F31 Research Training Plan
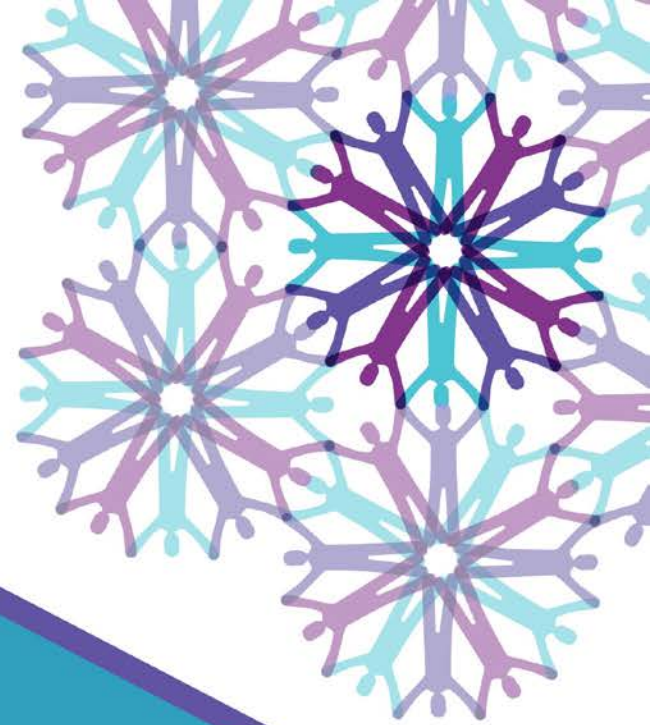
Guidance & tips

CENTER TO REDUCE
CANCER HEALTH DISPARITIES

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NIH | NATIONAL CANCER INSTITUTE

July 19, 2017

Outline

1. *Overview*
2. *Key Sections:*
   - *Specific Aims*
   - *Research Strategy*
   - *Training in Responsible Conduct of Research*
3. *Final Tips*

F31 Research Training Plan Overview

What is the F31 Research Training Plan?

- The Research Training Plan is the part of the application where the actual research is described

- It provides the background and significance for the project

- The scientific approach, methodology, and techniques are detailed, and the data analysis is explained

Tips for Writing a Research Training Plan

- Describe the relationship between the proposed research to the applicant's scientific career goals

- Demonstrate how the applicant's research will be independent & distinct yet related to the Sponsor's ongoing research program

- Should be tailored to experience level of applicant

- Must be achievable within requested time period

- Emphasize that research training will lead to publications and degree

Tips for Writing a Research Training Plan

- Highlight Significance & Impact of the proposed research

- Formulate logical hypothesis or approach

- Present clear, feasible, and alternative strategies

- Include statistics, vertebrate animals, human subjects

- Use sophisticated technologies and approaches
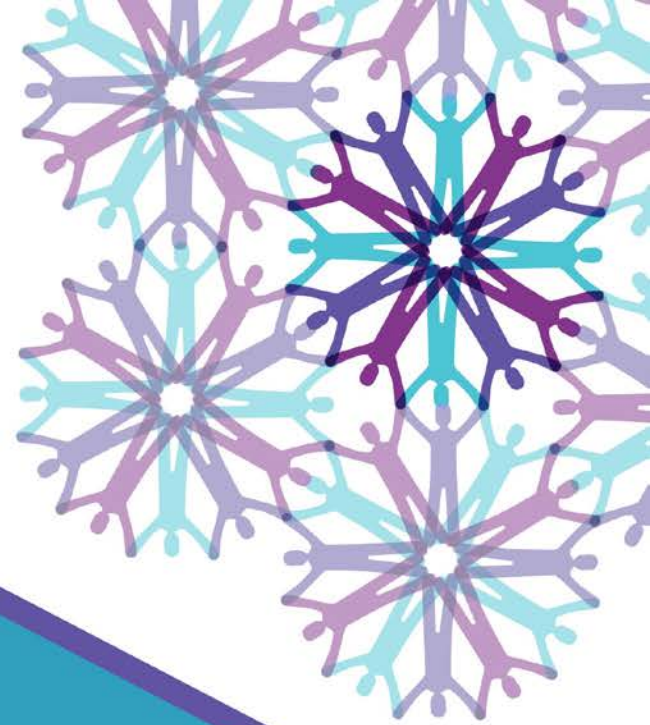
Key Sections

Key Sections of the Research Training Plan

I. Specific Aims

   A. Hypothesis

   B. Objectives

II. Research Strategy

   A. Significance

   B. Innovation

   C. Approach

III. Training in Responsible Conduct of Research

I. Specific Aims Section

- Includes a Hypothesis

  - State concisely the goals of the proposed research

  - Summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved.

