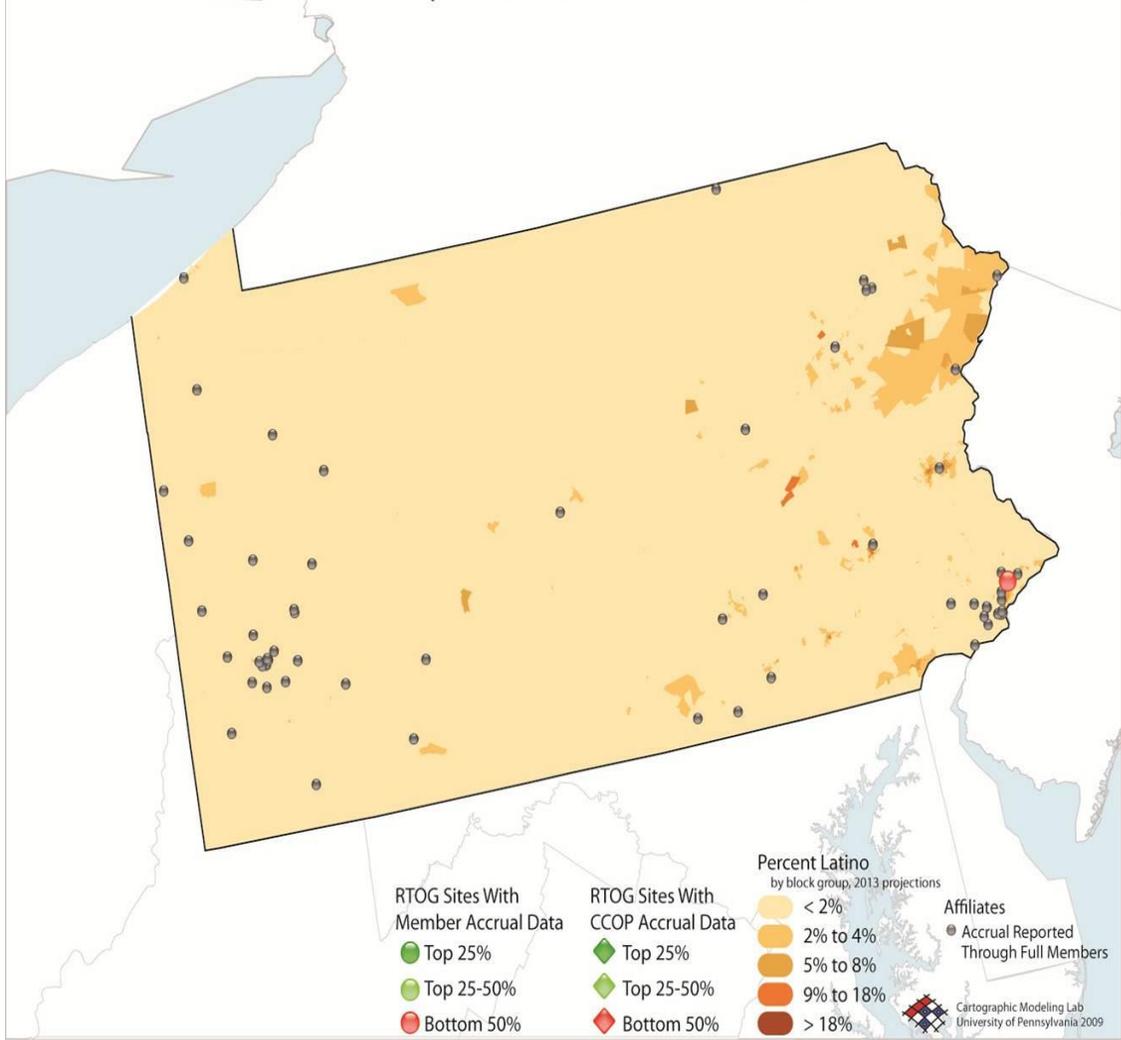
We then updated analysis of RTOG sites located by African-American (AA) population density and accrual using the same sample of RTOG sites listed above.

