RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

Date: Monday, January 13, 2014 1:06:28 PM
View: 1 - Study Identification Information

1.0 Study Identification. IRB: Newark

This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.

1.0 * **Select the type of submission for your project**:

- (●) **Research Protocol/Study**
- ( ) Research [Tissue or Data] Bank
- ( ) Facilitated Review or NCI-CIRB Independent Review
- ( ) Emergency Permission
- ( ) Humanitarian Use Device (HUD)
- ( ) Quality Assurance/Quality Improvement Only
- ( ) Western IRB (WIRB)

2.0 **Full Title of Project:** (If Research [Tissue or Data] bank, Describe where the research [Tissue or Data] bank is physically located (i.e. Institution / Department / Building / Floor / Room)
* **Full Title:**
Social Networks and Health Outcomes of HIV in Sub-Saharan African (SSA) Immigrants

3.0 * **Short Title (Study Name):**
Social Networks and Health Outcomes (SNaHO) in SSA Immigrants

4.0 * **Principal Investigator / Repository Administrator:**
Aramide Ayorinde

5.0 **Study Coordinator / Contact Person:**

6.0 **Co-Investigators:**

Last Name	First Name	Department/Division	Institutional Status	On Probation
Backstrand	Jeffrey	Urban Health Administration (URHA)	Rutgers Unpaid Faculty	no
Pacquiao	Dula	Primary Care	Rutgers Paid Faculty	no
Zha	Peijia	Capacity Building	Consultant	no

7.0 **Other Staff :**

Name Department Role Interaction or access to individuals Institutional Status On Probation Date Modified
There are no items to display

NOTE:

- **How do I add study team members not in the pick list?**
  - If your study team member does not appear in the pick list for a particular role, then they have may not have an account in eIRB. Your first step is to have the study team member register at https://eIRB.rutgers.edu . Registration is required during initial logon. An account will be created within 1 to 2 business days.
- All individuals responsible for or working on this project for whom a Rutgers IRB is the IRB of record must be listed here, including individuals who will have responsibility for the consent process, interactions or interventions with subjects, data collection, etc., or who will have access to identifiable private information for research purposes.
- All personnel whose role involves the interaction with living individuals or access to their identifiable information require CITI training.

- Detailed information for CITI Training can be found here.

View: 1.1 Study Contact List : Faculty Advisor

1.1 Study Contact List: Faculty Advisor

1.0 Specify your Faculty Advisor below:
All student Principal Investigators must specify and include their faculty advisor within the study contact list below: (if the name does not appear in the list below, click on the back button in order to add your faculty advisor to the study team)

* Email Contact List:

Name	E-Mail
Dula Pacquiao	pacquidf@rutgers.edu

View: 1.2 IRB Researcher Training Records

CITI Training Records:
The following information is a read-only view taken from your currently approved training records on your researcher profile:

- Verify that the information below is correct.
- Contact your local IRB office for any discrepancies.

Principal Investigator / Repository Administrator: Aramide Ayorinde
Date Completed: 1/12/2013 **Renewal Deadline:** 1/12/2016

Study Coordinator / Contact Person:
Date Completed: Renewal Deadline:

Co-Investigators:

Name	Date Completed	Renewal Deadline
Jeffrey Backstrand	10/28/2013	10/27/2016
Dula Pacquiao	4/22/2011	4/21/2014
Peijia Zha	6/25/2013	6/24/2016

Other:

Name	Role	Interaction or Access to Individuals/Identifier	Date Completed	Renewal Deadline
There are no items to display				

View: 1.3 Conflict of Interest
1.3 Conflict of Interest

1.0 * Upload a study specific Rutgers Financial Disclosure Form for all project personnel:

Name	Modified	Version
Rutgers Financial Disclosure Form	8/19/2013 8:54 PM	0.02

2.0 * Do any of the participating investigators or other project personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project?:

○ Yes ◉ **No**

View: 1.4 Required Departmental/Division Reviews
1.4 Required Reviews

- **Please indicate all department/division(s) providing administrative approval for this project.**
- **You are required to include the individual departments for each person listed.**
- **Refer to Section 1.0 "Study Identification" to verify each department involved in this project.**

In order to ensure that all selections have been saved, click on the **continue** or **save** option above. Navigating away from the screen (without either option) **will not** automatically save your selections.

