The Impact of Race on Cancer Health Prevention Behaviors in the Presence of a Patient-Family Communication Intervention

Study Identification

1. *Select the Principal Investigator:
   John Quillin

2. *Study Title:
   The Impact of Race on Cancer Health Prevention Behaviors in the Presence of a Patient-Family Communication Intervention

3. *Is this a student or trainee project in which activities will be carried out by that individual under your supervision:
   - Yes
   - No

4. Select any associated VCU IRB protocols:
   - ID PI
     HM12164 John Quillin

5. Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:
   - Last Name First Name E-Mail Phone Mobile
   - White Jessica whitejc5@vcu.edu

ID: HM20000021
View: SF - Research Determination

Student/Trainee Investigator Contact

1. *Name:
   Jessica White

2. *VCU Email:
   whitejc5@vcu.edu

3. *Phone:
   631-546-8931

ID: HM20000021
View: SF - Federal Regulations

Research Determination

1. *Select one of the following that applies to the project:
   - Research Project or Clinical Investigation
   - Exception from Informed Consent for Planned Emergency Research
   - Humanitarian Use of Device for Treatment or Diagnosis
   - Humanitarian Use of Device for Clinical Investigation
   - Emergency Use of Investigational Drug, Biologic or Device
   - Treatment Use (Expanded Access to Investigational Product for Treatment Use)
   - Center or Institute Administrative Grant Review
Federal Regulations

1. Is this a Clinical Trial:
   - Yes
   - No

2. Is this an Applicable Clinical Trial that must be registered and reported to clinicaltrials.gov:
   - Yes
   - No

3. Is this a FDA regulated study:
   - Yes
   - No

4. Is this study supported by the Department of Defense (DoD):
   - Yes
   - No

5. Check if any of the following funding sources apply to this research:
   - None of the above

Personnel

1. Indicate all VCU/VCUHS personnel that will be engaged in this study:

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
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<th>Responsibilities</th>
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<td>Donna McClish</td>
<td>Statistician</td>
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<td>Rosalie Corona</td>
<td>Co/Sub-Investigator</td>
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2. Identify all non-VCU personnel who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution:

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<thead>
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3. CV/Biosketch: (required for PI, Medically/Psychologically Responsible Investigators and Student/Trainee Investigators)

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Conflict of Interest

1. * To the best of your knowledge, do you (as PI) or any other engaged individual hold a financial conflict of interest related to this study?
   - [ ] Yes
   - [x] No

2. If Yes, provide:
   - Name(s) of the engaged conflicted individual(s)
   - Brief description of the financial conflict of interests

3. * Describe any potential non-financial conflicts of interest for members of the research team that could impact the conduct of the study (if None, please state "None"):
   - None.

4. Describe any institutional conflict of interest with this research that you or any member of the research team may be aware of:
   - None.

Communication Plan for Research Team

1. * Describe the process that will be used to ensure that all persons at all involved sites assisting with the research are adequately informed about the protocol and their research related duties and functions:
   - Weekly meetings have been established between the PI and the student researcher to maintain consistent communication. Email will be used as the main method of communication for the time between the weekly meetings.

IRB Panel Setup

ID: HM20000021
View: SF - Communication Plan for Research Team

ID: HM20000021
View: SF - IRB Panel Setup

ID: HM20000021
View: SF - Review Setup
1. To which IRB is this study being submitted for review:

- VCU IRB
- Western IRB
- NCI Central IRB
- Other IRB (Request to Defer to Another Institution)

ID: HM20000021  View: SF - Exempt Categories & Certification

Review Setup

1. Does this study involve greater than minimal risk:
   - Yes
   - No

2. Review Type Requested: (subject to IRB approval)
   - Full Board
   - Expedited
   - Exempt

ID: HM20000021  View: SF - Research Description

Exempt Categories & Certification

1. NOTE: If the entire study is not covered by one or more of these categories, this study does not qualify for exempt review.