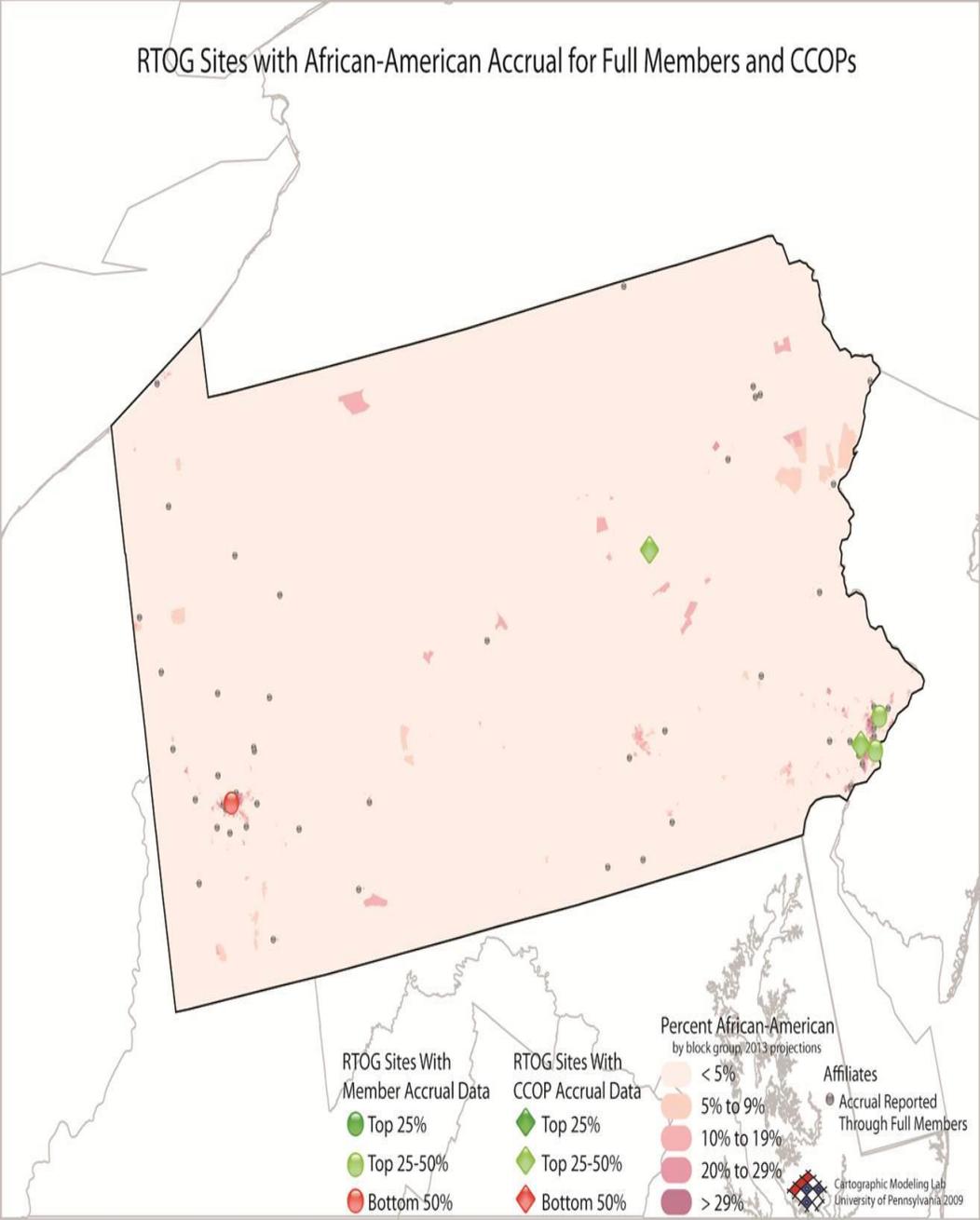




As in the Latino population, GIS mapping clearly depicts a lower concentration of RTOG member sites in areas of highest AA population density in the US. In addition, mapping indicates that the highest AA accruing sites to RTOG trials are not in high density geographic AA population areas. Further, we then mapped Hispanic and AA accrual to RTOG cancer clinical trials in the State of PA. Recall that shadings represent U.S Population minority density and are not adjusted for single state population; also RTOG accrual mapped is by ranking across the US RTOG accrual. The first map below shows we have no sites in the State of PA that rank in the top 25% or top 50% for Hispanic accrual to RTOG clinical trials. The second State map below shows the State of PA has four RTOG sites ranking among the top 25% for African Americans accrued to cancer clinical trials, with opportunities to improve, especially in the Western part of the State.