  - List the Aims that will be used to examine the Hypothesis

- Describe the Specific Objectives of the proposed research

  - Significance, Innovation, and Approach should be addressed. Can be for *each* Specific Aim individually or for *all* of the Specific Aims *collectively*

Guidance for Writing Specific Aims

- Begin with an **Introduction** of the problem, background, gaps of knowledge in the field, then **Hypothesis** (essentially an **Abstract**)

- State concisely the goals of the proposed research

- Summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved.

- List the Aims that will be used to examine the Hypothesis

- Describe the Specific Objectives of the proposed research

Sample of Specific Aims

Cervical cancer is the leading cause of cancer related death worldwide but particularly in sub-Saharan Africa, with 68,000 new cases detected each year, and a high percentage remaining undiagnosed [1]. In the United States (U.S), 12,990 new cases of cervical cancer are diagnosed, and about 4,120 deaths are reported each year [2]. An introduction of the Papanicolaou (Pap) test, a low-cost early detection procedure, has significantly decreased the incidence of cervical cancer in the US[2]. However, African immigrant women (AIW), of which over 700,000 reside in the US[3], are disproportionately burdened by this disease: African immigrant women often present to the hospital for treatment with later, metastatic stage cervical cancer[4-8], when chances of survival has dramatically decreased from 95% to less than 17%[2,9,10]. Worse cancer outcomes among AIW has been attributed to their underutilization of the Pap test[4,11,12].

Limited health literacy--"the degree to which individuals have the capacity to obtain, process and understand basic health information and services to make appropriate health decisions"[13]--is a strong predictor of the underutilization of preventive health services such as cancer screening and poor health outcomes [4,14,14,15]. Research on Asian and Hispanic immigrants show that those with low English proficiency have significantly lower health literacy levels than non-Hispanic Whites, which may lead to misconceptions about Pap testing, as well as an underestimation of their susceptibility to cervical cancer [4,12,15-17]. The interplay between low health literacy and misconceptions about cancer risk has been found to contribute to a significant number of Asian and Hispanic immigrant women not screening for cervical cancer [4,14,16,17]. Despite significant cervical cancer disparities, research on the cancer screening behaviors of AIW has been scarce. Epidemiological studies show a clear trend that recent immigrants are akin to diseases of their country of origin[18]. With a high incidence of cervical cancer in sub-Saharan Africa, and an exponential increase in Africans migrating to the US [3], there is a public health need to understand how health literacy influences Pap testing among AIW to ultimately decrease the incidence of cervical cancer in this vulnerable population.

The pathways through which health literacy affects health behaviors are not completely understood. Some studies report psychosocial factors (cancer knowledge, self-efficacy, decisional balance) as predictors of cancer screening behavior[15,19]. Sources (family/relatives, friends, ethnic church, TV/Radio, Internet, social media, physician) and types (verbal, written text, pictures) of health information exchange are also suggested as a possible mechanism through which health literacy is shaped and health behaviors are adopted[20]. For example, a significant number of adults with low health literacy (i.e., who are not equipped with the adequate skills needed to evaluate health information), often seek health information and advice from their friends/family[21,22]. Within the African cultural context, female friends/family serve as a central portal for the dissemination of women's health information[7,23-29], and hence, may play a crucial role in shaping health literacy and the adoption of health behavior such as cancer screening[30,31]. Since health literacy can be modified through culturally appropriate interventions[19], it is imperative that we examine and understand how health literacy is shaped among AIW and how, in turn, health literacy influences their Pap testing behaviors. The purpose of this explanatory mixed methods study is to understand how sources and types of health information exchange impacts health literacy and ultimately, Pap testing behaviors among AIW living in the US. The following specific aims are proposed:

Aim1: Examine the relationships of the number of sources (family/relatives, friends, ethnic church, TV/Radio, Internet, social media, physician) and types (verbal, written text, pictures) of health information with the level of health literacy among AIW. **Hypothesis 1**: AIW who use multiple sources and types of health information will have higher health literacy levels than AIW who use a single source and type of health information.