Select all Exempt Categories that apply to this study:

- Category 1 Educational Strategies, Curricula or Classroom Management Methods
- Category 2 Educational Tests, Surveys, Interviews or Observations of Public Behavior, Not Including Children or Elected Officials
- Category 3 Educational Tests, Surveys, Interviews or Observations of Public Behavior of Elected Officials
- Category 4 Secondary Data Analysis of Existing Data, Documents, Records or Specimens
- Category 5 Federal Department or Agency Research and Demonstration Projects for Evaluation of Public Benefit/Service Programs
- Category 6 Taste and Food Quality/Consumer Acceptance Studies (No Additives or Safety Questions)

ID: HM20000021  View: SF - Study Activities

Research Description

1. Describe the study hypothesis and/or research questions. Use lay language whenever possible.

We hypothesize that health behavior compliance will be lower in African Americans than in women of other races prior to the KinFact intervention due to their lower level of knowledge and awareness of cancer health prevention options. We hypothesize that due to the lower level of knowledge and awareness at baseline, African American women will demonstrate a more significant improvement in health behavior compliance following the KinFact intervention. We predict that the KinFact intervention will create a more equal level of knowledge and awareness among participants of all races.
2. **Describe the study's specific aims or goals. Use lay language whenever possible.**

The aim of this study is to assess the impact of a patient-family communication intervention on health behavior differences for BC and CC (chemoprevention, mammography, and colonoscopy) between African American participants and non-African American participants.

3. **Describe the study's background and significance, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

The mortality rates of breast cancer (BC) and colon cancer (CC) in African American women is higher than in Caucasian women. This may be attributed to lower adherence to cancer screening recommendations in African American populations. Research has shown that low cancer prevention rates among African American women may be due to a lack of knowledge and lower reports of physician recommendation (Fair 2012; Kinney 2001; O’Malley 1997). Educational interactive interventions have been shown to improve knowledge and adherence to cancer prevention screening practices in this population (Champion 2006; Lerman 1999; Russell 2010). Other studies have shown that increased communication from health care providers and among social groups has a positive effect on cancer health behaviors (Kinney 2005). The KinFact study (IRB # HM12164) used an intervention that included educational information, risk assessment, and familial communication. This unique combination addresses multiple areas of importance – general knowledge of cancer and genetics, personal cancer risk perception and actual risk, familial role in heritable cancers – in one succinct intervention. This study will examine a moderating effect of race for the KinFact intervention impact on cancer prevention health behaviors.


4. **Briefly describe the study design, including all interventions or interactions with research participants and access to identifiable data. Use lay language whenever possible.**

This research will be conducted from secondary data analysis. The data used will be from the KinFact study (IRB # HM12164), led by principal investigator, John Quillin. The data being analyzed were collected from the baseline surveys and follow-up surveys. These surveys measured family cancer communication, cancer screening and prevention behaviors, risk perception, and demographic information. De-identified data from these surveys have been entered into a Microsoft Access database and are housed within a secure server in the Department of Human and Molecular Genetics at VCU. Aside from data within the surveys, information from electronic medical records (EMR) is being collected as part of the parent study to determine if participants had a mammogram or colonoscopy post-baseline. Review of this information is necessary to supplement the large amount of missing data from follow-up surveys regarding participant health screening behaviors. Permission to access EMR was obtained from all participants at the beginning of the KinFact study via a signed HIPPA authorization regarding use of their personal health information.

Statistical analysis of these data will be conducted using SAS 9.3. We will compare the rates of three different cancer screening and prevention health behaviors (chemoprevention, mammography, and colonoscopy) between African American participants and non-African American participants at baseline in both the control and treatment groups. We will then compare the rates of the control group and the treatment group up to 14 months. The rate of change in uptake of cancer screening behaviors following the intervention will be compared between African American participants and non-African American participants. We anticipate analyses will utilize a linear regression model with an interaction term for race. If the interaction term is significant (p < 0.10) we will conduct subgroup analyses. The graduate student will work with the PI and KinFact biostatistician to create and conduct a detailed statistical plan.

