

# Examples of Funded Grants in Behavioral Research

## Overview

The National Cancer Institute (NCI) frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let the Behavioral Research Program (BRP) post excerpts of their grant applications online.

## About

We are grateful to the investigators and their institutions for allowing us to provide this important resource to the research community. To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application), where applicable. In addition, we only include a copy of SF 424 R&R Face Page, Project Summary/Abstract (Description), Project Narrative, Specific Aims, and Research Strategy; we do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., performance sites, key personnel, biographical sketches).

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## 424 R&R and PHS-398 Specific

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## **SF 424 R&R Face Page**

**PI:** Ramaswamy, Megha

**Grant Number:** 1 R01 CA181047-01A1

**Title:** Sexual Health Empowerment for Cervical Health Literacy and Cancer Prevention

**FOA:** PAR13-130

**FOA Title:** UNDERSTANDING AND PROMOTING HEALTH LITERACY (R01)

**Organization:** UNIVERSITY OF KANSAS MEDICAL CENTER

**Department:** Preventive Medicine and Public

**Senior/Key Personnel:** Megha Ramaswamy PhD

**Organization:** University of Kansas Medical Center

**Role Category:** PD/PI

## Abstract

Women in the criminal justice system are four-five times as likely to have cervical cancer compared to non-incarcerated women. In our previous research, we found that the most important contributor to cervical cancer risk, and perhaps lack of follow-up, is incarcerated women's low health literacy about broader reproductive health issues. Until we effectively address incarcerated women's unique reproductive health literacy needs, the cervical cancer health disparity between incarcerated and non-incarcerated women will persist.

The *objective* of this study is to assess the effectiveness of a sexual health empowerment (SHE Project) intervention to improve cervical health knowledge, reduce barriers to screening that are related to beliefs about cervical cancer, improve self-efficacy for navigating providers and health care systems, and ultimately work towards preventing cervical cancer. This objective is responsive to PAR-10-133 in that it develops an intervention strategy to address health literacy and broader health outcomes in a vulnerable population.

To meet the objectives of this study, we propose to assess the impact of a sexual health empowerment intervention (SHE Project) on cervical health knowledge, barriers to screening that are related to beliefs about cervical cancer, and self-efficacy for screening and follow-up among women leaving jail. More specifically, we will conduct a pre- and post-intervention assessment from baseline to the end of a weeklong intervention using a wait-list control design. Next, we will use a three-year observational study design employing both survey and ethnographic methods for follow-up, to understand how knowledge, beliefs, self-efficacy, and other factors change post-release cervical health prevention behaviors over time. This approach will allow us to observe the extent to which women translate, if at all, increased knowledge, reduced barriers, and increased self-efficacy into practice during clinical encounters, or if other factors explain health behaviors over time.

The public health impact of this study is its potential to reduce cervical cancer morbidity and mortality for this high risk and vulnerable group of women. Our development of an effective and easily disseminated health literacy intervention that can be adapted to many health conditions and broader cancer prevention efforts in institutionalized populations (jails, prisons, community corrections, military institutions) will have an impact on public health, and also on the science of developing effective health literacy interventions.

## **Public Health Relevance Statement**

The public health impact of this study is its potential to reduce cervical cancer morbidity and mortality for the high risk and vulnerable group of women in the criminal justice system. An empowerment approach to health literacy interventions will also have an impact on broader reproductive health problems in this high risk population. Further, the development of an effective and easily disseminated health literacy intervention that can be adapted to many health conditions and broader cancer prevention efforts in institutionalized populations (jails, prisons, community corrections, military institutions) will have an impact on public health, and also on the science of developing effective health literacy interventions.

## Specific Aims

Women in the criminal justice system are four-five times more likely to have cervical cancer compared to non-incarcerated women,<sup>1,2</sup> but little is known about how to address this health disparity. The one million women incarcerated in the US – 95% of whom will return to their communities – are mostly poor, racial/ethnic minorities,<sup>3,4,5</sup> with long histories of abuse, mental health problems, drug use, and STIs.<sup>6,7,8</sup> These complex factors exacerbate their risk for cervical cancer, as well as create barriers to follow-up health care. The few investigators that have studied cervical cancer among women in jails and prisons have found that, indeed, though many women get screened for cervical cancer, less than half gain access to recommended clinical follow-up.<sup>9,10</sup> In our pilot research, we found that the most important contributor to cervical cancer risk, and perhaps lack of follow-up, is incarcerated women's low health literacy about both cervical cancer and broader reproductive health issues.<sup>11</sup> Until we effectively address incarcerated women's unique reproductive health literacy needs, given the barriers of incarceration, release, and traumatic life experiences, the cervical cancer health disparity between incarcerated and non-incarcerated women will persist.

The *long-term goal* of this project is to improve incarcerated women's reproductive health literacy in order to bolster cervical cancer control efforts in this population and reduce the cervical cancer disparity between incarcerated and non-incarcerated women. The *primary objective* of this study is to assess the effectiveness of a sexual health empowerment (SHE Project) intervention to improve cervical health knowledge, reduce barriers to screening that are related to beliefs about cervical cancer, improve self-efficacy for navigating providers and health care systems, and ultimately work towards preventing cervical cancer. This objective is responsive to PAR-10-133 in that it develops an intervention strategy to address health literacy and broader health outcomes in a vulnerable population. To meet the objectives of this study, we propose the following *aims*:

**AIM 1: Using an experimental design, assess the impact of a sexual health empowerment intervention (SHE Project) on cervical health knowledge, barriers to screening that are related to beliefs about cervical cancer, and self-efficacy for screening and follow-up among women leaving jail.** To achieve this aim, we will conduct pre- and post-intervention assessments at baseline, and at the end of a weeklong intervention using a wait-list control design. The intervention's health empowerment approach to health literacy capitalizes both on unique problems of incarcerated women (sexual violence, disempowerment, discrimination, poor reproductive and cervical health outcomes) and on the institutionalized setting where dissemination of interventions is feasible and cost-effective. Outcome variable selection is guided by our prior research (NCI R03 and ACS pilot) on cervical cancer health literacy with women in jail, where we documented deficits in knowledge, beliefs, and self-efficacy in navigating providers and health care systems relating to these women's reproductive health. Thus, for AIM 1, changes in knowledge, beliefs, and self-efficacy pre- and post-intervention are the primary outcomes of interest.

**AIM 2: Using a three-year observational design employing both survey and ethnographic methods for follow-up, understand how knowledge, beliefs, self-efficacy, and other factors change post-release cervical health prevention behaviors over time.** This aim will allow us to observe the extent to which women translate, if at all, increased knowledge, reduced barriers, and increased self-efficacy (AIM 1) into practice during visits with clinicians. We also will be able to analyze which components of the intervention are associated with appropriate preventive health behaviors, or if other observed factors account for screening and follow-up over the three-year study period – for example, factors unrelated to the intervention, such as cost, transportation, or ongoing criminal justice involvement. The main barrier to cervical cancer prevention for women appears to be loss to follow-up, but little is known about what accounts for loss to follow-up. This aim will demonstrate whether an intervention that addresses knowledge, beliefs, and self-efficacy translates to improved screening uptake and follow-up, or if other factors explain poor cervical health screening behaviors. The primary outcomes for this observational AIM 2 are screening behaviors (Paps or STIs), clinical follow-up of screening, and strategies for navigating health care encounters.

Knowledge gained from this study will translate to the dissemination of strategies to improve reproductive health in high-risk incarcerated women, and address health literacy in light of the unique challenges this group of women face. The interdisciplinary team of investigators, which has both a strong history of working together and excellent access to the target population, is well prepared to conduct this R01 project that entails designing, implementing, and evaluating the effectiveness of a novel cervical cancer health literacy program.