Aim2: To examine the mechanism through which sources and types of health information and health literacy impact Pap testing behaviors among AIW. **Hypothesis 2a**: Sources and types of health information are associated with Pap testing through health literacy after controlling for individual characteristics. **Hypothesis 2b**: Relationship between health literacy and Pap testing is mediated by psychosocial factors (cancer knowledge, self-efficacy, decisional balance) after controlling for individual characteristics.

Aim3: Explore how sources of health information influence AIW Pap testing behaviors and how they seek health information using open-ended interviews.

Aim4: Describe how sources/types of health information impact health literacy and information sharing to guide Pap testing. *Research Question* How do sources and types of health information vary by levels of health literacy and Pap testing behavior?

Additional Tips for Writing Specific Aims

- Make Aims clear and descriptive

- Specific Aims should be related to, but not Interdependent of each other

- Significance, Innovation, Aims, and Approach should be addressed and elaborated. Can be for *each* Specific Aim individually or for *all* of the Specific Aims *collectively*

II. Research Strategy Section

- Applicants should **address an important problem in the field** and show how that the **project is of high scientific quality** and demonstrate **how it fits into the research training plan**

- Reviewers are scrutinizing this section to make sure that the project is likely to have a sustained and **powerful influence on the field of research**

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3 Components of the Research Strategy

A. Significance

B. Innovation

C. Approach

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Research Strategy: **Significance**

- Explain the importance of the problem or critical barrier that the proposed project addresses.

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

Sample Research Strategy: Significance

A. SIGNIFICANCE

RESEARCH STRATEGY

Ethnic/racial disparities in cancer screening persists as a major public health problem. Since 1970, the number of African immigrants in the US has increased exponentially from 80,000 to 1.8million[3]. As of 2013, Africans make up 4.4% of the national immigrant population, and are considered one of the fastest growing groups in the US[3]. A vast majority (41%) of recent African immigrants (residing in the US $\leq$ 5 years) migrated from the western and eastern regions of sub-Saharan Africa where the incidence of cervical cancer is about twice the global rate[9,3,32], and a high percentage of cases remain undiagnosed [1]. With an introduction of the Papanicolaou (Pap) test, cervical cancer incidence and mortality rates in the US has declined by over 60%[33,34]. However, AIW, of which over 700,000 reside in the US[3], continue to experience a disproportionate disease burden and worse cancer outcomes[4,11,12]: Women often present to the hospital for treatment with metastatic stage cervical cancer[4–8], when chances of survival has dramatically decreased from 95% to less than 17%[2,9,10]. A pilot analysis of the 2010-2014 National Health Interview Survey showed that in comparison to African Americans, AIW ages 21-65 years are 86% less likely to report receipt of a Pap test[35]. Another study among women of comparable socioeconomic statuses also showed that AIW are three times less likely than African Americans to report ever receiving a Pap test [8]. Since epidemiological reports show a clear trend that recent immigrants often exhibit diseases that are common in their countries of origin[18], the need to address the cancer screening behaviors and the health disparities faced by this steadily increasing, yet vulnerable ethnic/racial population is one that is identified as a significant public health problem by the American Cancer Society[2], and an important research priority by the National Institute of Nursing Research[36].

Low health literacy is a strong determinant of the underutilization of cancer screening services, particularly among vulnerable groups of women. In 2004, the Institute of Medicine report identified low health literacy as a primary predictor of poor use of preventative health services such as cancer screening[13]. This phenomenon is especially common among immigrant populations whose low English proficiency and poor cancer knowledge may lead to misconceptions about Pap testing, as well as underestimation of their susceptibility to cervical cancer [4,12,16,17]. This link between low health literacy and misconceptions contributes to a significant number of immigrant women not screening for cervical cancer [4,14,16,17,37,38]. Individuals with low health literacy who are not equipped to evaluate various sources of health information, often attain health information from friends/family, and are likely to perpetuate certain health beliefs and attitudes which result in poor health outcomes[6,29,37–40].

Informal communication methods are very common in the African cultural context with recent research showing a possible connection between sources and types of health information and individuals' perceptions and behaviors. A review of the literature indicates that within the African context, cultural familiarity impacts how health information is communicated[41–44]. Effectively communicating health information to influence individuals' perceptions and behaviors requires presenting the information in a manner that is culturally familiar, and allows for discussion and input from community members [41,42,45,46]. A study in Ghana showed that among adults with low literacy levels, peer education increases a person's likelihood of changing a health behavior by 1.74 times[46], and other studies have attributed this phenomenon to the cultural similarities that exist between the peer educator (i.e. family/relatives, friends) and the recipient[41,42,45]. In African communities, female friends/family also serve as portals for the dissemination of women's health information[7,23–29,40], and they play a crucial role in the African women's adaptation of health behaviors such as cancer screening[30,43,44,47]. In sub-Saharan Africa, intervention programs which have effectively improved women's reproductive health behaviors such as breast screening, have focused on improving communication and information sharing within participants' social networks (friends/family)[43,44,48]. This suggests an important pathway through which we can better understand the interplay between sources and types of health information and health literacy in the context of Pap testing among AIW.