5. **Upload any supporting tables or documents:**

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Study Activities

1. *Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.*

- Bio-Medical
- Qualitative - Social/Behavioral/Education (SBE)
- Quantitative - SBE
- Mixed Method - SBE
- Mixed Method - Biomedical

2. *This study will involve (check all that apply):*

- procedures such as surveys, interviews, field studies, focus groups, educational tests, deception, psycho-physiological testing, any other similar data collection
- secondary data analysis: procedures such as analysis of information collected for non-research purposes (includes both retrospective and prospectively collected information), or analysis of data previously collected for a prior research study
- drugs, devices, experimental interventions, biohazards, radiation, other medical or surgical procedures

Social/Behavioral Project Details

1. *Select all that apply to this study:*

- Analysis of Information Originally Collected for Non-Research Purposes
- Analysis of Data Originally Collected for a Previous Research Study
- Behavioral Intervention or Experimentation
- Observations
- Educational Settings/Assessments/Procedures
- Population Based Field Study
- Psychophysiological Testing
- Deception
- Oral History
- Interview/Focus Groups
- Surveys/Questionnaires/Psychometric Testing
2. * Will any portion of the research be potentially upsetting to the participants:
   - [ ] Yes
   - [x] No

3. If Yes, describe the nature of the questions and how you will manage the situation should participants become upset:

4. Upload ALL instruments/guides that will be used, including scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc.:

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ID: HM20000021

View: SF - HIPAA

Data Collection Details

1. * Select all involved in the study:
   - [ ] Specimen/Biologic Sample Collection
   - [x] Protected Health Information (PHI)
   - [ ] Audio/Video
   - [x] Existing Data or Specimens Not From a Registry or Repository
   - [ ] Use of Internet for Data Collection
   - [ ] Registries/Repositories (Includes Accessing, Contributing or Creating)
   - [ ] None of the Above

2. * Select all identifiers that will be collected as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:
   - [ ] Names
   - [ ] Geographic Locators Below State Level
   - [ ] Social Security Numbers
   - [x] Dates (year alone is not an identifier)
   - [ ] Ages >89
   - [ ] Phone Numbers
   - [ ] Facsimile Numbers
### E-mail Addresses

- [ ]

### Medical Record Numbers

- [ ]

### Device Identifiers

- [ ]

### Biometric Identifiers

- [ ]

### Web URLs

- [ ]

### IP Addresses

- [ ]

### Account Numbers

- [ ]

### Health Plan Numbers

- [ ]

### Full Face Photos or Comparable Images

- [ ]

### License/Certification Numbers

- [ ]

### Vehicle ID Numbers

- [ ]

### Other Unique Identifier

- [ ]

### No Identifiers

- [ ]

### Employee V#

- [ ]

3. If "Other Unique Identifier" was selected above, describe the identifiers:

- [ ]

4. *Will participants be able to withdraw their data (paper, electronic, or specimens) from the study if they no longer wish to participate:
  - [ ] Yes
  - [ ] No

5. If yes above, describe how participants will be able to withdraw their data:

   At the time of informed consent participants were told they could withdraw from the study at any time by contacting the KinFact study coordinator, PI, and/or VCU IRB. Phone numbers, mailing addresses, and email addresses were provided to participants.

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**HIPAA**

1. *Describe the protected health information that will be obtained or used in this research:

   We will obtain information regarding breast and colon cancer health screening behaviors. Specifically, mammogram and colonoscopy procedures and discussions with their health care providers about breast cancer chemoprevention (e.g., tamoxifen).

2. *Describe the source(s) of the protected health information:

   VCUHS medical records; Directly from the research participants (e.g. responses to surveys)

3. *Explain how the PHI collected or used in this research is the minimum necessary to accomplish this research:

   Review of patient medical records is necessary due to the large amount of missing data regarding participant health screening behaviors. Obtaining this information from medical records is consistent with the signed informed consent collected from participants. By accessing medical records, we will not have to re-contact participants, thus avoiding placing an additional research burden on them.

