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:
Empowering Daughters and Mothers Through Social Media

3.0 * Short Title (Study Name):
Empowering Daughters and Mothers

4.0 * Principal Investigator / Repository Administrator:
Donna Hill-Cill

5.0 Study Coordinator / Contact Person:
Donna Hill-Cill

6.0 Co-Investigators:
Last Name   First Name   Department/Division   Institutional Status   On Probation
There are no items to display

7.0 Other Staff :
Name   Department   Role   Interaction or access to individuals   Institutional Status   On Probation   Date Modified
Brooklynn Hitchens   Non-RBHS Department   research assistant   yes   Rutgers   Student   no   11/25/2013

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
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: Donna Hill-Cill
Date Completed: 8/24/2011 Renewal Deadline: 8/23/2014

Study Coordinator / Contact Person: Donna Hill-Cill
Date Completed: 8/24/2011 Renewal Deadline: 8/23/2014

Co-Investigators:

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Completed</th>
<th>Renewal Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There are no items to display

Other:

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Interaction or Access to Individuals/Identifier</th>
<th>Date Completed</th>
<th>Renewal Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>View Brooklynn Hitchens</td>
<td>research assistant</td>
<td>yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Modified</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial disclosure form</td>
<td>11/26/2013 3:43 PM</td>
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</tr>
<tr>
<td>financial disclosure form</td>
<td>9/12/2013 10:17 PM</td>
<td>0.01</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Category</th>
<th>School/Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Care</td>
<td>Institution Department</td>
<td>School of Nursing</td>
</tr>
</tbody>
</table>

View: 1.5 Review Type

1.5 Review Type

* Review Type - Requested:
Full IRB Review

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: 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:

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Funding Type</th>
<th>Grant/Protocol Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>View</td>
<td>Internal / Institutional Funding</td>
<td></td>
</tr>
<tr>
<td>View</td>
<td>Government / Foundation</td>
<td>Jewish Women's Foundation of New Jersey</td>
</tr>
</tbody>
</table>

View: 4.2 Other Funding Sources

4.2 Other Funding Sources

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

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 project costs will be covered in-kind through Rutgers School of Nursing

View: 5.0 Study Locations
5.0 Study Sites

1.0 Specify all Rutgers sites engaged in this project:

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Subjects will be treated here</th>
<th>Records will be stored/accessed here</th>
<th>Samples will be collected/analyzed here</th>
<th>Other study activities take place here</th>
</tr>
</thead>
<tbody>
<tr>
<td>View Other Rutgers School of Nursing 65 Bergen Street Newark NJ 07101</td>
<td>View Other Rutgers School of Nursing 65 Bergen Street Newark NJ 07101</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Site Address</th>
<th>Subjects will be treated here</th>
<th>Records will be stored/accessed here</th>
<th>Samples will be collected/analyzed here</th>
<th>Other study activities take place here</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
</tbody>
</table>

View: 5.20 Multi-Site Study
5.20 Multi-Site Study

1.0 * Is this a multi-site study?

- 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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Modified</th>
<th>Version</th>
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<tbody>
<tr>
<td>New Guidance with updates</td>
<td>11/11/2013 11:53 AM</td>
<td>0.02</td>
</tr>
<tr>
<td>New Assent Form with Updates</td>
<td>11/5/2013 10:54 AM</td>
<td>0.01</td>
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<tr>
<td>Guidance_UMDNJ_Protocol_Guidance.doc</td>
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<tr>
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<td>0.01</td>
</tr>
<tr>
<td>Pre enrollment Questionnaire.doc</td>
<td>10/17/2013 4:47 PM</td>
<td>0.01</td>
</tr>
<tr>
<td>PEQ-daughters questionnaire assessment version.doc</td>
<td>10/17/2013 4:47 PM</td>
<td>0.01</td>
</tr>
</tbody>
</table>
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
  - [x] Pilot
  - [ ] Quality Improvement / Quality Assurance (QI/QA)
  - [ ] Quality of life (health services delivery)
  - [ ] Registry
  - [ ] Retrospective review of charts/records
  - [ ] Specimen/Sample Analysis
  - [ ] Social / Behavioral
  - [ ] Survey
  - [ ] Therapeutic
  - [ ] Tissue repository establishment
  - [ ] Translational
  - [x] Other

If other, please specify:
Focus group

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
   - [x] No
*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".