Conceptual Framework : An extensive literature review revealed a scarcity of conceptual frameworks that postulate how the relationship between health literacy and health behavior is directly and indirectly associated with sources and types of health information and psychosocial factors[19,49]. In order to address our study aims, this study will be guided by an adaptation of the Health Literacy Skills (HLS) conceptual framework (see Figure 1)[50]. The original model includes determinants of health literacy (individual characteristics), and mediators (self-efficacy, decisional balance) of the relationship between health literacy and health behavior[50]. Based on a

> Explain the importance of the problem or critical barrier to progress that the proposed project addresses.

> Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Sample Research Strategy: Significance

and (3) the relationship between heath literacy and Pap testing is mediated by psychosocial factors (cancer knowledge, self-efficacy, decisional balance)[15,19.] Below are the concepts (underlined) and variables that will be examined in this proposed study:

(a) <u>Individual characteristics</u>: Age, education, employment, income, English proficiency, length of stay in the US, marital status, cultural beliefs/attitudes; (b) <u>Sources of health information</u>: Family/relatives, friends, ethnic church, TV/Radio, Internet, social media, physician; (c)<u>Types of health information</u>: Verbal, written text, pictures; (d) <u>Psychosocial factors</u>: Cancer knowledge (what a person knows about cancer); self-efficacy (how confident a person is in carrying out tasks such as receiving a Pap test); decisional balance (the ability to make a decision in relation to the perceived pros and cons of a health behavior)

Psychosocial factors which are known to impact cancer screening behavior, are also influenced by limited health literacy. Numerous studies have reported psychosocial factors (cancer knowledge, self- efficacy, decisional balance) as predictors of cancer screening behaviors. A separate line of literature indicates health literacy is associated with some of the determinants of cancer screening behaviors4,14,15. What is lacking, however, is a comprehensive understanding as to how these factors interplay to eventually influence individual's health behaviors such as cancer screening15,19. The study proposed by the applicant aims to address this critical knowledge gap.

In summary, despite the significant evidence to support the high incidence of cervical cancer in sub-Saharan Africa and the poor screening behaviors of AIW, research studies on this exponentially increasing target population have been scarce. <u>To address the critical gap in research and meet our long-term goal of designing effective, efficient and culturally appropriate interventions to increase cervical cancer screening and decrease the burden of disease among AIW, it is imperative that we examine and understand how health literacy, a key determinant of cancer screening behavior, is shaped in this vulnerable population and how, in</u> turn, health literacy influences Pap testing among AIW living the US.

Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

B. Research Strategy: **Innovation**

- What makes the project unique?

- What will be discovered/designed? (i.e. methodology, technology, instrumentation, cell line, mouse model)

- Are concepts, approaches, methodologies novel to the field?

- How will it contribute to the field or challenge the current paradigm?

Research Strategy: Innovation

B. INNOVATION

This proposed study is innovative in multiple ways. First, it will be the first to examine how sources and types of health information exchange serve as a mechanism by which health literacy influences Pap testing behavior among AIW. Investigating sources and types of health information in relation to health literacy is very much in line with the African cultural context of informal communication as a possible method of informing health behavior yet the topic has not been addressed in the literature. By systematically examining the relationship between sources and types of health information and health literacy, one can understand how health literacy is influenced among AIW. Secondly, the study is one of the first to comprehensively investigate plausible pathways through which health literacy interplays with other theoretically grounded concepts such as sources and types of health information, psychosocial determinants, and Pap testing. Using a mixed methods approach, the study will yield a comprehensive and an in-depth understanding of how sources and types of health information exchange impact health literacy and ultimately, Pap testing behaviors among AIW living in the US by building on knowledge of the importance of informal communication methods in influencing individuals' perceptions and behaviors within the African cultural context.

What will be discovered?