4. *Select all pathways this research will employ to use or access PHI:

   - [ ] De-Identified Data
   - [ ] Limited Data Set
   - [ ] Waiver of Authorization
   - [ ] Partial Waiver of Authorization
   - [ ] Signed Authorization Combined with Consent Form
   - [ ] Signed Authorization as Stand-Alone Form
Existing Data/Specimen Details

1. Describe the source and nature of the data/specimens being obtained:
   Data was collected from surveys at the Women's Health Clinics in the VCU Health System.

2. Describe how you have access to the data/specimens:
   De-identified data from the surveys have been entered into a Microsoft Access database and are housed within a secure server in the Department of Human and Molecular Genetics at VCU.

3. Describe any identifiers or coded information that will be obtained that can be linked directly or indirectly to the identity of participants:

   Medical record numbers and dates of health prevention behaviors will be used in this research. These data may be linked directly to the identity of the participants.

4. Did individuals provide consent for research when the data / samples were originally collected?
   - Yes
   - No

5. If yes, did the consent allow for sharing of the data:
   - Yes
   - No

Data Confidentiality and Storage

1. Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. Describe all of the precautions that will be used to maintain the confidentiality of identifiable information, samples or specimens:
   Paper-based records will be kept in a secure location and only accessed by authorized study personnel. Electronic records will be made available only to those personnel in the study through the use of access controls and encryption. Identifiers will be removed from study-related data (data is coded with a key stored in a separate secure location).

2. Who will have access to study data:
   John Quillin, Jessica White, Donna McClish, Rosalie Corona

3. If applicable, describe the process for assigning codes to the data including:
   - how codes will be assigned
   - whether there will be a key linking identifiable information to the data
   - where the key will be stored
   - who will have access to the key
   - when the key will be destroyed
   Most of the data has already been de-identified (linked with a key accessible to the PI). If additional data are collected via participants' medical record numbers, the collected data will be entered into the de-identified database without personal identifiers.

4. Will the sponsor or investigator obtain a certificate of confidentiality for this study:
   - No - CoC will not be Obtained
   - Yes - CoC has been Obtained
   - Yes - CoC Request is Pending
   - Yes - Plan to Submit CoC Request

5. If the Certificate of Confidentiality has been obtained by the PI, upload it here:

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6. **What will happen to the research records when the research has been completed:**

- Stored indefinitely with identifiers removed
- Stored indefinitely with identifiers attached
- Destroyed at end of study and not less than the minimum time required for data retention (min 5 yrs, 6 if HIPAA)
- Destroyed when notified by sponsor but not less than the minimum time required for data retention (min 5 yrs, 6 if HIPAA)
- Other

7. **If Other, explain:**

8. **If "stored indefinitely with identifiers attached", explain why identifiers are necessary:**

**Types of Sites**

1. **Select which of the following accurately describes this study:**

- Not Multicenter Study
- Multicenter Study - VCU Lead
- Multicenter Study - Non-VCU Lead

2. **Select all sites where study interventions or interactions will occur and/or identifiable data will be held:**

- VCU Site
- Non-VCU Site (VCU Investigators are conducting/overseeing the conduct of the study)

3. **Is there a community partner in this research study:**

- Yes
- No

**VCU Site Details**

1. **Select all VCU sites that will be utilized in this study:**
Provide details regarding each VCU Site including:
- what clinics / facilities will be used
- resources that are available for the conduct of this study:
This study is a secondary data analysis. No new data will be collected from the clinics.

VCU Health System

1. "The PI has reviewed and agrees to comply with the Conduct of Clinical Research in VCU Health System Patient Care Areas policy:
   - Yes
   - No

2. "Explain how you will notify and obtain support from patient care providers in the units where the study will be conducted:
   This is a secondary data analysis, no new data will be collected.

Study Funding

1. "Have you applied for funding:
   - Yes
   - No

2. If so, is this study already funded:
   - Yes
   - No

Study Population

1. "Provide the total number of participants you expect to enroll in this study under the VCU IRB:
   490

2. If this is a multi-Center Project, what is the total anticipated number of subjects across all sites:

3. "Provide justification for the sample size:
   This is the number of participants data was collected from for the KinFact study.