# RTOG Sites with Hispanic Accrual for Full Members and CCOPs





*Limitations to Current Maps*

This was our first study to attempt mapping clinical trials accrual. We discovered that some accrual is reported by affiliate sites through their full member sites. Most of the time the affiliates are closely geographically located but there were multiple cases where sites have affiliated with full member sites across the country, thus geographic attribution is not completely accurate. We are developing methods to correct this for future studies.

Second, the State maps are pull-outs of the larger US map. There was no additional funding for individual State population density and accrual. The State data would be strengthened by future maps that provide top accrual levels within in the State.

*Conclusions from Aim 3:* “A picture is worth a thousand words.” GIS mapping has helped identify geographic issues of site location relative to minority population US density. It has proved feasible in beginning to document Latino and AA accrual to clinical trials. It has highlighted geographic gaps and opportunities to reach out to radiotherapy sites in high minority dense sites. Based on the recent Institute of Medicine report on restructuring the national cancer clinical trials infrastructure, RTOG will merge in 2014 with two other cooperative groups, This will provide immense opportunities to negotiate partnerships with new sites around the country. The data from this study will help us strategically identify radiotherapy sites for outreach efforts as new partners in Latino and AA dense locations to facilitate minority access to state-of-the-art cancer clinical trials. Mapping also identified high Latino and AA RTOG clinical trial accrual in low Latino dense sites which would not have been easily identified without mapping. Some of this is likely related to urban site accrual and some may be a limitation of affiliate accrual reporting through full member sites. The former helps form new hypotheses for assessing minority accrual in future trials and the latter issue has helped us refine our methods for an upcoming grant submission.

Two Abstracts were presented:

Bruner, J., Stine, S.H., James J., Heron, D., Curran, W., **Bruner, D.W.** Using Cartographic Mapping to Assess and Develop Strategies to Improve Latino Recruitment to Radiation Therapy Oncology Group Clinical Trials. Poster Abstract Presentation at NCI-ASCO Cancer Trial Accrual Symposium, Bethesda, MD., April 29-30, 2010.

Consoli, S., James, J., Pisansky, T., Rotman, M., Corbett, T., Speight, J., Byhardt, R., Sandler, H., Kachnic, L., Berk, L., **Bruner, D.W.** Process and Funding Barriers to Symptom Management Trials Conducted through NCI Cooperative Groups: the Example of RTOG 0215. Using Cartographic Mapping to Assess and Develop Strategies to Improve Latino Recruitment to Radiation Therapy Oncology Group Clinical Trials. Poster Abstract Presentation at NCI-ASCO Cancer Trial Accrual Symposium, Bethesda, MD., April 29-30, 2010.

**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?

\_\_\_\_\_ 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?

\_\_\_\_\_ Number of subjects originally targeted to be included in the study

\_\_\_\_\_ 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:

\_\_\_\_\_ Males

\_\_\_\_\_ Females

\_\_\_\_\_ Unknown

Ethnicity:

\_\_\_\_\_ Latinos or Hispanics

\_\_\_\_\_ 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.)

