

HUNTER COLLEGE

INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS
 695 PARK AVENUE, ROOM E1426
 NEW YORK, NY 10021
 PHONE (212) 650-3053 ♦ FAX (212) 650-3055
<http://www.hunter.cuny.edu/IRB>

IRB PROTOCOL COVERSHEET

INSTRUCTIONS: *This form must be reviewed and completed in its entirety. This form must be signed by the Principal Investigator, and if applicable, the Faculty Advisor or Co-Principal Investigator(s). Attention to these elements will facilitate the IRB's review of your protocol.*

PLEASE TYPE OF PRINT LEGIBLY

PROTOCOL INFORMATION

TITLE	
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FUNDING SOURCE	
DOES THE FUNDING SOURCE REQUIRE NOTIFICATION OF THE IRB'S DECISION? <input type="checkbox"/> Yes <input type="checkbox"/> No	

PRINCIPAL INVESTIGATOR (PI) and FACULTY ADVISOR (if applicable) INFORMATION

1) PI NAME				
DEPARTMENT				
E-MAIL ADDRESS				
HOME ADDRESS (necessary for mailing)				
Faculty Advisor <input type="checkbox"/>	Hunter Faculty/Staff <input type="checkbox"/>	Graduate Student <input type="checkbox"/>	Undergraduate Student <input type="checkbox"/>	Other <input type="checkbox"/>

2) PI NAME				
DEPARTMENT				
E-MAIL ADDRESS				
HOME ADDRESS (necessary for mailing)				
Faculty Advisor <input type="checkbox"/>	Hunter Faculty/Staff <input type="checkbox"/>	Graduate Student <input type="checkbox"/>	Undergraduate Student <input type="checkbox"/>	Other <input type="checkbox"/>

3) PI NAME				
DEPARTMENT				
E-MAIL ADDRESS				
HOME ADDRESS (necessary for mailing)				
Faculty Advisor <input type="checkbox"/>	Hunter Faculty/Staff <input type="checkbox"/>	Graduate Student <input type="checkbox"/>	Undergraduate Student <input type="checkbox"/>	Other <input type="checkbox"/>

4) PI NAME				
DEPARTMENT				
E-MAIL ADDRESS				
HOME ADDRESS (necessary for mailing)				
Faculty Advisor <input type="checkbox"/>	Hunter Faculty/Staff <input type="checkbox"/>	Graduate Student <input type="checkbox"/>	Undergraduate Student <input type="checkbox"/>	Other <input type="checkbox"/>

OTHER PROTOCOL INFORMATION

Will the study be administered in a language other than English? <input type="checkbox"/> No <input type="checkbox"/> Yes Be sure to attach translations of all instruments, consent and/or assent form(s), script(s) and instrument(s) or submit these for approval after the English version has been approved.	How many participants will be surveyed, interviewed, tested or otherwise involved in the project? _____ # of participants How many: _____ # male _____ # female (estimate if doing a random sample)	Will your sample include participants from diverse ethnic groups? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, what are the groups and their anticipated proportions? _____	Does the study involve vulnerable subjects? <input type="checkbox"/> No <input type="checkbox"/> Yes	Will participants have health or mental health issues? <input type="checkbox"/> No <input type="checkbox"/> Yes Is the health or mental health of the participants the focus of the research? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes to either above, please provide details in the narrative.
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PLEASE CHECK THE BOX NEXT TO EACH ITEM THAT YOU HAVE ADDRESSED.

* SECTION 1 - ITEMS REQUIRED FOR AN IRB PROTOCOL *

COVERSHEET

- Did you complete and review this coversheet in its entirety? **You must include all 12 pages of this coversheet with your application?**

APPLICATION

- Did you complete the Hunter College Institutional Review Board Application for Approval to Use Human Subjects in Research (8 pages)? You must answer **all** questions asked in the format requested. Not adhering to the questions or format will result in delays, as your protocol will be returned.
- Did you summarize your research question(s) and their significance? **DO NOT ATTACH YOUR WHOLE RESEARCH PAPER.**
- Did you select the type of review requested (Expedited, Exempt or Full Review)?
- Did you provide only the original copy of the application? No copies are necessary. Please do not staple individual sections of the application.
- Did you sign the protocol forms and obtain the signature of the Co-Principal Investigator or Faculty Advisor?

KEY PERSONNEL FORM

- Did you complete a key personnel form? Key personnel are defined as any individual who will be involved in the design and conduct of human subjects research project. A copy of this form is available on our website.