4. "List the study inclusion criteria:
   Eligibility of the study included adult, English-speaking VCU Women's Health Clinic patients.

5. "List the study exclusion criteria:
   Participants were females over the age of 18. Participants who could not provide consent for themselves were excluded. Prisoners were excluded.

6. "Check all participant groups that are likely to be involved in this study. If it is possible that a regulated vulnerable population (children, pregnant women, prisoners) COULD BE involved in the study, be sure to check

ID: HM20000021
View: SF - Study Funding

ID: HM20000021
View: SF - Study Population

ID: HM20000021
View: SF - Cancer Related Studies
7. If you are either targeting, or excluding, a particular segment of the population/organization/community, provide a description of the group/organization/community and provide a rationale:

Please note that this study involves secondary data analysis. Therefore, we have no way of knowing the current status of participants with respect to pregnancy status, imprisonment, etc. This project involves no interaction with participants.

8. Select the age range(s) of the participants who may be involved in this study:

- < 1 Year
- 1 - 6 Years
- 7 - 12 Years
- 13 - 17 Years
- 18 - 20 Years
- 21 - 65 Years
- > 65 Years

ID: HM20000021

Cancer Related Studies

1. All studies targeting cancer patients, family members of cancer patients, cancer healthcare providers, or cancer prevention where cancer is integral to the research question require review by Massey Cancer Center Protocol Review and Monitoring Committee (PRMC). Upload documentation of PRMC approval.

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<tr>
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<td>John Quillin</td>
<td>CV/Biosketch</td>
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</table>
Potential Subject Identification and Recruitment

1. * Choose all recruitment methods that may be used:
   - [ ] E-mail Campaign
   - [ ] Phone Solicitation
   - [ ] Flyers, Letters or Newspaper/TV/Radio Ads
   - [ ] Website
   - [ ] Direct Contact
   - [ ] Psychology Research
   - [ ] Participant Pool (SONA)
   - [ ] Word of Mouth
   - [ ] Other

2. If Other, please describe:
   This is a secondary data analysis, participant recruitment will not occur.

3. * Select the methods used to obtain names and contact information for potential subjects:
   - [ ] Pre-Existing Relationship with Participants
   - [ ] Selected from Pre-Existing VCU Records
   - [ ] Selected from Pre-Existing Non-VCU Records
   - [ ] Selected from Publicly Available Records
   - [ ] Referred by Health Care Provider or Other Health Professional
   - [ ] Recruited from Database or Registry
   - [ ] Identified through Community Based Organization (Schools, Church Groups, etc.)
   - [ ] Self Referred (Flyer/Ad)
   - [ ] Other

4. If Other, please describe:
   This is a secondary data analysis, participant recruitment will not occur.

5. * Describe specific details for identifying and recruiting participants, including but not limited to:
   - Specific locations where recruitment materials will be displayed
   - How contact information is obtained for any direct contact with potential participants
   - Who will approach and/or respond to potential participants:
   This is a secondary data analysis, participant recruitment will not occur.

6. Describe any special recruitment procedures for vulnerable populations:

7. Upload all recruitment materials including ads, flyers, scripts, letters, email invitations, and postcard reminders:
### Privacy

1. *Privacy is an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as being asked personal questions in a public setting; being publicly identified as having a particular characteristic or diagnosis; being photographed, videotaped or observed without consent; or disclosing personal information.*

Describe how participants' privacy will be protected during:
- identification,
- recruitment,
- screening,
- the consent process,
- conduct of the study, and
- data dissemination:

This secondary data analysis does not involve any further interaction with participants. Data, including those that might be considered sensitive or private, will be held confidential.