# Research Strategy

## SIGNIFICANCE

Public Health Problem. Women serving time in the criminal justice system are disproportionately affected by cervical cancer and poor health. In the general population in the U.S. about 12,000 new cases of cervical cancer are diagnosed each year.<sup>12</sup> Over the past 40 years, however, incarcerated women in North America have consistently been four to five times more likely to have cervical cancer compared to age-matched samples of non-institutionalized women.<sup>1,2</sup> Incarcerated women are also 6-11 times more likely to have abnormal cervical exams.<sup>13,14</sup>

The one million women incarcerated in U.S. jails and prisons also have high rates of sexually transmitted infections,<sup>3,8,15,16,17</sup> exacerbated by patterns of violence and abuse, drug use, and mental health problems, all of which are present in as many as 60-90% of women in correctional facilities.<sup>7,18,19,20,21,22</sup> Women in U.S. jails represent a unique population compared to women in U.S. prisons. Jails house individuals awaiting adjudication, sentenced to terms of one year or less, as well as probation and parole violators.<sup>23</sup> Because of the relatively short length of stay and rapid turnover – women leave jails days, weeks, and months after arrest – there is substantial opportunity to engage these women in community health prevention programs.<sup>24</sup> This becomes especially important for women with a disproportionate burden of substance abuse problems, mental health history, and sexually transmitted infection risk, all of which contribute to cervical cancer health disparities among women in jail as compared to non-incarcerated women.

The combined risks and burdens of cervical cancer increase the existing health disparities between incarcerated and non-incarcerated women. Thus far, little research has focused on closing this cervical cancer health disparity. Some studies suggest that although women with criminal justice involvement do get screened, follow-up care after screening remains problematic.<sup>9,10,25</sup> Little is specifically known about why women involved in the criminal justice system have suboptimal abnormal Pap follow-up experiences. An understanding of these experiences among women who move in and out of jails can help us mitigate the cervical cancer health disparity between these women and their sisters in the “free” world.

Cervical Cancer Prevention and Health Literacy. Health literacy is defined as “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”<sup>26</sup> Though low health literacy has been associated with numerous adverse health outcomes, ranging from poor chronic disease management, risky health behaviors, hospitalizations, and fewer cancer prevention behaviors, interventions that address health literacy in cancer prevention are rare. One of the innovations of our proposed study, as described below, is the development of a transferable intervention that addresses reproductive health literacy, and capitalizes on the unique problems of a high risk and vulnerable population, and on the opportunity that criminal justice facilities offer for controlled interventions.

Our rationale is based on our previous research that has demonstrated the association between reproductive/cervical health literacy and cervical cancer risk.<sup>27,28,29,30,31,32</sup> For example, investigators have argued for more cervical health literacy programs due to women’s inability to identify and understand basic anatomical terms, fear and shame related to Pap screening, confusion about screening recommendations,<sup>28</sup> and low levels of knowledge about the link between HPV and cancer.<sup>27</sup> Others have found that patients with physician-estimated low health literacy were less likely to follow-up after an abnormal Pap exam<sup>29</sup> and that low health literacy may be related to psychological distress about abnormal Pap follow-up, which could impede follow-up care.<sup>30</sup>

In our own exploratory research (R03 CA162869, Ramaswamy PI) we found that perhaps the most important contributor to cervical cancer risk, and perhaps lack of follow-up, is incarcerated women’s low health literacy about reproductive health issues – broadly defined as their knowledge about reproductive health, beliefs about cervical cancer, and self-efficacy related to screening and follow-up. For our preliminary R03 study, we analyzed data collected with 45 women in a Midwestern county jail through focus groups and in-depth interviews.<sup>11</sup> Though we recruited women based on their self-report of abnormal Pap history in the last five years, we found through in-depth interviews with the participants that almost half of the women misinterpreted abnormal Pap events as any

reproductive health problem diagnosis, such as ovarian cysts, bleeding, and sexually transmitted infections. Women's lack of understanding about the meaning of "abnormal Pap" was common, despite overall high general health literacy scores on a standardized instrument – 91% had "adequate" levels of health literacy when measured with the Short Test of Functional Health Literacy in Adults (S-TOFHLA). Additionally, the women showed deficits in their ability to process and understand information relevant to their cervical health. For example, the women believed that the Pap was an all-purpose test used to detect cancer, but also sexually transmitted infections, pregnancy, and rape (see Appendix 1 – themes related to cervical health literacy). The women in our study also had misinformation about Pap screening recommendations, with some thinking screening should occur monthly or whenever a woman engaged in risky sex behavior. The women reported conflicting notions of the etiology of cervical cancer – infectious, hereditary, and even related to hygiene. Only one out of 45 participants correctly identified the connection between HPV and cervical cancer. Aside from knowledge and beliefs about the Pap test and cervical cancer, our participants reported barriers to self-efficacy and being able to navigate health care systems – the perception of mistrust towards clinicians inside jails and in the community, and the feeling that preventive sexual health care is a low priority due to competing needs related to drug use, money, and repeated episodes of criminal justice involvement. From this preliminary work, we hypothesize that what may account for the cervical cancer disparity between incarcerated and non-incarcerated women are issues related to health literacy and the ability to navigate health care systems. The goal of this proposal is to address reproductive health literacy in order to bolster cervical cancer prevention efforts in this group of women.

PAR-10-133, as well as the Institute of Medicine Report, *Health Literacy, A Prescription to End Confusion*, serves as a call to action to capitalize on findings about health literacy in novel intervention development. Cervical cancer prevention, in particular, requires knowledge about sexual health, commitment to and self-efficacy for screening and follow-up, and high levels of health literacy in interactions with clinicians and broader health care systems. In fact, some studies have found that health literacy is a better predictor of cervical cancer knowledge and screening than education level or ethnicity.<sup>32,33,34</sup> As described above, we conceive of health literacy broadly as encompassing knowledge, beliefs, self-efficacy,<sup>35</sup> and the confidence to navigate patient-provider interactions and health systems, given incarcerated women's unique challenges and risks.

**We operationalized the definition of health literacy so broadly, in part because of grounding in the literature (e.g., IOM report), but also because such an operationalization would allow us to develop an effective intervention tailored specifically to our population and responsive to findings from our preliminary studies. We realize there is substantial debate in the field of health literacy, with initial definitions of health literacy as reading, writing, and deciphering medical labels. The IOM report highlighted the need, however, to move beyond knowledge and focus on people's ability to act upon that knowledge, which we feel encompasses their beliefs about health, self-efficacy, and confidence in navigating health systems. Thus, our conception of the proposed intervention is one that focuses on "interactive health literacy," where we impart both knowledge and skills.**

Indeed, a recent comprehensive review of all health literacy interventions demonstrated that effective interventions were of high intensity, based on theory, pilot tested, delivered by health professionals, and emphasized skill-building.<sup>35</sup> The Community Preventive Services Taskforce review of interventions focused on increasing cervical cancer screening found that effective interventions addressed benefits of screening and overcoming barriers to screening with the goal of informing, encouraging, and motivating women to change behavior.<sup>36</sup> Though this group recommended one-on-one intervention rather than a group-based format, they acknowledged that interventions can be tailored to special populations. Given our experience in the criminal justice system and delivering interventions, small group format may be the optimal way to tailor interventions for this group of highly transient women. Our participants have appreciated the opportunity to form a small social network in a group context in which they could share ideas, get feedback, and help each other.