The goal of this study is to identify positive and negative communication patterns between daughters and mothers. 14 mother daughter dyads will be chosen from two different schools. The daughters will be selected according to age, living status with mother, academic status, school of attendance and proficiency of English. There will be a total of 28 mothers and daughters that will be a part of this study. There will be an intake phone interview with individual mother daughter dyads and three focus groups per school. There will be a total of six focus groups to obtain information about how mothers and daughters communicate. The focus groups will be tape recorded and the mother/daughters will be identified by a "Study name" (A pseudonym created of assigned to the participants). The first focus group will be daughters only, the second focus group will be mother only and the last focus group will be both mothers and daughters. The data will be transcribed and then analyzed for common themes.

View: 7.2 Study Summary / Protocol Section 3

7.2 Study Summary

1.0 *What is your research question (hypothesis):*
What are the effective and ineffective aspects of interaction that effectively maintain or negatively impact communication in mothers and daughters.

2.0 *Describe your research design:*
Goal: Identify effective communication skills between mothers and daughters to address health risk behaviors.

Process Objectives/Activities:
1. Recruit 28 participants (14 students and 14 mothers) for 2 groups; to participate in 6 focus groups.
   - Group A: 7 pairs of mothers-daughters from The participants of this group will be selected from the group of students at the lowest academic quartile of the class/school.
   - Group B: 7 pairs of mothers-daughters from The participants of this group will be selected from the group of students at the highest academic quartile of the class/school.

2. Conduct focus groups for the groups
   - Group A: Focus group with the students only; Focus group with the mothers only Focus group with the mothers and daughters together
   - Group B: Focus group with the students only; Focus group with the mothers only Focus group with the mothers and daughters together

3. Transcribe data collected from the focus groups

4. Conduct thematic analysis of the transcribed data to identify and compare evidence based themes of positive and negative attributes of communication from the focus groups.

Data Collection Strategy
Focus Groups will examine the daughters' perspective on communication: SWOT analysis: Strengths, Weaknesses, Opportunities, Threats. Specifically the focus group questions will aim to explore the participants' perspectives.

5. Use the comparative attribute themes to identify the desirable communication skills and attributes that can improve lines of communications between mothers and daughters and the undesirable communication skills.

3.0 *What will the subjects be asked to do? What will be done to subjects?:*
Subjects will be asked to participate by answering a series of questions in a focus group session, questionnaires and intake with the principle investigator.

4.0 *Describe risks to subjects:*
There is minimal risk in this study. Daughters and mothers are being asked a series of questions to provide data to assess critical communication patterns. Potentially during the study a daughter or mother may disclose a
situation that evokes a negative experience or emotion.

5.0 * Describe potential benefits to subjects or others:
The benefits of taking part in this study may be:

Participants will have a higher consciousness of the importance of communication. This awareness can improve their relationship and assist in lowering health risk behaviors.

The data obtained from focus groups can assist other mothers and daughters to have more effective communication and lower health risk behaviors and provide healthier outcomes for young girls.

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

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: 10.01 Subject Population - Children
10.01 Subject Population - Children

1.0 * Since children will be enrolled in this study, indicate one of the criteria for risk/benefit assessment met according to federal regulations (45CFR46, subpart D):
   ○ (404) Minimal Risk
   ○ (405) Greater than minimal risk, but holds prospect of direct benefit to subjects
(406) Greater than minimal risk, no prospect of direct benefit to subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition

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
- 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?  
   28

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.)  
   36

3.0 * Recruitment Methods / Source of subjects:

- E-mail announcements
- Emergency Room
- Employees
- Inpatients
- Internet sites
- Letters / Mailings
- Medical records / Patient databases
- Newspaper / radio / television advertising
- Outpatients
- Physician
- Postings / bulletin boards / flyers
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.