1.0 * **Enter each department and/or division for all project team members**:

Name	Category	School/Unit
Primary Care	Institution Department	School of Nursing

View: 1.5 Review Type

1.5 Review Type

* **Review Type - Requested**:
Expedited

View: 3.0 Risk Determination

3.0 Review Type/Risk Determination

1.0 * **Does the proposed study present greater than minimal risk to subjects?**

Yes **No**

2.0 * **Will the study collect sensitive information about subjects that could place them at risk for criminal or civil liability, be damaging to their financial standing, insurability, reputation, or be stigmatizing?**

Yes **No**

View: 3.1 Risk Determination - Expedited Qualification

3.1 Expedited Qualification

Check all **categories** that apply to this research

1.0 * **Select all that apply**:

Category	Description
7	Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that in not exempt)

View: 4.0 Funding Information

4.0 Funding Information

1.0 * **Is this project funded?** (Select YES if Department Funded. Funding sources include department/internal funding)

Yes No

View: 4.1 Project Sponsors

4.1 Funding Information: Project Sponsors

1.0 * **Indicate all funding sponsors for this project:**

	Sponsor	Funding Type	Grant/Protocol Number
View	Department Funded	Internal / Institutional Funding	

View: 4.2 Other Funding Sources

4.2 Other Funding Sources

1.0 **If applicable, describe other funding source(s) for this project.**

All other study costs will be funded by the PI.

View: 4.3a Coverage of project related costs - Section 1
4.3 Coverage of project related costs - Section 1

1.0 * **Will sponsor/funding source(s) cover all project-related costs?**

○ Yes ◉ **No**

2.0 * **Will sponsor/funding source(s) cover costs of any project-related injury?**

○ Yes

◉ **No**

○ NA

View: 4.3b Coverage of project related costs - Section 2
4.3b Coverage of project related costs - Section 2

1.0 * **What project costs will be covered?**

Some study costs (e.g., salary support, tests, etc.)

2.0 * **How will unfunded project costs be covered?**

Unfunded study costs will be covered by the principal investigator (PI).

View: 5.0 Study Locations
5.0 Study Sites

1.0 **Specify all Rutgers sites engaged in this project:**

	Name	Address	Subjects will be treated here	Records will be stored/accessed here	Samples will be collected/analyzed here	Other study activities take place here
View	Other	Rutgers University, School of Nursing, 65 Bergen Street, Newark NJ 07016	no	yes		yes

View: 5.01 Non-Rutgers Study Locations
5.01 Non-Rutgers Study Sites

1.0 **Specify all non-Rutgers sites engaged in this project:**

	Site Name	Site Address	Subjects will be treated here	Records will be stored/accessed here	Samples will be collected/analyzed here	Other study activities take place here
View	[redacted]	[redacted]	yes	no		yes
View	[redacted]	[redacted]	yes	no		yes
View	[redacted]	[redacted]	yes	no		yes
View	[redacted]	[redacted]	yes	no		yes

View: 5.20 Multi-Site Study

5.20 Multi-Site Study

1.0 * **Is this a multi-site study?**

Yes **No**

View: 5.30 Research Data

5.30 Research Data

1.0 * **Please confirm that the research data will be given to your advisor:**

Yes No

View: 6.01 Biosafety

6.01 Biosafety

Indicate whether this project involves any of the following:

1.0 * **Infectious Agents?**

Yes **No**

2.0 * **Recombinant DNA/human gene transfer?**

Yes **No**

3.0 * **Biologically-derived toxins?**

Yes **No**

4.0 * **Collection of human blood, body fluids, specimens, and/or cell lines?**

Yes **No**

5.0 * **Will immortalized lymphoblastoid cell lines, fibroblast cell lines or tumor cell lines be created from the collected human biological material collected?**

Yes **No**

View: 6.02 Radiation Safety

6.02 Radiation Safety

Indicate whether this study involves any of the following:

1.0 * **Exposure to X-rays that subjects would not receive if not enrolled in this study?**