We also recognize that per the Institute of Medicine (IOM), "Health literacy level is the product of a complex set of skills and interactions on the part of the individual, the health care system, the education system, and the cultural and societal context."<sup>37</sup> IOM has articulated a need for health literacy interventions that address culture, society, the education system, and health system. When working with vulnerable populations, it might make sense to design interventions that empower specific groups of people in order to optimize their ability to navigate larger social



systems in real time. This approach might mitigate vulnerable population's elevated health risks. Therefore we have developed an intervention that is embedded in the context of how women move through larger social systems, including health care, criminal justice systems, and their own communities and interpersonal relationships. Our goal was to determine how to empower a unique and vulnerable sample of women leaving jails to navigate these systems more effectively and improve their health outcomes.

The feasibility and potential for replication of our intervention is that we can implement a short-term, high- impact intervention with a captive audience. As women leave jails, we then will be able to observe them navigate their social worlds. The in-jail intervention will address the very likely difficult social-cultural landscape to which women will return post-incarceration. We anticipate that 95% of women in our local jails will return to their communities to confront their ongoing health problems.<sup>23</sup>

Public Health Impact. The public health impact of this study is its potential to reduce cervical cancer morbidity and mortality for this high-risk and vulnerable group of women. An innovative and broader empowerment approach to interventions that address low reproductive health literacy also will have an impact on complex sexual health problems in this high-risk population. The development of an easily disseminated reproductive health intervention that can be adapted to many health conditions and broader cancer prevention efforts in institutionalized populations (jails, prisons, community corrections, military institutions) also will have an impact both on public health and the science of developing effective interventions that address low health literacy.

Finally, as implementation of provisions of the Affordable Care Act (ACA) draw near, cervical cancer screening, follow-up, and HPV vaccination will be made widely available to all women.<sup>38</sup> Recent estimates suggest that up to half of all prisoners returning home may be eligible for new health coverage under the ACA. The timing of our intervention could capitalize on these systems-level changes.<sup>39</sup>

## INNOVATION

Innovative Theoretical Framework. The theoretical orientation of this project stems from sociologist Pierre Bourdieu's argument that social transformation occurs through a network of social relations.<sup>40</sup> We conceive of that network of social relations as the incarcerated woman's ability to navigate her ongoing criminal justice involvement, community reentry, family, romantic and sexual partners, **cultural influences on health beliefs**, and health services. **Designing a health literacy intervention that builds knowledge, reduces barriers related to beliefs, and improves self-efficacy and confidence, can empower women to better navigate their lives to improve health.** For this high-risk and vulnerable population – and perhaps for any group of people – health literacy represents a complex interaction between individuals and their ability to navigate and process information and resources related to their health.<sup>35,37</sup> The application of Bourdieu's theory to an intervention that addresses low health literacy is innovative in that he wrote about "habitus" as the set of transposable dispositions, perceptions and patterns that the individual has picked up through the process of socialization.<sup>40</sup> **Habitus encompasses the women's cultural beliefs, which are informed by race, ethnicity, poverty, and gendered experiences of stigma, violence, and incarceration, specifically.** Habitus is *learned*. A health literacy intervention can help shape habitus **and the way women navigate their social worlds**. An empowerment approach to health literacy, as described below, constitutes a person's field in such a way that is meaningful and worthy of time and energy,<sup>40</sup> **even for the most vulnerable women**. The application to cancer prevention is that the field can take on a character that values *prevention* and *empowers* high-risk and vulnerable women to take action to reduce reproductive health morbidity and mortality.

Innovative Intervention Design. The proposed intervention will be innovative in that it capitalizes on the unique problems of incarcerated women – sexual violence, sexual health, disempowerment, **discrimination**, and poor cervical health outcomes. We have taken what we have learned from previous research (NCI R03 and ACS IRG-09-062-01, Ramaswamy PI of pilot study – described further in Approach section) about the complexity of incarcerated women's cervical health stories, and how they relate to broader themes of sexually transmitted infections, drug use, abuse, violence, distrust of romantic, sexual partners, clinicians, health care systems, neighborhood disadvantage, and larger reproductive health problems beyond cervical cancer.<sup>11,13</sup> We have found that broader reproductive health issues – for sexually transmitted infections, pregnancy, cysts, and the resolution of other reproductive health problems – may be an important mediator for cancer prevention. Therefore we propose an empowerment approach to intervention development, a call echoed in AHRQ's report on health literacy

interventions.<sup>35</sup> Empowering women to tackle the range of their reproductive health needs may make the perception of a more “distant” problem of cervical cancer prevention a priority.

The sexual health empowerment component of the intervention stems from a feminist perspective on health – understanding women’s experience within their social and political context, as well as a *health-focused approach*, not disease or illness-focused.<sup>41,42,43,44,45,46</sup> This approach emphasizes the context of romantic and sexual partnerships, family, and community in women’s lives; the role of the intersection of race, class, and gender-specific health outcomes; and rejection of status quo values and assumptions about women.<sup>41,47,48</sup>

The innovation of our study is that we have incorporated the sexual health empowerment elements directly into our intervention that address low reproductive health literacy, given the unique needs of our population of incarcerated women. Our intervention will address knowledge about a broad range of reproductive health problems, including cervical cancer prevention. We will use an empowerment approach to address beliefs and improve self-efficacy related to screening and treating these problems. We will discuss openly challenges and participant-driven solutions to navigating health care providers and broader health systems.

Finally, our intervention is innovative because of the unique institutionalized setting – jails – where dissemination of interventions is highly feasible and potentially cost-effective. For better or worse, jails represent an important opportunity for intervention when women are temporarily removed from the complexity of their daily lives, interpersonal relationships, and communities.<sup>24</sup> Because jails are short-term facilities, the benefits of interventions have broad implications for community-based health care seeking behaviors and ongoing cancer prevention efforts.

## APPROACH

Overview. The *primary objective* of this project is to assess the effectiveness of a sexual health empowerment (SHE Project) intervention to improve cervical health knowledge, reduce barriers to screening that are related to beliefs about cervical cancer, improve self-efficacy for navigating providers and health care systems, and promote preventive cervical health behaviors. Table 1, below, describes main the project activities, key outcomes, and benchmarks for success.