**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, the number of the publication and an abbreviated research project title. For example, if you submit two publications for PI Smith for the “Cognition and MRI in Older Adults” research project (Project 1), and two publications for PI Zhang for the “Lung Cancer” research project (Project 3), the filenames should be:

- Project 1 – Smith – Publication 1 – Cognition and MRI
- Project 1 – Smith – Publication 2 – Cognition and MRI
- Project 3 – Zhang – Publication 1 – Lung Cancer
- Project 3 – Zhang – Publication 2 – Lung Cancer

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:

1 manuscript on CCTRP impact on knowledge, attitudes and change in minority accrual pre-and 1 year post training

1 manuscript on CCA validation

1 manuscript on mapping clinical trials accrual

**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 have developed a theory driven CCTRP that was tailored to cancer clinical trials research recruitment. The CCA was adapted for pre-post test evaluation and preliminary results of the CCTRP show improvement at 3 months post training on the CCA regarding cultural attitudes and assessing cultural needs. The training was video-taped and is available free to the public on the RTOG website. It is being refined to be tested in a larger grant application. Findings have the potential to inform cultural competency training across the national cancer clinical trials infrastructure and will be assessed for impact on minority accrual to clinical trials.

GIS mapping has helped identify geographic issues of site location relative to minority population US density. It has proved feasible in beginning to document Latino and AA

accrual to clinical trials. It has highlighted geographic gaps and opportunities to reach out to radiotherapy sites in high minority dense sites. Based on the recent Institute of Medicine report on restructuring the national cancer clinical trials infrastructure, RTOG will merge in 2014 with two other cooperative groups. This will provide immense opportunities to negotiate partnerships with new sites around the country. The data from this study will help us strategically identify radiotherapy sites for outreach efforts as new partners in Latino and AA dense locations to facilitate minority access to state-of-the-art cancer clinical trials. Mapping also identified high Latino and AA RTOG clinical trial accrual in low Latino dense sites which would not have been easily identified without mapping. Some of this is likely related to urban site accrual and some may be a limitation of affiliate accrual reporting through full member sites. The former helps form new hypotheses for assessing minority accrual in future trials and the latter issue has helped us refine our methods for an upcoming grant submission.

**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.

None

**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

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

<b>NAME</b> Bruner, Deborah Watkins	<b>POSITION TITLE</b> Robert W. Woodruff Professor of Nursing, Nell Hodgson Woodruff School of Nursing, Associate Director for Cancer Outcomes, Winship Cancer Institute, Emory University
<b>eRA COMMONS USER NAME</b> (credential, e.g., agency login)    dbruner	

**EDUCATION/TRAINING** (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.*)

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
West Chester University West Chester, PA	BSN	05/78	Nursing
Widener University, Chester, PA	MSN	05/85	Oncology
Widener University, Chester, PA	MSN	05/88	Nursing Administration
University of Pennsylvania, Philadelphia, PA	Ph.D.	05/99	Nursing Research

### A. Personal Statement

Dr. Bruner is the Robert W. Woodruff Professor of Nursing in the Nell Hodgson Woodruff School of Nursing, Associate Director for Cancer Outcomes, Winship Cancer Institute, Emory University. She is Vice Chair for Outcomes of the Radiation Therapy Oncology Group (RTOG), and PI of the RTOG Clinical Community Oncology Program. Dr. Bruner serves on the Executive Committee of NRG Oncology and leads the Outcomes and CCOP Working Groups. She was also a founding member of the Gynecologic Oncology Group Quality of Life Committee on which she served for 17 years. She serves as Co-Chair of the NCI Symptom Management and Health Related Quality of Life Steering Committee. Dr. Bruner's research focuses on symptom management across cancer sites with a focus on pelvic tumors and sexual function, quality of life, patient reported outcomes (PROs) and health disparities in recruitment to clinical trials. She has conducted numerous studies in symptom management, quality of life, and comparative effectiveness with a particular focus on the sexual function of both males and females. She has published over 200 manuscripts, abstracts and book chapters. She has been continuously and well-funded since completing her doctoral studies through the NIH, NINR, DOD, ACS and the State of Pennsylvania.