Yes **No**

2.0 * **Exposure to radionuclides that subjects would not receive if not enrolled in this study?**

Yes **No**

View: 6.03 Embryonic Stem Cell Review

6.03 Embryonic Stem Cell Review

1.0 * **Does your project involve the use of human embryonic stem cells?**

Yes **No**

View: 6.04 Scientific Review Board (SRB)

6.04 Scientific Review Board (SRB)

1.0 * **Is this a cancer-related project involving a Robert Wood Johnson Medical School (RWJMS) faculty member or a CINJ member?**

Yes **No**

View: 7.0 Study Summary / Protocol Section 1

7.0 Study Summary

1.0 Upload Protocol with version date (Microsoft Word format is required). Include screening instruments, questionnaires, data collection forms, etc.

Please upload consent/assent forms, surrogate consent forms, information sheets, and verbal script documents in Section: 13.2 Consent Forms Process of Consent.

PLEASE NOTE: For eIRB conversion requests there are two requirements:

1. Please upload most recently approved stamped versions of all , recruitment materials, questionnaires, etc.
2. Please upload a clean (unstamped) Word version (non-pdf) of all recruitment materials, questionnaires, etc.

*** Protocol:**

Name	Modified	Version
SNaHO Study Information Sheet | History	9/11/2013 9:43 AM	0.02
SNaHO Survey Questionnaire | History	8/11/2013 11:50 PM	0.02

2.0 Study type. Check all that apply*:*

*** Protocol Study Types:**

- [ ] Biomedical / Clinical
- [ ] Data repository establishment
- [ ] Diagnostic
- [ ] Epidemiologic
- [ ] Gene Transfer
- [ ] Genetic
- [ ] Outcomes (health services delivery)
- [ ] Pharmacogenomic
- [ ] Pharmacokinetic
- [ ] Physiologic
- [ ] Pilot
- [ ] Quality Improvement / Quality Assurance (QI/QA)
- [ ] Quality of life (health services delivery)
- [ ] Registry
- [ ] Retrospective review of charts/records
- [ ] Specimen/Sample Analysis
- [x] **Social / Behavioral**
- [x] **Survey**
- [ ] Therapeutic
- [ ] Tissue repository establishment
- [ ] Translational
- [ ] Other

If other, please specify:

View: 7.1 Study Summary / Protocol Section 2
7.1 Study Summary

1.0 **Is this a Research Study which prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes?**

○ Yes ○ No

2.0 * **Is this a clinical trial** defined as an Interventional trials (drugs, biologics, device), Phase II-IV , device trials for which FDA approval is sought(IND/IDE)?

○ Yes ◉ **No**

2.0 * **Summary of Study: The following must be answered in lay language or language understood by a person unfamiliar with your area of research. Jargon or technical terminology should be avoided or explicitly explained. Do not say "see protocol" or "protocol attached".**

Despite the many developments in the fight against HIV/AIDS in the US, many sub-populations continue to be disproportionately affected by the disease. One such population is that of sub-Saharan African (SSA) immigrants. With increasing numbers of African immigrants settling in the US, it is important to understand the social context of HIV/AIDS in efforts to combat the disease in this immigrant community. High prevalence rates of HIV/AIDS in Africa, coupled with settlement patterns in urban communities with high exposure pools to HIV/AIDS makes it imperative to understand how social environments impact health outcomes.

Using a survey approach, this quantitative study seeks to examine the influence of social networks on access to healthcare services and health outcomes of HIV positive SSA immigrants in the US. Insight from the study will allow for better prevention and treatment intervention strategies for a population often overlooked in comparison to other populations .

View: 7.2 Study Summary / Protocol Section 3
7.2 Study Summary

1.0 * **What is your research question (hypothesis):**
H1. To determine whether social networks of SSA immigrants are comprised of higher numbers of strong ties compared to weak ties.
H2. To determine whether social networks comprised of weak ties facilitate greater access and utilization of healthcare services.
H3. To determine whether higher levels of social integration facilitate positive HIV/AIDS related health outcomes in SSA.

2.0 * **Describe your research design:**
SNaHO is a descriptive quantitative study with a cross sectional survey design. Using a self-administered survey, participants will be asked questions pertaining to demographics, social networks, access and utilization of healthcare services, and self-reported HIV related health outcomes.