Table 1. Main Project Activities, Key Outcomes, and Benchmarks for Success		
Activities	Key Outcomes	Benchmarks for Success
<i>Aim 1. Assess the impact of a sexual health empowerment intervention (SHE Project) on cervical health knowledge, barriers to screening that are related to beliefs about cervical cancer, and self-efficacy for screening and follow-up among women leaving jail.</i>		
<ul style="list-style-type: none"> <li>Develop SHE Project intervention</li> <li>Recruit 20 women to pilot test SHE Project</li> <li>Revise SHE Project after pilot testing</li> <li>Recruit 200 participants for SHE Project (given wait-list control design and number of women available for recruitment, each phase of recruitment will include ten groups of 20 women each, over a 7 month period)</li> <li>Assess immediate impact of SHE Project at end of 5-session intervention through participant self-report</li> </ul>	<ul style="list-style-type: none"> <li>Feasibility of implementing SHE Project</li> <li>Participant satisfaction with SHE Project</li> <li>Knowledge about cervical health</li> <li>Beliefs about screening for cervical health promotion</li> <li>Self-efficacy for screening, treatment, prevention for poor cervical health outcomes, and increased confidence in navigating providers and health care systems, given long-term criminal justice involvement</li> </ul>	<ul style="list-style-type: none"> <li>Development of intervention materials, IRB approval, pilot testing, and revision of intervention materials in Year 1</li> <li>SHE Project recruitment in Year 2 (N=200)</li> <li>SHE-Project impact assessment in Year 2</li> <li>Manuscript A describing intervention development submitted in Year 2</li> <li>Manuscript B describing Aim 1 results in Year 3</li> </ul>
<i>Aim 2. Using a three-year observational design employing both survey and ethnographic methods for follow-up, understand how knowledge, beliefs, self-efficacy, and other factors change post-release cervical health prevention behaviors over time.</i>		
<ul style="list-style-type: none"> <li>Recruit a sub-sample of at least 15 women for ethnographic study to follow over the 3-year study period</li> <li>Conduct 3-, 6-, 18-month, and 3-year <i>post-jail release</i> follow-up surveys</li> <li>Understand how knowledge, beliefs, self-efficacy, and other factors influence behaviors</li> <li>Understand how women navigate everyday social circumstances and health care encounters to engage in preventive reproductive health care</li> </ul>	<ul style="list-style-type: none"> <li>Reproductive health screening behaviors (including for Pap or STIs)</li> <li>Clinical follow-up, if necessary</li> <li>Strategies for navigating health care encounters (health literacy as social capital; structural barriers to preventive health behaviors; beliefs about health systems)</li> </ul>	<ul style="list-style-type: none"> <li>Ethnographic sub-sample identified</li> <li>~95% follow-up rate at 3 and 6 months, 85%, and 75% follow-up at 18 months and 3 years, respectively</li> <li>Manuscript C describing Aim 2 results based on 3-, and 6-month follow-ups in Year 4</li> <li>Manuscript D describing Aim 2 results based on 18-month and 3-year follow-ups in Year 5</li> <li>Manuscript E, F describing findings from ethnographic study in Years 4, 5</li> </ul>

Investigators. The PI of the study, *Megha Ramaswamy, PhD, MPH, Assistant Professor of Preventive Medicine and Public Health*, is a New Investigator who shows promise for a career in cancer control research, as evidenced by an excellent publication record in health promotion, eight years of experience in mixed methods criminal justice research, a strong academic trajectory, and recent funding in cancer prevention research from the American Cancer Society (ACS) and NCI (R03). She has been involved in the design, implementation, and evaluation of two intervention studies (both NIDA-funded) and has a current KL2 award. Dr. Ramaswamy received intensive training in ethnographic methods during doctoral study and employs quantitative and qualitative methods in her three recently funded studies. **As for grant management experience, Dr. Ramaswamy has been PI of three studies (ACS pilot, NCI R03, and KL2), and Coordinator and Research Associate of two separate NIDA R01s.** *Co-I and jail research collaborator, Patricia J. Kelly, PhD, MPH, APRN, Associate Dean for Research and Professor of Nursing*, has been funded by NINR, NCI, and DoD to do women's health research with women in jails and other vulnerable populations, with a particular emphasis on sexual health empowerment approaches to intervention. Two of her projects were health promotion interventions (NINR-funded). *Co-I and cancer control expert of this project, Kimberly Engelman, PhD, Associate Professor of Preventive Medicine and Public Health and Co-Lead of the NCI-CC KU Cancer Center Cancer Control & Population Health program*, is funded by NCI, NCMHD, Komen, and ACS to conduct breast and colorectal cancer screening and control programs among American Indian, Latina, and rural women in the U.S. Both Drs. Engelman and Kelly have served as Dr. Ramaswamy's mentors on her ACS study, the NCI R03, and on a CTSA KL2 study (KL2 RR033177, Ramaswamy PI of KL2 study), setting the foundation for Dr. Ramaswamy's success as an independent investigator. *Statistical support for the project will be provided by Co-I and statistician, Jaehoon Lee, PhD, Research Associate.* Dr. Lee is a statistician with the Center for Research Methods and Data Analysis (CRMDA). Personnel at CRMDA (including one director, two associate directors, nine PhD-level statisticians, and 25 graduate assistants) have been conducting longitudinal research for over 20 years. As of this submission, CRMDA is involved in over \$35 million in federal and state grants and contracts, including collaborations with Dr. Ramaswamy.

Previous Research. Over six months in Spring/Summer 2010, Investigators Ramaswamy, Kelly, and Engelman conducted a health care use assessment<sup>13,49,50</sup> with men and women (N=596) in three Kansas City jails (two facilities to be used for this study). Data collection for women was supported by an ACS pilot grant to Dr. Ramaswamy to study risk factors for cervical cancer and barriers to cervical cancer screening and follow-up care among women leaving Kansas City jails.<sup>13</sup> We found that the majority (84%) of participants reported being screened for cervical cancer in the last three years. Over one-third of all the women in the sample had an abnormal Pap in their lifetime (40.1%), but only 10% of the entire sample said they had ever been diagnosed with HPV. Eleven percent were diagnosed with cervical cancer, and 7% of the women said they received treatment for their cervical cancer. These data suggested that our sample of women got screened for cervical cancer with regular Pap smears, as others have demonstrated, but still had high risks for cervical cancer given high abnormal Pap rates and other sexual health risks (29.9% exchanged sex for drugs or money in their lives; 24.9% had a lifetime history of STDs; and 38.2% experienced childhood sexual abuse).

This study and unanswered questions about the women's cervical cancer screening health literacy led to a subsequent NCI R03 to Drs. Ramaswamy, Kelly, and Engelman. For one, 14% of our ACS sample reported getting Pap screenings in a hospital, although it is rarely a standard procedure to conduct Pap screenings among women in U.S. emergency rooms (though not in hospital clinics). How did the literacy of this group differ from that of women who visited a family physician for their screenings? This finding may have represented a misunderstanding of the distinction between Pap screening and pelvic exams – or simply a lack of understanding about Pap screenings – among disadvantaged women. For example Binswanger found that only 61% of women in jails could describe how health providers screen for cervical cancer.<sup>51</sup> Our findings suggested that we still did not have enough information about why high-risk women might fail to get follow-up after an abnormal Pap exam and led to our conducting an R03 study to understand the interpretation of abnormal Pap events and their subsequent follow-up from the perspective of incarcerated women. We found that though we recruited 45 women based on their self-report of abnormal Pap history in the last five years, half of the women misinterpreted abnormal Pap events as any reproductive health problem diagnosis, such as ovarian cysts, bleeding, and sexually transmitted infections. The women's misinterpretation of "abnormal Pap" was common, despite overall high general health literacy scores (91% scored adequately or high on the S-TOFHLA). Their cervical health histories were confounded by a variety of complex social problems ranging from lack of knowledge about procedures, romantic and sexual partner issues,

children, drug problems, issues with health care providers, fear, avoidance, and inability to navigate health care systems.<sup>11</sup> A first glance at the data made it very clear to us that the next logical step was to address their unique cervical health literacy needs. The S-TOFHLA failed to capture these women's misperceptions and difficulties in engaging in sexual health promotion and cervical cancer prevention. Therefore we propose the intervention, described below, that addresses incarcerated women's unique health literacy problems and the social context in which they occur.