Innovation:
- Does it shift or challenge current research paradigm?
- Are concepts, approaches, methodologies, innovations novel to the field?
- What makes this project unique?
- What will be discovered/designed? (i.e. technology, cell line, mouse model, methodology, , technology)
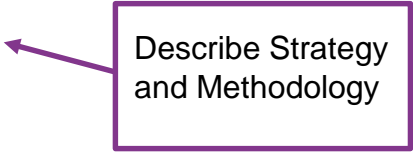- How will it contribute to or change the field?

C. Research Strategy: **Approach**

- Describe the overall strategy and methodology used to accomplish the Specific Aims.

- Preliminary Data should be included

- Make sure that the Data Analysis is clearly described and can be understood by someone who is not familiar with this field

- Include how the data will be collected, analyzed, and interpreted

- Statistics and Power Analysis should be discussed (if applicable)

- Discuss potential problems, how they will be managed, and alternative approaches

Research Strategy: Approach

C. APPROACH

1. Study Design: The proposed study will utilize an explanatory mixed methods design[51] (see Figure 2). The purpose of using an explanatory mixed methods design is to have the quantitative strand of the study provide a general understanding of the statistical relationships among sources and types of health information and health literacy. The qualitative strand then provides an in-depth understanding of the quantitative data by explaining how AIW seek and share health-related information to guide Pap testing behaviors[51]. The proposed study will consist of four study phases: planning, quantitative data collection/analysis, qualitative data collection/analysis,
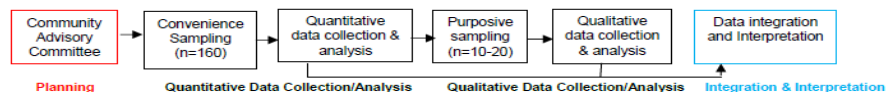
Describe Strategy and Methodology

Discuss how data will be collected, analyzed and interpreted

Methodology

and integration/interpretation. In the **first phase** (planning) the applicant and her mentorship team's collective expertise will be matched by a community advisory committee comprised of key community stakeholders such as AIW, African church leaders, and clinicians. The community advisory committee will be led by Mrs. Ify Nwabukwu (see Letter of Support), founder and president of African Women's Cancer Awareness Association (AWCAA), a well-integrated African immigrant, community-based organization in the Washington DC-Maryland-Virginia metropolitan area. The committee will assist the study team to: (1) develop a culturally acceptable plan to administer study surveys; and (2) develop strategies that promote the recruitment of AIW from the community. The committee will meet at least biweekly in the planning phase and once a month during the remainder of the study. The **second phase** (quantitative strand), we will conduct cross-sectional surveys. An analysis of the quantitative data will inform the **third phase** (qualitative strand) of the study which will comprise of one-on-one interviews with a subset of the research participants. For the **fourth phase** (data integration and interpretation), we will integrate both quantitative and qualitative findings to explain our study purpose and aims.

Figure 2: Study Design (Explanatory Mixed Methods)

Community Advisory Committee	→	Convenience Sampling (n=160)	→	Quantitative data collection & analysis	→	Purposive sampling (n=10-20)	→	Qualitative data collection & analysis	→	Data integration and Interpretation
Planning		**Quantitative Data Collection/Analysis**				**Qualitative Data Collection/Analysis**				**Integration & Interpretation**

2. Target population: African immigrant women ages 21 years and older living in the Washington DC-Maryland-Virginia (DMV) metropolitan area will be recruited for this proposed study. To date, there are over 191,000 African immigrants living in the DMV area, a concentration (13%) that is over three times the national average (4%)[52]. Majority of African immigrants in the DMV area are from the English speaking regions of East and West Africa where the incidence of cervical cancer is about twice the global rate[9,3,32].

3.1 Methodology for Aims 1& 2
Aim1: Examine the relationships of the number of sources (family/relatives, friends, ethnic church, TV/Radio, Internet, social media, physician) and types of health information (verbal, written text, pictures) with the level of health literacy among AIW. **Aim2:** To examine the mechanism through which sources and types of health information and health literacy impact Pap testing behaviors among AIW.