Subjects will be recruited using opportunistic, purposive and snowball sampling techniques. These approaches will be used due to the high sensitivity associated with HIV/AIDS in this target population. In addition, these techniques are ideal due to the difficulty in recruiting individuals from the target population.

3.0 * **What will the subjects be asked to do? What will be done to subjects?:**
Subjects will be asked to complete a survey questionnaire pertaining to their social networks, self reported HIV related health outcomes (CD4 and Viral Load) and access/utilization of healthcare services. The survey also includes 35 questions on demographic background.

This study does not involve any medical or other interventions with study subjects.

4.0 * **Describe risks to subjects**:
Subjects may experience a level of discomfort when completing the survey; however, this study does not pose

greater than minimal risk to subjects.

5.0 * **Describe potential benefits to subjects or others**:
The potential benefits to subjects or others is that the study will provide insight to the social environments of Sub Saharan African (SSA) immigrants living in the US. In addition it will provide insight on how HIV positive SSA access and utilize healthcare services in the US.

View: 8.0 Drugs/ Devices / Biologicals
8.0 Drugs / Devices / Biologicals

1.0 * **Does your study involve drugs, devices and/or biologicals?**

○ Yes ◉ **No**

View: 9.0 Use of Specimens and Samples
9.0 Use of Specimens/Samples
Select each type of specimen/sample that will be used under the proposed study. If none are appropriate, select "Not Applicable".

1. * **Select all that apply:**

- ☑ **Not Applicable**
- ☐ Excess specimens previously collected for non-research purposes will be used in this study
- ☐ Specimens/samples from a research tissue bank(s) will be used in this study.
- ☐ Specimens/samples previously collected from another study not stored in a research tissue bank will be used in this study.
- ☐ Specimens/samples will be stored/banked for future use.
- ☐ Specimens that are being collected will be used in this study only.

View: 10.0 Subject Population
10.0 Subject Population

1.0 * **Which gender(s) do you plan to enroll?**

Female
Male

2.0 * **Check all age ranges of subjects to be enrolled:**

- ☐ Neonates (1-30 days)
- ☐ 31 days - 6 years
- ☐ 7 - 12 years
- ☐ 13 - 17 years
- ☑ **18 - 64 years**
- ☑ **65 - 89 years**
- ☐ 90 years and older
- ☐ N/A

View: 10.02 Subject Population - No Children
10.02 Subject Population - Exclusion of Children

1.0 * **Provide the justification for excluding children:**
Children are excluded from the study for the following reasons:
1. The objectives of the study can be met by enrolling adults
2. The level of comprehension of survey questionnaire may exceed what children can understand
3. Agencies participating in the study provide services only to adults

View: 10.1 Subject Population - Additional Vulnerable Populations

10.1 Study Population: Populations Requiring Additional Protections

1.0 * **Other populations which may require additional protections under the regulations to be included in this study**:

- [ ] Diminished decision-making capacity
- [ ] Economically or educationally disadvantaged
- [ ] Elderly
- [ ] Employees
- [ ] Fetuses
- [ ] Involuntary Patients
- [x] **Minorities**
- [ ] Neonates
- [ ] Non-English-speaking
- [ ] Pregnant Women
- [ ] Prisoners
- [ ] Students
- [ ] Wards of the state or foster children
- [ ] Other
- [ ] None

View: 11.0 Recruitment of Subjects

11. Recruitment of Subjects

1.0

* **How many subjects do you need to meet your target enrollment?**
207

2.0 * **How many subjects in total will need to be screened for enrollment eligibility to reach the above total number? Subjects who go through the consent process come under IRB protection, even if they have no further participation in the study, (i.e, screen failures, etc**.)
300

3.0

* **Recruitment Methods / Source of subjects:**

- [ ] E-mail announcements
- [ ] Emergency Room
- [x] **Employees**
- [ ] Inpatients
- [ ] Internet sites
- [ ] Letters / Mailings
- [ ] Medical records / Patient databases
- [ ] Newspaper / radio / television advertising
- [x] **Outpatients**
- [x] **Physician**
- [x] **Postings / bulletin boards / flyers**
- [ ] Public records / Mailing lists
- [ ] Registries (e.g. cancer registry)
- [ ] Students