**In June 2013, we conducted a small feasibility pilot with seven women. We successfully recruited and retained seven women for a one-week pilot at one of the jails. We developed a first draft of intervention materials and piloted these along with survey instruments. At the beginning of the intervention none of the women knew current Pap screening recommendations, but by the end 71% knew the recommendations. Immediately post intervention, we found increased scores in knowledge about cervical cancer ( $p=0.13$ ), decreased fear about cervical cancer ( $p=0.11$ ), increased self-efficacy for screening ( $p=0.61$ ), and increased confidence navigating providers and health systems ( $p=0.02$ ). We attribute lack of statistically significant results to small sample size ( $N=7$ ), but are optimistic that we can have a significant impact in the larger proposed study. We will use the pilot period of the proposed study to refine intervention materials and survey instruments.**

Intervention. The sexual health empowerment intervention (SHE Project) will be delivered in small group (cohort) format, based on our previous experience with delivering interventions in jails.<sup>52,53</sup> Each cohort will have approximately 10 participants, and we intend to run about 10 cohorts in each of two jails (see Settings below) for a total projected sample size of 200. To assess the impact of the intervention, we will employ a wait-list control design. It would be unethical to use an untreated control group, since we feel strongly that all participants would benefit from a reproductive health intervention beyond just providing pamphlets or some other form of basic self-directed health education. Our wait-list control design, along with the use of multiple cohorts, would provide for a sufficient sample and appropriate study design to test the intervention with a control group. For example, we will recruit first two cohorts of 10 women in jail facility 1 and randomly assign one cohort (10 women) to receive the intervention in Week 1 and the other cohort (10 women) to the wait-list control group to receive the intervention in Week 2. To account for turnover of women in the jails, we will wait one month before recruiting the next two cohorts in jail facility 1. We will repeat these procedures in Facility 2 (see Appendix 2 for sample recruitment/intervention delivery schedule). We estimate that this strategy will take seven months to recruit and deliver the intervention to a total of 200 participants in the two jails (100 in each jail facility). We will collect baseline data and one-week follow-up data for all 200 women. Once the participants assigned to the wait-list control group (100 women) have completed the baseline and first follow-up assessments, they will be given the opportunity to receive the intervention. We then will complete 3-, 6-, 18- month, and 3-year post-jail release follow-up surveys with all 200 participants to achieve the observational goals of Aim 2.

The intervention will consist of five-sessions, starting on a Monday of a week without a holiday and ending on a Friday. This format follows the structure of previous interventions that we have successfully conducted<sup>49</sup> and accounts for rapid turnover of women from jails. Because of this turnover, we will have limited time with each cohort of women and have found that a one-week, five-day/session intervention is feasible, effective, and reaches the largest number of potential participants. We anticipate low to no attrition over the five-day period (**verified, in part, through our June 2013 feasibility pilot**), and will recruit women who will be in the facility at least through the week. Each intervention session will last approximately two hours from 10am-12pm or from 1pm-3pm, given jail schedules (meals and court visits). Session 1 will include the baseline survey and might take three hours, and Session 5 will include a satisfaction survey (see Data Collection and Instruments below).

Table 2, below, describes the key components of the SHE Project. The intervention sessions are primarily organized around improving knowledge, reducing screening and treatment barriers related to beliefs, and improving self-efficacy and women's ability to navigate interactions with providers and health care systems, all of which is driven by the literature on health literacy,<sup>27,28,29,30,31,32,33,34,35,36,37</sup> Bourdieu's conceptualization of improving the ability to navigate social relations and changing participants' habitus/their orientation to reproductive health literacy,<sup>40</sup> and our own focus groups on incarcerated women's cervical health literacy (see Appendix 1). Secondly, the sessions are roughly organized based on Doak and colleagues'<sup>54</sup> recommendations for clinicians on improving

comprehension for patients with low literacy skills: give an agenda first, focus on behavior and action, provide context first and then information, use visual examples, and finally get feedback from participants. Finally, we have infused elements of sexual health empowerment, as described in the Innovation section of this application, that are sensitive to the women's social positions and the culture of ongoing criminal justice involvement.

The SHE Project will be delivered by Investigators (primarily Drs. Ramaswamy and Kelly – Ramaswamy has led focus groups in vulnerable populations in several studies, as well as has been recognized for her teaching and engagement of students for the last seven years; Kelly has been a women's health practitioner for the last 30 years); the Project Director (see Personnel – Mr. Pankey, has led interventions at KUMC for the last five years, including three of Dr. Ramaswamy's jail-based studies, and his own writing intervention in the jails<sup>52</sup>); and a group of trained students in the KUMC Master of Public Health (MPH) program. These students have been utilized in seven jail-based research studies in collaboration with Drs. Ramaswamy, Kelly, and Mr. Pankey. Engagement of students in research and delivering health interventions is both a smart utilization of resources, but also provides for an excellent opportunity for hands-on intervention and research experience with a high-risk and vulnerable population. Such student-faculty collaborations have resulted in 3 grant-funded studies, 4 publications, and 22 presentations for Dr. Ramaswamy's jail health research team. We also will bring in volunteer doctors, nurses, and jail medical staff so that participants can practice interacting with clinicians in mock scenarios, and openly ask questions both to build self-efficacy and confidence.

**Table 2. Key Components of Sexual Health Empowerment Intervention (SHE Project)**

**SESSION 1 KNOWLEDGE**

- Female body: review female anatomy with visuals, get women to talk about body parts with lay words (across race, class, cultural lines)
- Meaning of words: review cervical health words, such as "Pap, abnormal Pap, not normal, positive Pap, pelvic exam, colposcopy, HPV, malignant, terminal, sexually transmitted infection," and encourage women to talk about their understandings of these words
- Reading pamphlets: review standard cervical health education materials from NCI fact sheets, Planned Parenthood fact sheets, local health department fact sheets, fact sheets from women's health clinics at large local hospitals, and engage women in an open discussion about what works/what doesn't/what can be gleaned from written information
- Procedures and routine: How often do you need a Pap giving frequently changing recommendations? What happens during a pelvic exam vs. a Pap test? (demo by nurse), Why do doctors do a colposcopy, why important, what happens during test? Have women explain in their own words before nurse provides an explanation

References: Lindau et al (2002),<sup>42</sup> Hunter (2005),<sup>28</sup> Koay et al (2012),<sup>55</sup> Simon et al (2010)<sup>31</sup>

**SESSION 2 BELIEFS**

- Family perspectives: what did your mother say about sexually transmitted infections, pregnancy, cancer? What do you say to your kids? How do romantic or sexual partners react to your news about sexually transmitted infections, HPV, cervical cancer? Engage women in discussion about what kinds of information and beliefs get passed down to them, discussion facilitated by study staff
- **Race and culture: what stories have been passed down to you by family members about cancer and cervical cancer, in particular [note race/ethnic differences in kinds of stories]? Do you think your culture/where you came from/your race influences your beliefs about your health? How? What about your beliefs about cancer? Sex? Seeking health care?**
- Fear/"If it ain't broke": what fears do you have about cervical cancer screening? What motivates you to get screened?
- HPV vaccine: vaccine beliefs/experiences/knowledge/acceptability of vaccine for girls and boys/prevention/role of men in HPV transmission: get women to discuss openly, discussion facilitated by study staff
- Informed consent: review consent forms for research, procedures, surgery; get women to discuss how they feel about each, do they understand forms, do they feel used/like guinea pigs?
- Perceived susceptibility: who is at risk? What does "risk" mean in context of sexually transmitted infections, HPV, cervical cancer? After women discuss openly, practice risk communication with nurses/doctors for risk of cancer/success of treatment rates. Encourage women to ask questions to help them interpret meaning of "risk."