### Costs to Participants

1. Select all categories of costs that participants or their insurance companies will be responsible for:

- Participants will have no costs associated with this study
- Study related procedures that would be done under standard of care
- Study related procedures not associated with standard of care
- Administration of drugs / devices

*Before potential participants consent to the study, will screening questions be asked or will any screening procedures/tests be done that would not otherwise be done as standard of care:*

N/A. Consent will not be obtained.

*If Yes, will identifiable information about individuals be recorded during screening:*

- Yes
- No

8. Before potential participants consent to the study, will screening questions be asked or will any screening procedures/tests be done that would not otherwise be done as standard of care:

N/A. Consent will not be obtained.

9. If Yes, will identifiable information about individuals be recorded during screening:

- Yes
- No

ID: HM20000021

View: SF - Costs to Participants

ID: HM20000021

View: SF - Compensation
Study drugs or devices

Other

2. If Other, explain:

3. Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.

This is a secondary data analysis, there will be no financial costs to the participants.

4. If applicable, upload a Cost Analysis form here:

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View: SF - Risks, Discomforts, Potential Harms and Benefits

Compensation

1. Describe any compensation that will be provided including:
   - items such as parking/transportation
   - total monetary amount
   - type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)
   - how it will be disbursed:

   This is a secondary data analysis, there will be no participant compensation.

2. If compensation will be pro-rated, explain the payment schedule:

View: SF - Consent Qualifiers

Risks, Discomforts, Potential Harms and Benefits

1. Describe the risks to participants associated with this study:
   - physical, psychological, social, legal, financial, and other risks
   - seriousness of given risks
   - probability or likelihood of given risks

   There are no foreseeable risks to participants.

2. Describe how the risks / harms will be minimized:

   N/A

3. If the disclosure of any of the information obtained during the study would place the individual at risk for harm (legal, reputation, emotional etc.) and the information will be recorded so that the individual could be identified, explain the protections that will be put in place to decrease the risk of disclosure:

   The dataset utilized for analyses will be de-identified.

4. Is it likely investigators could discover information that would require mandatory reporting by the investigators or staff, such as child or elder abuse:
5. Is it likely investigators could discover a participant’s previously unknown condition (eg disease, suicidal thoughts, wrong paternity) or if a participant is engaging in illegal activities:

- Yes
- No

6. If yes, explain how and when such a discovery will be handled:

7. Describe any potential risks or harms to a community or a specific population based on study findings:

The study does look for group differences by race. However, the aim is to provide scientific understanding for an established health disparity. Therefore, we do not anticipate any potential risks or harms for publishing findings from this study. Rather, we aim to contribute to the reduction of a disparity.

8. Describe criteria for withdrawing an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:

N/A. This study does not involve participant interaction.

9. Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns:

N/A.

10. Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:

N/A.

11. Describe any potential for direct benefits to participants in this study:

N/A. There is no interaction with participants.

12. Describe the scientific benefit or importance of the knowledge to be gained:

Cancer screening significantly decreases mortality. Previous studies show disparities by race in cancer mortality. Our study will investigate the impact of an educational intervention for cancer screening, moderated by race. If successful, the intervention could serve as a model for reducing cancer disparities.

13. If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:

N/A.

14. Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all Full Review studies]

- DSMB Review Required
- DSMP Required
- Not Required

ID: HM20000021  View: SF - Exempt Information Sheet Upload

Consent Qualifiers

1. Are you submitting your study as exempt and therefore no consent is required:

- Yes
- No

ID: HM20000021  View: SF - Documents

Exempt Information Sheet Upload

1. Upload information sheets:

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View: SF - Protocol Complete

### Documents

1. *Upload any documents that the VCU IRB will need to conduct a review of this submission (NOTE: The delete function should only be used if an incorrect document is uploaded):*

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ID: HM20000021

View: Personnel

### Section Complete:

**SUMMARY**

**End of Application:**

**IRB HUMAN SUBJECTS STUDY**

Click Continue Below

ID: HM20000021

View: Personnel
Personnel

1. *Name:*
   Jessica White

2. *Is this individual a 'COI Investigator'?*
   - [ ] Yes
   - [x] No

3. *Roles:*
   - [ ] Principal Investigator
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [x] Trainee/Student
   - [ ] N/A: Requesting Waiver of Consent
   - [ ] Other