### B. Positions and Honors

#### Positions and Employment

1978-86	Oncology/Critical Care Staff Nurse, Crozer-Chester Medical Center, Chester, PA
1986-89	Gyn-Oncology Clinical Nurse Specialist, Albert Einstein Medical Center, Philadelphia, PA
2002-06	Director, Symptoms & Outcomes Research Program, Fox Chase Cancer Center, Philadelphia, PA

- 2002-06 Associate Member, Population Science & Radiation Oncology, Fox Chase Cancer Center, Philadelphia, PA
- 1999-02 Assistant Member, Population Science & Radiation Oncology, Fox Chase Cancer Center, Philadelphia, PA
- 1999 - 01 Research Fellowship, Cancer Prevention and Control, PA, NCI R25 (CA57708), Fox Chase Cancer Center, Philadelphia, PA
- 1996-06 Director, Prostate Cancer Risk Assessment Program, Fox Chase Cancer Center, Philadelphia, PA
- 1989-96 Nurse Coordinator/Clinical Specialist, Department of Radiation Oncology, Fox Chase Cancer Center, Philadelphia, PA
- 2006-10 Director, Recruitment, Retention and Outreach Core Facility, Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA
- 2006 - Independence Professor, School of Nursing, University of Pennsylvania, Philadelphia, PA
- 2008 - Professor of Radiation Oncology, University of Pennsylvania, Philadelphia, PA
- 2009-10 Interim Associate Dean for Research, School of Nursing, University of Pennsylvania, Philadelphia, PA
- 2010 - Director, Biobehavioral Research Center, School of Nursing, University of Pennsylvania, Philadelphia, PA
- 2011 - Robert W. Woodruff Professor, School of Nursing, Emory University, Atlanta, GA
- 2011 - Professor of Radiation Oncology, School of Medicine, Emory University, Atlanta, GA
- 2011 - Associate Director for Outcomes, Winship Cancer Institute, Emory University, Atlanta, GA

**Other Experience and Professional Memberships**

- 1993-09 Gynecologic Oncology Group (GOG) Founding Member-QOL Committee
- 2000- Radiation Therapy Oncology Group (RTOG) Founding Chair- Outcomes Committee
- 2001-03 Elected to Executive Board of Directors, American Society of Prevention Oncology (ASPO)
- 2001-05 Elected to Board of Directors, American Cancer Society, Southeast Region, PA
- 2002- Member, Lent IV Late Effects Workshop: Incorporation into the NCI-CTC
- 2002-07 Member, Pennsylvania Cancer Control Consortium (PAC3) Health Disparities Task Force
- 2004 - Oncology Nursing Society Excellence in Radiation Therapy Nursing Award
- 2007 - Member, NCI Clinical Trials Advisory Committee (CTAC)
- 2007 - Fellow, American Academy of Nursing
- 2008 - Senior Fellow, Center for Public Health Initiatives, University of Pennsylvania
- 2011 - Senior Faculty Research Award, Biobehavioral Department, School of Nursing University of Pennsylvania

**Honors**

- 1995 President's Award, Phila. Area Chapter, ONS

1995-1998	Doctoral Scholarship, American Cancer Society
1995	Doctoral Scholarship, Oncology Nursing Society
1996, 2000	Who's Who in Medicine and Healthcare (1996 1st edition)
1997-1999	American Nurses Association-Chair-Expert Task Force on Prostate Cancer Education
1999	RTOG Chair QOL
1999-2000	Oncology Nursing Foundation/Amgen Inc. Research Award
2000	Linda Hunter Quality of Life Lecture, Society of Gynecologic Nurse Oncologists
2000	Best New Investigator Poster Presentation – Internat'l Soc for Pharmacoeconomics & Outcomes Research (ISPOR)