References: Hunter (2005),<sup>28</sup> Sharp et al (2002),<sup>30</sup> Vanslyke et al (2008),<sup>27</sup> Davis et al (2002),<sup>56</sup> Eggleston et al (2007),<sup>57</sup> Brewer et al (2009)<sup>58</sup>

### SESSION 3 SELF-EFFICACY

- Interpreting the Pap test: have guest nurses/doctors come in and deliver letters, phone messages, verbal “results” for Pap test, abnormal Pap tests, and follow-up instructions. Get women to critique delivery – what works, what doesn’t, and ask questions about meaning of words, what are “right” questions to ask?
- Navigating Kansas City: get women to engage in a discussion about how to navigate free or low cost services locally, transportation options. Use women’s own experiences to illustrate methods for navigating but also have study staff do survey of where to go, where to follow-up for free or low cost.
- Navigating the Web after jail: what are the most useful, timely, user-friendly resources on the Web for sexual, reproductive, and cervical health information? Practice navigating the Web with women.
- Risk factors: open discussion of role of smoking, drug use, alcohol in women’s lives; sexually transmitted infection-type problems and other gynecological infections, get women to brainstorm ways to prevent these problems/barriers to preventing/reality of women’s lives. Brainstorm strategies for safe sex given drug use, partners who cheat, having multiple sex partners, abuse

References: Hunter (2005),<sup>28</sup> Davis et al (2002),<sup>56</sup> Lindau et al (2006),<sup>29</sup> Enders et al (2005),<sup>59</sup> Simon et al (2010),<sup>31</sup> Lindau et al (2002),<sup>42</sup> Binswanger et al (2011),<sup>60</sup> Gonzalez et al (2008)<sup>61</sup>

### SESSION 4 NAVIGATION OF PROVIDERS AND SYSTEMS

- Trust: what are range of trust issues with nurses, doctors, clinicians in jail: get women to discuss openly
- Jail and prison health: if you have to seek health services while incarcerated, how do you get preventive screening? Have women talk about issues openly, and then bring in jail medical staff to talk about barriers, rules, then talk to women openly again post-discussion (without jail staff)
- Stigma: how to go to doctor or hospital without fear of being reported to police? Review options for *avoiding* police reporting in health care settings. Talk openly about how women think clinicians perceive them based on their criminal justice status.
- **Race/ethnic discrimination: do you ever feel discriminated against because of your race/ethnicity? In particular, do you feel this kind of discrimination when you go see a doctor, nurse, or go to a hospital? Review scenarios/strategies for which women can be more comfortable in health care encounters, e.g. clinicians of same race/ethnicity? Clinicians more understanding of everyday discrimination and stigma?**
- ER care: review local health care options from Session 3; review when it’s appropriate to go to ER and other options, as well as motivations to use ER for sexual, reproductive, and cervical health
- Social support: who can go with you to clinic visits? Do you want/need someone to go, or not? What are benefits and pitfalls of social support?

References: Magee et al (2005),<sup>62</sup> Lindau et al (2006),<sup>29</sup> Enders et al (2005),<sup>59</sup> Simon et al (2010),<sup>31</sup> Eggleston et al (2007),<sup>57</sup> Elwood Martin et al (2004),<sup>9</sup> Plugge et al (2004),<sup>63</sup> Goffman (2009)<sup>64</sup>

### SESSION 5 WRAP-UP

- Leftovers: review any material from Sessions 1-4 that did not receive enough attention/discussion
- Wrap-up exercise: have participants make their own sexual, reproductive, cervical health materials that represent values, languages, experiences associated with their own culture and challenges of ongoing criminal justice involvement
  - Brainstorm values, languages, experiences that help women understand issues/take action
  - Brainstorm what kinds of information women would pass on to their sisters, daughters, friends, fellow inmates
  - Start creating materials: pamphlets, drawings, resource boxes to be placed at jail, voice recordings, etc.

References: Mangan et al (2006),<sup>65</sup> Doak et al (1998)<sup>54</sup>

Settings. Participant recruitment will occur within two county jails that serve the greater Kansas City metropolitan area. These two jails straddle the Kansas/Missouri state line, and are about five miles apart. Jackson County Detention/Regional Correctional Center (Kansas City, Missouri) has an average daily population of 814 adult inmates. At this facility, on average more than 90 percent of the inmates are awaiting trial, meaning that only 10 percent of detainees are in the post-trial phase of incarceration. Wyandotte County Detention Center is a consolidated jail between the Unified Government of Wyandotte County/Kansas City, Kansas, Bonner Springs, Kansas, and Edwardsville, Kansas. This facility holds both adult and juvenile inmates, though only people aged 21 and over will be enrolled in this study, since few women under this age receive routine Pap screenings. Adults housed in the detention center are either awaiting sentencing for misdemeanor convictions or have been sentenced. The average daily population of the adult facility is approximately 300 inmates – there are beds for 289 males and 38 females. Both of these jails were selected because they represent the county jails in the center of Kansas City on both sides of the state line. We also have conducted several pilot projects at each of these facilities. Though women make up a much smaller proportion of people in jails (about 10%), in our pilot study we found that it took four months to recruit 200 women in these facilities, given turnover and number of women available to recruit. We also estimated that about half of all female inmates were willing to participate in our pilot studies. We plan to randomize within each facility (i.e., randomized block design), since each facility has its own culture and may influence women’s participation in the intervention.

Post-jail release follow-up interviews will take place in two locations. For Kansas City, Missouri participants,

interviews will be conducted at the Kansas City, Missouri Health Department, which is centrally located and widely used by people in the community according to our pilot research. For Kansas City, Kansas participants, interviews will be conducted at the Wyandotte County Health Department, a centrally located clinic that also provides women's health services. Both health departments are located within one mile from each facility. We will provide bus passes to all participants to facilitate these visits. These sites provide comprehensive women's health services, if participants seek out care at these facilities during the course of the study.

Ethnographic follow-up (participant observation) will occur as needed in the community. Participant observation is the study of micro interaction to elucidate macro social processes. It entails spending time with participants and observing them as they navigate the environment, institutions, agencies, and interpersonal relationships in their communities. In our KL2 study that is ongoing, formerly incarcerated participants have been willing to meet us at community locations and have been open to study staff accompanying them to public locations in the community, as well as personal homes. As a safety precaution for all parties involved, we will only ever send teams of two study staff members on ethnographic visits in the community – to homes, clinics, or hospitals, for example. All study staff will have study cell phones in case of emergency.

Participant Eligibility/Recruitment. Participants will be eligible if they are sentenced or anticipate a sentence of one year or less, in order to ensure that we recruit a sample we can follow into the community. The ability to follow people into the community will result in higher use of health services and community-based health-seeking behavior post-release. We will recruit English-speaking participants only, given that less than 10% of the local jailed population is Latina. In previous research at these facilities we found that almost all of these Latina women are fluent in English. Women aged 21 and over will be enrolled in this study, since few women under this age receive routine Pap screenings. Medical exclusions for the study will include those women who have been treated for cervical cancer with procedures that would obviate the need for regular screening (one of our outcomes for Aim 2). We also will exclude participants who exhibit severe psychological distress that prohibits them from participating in our intervention or long-term research program. We will screen for eligible participants through word of mouth (via jail special programs staff) and by posting recruitment flyers in the housing units. We will use a recruitment flyer that might say, "Are you interested in participating in a study about your sexual health?" Such a recruitment technique has been feasible in several past studies that we've conducted.<sup>11,13,47,48,49</sup> Prior to reviewing informed consent documents with participants, we will use screening questions to determine eligibility, which has been successful in our previous jail-based studies.<sup>50</sup>