☐ Telephone list

☑ **Other**

Describe other:
Participating Subjects (Snowball)

4.0 **Attach a copy of all recruitment materials to be used, e.g., flyers, brochures, advertisements, bulletin board notices, E-mails, letters, phone scripts, URLs, audiotapes, videotapes, etc.**

Recruitment Materials:

Name	Modified	Version
SNaHO Study Flyer	8/12/2013 12:15 AM	0.02

5.0 * **Will subjects receive financial compensation or other non-financial enrollment incentives?**:

◉ **Yes** ○ No

View: 11.1 Recruitment of Subjects - Financial compensation

11.1 Recruitment of Subjects - Financial compensation

1.0 * **Compensation**: (Select all that apply).

Enrollment Incentive

Other

If Other, describe:
Gift Card

2.0 * **Indicate the amounts and describe when the compensation or incentive(s) will be given**:
A $10.00 gift card to local grocery stores will be given to subjects participating in the study. Gift cards will be given upon submitting the survey questionnaire in a sealed envelop to PI or agency point of contact (POC).

View: 12.0 Subject Privacy and Confidentiality - Section 1

12.0 Subject Privacy and Confidentiality - Section 1

Privacy is a subject's ability to control how other people see, touch, or obtain information about the subject.

1.0 * **Please describe a plan to assure subject privacy and the confidentiality of subject data. Indicate how research data will be stored and secured. If links to personal identifiers will be used, please describe the coding mechanism, and detail how health identifiers will be secured against improper use or disclosure.**
No personal identifiers will be collected on the survey questionnaires from study subjects. All pages of the survey will have a reminder for subjects not to include any identifiers.

No written consent will be required of each subject. Each subject will be required to provide verbal consent to participate after they have received information about the study and their questions have been answered by the PI or POC.

Each subject will be provided an envelop to seal completed surveys before submitting surveys to PI or designated POC. The agency POC will then collect all sealed surveys in a large pre-addressed and stamped envelop to be mailed to the PI at Rutgers University, School of Nursing. Each designated agency POC will be provided a locked box for storing individual sealed completed surveys before they are mailed to the PI.

Completed study surveys will be mailed in the pre-addressed stamped envelop to the PI at Rutgers University, School of Nursing. Completed surveys will be stored in a locked file cabinet in the office of Dr. Dula Pacquiao (dissertation advisor), 65 Bergen Street, Room 1112. These files will only be accessed by the PI and Dr. Pacquiao.

Data collected will be stored in the locked file cabinet and kept for a 6 year period after study completion.

Surveys will be destroyed by PI after 6 year period.

2.0 * **Check off in the table below which identifiers will be collected/accessed**:

☐	Account numbers
☐	Address by street, town, city, zip code
☐	Age 90 or older
☐	All elements of dates(except year),e.g., date of birth, admission/discharge date, date of procedure, date of death
☐	Biometric Identifiers(fingerprints, voiceprints)
☐	Certificate/license numbers
☐	Email Address
☐	Fax numbers
☐	Full face photographic image
☐	Health plan beneficiary numbers
☐	Internet protocol (IP) address numbers
☐	Medical device and serial numbers
☐	Medical Record Identifiers
☐	Name
☐	Social Security Number
☐	Telephone Numbers
☐	Vehicle identification and serial numbers, including license plate numbers
☐	Web universal resource locations (URLs)
☑	**None (No identifiers will be collected)**
☐	Other

Describe other identifier:

3.0 * Protected Health Information (PHI) is health/medical data that include any of the previous personal identifiers.
Will data collected for this project contain any PHI?