**C. Selected Peer-reviewed Publications** (Selected from 42 peer-reviewed publications)

1. **Watkins-Bruner, D.**, Scott, C., Lawton, C., DelRowe, J., Rotman, M., Buswell, L., Beard, C., Cella, D. (1995). RTOG's First Quality-of-Life Study - RTOG 9020: A Phase III Trial of External Beam Radiation Therapy with Etanidazole for Locally Advanced Prostate Cancer. *International Journal of Radiation Oncology Biology Physics*, 33(4): 901-906.
2. **Bruner D.W.** Lanciano, R., Keegan, M., Corn, B., Martin, E., and Hanks, G. (1993). Vaginal Stenosis and Sexual Functioning Following Intracavitary Radiation for the Treatment of Cervical and Endometrial Carcinoma. *International Journal of Radiation Oncology, Biology, Physics*, 27 (4): 725-830.
3. **Bruner, D.W.**, Nolte SA, Shahin MS, Huang HQ, Sobel E, Gallup D, Cella D. (2006). Measurement of Vaginal Length: Reliability of the Vaginal Sound--a Gynecologic Oncology Group Study. *International Journal of Gynecological Cancer*, 16(5):1749-1755.
4. **Bruner, D.W.**, Barsevick, A., Tian, C., Randall, M., Mannel, R., Cohn, D., Sorosky, J., Spirtos, N. (2007). Randomized Trial Results Of Quality Of Life Comparing Whole Abdominal Irradiation And Combination Chemotherapy In Advanced Endometrial Carcinoma: A Gynecologic Oncology Group Study. *Quality of Life Research*, 16(1):89-100.
5. **Bruner, D.W.** (2007) Outcomes Research in Cancer Symptom Management Trials: The Radiation Therapy Oncology Group (RTOG) Conceptual Model, *JNCI Monographs*, 37:12-15.
6. **Bruner, D.W.**, Bryan, C., Aaronson, N., Blackmore, C., Brundage, M., Cella, D., Ganz, P., Gotay, G., Hinds, P., Kornblith, A., Movsas, B., Sloan, J., Wenzel, L., Whalen, G. (2007) Issues and Challenges with Integrating PROs in Clinical Trials Supported by the NCI-sponsored Clinical Trials Networks, *Journal of Clinical Oncology* 25(32):5051-5057.
7. Kanski, A., James, J., Hartsell, W., Leibenhaut, M.H., Janjan, N., Curran, W., Roach, M., **Watkins-Bruner, D.** (2009). Economic Analysis of Radiation Therapy Oncology Group 97-14: Multiple Versus Single Fraction Radiation Treatment of Patients With Bone Metastases. *Am J Clin Oncol.* 32(4):423-8.
8. **Watkins Bruner, D.**, James, J, Bryan, C, Pisansky, T, Rotman, M, Corbett, T, Speight, J, Byhardt, R, Sandler, H, Bentzen, S, Kachnic, L, Berk, L. (2011). Randomized, Double-Blinded, Placebo-Controlled Crossover Trial of Treating Erectile Dysfunction

- with Sildenafil after Radiotherapy and Short-Term Androgen Deprivation Therapy: Results of RTOG 0215, *Journal of Sexual Medicine*, 8(4):1228-1238.
9. Bahng, A., Dagan, A., **Bruner, D.W.**, Lin, L.L. (2011). Determination of Prognostic Factors for Vaginal Mucosal Toxicity Associated with Intravaginal High-Dose Rate Brachytherapy in patients with Endometrial Cancer. *International Journal of Radiation Oncology, Biology, Physics*, [Epub ahead of print]
  10. Giarelli, E., **Bruner, D.W.**, Nguyen, E., Basham, B., Marathe, P., Dao, D., Huynh, T.N., Cappella, J., Nguyen, G. (2011). Research Participation among Asian American Women at Risk for Cervical Cancer: Exploratory Pilot of Barriers and Enhancers. *Journal of Immigrant and Minority Health*, [Epub ahead of print]
  11. Dilling, T., Bae, K., Paulus, R., **Watkins-Bruner, D.**, Ang, K., Forastiere, A., Garden, A., Movsas, B. (2011). The Impact of Gender, Partner Status, and Race on Locoregional Failure and Overall Survival in Head and Neck Cancer Patients in Three Radiation Therapy Oncology Group (RTOG) Trials. *International Journal of Radiation Oncology, Biology, Physics*, [Epub ahead of print]
  12. Du, K., Bae, K., Movsas, B., Yan, Y., Bryan, C., **Bruner, D.W.** (2011). Impact of Marital Status and Race on Outcomes of Patients Enrolled in Radiation Therapy Oncology Group Prostate Cancer Trials. *Supportive Care in Cancer*, [Epub ahead of print]
  13. Jones, C., Hunt, D., McGowan, D., Amin, M., Chetner, M., **Bruner, D.W.**, Leibenhaut, M., Husain, S., Rotman, M., Souhami, L., Sandler, H., Shipley, W. (2011). Radiotherapy and Short-Term Androgen Deprivation for Localized Prostate Cancer. *New England Journal of Medicine*, 365(2):107-18.
  14. **Bruner, D.W.**, Hanisch, L., Trotti, A., Reeve, B., Schrag, D., Sit, L., Minasian, L, O'Mara, A., Denicoff, A., Rowland, J., Montello, M., Geoghegan, C., Abernethy, A., Clauser, S., Castro, K., Mitchell, S., Burke, L., Trentacosti, A.M., Mendoza, T., Basch, E. (2011). Stakeholder Perspectives on Implementing the National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), *Translational Behavioral Medicine: Practice, Policy and Research*, 1(1):110-122.
  15. Hanisch, L., Bryan, C., James, J., Pisansky, T., Corbett M, T.,Parliament, M., Stewart,C., Hartford, A., Sandler H.,Berk, L., Kachnic, L., **Bruner, D.W.** (2012) Impact of sildenafil on marital and sexual adjustment in patients and their spouses after radiotherapy and short-term androgen suppression for prostate cancer: Analysis of RTOG 0215. *Supportive Care in Cancer*. [Epub ahead of print]