Table 1: Inclusion and Exclusion Criteria and Rationale	
Criteria	Rationale
Inclusion: (a) > 21 years; (b) Self-identify as African immigrant woman; (c) Reside in the DMV area	((a)Recommended age to begin Pap testing; (b)Target population is African immigrants (c) Highly populated area with AIW; accessible to research team
Exclusion: (a)Unable to provide informed consent (b) History of hysterectomy	(a) Minimize risk of coercion (b) Pap testing is not recommended for women who have received a hysterectomy

Sample Size: The study is powered based on the proposed analysis for Aim 2, to examine a mechanism through which sources and types of health information and health literacy impact Pap testing behaviors among AIW using path analysis and multivariate logistic regression. A sample size of 160 will be used in this proposed study. The sample size estimate is based on: General guidelines for path analysis which recommends a sample size of 10-20 per each study concept[53], and a decline rate of 30% based on previous studies which included the variables of interest in this proposed study[54,55]. Since 8 concepts (individual characteristics, health literacy, cancer knowledge, self-efficacy, decisional balance, sources of health information, types of health information, Pap testing) will be measured in this proposed study, sample size was calculated using this formula:(8 study constructs x15=120) + (30% of 120). **Sampling:** 160 women who self-identify as African immigrants will be recruited from the Washington DC-Maryland-Virginia metropolitan area. Recruitment: The applicant will approach pastors and heads of women's ministries, owners of local African restaurants and markets to discuss study's purpose/aims, and request for them to serve as potential recruitment sites. Once a collaborative relationship is established, study flyers will be advertised on site, and the leaders/owners will be encouraged to share study flyers with their congregation/clients. Possible participants who contact the study team will be screened, and if they meet edibility criteria (see Table 1), the applicant will set up an appointment for data collection at a site that is convenient for the participant. The applicant will give the participant a reminder phone call or send a text message (based on participants' preference) 24 hours prior to appointment date. All participants will sign informed consents on the day of data collection. Relying on the importance of information sharing within African immigrant communities, enrolled participants will be given study flyers and encouraged to share with female friends/family. Advertisement: To enhance the diversity of participants recruited, our study will be

Research Strategy: Approach (cont.)

Describe Analysis to be used to accomplish the Specific Aims of Project

D. DATA ANALYSIS

After parent study data is entered into Qualtrics, data will be downloaded from Qualtrics into STATA for use by the applicant. Downloaded data will be assessed for completeness. After data cleaning, statistical analysis will be conducted using STATA. Exploratory and descriptive analysis will be completed for all study variables. Variables will be examined for normality and examined with means and standard deviations or medians and interquartile ranges accordingly. The significance level will be set at 0.05. The applicant will use SAS software for path analysis. See Human Subjects Research section for data safety plan. Below are the analyses plans for each study aim:

Hypothesis for Aim 1: AIW who use multiple sources and types of health information will have higher health literacy levels than women who use a single source and type of health information. **Analysis plan:** Multiple logistic regression will be used to examine the relationships of sources and types of health information and health literacy levels. Health literacy level, measured by the number of items scored correctly on the Assessment of Health Literacy-Cancer scale will be categorized as high (score $\geq$ 26) and low (score < 26). Categorical dummy variables will be created for the number of sources and the types of health information. The covariates (age, education, employment, income, English proficiency, length of stay, marital status, cultural beliefs/attitudes) will be entered into the model first, followed by the independent variables of interest (types and sources of health information). To evaluate how much predictive power was added to the model by adding the variable(s) of interest, the change in likelihood ratio test will be evaluated[53].

Hypothesis for Aim 2(a): Sources and types of health information are associated with Pap testing through health literacy after controlling for individual characteristics. **Analysis plan:** Multiple logistic regression will be used to examine the mediating effect of health literacy on the relationship between sources/types of health information and Pap testing. Pap testing will be measured as a binary variable (yes/no). The covariates (age, education, employment, income, English proficiency, length of stay, marital status) will be entered into the model first, followed by the independent variables of interest (types and sources of health information). For the second model, the hypothesized mediator (health literacy) will be entered into the model followed by the covariates and independent variables of interest. To evaluate the mediating effect of health literacy, the odds ratio of the two models will be assessed for significant differences >10%[53].

Hypothesis for Aim 2(b): Relationship between health literacy and Pap testing is mediated by psychosocial (self-efficacy, decisional balance, knowledge) and cultural (fatalism, attitudes, beliefs) factors after controlling for individual characteristics. **Analysis plan:** Path analysis will be conducted in two steps using SAS software. In the first step, confirmatory factor analysis will be used to test the measurement model[53]. Theoretically plausible error correlations and cross-loading indicators will be tested individually and retained in the model if they improve model fit and have statistically significant coefficients[58]. Variables which show a poor fit (Comparative Fit Indices $\leq$ 0.90, Tucker-Lewis Index $\leq$ 0.90 and the root mean square error of approximation $\leq$ 0.08) will be deleted from the model[53,58]. In the second step, a structural model which examines the coexistence of a direct effect of health literacy on Pap testing and an indirect effect of health literacy on Pap testing through the proposed mediators will be tested.