4. If other role is selected, explain:

5. *Study related responsibilities:*
   - [x] Study Design
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical
   - [ ] Data Collection - Interviews/Surveys
   - [ ] Data Collection - Direct Observation
   - [ ] Clinical Services
   - [ ] Intervention Services
   - [x] Data Entry
   - [x] Data Coding
   - [ ] Data Management
   - [ ] Data Analysis
   - [x] Project Coordination
   - [ ] Participant Identification
   - [ ] Participant Recruitment
   - [ ] Participant Consent
   - [ ] Regulatory Management
   - [ ] Other

6. If other responsibility is selected, explain:

7. *Qualifications to carry out study related responsibilities: (you may select multiple answers)*
8. If other qualification is selected, explain:

9. Additional or Emergency Phone:

ID: HM20000021

Personnel

1. *Name:
   John Quillin

2. *Is this individual a 'COI Investigator'?
   • Yes
   • No

3. *Roles:
   - [ ] Principal Investigator
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student
   - [ ] N/A: Requesting Waiver of Consent
   - [ ] Other

4. If other role is selected, explain:

5. *Study related responsibilities:
   - [ ] Study Design
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical
   - [ ] Data Collection - Interviews/Surveys
   - [ ] Data Collection - Direct Observation
   - [ ] Clinical Services
### Personnel

1. **Name:**
   Donna McClish

2. **Is this individual a 'COI Investigator'?**
   - Yes
   - No

3. **Roles:**
   - Principal Investigator
   - Co/Sub-Investigator
   - Medical or Psychological Responsible Investigator
   - Research Coordinator
   - Research Nurse
   - Consultant
   - Research Assistant
   - Pharmacist
4. If other role is selected, explain:

5. Study related responsibilities:

- Study Design
- Data Collection - Lab
- Data Collection - Clinical
- Data Collection - Interviews/Surveys
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- Data Management
- Data Analysis
- Project Coordination
- Participant Identification
- Participant Recruitment
- Participant Consent
- Regulatory Management
- Other

6. If other responsibility is selected, explain:

7. Qualifications to carry out study related responsibilities: (you may select multiple answers)

- Education and/or Professional Preparation
- Experience - Research
- Experience - Clinical
- Experience - Related Skills
- Trainee
- Student
- Other

8. If other qualification is selected, explain:

9. Additional or Emergency Phone:
Name: Rosalie Corona

2. *Is this individual a 'COI Investigator'?*
   - Yes
   - No

3. *Roles:*
   - Principal Investigator
   - Co/Sub-Investigator
   - Medical or Psychological Responsible Investigator
   - Research Coordinator
   - Research Nurse
   - Consultant
   - Research Assistant
   - Pharmacist
   - Statistician
   - Regulatory Coordinator
   - Trainee/Student
   - N/A: Requesting Waiver of Consent
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6. If other responsibility is selected, explain:

7. *Qualifications to carry out study related responsibilities: (you may select multiple answers)*
   - Education and/or Professional Preparation
### Experience - Research

- [ ]

### Experience - Clinical

- [ ]

### Experience - Related Skills

- [ ]

### Trainee

- [ ]

### Student

- [ ]

### Other

- [ ]

8. If other qualification is selected, explain:

9. Additional or Emergency Phone:

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**Add Document**

1. **Document Name:** Baseline Survey
   - Type: Research Measure
   - File: Baseline Survey.doc(0.01) | History

ID: HM20000021

**Add Document**

1. **Document Name:** 14 month Follow Up Survey
   - Type: Research Measure
   - File: 14m Follow Up Survey.doc(0.01) | History

ID: HM20000021

**Add Document**

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   - Type: Ancillary Committee Approval
   - File: PRMC Approval.pdf(0.01) | History

ID: HM20000021

**Add Document**

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2. **Type:**  
   Research Measure

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