## D. Research Support

### Ongoing Research Support

R21CA140766-02

Bruner (PI)

09/01/09-04/30/13

NIH/NCI, Randomized Feasibility Study of Dilator Use and an Educational Program to Increase Compliance After Vaginal Brachytherapy for Endometrial Cancer. The purpose of this study is to advance the much neglected area of research into interventions to prevent sexual dysfunction after treatment for gynecological malignancies. Specifically, this pilot study will provide preliminary data on feasibility and effect size calculations for a larger randomized trial of the use of vaginal dilators to maintain vaginal length after vaginal

brachytherapy (VBT) for endometrial cancer.

Role: PI

U10 CA037422-23 Bruner (PI) 07/02/10–05/31/15  
NIH/ NCI, Community Clinical Oncology Program Research Base. The goals of the Radiation Therapy Oncology Group's (RTOG) Community Clinical Oncology Program (CCOP) are to design and implement the RTOG's Cancer Prevention and Control Program (CPC) and to integrate community oncology programs into the scientific program of the RTOG.

Role: PI

HHS-NIH-NCI-PCPSB-5027-29 Basch (PI) 09/30/10–09/29/15  
NIH/ NCI, Patient Reported Outcomes version of the Common Terminology Criteria for Adverse Events. The overall objective of this project is to bring the PRO-CTCAE from its current "in development" status to a "fully operational" system which can be implemented in any NCI cooperative group trial, and which will yield meaningful, interpretable results about patients' experiences with adverse symptoms.

Role: Co-I

U01-AR052186-07 Weinfurt (PI) 09/01/09-07/31/13  
NIH/NIAMS, Validating and Extending the PROMIS Sexual Function Measure for Clinical Research. The major goal of the Patient-Reported Outcomes Measurement Information System (PROMIS) Network is to develop comprehensive, standardized, and efficient means of measuring patient-reported outcomes in persons with chronic diseases.

Role: Co-I

2008 Health Research Formula Neiman (PI) 01/01/09-12/31/12  
Pennsylvania Department of Health, Commonwealth Universal Research Enhancement (C.U.R.E.) Program – Project 4, Assessment of Methods to Increase Latino Enrollment into Cancer Clinical Trials. The goal of the study is to increase the enrollment of Latinos into cancer clinical trials in Pennsylvania and nationally. We will also use cartographic modeling techniques to do a gap analysis through identification of current Radiation Therapy Oncology Group (RTOG) sites and their Latino population density compared to high density areas of Pennsylvania and the United States where we do not have RTOG sites.

Role: Co-I

U10 CA021661-35 Curran (PI) 01/01/09–12/31/14  
NIH/NCI, Radiation Therapy Oncology Group (RTOG). The major goal of the RTOG is to conduct multicenter, multidisciplinary clinical trials that systematically test novel radiotherapy approaches against cancer.

Role: Co-I; Chair, HSR Outcomes

### **Completed Research Support**

None