Attrition/Retention. In pilot studies<sup>13,49,50,52</sup> we found that on average women had been in Kansas City jails for 2.7 months. **In a previous intervention study<sup>52</sup>, we had no attrition during the one-week intervention period. For the follow-ups, we expect the following rates of attrition based on our prior experience: ~5% attrition at 3 and 6 months, 15%, and 25% attrition at 18 months and 3 years, respectively.** In order to conduct the 3-month, 6-month, 18-month, and 3-year *post-jail release* follow-up visits, we will maintain contact with participants using multiple methods: multiple points of phone contact, mailing letters to reach out to participants, attempts to locate them either at their reported place of residence upon discharge from jail, phone and address contact for participants' closest family member or friend, or we will contact the respective jails to check if participants have returned, all of which are strategies that have been successful in our studies.<sup>53,66</sup> In our own studies<sup>53,66</sup> these methods have resulted in as high as 75-85% follow-up rates up to one year after participants' release from jail. These same methods will be employed to maintain contact with a subsample of participants (N=15) for ethnographic follow-up, but may also include collection of much more comprehensive data about how to find participants. For example, we might ask this subsample for contact information for close family members or friends, a probation officer, favorite hangout, or social media account contact information. These methods, as well as including reasonable compensation for participation (see Human Subjects section), have helped us avoid problems with attrition in previous studies. Moreover, we have found that by conducting an intervention with incarcerated participants, we are able to build enough rapport with participants to facilitate high rates of follow-up.<sup>53,66</sup>

Sampling. For Aims 1 and 2, we plan to recruit a sample of 200 women from the two county jails described above (with about 100 women from each jail). Though we will not purposefully sample by race, Blacks make up 40% of the Kansas City jail population and Whites make up 40%. We will approach all people who are eligible to participate. Given an expected denominator of about 150 women at any given time across the two jails, rapid

turnover of female inmates, and based on prior experiences of recruitment of women in these jails, we estimate about half the population of women on any given day will be interested in participating. In prior studies, our sample was similar to people who did not participate in the study based on sociodemographic and criminal justice characteristics.<sup>13,49,50,52</sup> We will conduct a similar assessment after recruitment is completed. Sample size was determined to provide sufficient power for addressing our specific aims and expected outcomes. Power calculations using G\*Power 3.0.1.<sup>67</sup> indicated that our sample size proposed for the Aim 1 analysis (200 women) will achieve 80% power in testing a small to medium difference between the intervention and control groups (group effect as small as  $f = 0.16$ ), assuming a correlation of 0.30 between repeated measures. This sample size also is expected to provide 80% power for detecting a small change from baseline to 1-week follow-up (time effect of  $f = 0.12$ ) as well as a small group by time interaction effect ( $f = 0.12$ ). **For Aim 2 analysis, with our sample of 128 women after attrition (an ethnographic sample of at most 30 women drawn from the 200 participants will be excluded from hypothesis testing and we expect 75% follow-up rate at 3 years;  $(200-30)*.75=128$ ), we will have 80% power to assess the impacts of intervention components in the small to medium range (as small as  $f = 0.17$ ).** Our statistical models will include covariates, thereby further increasing power. In addition, the statistical power for our randomized block design (i.e., randomization within each jail) is expected to remain higher than the power for a cluster randomized design even when potential contamination between intervention and control participants causes the true intervention effect to decrease by as much as 10-60%.<sup>68</sup> Taken together, we believe this study will achieve adequate power in testing the hypotheses about the effects of the SHE Project intervention. For the ethnographic component of the study, we plan to recruit a subsample of 15 women who would be willing and able ("ability" includes being able to provide several types of contact information and information about a social network through which we can contact participant, for example) to participate in long-term follow-up in the community over the 3-year period. Follow-up would include accompanying the women to clinic visits, visits for health screenings for the women themselves or their children, or being with women as they make follow-up phone calls to clinicians or process information about health visits received through the mail. In the process of trying to facilitate our presence for these events, we will also visit with the women in the subsample on a regular and more casual basis (monthly in the first year and bimonthly or quarterly in the years after) in order to build rapport and establish trust with the women. We will volunteer ourselves as drivers to health appointments or offer to have one of our staff members sit with children in clinic waiting rooms, as part of this rapport and trust-building process. To the extent possible, these encounters will be solely observational. If ethnographers become involved in facilitating any preventive health behaviors, then those encounters will be documented as part of the ethnographic process, which is not uncommon to this method of research.<sup>69</sup> In addition and to avoid contamination of the quantitative results, we will exclude this subsample of women from hypothesis testing. The sample will be drawn from the original 200 participants who participate in the study. We will approach about half of the participants from one facility and half from the second facility to be included in this study. We will choose women based on their interest in ethnographic follow-up (which will not be compensated monetarily so as to avoid coercion based on money) over the three-year study period. We will over-recruit for the ethnographic sample (to **45 participants**), expecting that some may no longer be interested in long-term follow-up or not available for follow-up for reasons beyond the researchers control, e.g. cannot locate women in community. Ultimately, the recruitment of **at least 15 women for in-depth study (and no more than 30)** should be sufficient for us to achieve our analytic aims. Based on our own previous research,<sup>11,70</sup> we believe we will reach thematic saturation with this sample size. However, if we find that more participants are needed, and if we have problems with attrition in the ethnographic study, **we have budgeted for recruitment of additional participants.**

Outcomes and Instruments. Data collection and instruments for this pilot study correspond to the outcomes outlined in the objective and in Aim 1: addressing cervical health knowledge, beliefs, self-efficacy, and confidence in navigating providers and health care systems. Aim 2 also will examine preventive health behaviors related to reproductive health in these women's lives. Outcomes and instruments are listed in Table 3, below (instruments are included in Appendix 3; areas of interest for ethnographic study are listed in Appendix 4). For Aim 1, we will conduct pre- and post-intervention assessments using surveys at baseline and at the end of the 5-session intervention. Longitudinal follow-up and Aim 2 will include assessments at a 3-, 6-, 18-months, and 3-years *post-jail release*, in addition to ethnographic follow-up of a subsample of women.



<b>Table 3. Data Collection and Instruments</b>	
<b>Aim 1 Outcomes</b>	<b>Aim 1 Data Collection/Instruments</b>
Knowledge about cervical health	Pap Knowledge Scale <sup>71</sup>
Beliefs about screening for cervical health promotion	Health Belief Model Scale for Cervical Cancer and Pap Smear Test <sup>72</sup>
Self-efficacy for screening, treatment, and prevention for poor cervical health outcomes	Self-Efficacy Scale for Pap Smear Screening Participation <sup>73</sup>
Confidence in navigating providers and health care systems, given long-term criminal justice involvement	3 questions developed specific to women with criminal justice involvement and based on qualitative preliminary data collection (used in our NCI R03)
Participant satisfaction with intervention	10-question satisfaction survey
<b>Aim 2 Outcomes</b>	<b>Aim 2 Data Collection/Instruments</b>
Reproductive health screening behaviors (including Pap and/or STIs) Clinical follow-up of screening, if necessary	Self-report of screening and clinical follow-up <b>(with medical record validation of screening/follow-up for subsample of 20 participants)</b>
Strategies for navigating health care encounters (health literacy; structural barriers to preventive health behaviors; beliefs about health systems; <b>culture and health care seeking</b> )	Ethnographic study of participants' clinically relevant events (see below for details under Data Collection section, as well as Appendix 4)

**For the Aim 2 outcomes of screening behaviors and clinical follow-up, we will employ medical record validation of self-report for a subsample of 20 participants. To do this, we will utilize methods that we used in our preliminary R03 study with success. At the 18-month follow-up, we will request permission to retrieve medical records for the first 20 women who reported screening in the past 18-month period using a standard IRB-approved medical record release form. We will negotiate access to medical records with providers (which we have done for our R03 study already for several Kansas City providers); pull medical records for participants' screening and follow-up events; and describe congruence between women's self-report of events and medical records. We will end the validation study once we have 20 medical records for participants who have completed the 18-month follow-up. Thus, we will be able to report the congruence between self-report and medical record review for a subsample of participants when we report follow-up results for the entire sample.**

Data Collection. Data collection through surveys will be conducted using paper and pencil instruments. Research staff will administer surveys one-on-one during follow-up interviews. During the intervention period (pre-and post-assessment), staff will pass out surveys to participants, and read questions and all response options with the group of participants. Such a method has been employed in our previous work and has minimized problems due to low literacy levels in this group of women (though we found that 70% of women in our local jails had a high school education or GED).