Aim 3: Explore how cancer-related health information is sought and shared to guide Pap testing behaviors in AIW. **Analysis plan:** A qualitative descriptive analysis approach will be used for data analysis. Interviews will be read to gain a general understanding of the content and to ensure the accuracy of all transcribed data. Data will be coded using QUIRKOS®, an interview data analysis software. A codebook will be created and reviewed with the applicant's mentorship team to discuss discrepancies, eliminate bias and group codes into emerging themes. Throughout the process, reflexivity will be maintained through written memos. Trustworthiness will be achieved through discussions with applicant's mentorship team, along with audit trail documentation[57]. To increase transferability of findings, detailed inclusion and exclusion criteria of sample, an example of the interview guide used, and an in-depth discussion of the data analysis process will be provided in future manuscripts.

Research Strategy: Approach (cont.)

Research Question for Aim 4: How do sources and types of health information vary by levels of health literacy and Pap testing behavior? **Analysis plan:** To describe if AIW, based on health literacy levels and Pap testing behavior, seek and share health information differently, congruence between the theoretical framework quantitative findings and emergent qualitative themes will be examined, and placed in a mutual context[51]. Quantitative and qualitative data mergers will be facilitated through data displays and matrices (see Appendix for proposed example). We will relate emerging themes to participants' Pap testing behaviors and health literacy levels[51] to provide an in-depth understanding of how sources and types of health information impact health literacy and information sharing to guide Pap testing among AIW. (See Appendix for an example of how the applicant would organize quantitative and qualitative data)

Discuss Potential Problems and Alternative Strategies

Potential Challenges and Alternative Strategies (1) Data entry and statistical analyses: As part of the applicant's role as study coordinator, she has experience with participant recruitment using a community based participatory approach, data quality assurance procedures, and data entry into Qualtrics. The applicant will be working with her sponsor and a biostatistician consultant to prepare and refine her analyses. In addition, the applicant has completed PhD courses in statistical analysis, mixed methods design and qualitative study analyses. The applicant plans to take more PhD courses in biostatistics and path analysis to hone her skills. (2) Self reports: AIW are less likely to have a primary care physician from whom they seek routine medical care[8,40]. Although self-reported data will be collected for this proposed study, all instruments have been validated in immigrant populations with low English proficiency. In addition, studies have shown that with limited access to administrative data such as medical records, self-reports are also reliable method to collect data[59–61]. The applicant also plans to work with her mentorship team and a community advisory committee in the structuring and wording of study questionnaires. (3) Sample size and study feasibility: A sample of 160 participants recruited over 12 months is proposed for this study. There are over 191,000 African immigrants living in the DMV area, a concentration (13%) that is over three times the national average (4%)[52]. The applicant has helped recruit over 200 participants within 8 months for a cross-sectional study. She also has strong ties with leaders in the African immigrant community, and currently serves as a member of the African Women's Cancer Awareness Association (see Letter of Support), which organizes outreach programs for 400 African immigrant women in a year. In addition, a $20 incentive will be provided to participants at the end of the enrollment visit to compensate for their time to reduce the barrier of participant interest.

Benchmarks for Success

Table 4: Proposed study timeline and benchmarks						
Activity	**2017**			**2018**		
	Apr-Jun	Jul-Sept	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sept
Development of study protocol	X					
IRB application/Training	X					
Recruitment/Data collection		X	X	X	X	
Quantitative Analysis			X	X		
Qualitative Analysis			X	X	X	
Presentation at conferences/Manuscripts				X	X	X

III. Training in the Responsible Conduct of Research

- Responsible Conduct of Research is defined as:

The practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

NOT-OD-10-019

Training in the Responsible Conduct of Research

- **Format:** the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable)

- **Subject Matter: e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics**

- **Faculty Participation:** the role of the sponsor(s) and other faculty involvement in the fellow's instruction

- **Duration of Instruction:** the number of contact hours of instruction (at least eight contact hours are required)

- **Frequency of Instruction:** should be for the duration of funding & updated annually

Training in the Responsible Conduct of Research

Reviewers will evaluate the adequacy of the proposed RCR training in relation to **Five Required Components:**

1. **Responsible Conduct of Research**

Format: The Johns Hopkins University provides training for early stage researchers in the responsible conduct of research through multiple in-person, blended in-person/online, and online classes/training.

2. **Subject Matter**: Through the in-person and blended classes/trainings the following topic/objectives are met in compliance with NOT-OD-10-019.