<table>
<thead>
<tr>
<th>Recruitment Materials:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Modified</td>
</tr>
<tr>
<td>Version</td>
</tr>
<tr>
<td>flyer - to select candidates</td>
</tr>
</tbody>
</table>

5.0 * Will subjects receive financial compensation or other non-financial enrollment incentives?:
- Yes
- No

11.1 Recruitment of Subjects - Financial compensation

1.0 * Compensation: (Select all that apply).
- Enrollment Incentive
- Other
  - If Other, describe:
    - gift cards

2.0 * Indicate the amounts and describe when the compensation or incentive(s) will be given:
1. Each participant will receive $150 gift card. Each mother will receive a $150 gift card and each daughter will receive a $150 gift card. The mother and daughter dyad will receive a total of $300, or $150 each.

   The gift cards will be distributed:
   - $50.00 gift card in the middle of the study and $100.00 gift card at the end of the study.
   - In an effort to get mothers and daughters to attend all three sessions, (after work and after school; including a phone questionnaire. The goal is to reimburse them for their time, gas and efforts by providing them with the equivalent reimbursement. We also need to have the same participants attend ALL sessions and providing half of the reimbursement mid-way and the remainder at the end will assist with participants attending all sessions.

   2. Food/refreshments at each focus group

11.7 Recruitment of Subjects - Students

You have indicated that students will be recruited for this study.

1.0 * Please describe your method of enrollment:
The school will be asked to generate a list of names of students that qualify for the study due to their academic status, age and gender. Those students will be sent a flyer about the study and a pre-screening questionnaire to fill out if they and their mothers are interested.
When students return their flyers and questionnaires, they will receive a copy of the consent and assent form.

The PI will collect all flyers and questionnaires from the school and begin to contact the potential candidates.

The PI will contact the mother daughter dyads and inform them that they are selected. At that time I will answer all their questions and provide them with my contact information for any additional questions. I will review the consent and assent and arrange a time for pick up of forms.

After I received the forms I will arrange a time for a phone conference and provide the mother daughter dyad with the first date of the focus group session.

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.

All subjects will be assigned a “study name” and will use that name as an identifier when speaking in the focus group. There will be roster in the PI's office that will pair the subjects “study name” with their authentic name and demographics. All study records will be stored in the PI's office in a locked drawer and a locked office. Only the PI will have this information and it will be held secure.

Any flash drive, computer or records for this study will be password protected and stored in locked office and a locked suite. Documents will be held for 6 years and then destroyed.

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

- [ ] Account numbers
- [x] Address by street, town, city, zip code
- [x] Age 90 or older
- [x] 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
- [x] 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
- [x] Name
- [ ] Social Security Number
- [x] 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?

   Until close of study

View: 12.14 Retention of link to PHI

12.14 Retention of link to identifiers

You have indicated that the link will be kept for:

1.0  * Why must the link be retained for this period of time? If you have indicated "other", include the retention period. If there is a health or research justification or a legal requirement for retaining the identifiers, please explain.

   The link to PI's name and contact information will be kept until all of the focus groups and transcripts have been coded and entered into the database keeping the link will allow the PT to answer questions and clarify any responses made during the coding process.

2.0  * Describe the plan (how and when) health information identifiers will be destroyed at the earliest opportunity consistent with the conduct of the research:

   The link will be shredded according to the policy for Rutgers School of Nursing once the data is complete.

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
   - 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
   - Written consent document will not be signed by subject (requires a waiver of documentation of consent)

View: 13.2 Consent Forms & Process of Consent

13.2 Consent Forms & Process of Consent

1.0 Upload copies of the informed consent/assent forms, surrogate consent form, information sheet, departmental letterhead and verbal script documents that will be used for this study. (You may also upload a surrogate consent for subjects who regain capacity to consent)

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

1. Please upload most recently approved stamped versions of all consent forms.
2. Please upload a clean (unstamped) Word version (non-pdf) of all consent forms.