○ Yes ◉ **No**

View: 12.1 Subject Privacy and Confidentiality - Section 2

12.1 Subject Privacy and Confidentiality - Section 2

1.0 * **Will data be obtained from subjects' health/medical records for study purposes?**

○ Yes ◉ **No**

2.0 * **Will identifiable data be disclosed to anyone not listed in this project?**

○ Yes ◉ **No**

3.0 * **How long will you keep the link (identifying code) to the personal identifiers?**
Not applicable. No link will be retained

View: 12.2 Subject Privacy and Confidentiality - Section 3

12.2 Subject Privacy and Confidentiality - Section 3: Data Storage & Authentication

1.0 * **Is/are your computer(s) authenticated on Rutgers' network?:**

(●) **Yes** ( ) No

2.0 * **Is the Principal Investigator the data steward?**:

(●) **Yes** ( ) No

View: 12.2 Subject Privacy and Confidentiality - Section 4

12.2 Subject Privacy and Confidentiality - Section 4: Data Storage & Authentication

1.0 * **Do you have encryption capabilities for the transmission of PHI:**

(●) **Yes** ( ) No

2.0 * **Will your data be used to create a data repository:**

( ) Yes (●) **No**

3.0 * **Will your research data be stored in a repository:**

( ) Yes (●) **No**

View: 13.0 Informed Consent Determination

13.0 Informed Consent

If informed consent will not be obtained from subjects, a request for a consent waiver must be completed.

1.0 * **Indicate the types of consent that will be involved in this project (check any or all that apply):**

- [ ] Written consent document will be signed by the subject
- [ ] Written consent document will be signed by a surrogate
- [ ] Written permission for a minor will be signed by a parent or legal guardian
- [ ] Written assent will be signed by a minor
- [x] **Verbal consent will be obtained (requires a waiver of documentation of consent)**
- [ ] Consent/Assent will not be obtained from all subjects to be enrolled for this study
- [x] **Written consent document will not be signed by subject (requires a waiver of documentation of consent)**

View: 13.01 Informed Consent Determination Waiver of Consent

13.01 Waiver of Consent

If informed consent will not be obtained from research subjects, a request for a consent waiver must be completed.

1.0 * **Waivers: If you are applying for any waivers of consent and/or HIPAA Authorization (check any or all that apply):**

- [ ] Waiver of Consent
- [ ] Waiver of Assent
- [ ] Waiver of Parental Permission
- [ ] Waiver of HIPAA Authorization
- [x] **Waiver of Written or Signed Consent(i.e. Information Sheets, telephone consent, verbal script)**
- [ ] No Waiver at all

View: 13.7 Waiver of Written or Signed Consent

13.7 Waiver of Written or Signed Consent

1.0 * **The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether he or she wants documentation linking him or her with the research, and his or her**

wishes will govern.

(•) **Yes** ( ) No

2.0 * **Does this study involves any procedures for which written consent is normally required outside of the research context?**

( ) Yes (•) **No**

View: 15.0 Additional Supporting Information

15.0 Additional Supporting Information

1.0 **Attach any other documents that have not been specified in previous questions, but are needed for IRB Review.**

NOTE: For clinical QA/QI projects, include clinical supervisor permission

Name	Modified	Version
Dissertation Proposal	9/10/2013 1:50 PM	0.01
Rutgers Consent Waiver Form	9/10/2013 1:45 PM	0.01
CITI Training Completion Report - Peijia Zha	7/24/2013 11:24 AM	0.01
Permission from Instrument Author to Use Survey	7/14/2013 7:25 PM	0.02
Citi Training Completion Report	7/5/2013 11:48 AM	0.01

2.0 **If there is any additional information that you wish to communicate about the project please include it below. Please note, this section should not be used in lieu of the standard application items.**

View: SF - Final Page

Final Page:

Submission Type:	Research Protocol/Study
Review Type- Requested:	Expedited
Submission ID:	Pro2013003316

Next Steps:

Submit study for IRB review:

Your application form **will not** be submitted for review until the Principal Investigator returns to the study "workspace," and clicks on "**Submit Study".** You can track the status of this study's submission by logging into the study workspace.

To submit the study:

- Ensure that you have answered all questions in the application and all sections are error-free
- Click **Finish**" to exit the application and return to the "**workspace**"
- Navigate to the left of your screen, and under "**My Activities**," click "**Submit Study"** to initiate IRB review

Note:

All co-investigators listed in this study **must** also agree to participate in the study prior to submission. They will be required to log into this workspace and click on "**Agree to Participate".**

View: Adding a Sponsor

Study Sponsor

Instructions:

- Use this form to complete the information about a sponsor of this protocol.
- You may **add** multiple sponsors by clicking the **'OK Add Another'** button.