During ethnographic observation, research staff, who will be trained in ethnographic methods, will take fieldnotes during the encounters, and then longer, more detailed notes immediately upon leaving the participants. In addition, and when possible, research staff will ask permission to audio-record encounters. The goal of such observation is to document the women's strategies for navigating health care encounters – the way they think about, talk about, and interact with the health care system.

To undertake the ethnographic fieldwork, we will focus on four processes during data collection and interpretation:<sup>74</sup>  
 1) Description of the setting, with a particular focus on documenting health care settings and how women get to them in narrative form; 2) Reflexivity, which is taking into consideration our place as ethnographers in the field and in our interactions with the women; 3) Micro interaction or spending time with participants, documenting conversations, practices, and participants' interpretation of events; 4) Theory and focusing on micro-macro connections from data. In other words, how do observations of micro interactions reveal broader social processes? Our guiding theoretical framework will be Bourdieu's notion of **social relations and how a health literacy intervention can help women better navigate health information and systems**. How do women leverage their health literacy to navigate ongoing criminal justice involvement, community reentry, family, romantic and sexual partners, **cultural beliefs about health**, and health services? What are the everyday barriers to preventive health care as the women move through their lives and communities? How do the women process health information in

the context of health systems, culture, and society, and how can that ultimately influence their health seeking behavior and health outcomes?

Data Management and Analysis. Survey data will be processed by Captricity, a company that transforms paper data into electronic databases, such as in Excel or SPSS. De-identified paper surveys will be scanned and sent securely to Captricity for processing. Captricity will send back a secure and password-protected data file. Since Captricity is a third party, they will be blinded to the experimental conditions of the study. At a logical timepoint, CRMDA staff will check data for outliers and normalcy. Questionable data will be re-checked for accuracy and re-entered if necessary. Captricity files also will allow researchers to check paper data against electronic data easily. Using this company will obviate the need for double data entry, will help us avoid making mistakes during data entry, and will allow us to engage study personnel in other aspects of the study – implementation, analysis, and dissemination. We have used this service in prior studies and it has saved considerable time, making it preferable to using students or staff for data entry. All key personnel will have current Human Subjects and HIPPA training certificates. Researchers will work with the IRB to ensure that management of survey data with a third party meets all ethical and security requirements.

We will summarize sample sociodemographics and outcome measures using descriptive statistics and examine their distributional properties within and between the intervention and control groups. To address the primary aim of this study (Aim 1), **for which we hypothesize the intervention will improve cervical health knowledge, reduce barriers to screening related to beliefs about cervical cancer, and improve self-efficacy for screening and follow-up**, mixed models will be fitted with the baseline and 1-week follow-up data in order to estimate the intervention effects – time effect (change from baseline to 1-week follow-up), group effect (i.e., overall group difference across time), and their interaction effect (group difference in change). Models will be adjusted for the participants' sociodemographic (**e.g. for racial and ethnic differences, for example**) and criminal justice characteristics as well as the jail characteristics (i.e., site differences), particularly if they are imbalanced after randomization, thereby improving the accuracy of the effect estimates. A proper error covariance structure will be chosen for each outcome based on model fit indicated by model likelihood, Akaike Information Criterion (AIC), and Bayesian Information Criterion (BIC). **For Aim 2, we hypothesize that the intervention will improve appropriate rates of screening (based on current guidelines) and clinical follow-up, where necessary.** Similar to our analysis for Aim 1, mixed models for discrete outcomes will be fitted with the 3-, 6-, 18-month, and 3-year follow-up data to examine the influences of intervention components (knowledge, beliefs, self-efficacy) and other factors (cost, transportation, ongoing criminal justice involvement, etc.) on post-release cervical health prevention behaviors (Aim 2). Also, we will examine the (linear, quadratic, cubic, etc.) pattern of change over time as well as its interaction with the intervention components. Statistical significance will be determined at 0.05 alpha level and all analyses will be conducted using SAS 9.3.<sup>75</sup>

Our data will include missing observations that may be related to either attrition or nonresponse which can be reasonably assumed to be missing due to known characteristics of our database (i.e., missing at random). Thus, incomplete data will be handled by utilizing Monte Carlo Markov Chain (MCMC) multiple imputation. A large number (e.g., 50-100) of imputed datasets will be created via using expectation-maximization algorithm as prior estimates for subsequent MCMC procedure,<sup>76</sup> and then results from each complete dataset will be combined to make valid statistical inferences.<sup>77</sup> This approach will allow us to include all selected variables in the imputation process, which allows for greater recovery of the missing data.<sup>78</sup> It is possible that some women will reenter the jail facility during the recruitment period. In order to avoid re-randomizing these same participants, we will collect basic identifying information recruitment (name, DOB, race) so that we can double check to see if the participant already is enrolled in our study.

For the ethnographic component of Aim 2, we will employ a grounded theory approach for the analysis, meaning that data collection, management, analysis, and theory development will occur simultaneously.<sup>79</sup> Conversations with participants, and when possible - interactions with providers - will be audio-taped with a digital recorder. Research staff will take detailed field notes during all ethnographic follow-up, and all materials will be transcribed. Transcriptions will be checked against the original recordings to ensure accuracy.

Open coding will be used for delineating conceptual categories for each transcription, and previous transcription coding will be kept in mind for analysis of subsequent data. Each researcher will read through the transcripts and open-code each transcript independently, in order to establish inter-rater reliability. Dominant themes will be extracted from these transcripts and guided by our theoretical framework outlined in the Innovation section of this application. To compare ethnographic findings to surveys, the mixed method analytic approach suggested by Creswell and Clark<sup>80</sup> will be used. The following questions will guide the analysis: To what extent do qualitative and quantitative data converge? To what extent do ethnographic data support any trends found in surveys and vice versa? As described above, research reports will be organized according to four areas, where possible: settings (our participants in the context of community dynamics), reflexivity (ethnographer-participant interaction), micro interaction (participants in action), and theory (overall framework for interpreting data, linking micro interactions to macro social processes).

Human Subjects. We realize that jail inmates represent a vulnerable and understudied population, particularly for participation in research and trials. Because the investigative team has conducted in research in jails and prisons for over a decade in New York City, San Antonio, and Kansas City, we are fully aware of the care and diligence required in protecting this population by working with our Institutional Review Boards, correctional facility administrators, community-based resources for our participants, and most importantly – protecting the confidentiality and rights of our participants by listening to them and respecting their decisions. We have also been very clear in previous work to distinguish ourselves from correctional operations and communicate our independence from criminal justice proceedings (e.g. that participation or lack of participation in the study will not have any impact on time of release from jail). We will make every effort to protect our participants, and have designed the study such that participants in both arms will receive some type of health information. A full description of our human subjects protections strategies is provided in a separate section of this application.

Feasibility and Impact. The aims and activities for the proposed project are feasible since all investigators on the team have conducted health behavior interventions and have successfully conducted jail research in several jurisdictions around the country. Drs. Ramaswamy, Kelly, Engelman, and Lee also have the quantitative and qualitative experience to achieve the analytic goals of the project. The public health impact of this study is its potential to reduce reproductive health morbidity and mortality for this high risk and vulnerable group of women. This study will have an impact on the field in its contribution to the dissemination of strategies to improve reproductive health literacy and health outcomes in high risk incarcerated women, given the unique challenges this group of women face.

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