* Consent Forms:

<table>
<thead>
<tr>
<th>Name</th>
<th>Modified</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forms_AssentForm.doc</td>
<td>11/12/2013 11:03 AM</td>
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<tr>
<td>Forms_AdultConsent_v4_24_13-1.asd.doc</td>
<td>11/12/2013 11:03 AM</td>
<td>0.02</td>
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<td>11/5/2013 10:56 AM</td>
<td>0.01</td>
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<tr>
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2.0 * Personnel Obtaining Consent: Indicate the names and qualifications of study personnel who will be involved in the informed consent process:

Donna Cill RN, FNP-BC, DNP - Principle Investigator

3.0 * Describe the consent process. Discuss when and where the consent process will take place relative to the initiation of the study procedures, as well as, how opportunities will be made for possible participants/families to discuss their participation with others before signing the consent form. Describe the steps taken to provide the prospective participant sufficient opportunity to consider whether or not to participate in the study.

The interested mother daughter dyad will have a packet with the assent and consent form. The study will be explained to the potential subject by the Principal Investigator, the consent will be read, and their questions will be answered. If s/he wishes to enroll, the subject will sign the consent form. The PI will obtain consent and will also sign and date the consent form, and a copy will be given to the subject.

View: 13.3 Consent Forms & Process of Consent

13.3 Consent Forms & Process of Consent

1.0 * Describe the steps that will be taken to assure that subjects (including children) fully understand the nature of their involvement in research / bank:

1. There will be a flyer that describes the program.
2. There will be a pre-screening questionnaire.
3. The interested mother-daughter dyad will be called by the PI or the PI will meet the participant at their school to review the study and answer any questions.
4. The consent and assent will be fully read and reviewed by the PI with the mother and daughter. All questions will be answered.

2.0 * Describe how capacity for consent will be determined if some or all of the subjects have cognitive and/or language/hearing impairments. Include how continued capacity for consent will be monitored:
The study cannot accommodate subjects with cognitive or language/hearing impairments, as the study is based on obtaining rich data based on cognitive function. The participants will need to be able to express their thoughts, opinion and emotions freely. The study heavily relies on participants being able to speak and understand questions without impairment.

Future studies are being developed that address these impairments and also language barriers.

3.0 If applicable, attach any instruments that will be used to determine the subject’s capacity to consent:

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

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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: Full IRB Review
Submission ID: Pro2013003512

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: Add Other Study Staff Member

**Study Staff: Designation of Responsibilities**

**Instructions:**
- Use this form to add additional personnel to the team
- Do not add Co-Investigators or the primary Study Coordinator here
- You may add multiple people by clicking the 'OK Add Another' button

* * Other Study Team Member - click on the button, find the person you want to add:

* Role - enter a description of the role this person will be performing:
  research assistant

* Designated Tasks:
  Data Analysis

* Will the staff member interact with living individuals or have access to their identifiable information:
  - [ ] Yes
  - [x] No

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:
Part A. Sponsor Information:

1.0 * Funding Sponsor Type:
   Government / Foundation

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:
   Pending

3.0 Sponsor Grant/Protocol Number (if known): Jewish Women's Foundation of New Jersey

4.0 Upload the Grant Application(s) or Contract/CTA Agreement(s):
   Document
   Grant.pdf

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:

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.

View: Adding a Sponsor
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: 

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: 

A data reveal showcase for the participants. 

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: 

* Site Address: 

* Address: 

1/13/2014 1:17 PM
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:  
Focus Groups for daughters and mothers will be held at this school. is one of the School that are under the.

Upload IRB approval, authorization agreement or other proof of agreement:  
Document

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:

Site Address:

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:  
Focus groups will take place here.

Upload IRB approval, authorization agreement or other proof of agreement:  
Document

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:

* Site Address:

* 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:
  focus groups

* Upload IRB approval, authorization agreement or other proof of agreement:
  Document
  History