Responsibilities and Activities of the Nurse Scientist (JHU School of Nursing NR110.891):

- Demonstrate knowledge of and analyze and apply principles of research ethics and the responsible conduct of research, regarding conflict of interest, human subjects protection, data acquisition and management, authorship, social responsibility, collaboration, scientific freedom, and misconduct in the planning and conduct of scientific research.
- Characterize and evaluate various strategies for building a career in research, such as postdoctoral experiences and initiation of independent research, including identification of and application to various funding agencies.
- Design a plan for dissemination of research findings.
- Examine issues related to collaboration in intradisciplinary and multidisciplinary research and mentorship.
- Evaluate various career trajectories and opportunities in nursing research.
- Critically evaluate all aspects of a scientific research proposal.

Dean's Research Integrity Lecture Series (JHU School of Medicine) This lecture series is part of the Responsible Conduct of Research Program at Johns Hopkins University, administered by the Division of Research Integrity in the Office of Policy Coordination. The series is in compliance with the National Institutes of Health and National Science Foundation guidelines. Topics include:

- The Importance of the Scientist as a Responsible Member of Society
- The Importance of Data Acquisition and Management
- The Importance of Mentor/Mentee Relationships
- The Importance of Collaborative Research

Supplemental online training is also required for scientists at all career levels and provided in the areas of Human Subjects Research, HIPAA and Research, HIPAA General Privacy Issues, and Conflict of Interest and Commitment.

3. **Faculty Participation:** Training faculty/mentors have all taken multiple trainings in the responsible conduct of research and will provide informal instruction in the responsible conduct of research in the day-to-day interactions with their mentees/trainees. Certain faculty/mentors may participate in NR110.891 as discussion leaders, speakers, or lecturers.

4. **Duration of Instruction:** The classes/trainings provided fulfill and exceed the recommended 8 contact hours (NOT-OD-10-019) through the monthly Research Integrity Lectures and the semester-long course (NR110.891). The training program is enriched by the addition of online courses (supplemental to the in person instruction).

5. **Frequency of Instruction:** NR110.891: Required be taken for credit during pre-doctoral level. Dean's research Integrity Lecture Series: May be attended monthly at pre-doctoral, postdoctoral, or faculty level. **Monitoring:** Compliance with the instruction in the responsible conduct of research is monitored via the Research Compliance Administrator in the Office of Research Administration. The Compliance Administrator has access to all training certificates and course attendance. A database is kept to track the fulfillment of training requirements for all individuals involved in research at the Johns Hopkins School of Nursing.

Final Tips

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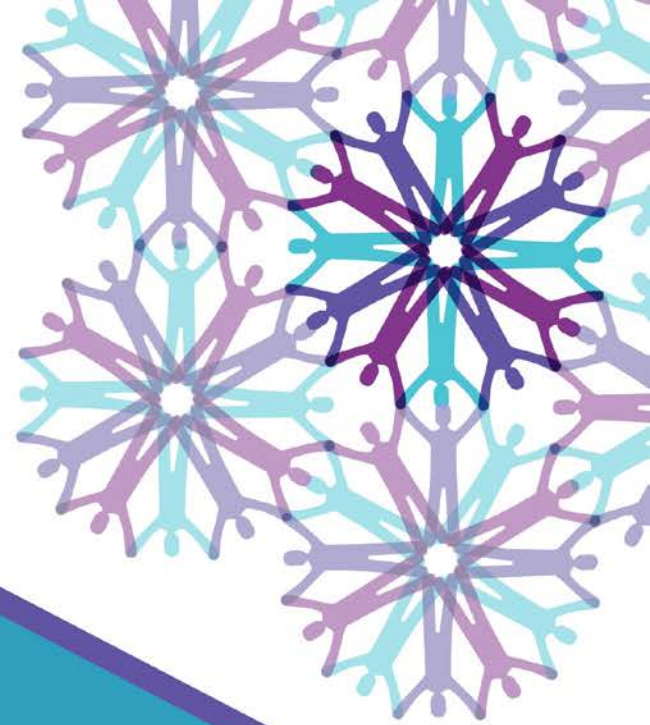
Final Tips for Developing Research Training Plan

- Develop Specific Aims and include Significance, Innovation, and Approach (for each or all)

- Consider how your proposal develops skills you need for your science and for your career development

- Make sure your figures/figure legends are correctly labeled to match the figure reference in the text

- Have someone not involved with your project read & critique your Research Training Plan/Research Strategy

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