Part A. Sponsor Information:

1.0 * **Funding Sponsor Type**:
Internal / Institutional Funding

2.0 **NOTE:** Select **Department Funded** if funding type is **Internal / Institutional**

Email eirb@ca.rutgers.edu for sponsors **not** provided in list**.** Select **Pending** until the sponsor is confirmed and the list is updated.

* **Sponsor Name**:
Department Funded

3.0 **Sponsor Grant/Protocol Number (if known):**

4.0 **Upload the Grant Application(s) or Contract/CTA Agreement(s)** :
Document
There are no items to display

Part B. Corporate / Industry Sponsor Information Only:

1.0 **Regulatory Overseer:**

2.0 **Sponsor Contact Name:**

3.0 **Sponsor Contact's Phone Number**:

4.0 **Does the contract or clinical trial agreement specifically mention ICH GCP Guidelines?:**
Yes No

Part C. Government / Foundation Sponsor Information Only:

1.0 **Type of Grant:**

2.0 **Subcontracting Institution (If applicable):**

3.0 **Grant/Contract Title:**

4.0 **PI of Grant/Contract:**

View: Add a University Site

RUTGERS SITE(s)

Instructions:

- Use this form to complete the information about only study site(s) engaged in this research where Rutgers is the IRB of record.
- You may add multiple study sites by clicking the 'OK and Add Another' button.

1.0 * **Site:**
Other

* **Address**:
Rutgers University, School of Nursing, 65 Bergen Street, Newark NJ 07016

2.0 * **Subjects will be recruited/treated here:**
Yes **No**

3.0 * **Records, specimens or data will be stored or accessed here:**
Yes No

4.0 **Samples will be collected/analyzed here:**
Yes No

5.0 * **Other activities will take place here:**
Yes No

6.0 **If other activities take place here, please describe:**
Data analysis

View: Add a non-UMD Site

NON-RUTGERS SITE(s)

Instructions:

- Use this form to complete the information about a study site engaged in this research where Rutgers is not the IRB of record.
- You may add multiple study sites by clicking the 'OK Add Another' button.

* **Site Name:**
[redacted]

* **Site Address**:
[redacted]

* **Subjects will be recruited/treated here:**
Yes No

* **Records, specimens or data will be stored or accessed here:**
Yes **No**

Samples will be collected/analyzed here:
Yes No

* **Other activities will take place here:**
Yes No

If other activities take place here, please describe:
Study participants will complete survey's at this agency location. In addition, training of point of contact staff will occur

at this agency location.

*** Upload IRB approval, authorization agreement or other proof of agreement:**
Document
[redacted] | History

View: Add a non-UMD Site

NON-RUTGERS SITE(s)

Instructions:

- Use this form to complete the information about a study site engaged in this research where Rutgers is not the IRB of record.
- You may add multiple study sites by clicking the 'OK Add Another' button.

*** Site Name:**
[redacted]

*** Site Address**:
[redacted]

*** Subjects will be recruited/treated here:**
Yes No

*** Records, specimens or data will be stored or accessed here:**
Yes **No**

Samples will be collected/analyzed here:
Yes No

*** Other activities will take place here:**
Yes No

If other activities take place here, please describe:
Study participants will complete survey's at this agency location. In addition, training of point of contact staff will occur at this agency location.

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[redacted] | History

View: Add a non-UMD Site

NON-RUTGERS SITE(s)

Instructions:

- Use this form to complete the information about a study site engaged in this research where Rutgers is not the IRB of record.
- You may add multiple study sites by clicking the 'OK Add Another' button.

*** Site Name:**
[redacted]

*** Site Address**:
[redacted]

*** Subjects will be recruited/treated here:**
Yes No

*** Records, specimens or data will be stored or accessed here:**
Yes **No**

Samples will be collected/analyzed here:

Yes No

*** Other activities will take place here:**

Yes No

If other activities take place here, please describe:
Study participants will complete survey's at this agency location. In addition, training of point of contact staff will occur at this agency location.

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