EVIDENCE OF TRAINING

- Did you complete the Collaborative Institutional Training Initiative (CITI) and attach a copy of the certificate for all key personnel. Training can be completed at: www.citiprogram.org. If your certificate is on file at the IRB Office, you do not need to re-submit. Your certificate is valid for a three-year period. After that time, you must complete the CITI refresher course. Information about the training can be found on the IRB website. **We cannot accept other certification programs to meet this requirement.**

CONSENT

- Did you follow the template in Section 4 of this document?
- Did you copy the first page of all consent/assent documents on letterhead? Studies conducted by Hunter students, faculty or staff must be on Hunter College letterhead. If you do not have Hunter College letterhead, please leave a 2 inch margin at the top of the document, and upon approval it will be copied onto Hunter College letterhead.

INSTRUMENTS

- Did you include your research instrument (questionnaire, interview protocol, record review summary sheet, etc.)? If your instrument is a questionnaire or interview, be mindful of the way the study is presented to the participants.
- Is the language of the instruments to be used compatible with the reading/literacy level of the possible research participant?
- Did you label all instruments clearly?
- If you are using an online instrument, did you provide the online version of the instrument and review the requirements on the IRB website.

LETTER FROM COOPERATING AGENCY

- Did you include a letter from an executive in the cooperating agency or organization (if applicable)? If the agency has an IRB, the approval letter must be from the IRB. A sample of what this letter should entail is included on our website.

RECRUITMENT

- Did you provide recruitment materials?
 - You can contact participants by use of flyers, postcards, advertisements, press releases, brochures, verbal exchanges, and postings on the Internet.
 - For written contact (e-mail, letters, etc.) the recruitment script should be in the form of a letter. For some anonymous studies, researchers may choose to combine the consent form and recruitment letter. (see Chapter 8 of the Policies & Procedures Manual)
 - For in-person contact, a recruitment script should be an introduction which the researcher will use with potential participants to introduce the study.
 - For telephone contact, a recruitment script should be an introduction that the researcher will use with potential participants to introduce the study. Researcher should establish that the participant fits the group or class of participants you are seeking, i.e., "Are you/I assume you are ..."
 - For flyers and advertisement did you include names of the researchers and contact information, Hunter's name and researcher's affiliation, purpose of the research, general eligibility criteria, accurate and honest description of benefits and/or compensation (free treatment, payment), a statement that it is a research study?
- Did you indicate in the recruitment materials that you are conducting a research study?
- Did you include a brief synopsis of the study, your name, affiliation and contact information and criteria for participation in your recruitment materials?
- Did you specify how participants are selected? Are you using an entire population? Are you using (number) potential participants from (number) of the available population? Is it a random or systematic (5th person out of every 10 people) sample? Are participants from a public list?
- Did you include language on how you will obtain your subject pool?
- Did you describe the challenges to privacy and confidentiality in the study and describe how you will address them?
- Were you sensitive to actual or perceived coercion?
- In describing your recruitment in the narrative, did you describe how you will eliminate or minimize actual or perceived coercion?

REFERRALS

- If your study involves more than minimal risks, did you provide specific contact information for referrals? This includes a contact person within an agency and a direct phone number. e.g., Jane Doe, North General Hospital, (212) 595-1234.
- Did you include a list of referrals to help participants deal with unexpected outcomes, if participants should need them, which are appropriate to your research?
- If it is an agency based research did you provide in agency and out of agency referrals?
- If your study involves more than minimal risks, does this referral agency have specific expertise in the area of risk?

FOR EXEMPT STUDIES ONLY

- Did you explain in which exempt category your protocol qualifies for and justify why your protocol meets the exempt criteria?
- For review of records, did you attach a copy of the tool that will be used to transfer the data?
- For review of records, did you provide a model record which will be reviewed?
- For review of records from an agency, does the letter from the official state that you have permission to use the data?
- For review of records from an agency, does the letter from the official state how the data can be used?
- For review existing data, did you provide details about how the original data was obtained? Did you supply a letter of IRB approval?

*** SECTION 2 - OTHER ITEMS THAT MAY BE NECESSARY ***

PERMISSION TO AUDIO TAPE OR VIDEO TAPE

- Did you complete a Video Recording or Audio Recording Release Consent Form if you will audio or video record participants? You should select the options that are appropriate for your study. A copy of this form is available on our website. You must use this format.

UNAFFILIATED INVESTIGATOR FORM

- If you are a non-CUNY person, did you indicate a Hunter College faculty contact and complete the Unaffiliated Investigator Agreement Form? A copy of this form is available on the IRB website.

DATA USE AGREEMENT

- If your study involves the use of existing data and it is created by or obtained from a HIPAA covered entity, you must provide a data use agreement. This form is completed by an official in the institution granting access to the data and specifies how the data may be used. Did you provide this form?

TRANSLATIONS

- Did you attach translations of all instruments, consent and/or assent form(s), script(s) and instrument(s) if your study is in a language other than English?
- OR**
- Will you submit the translations once the English version is approved?

*** SECTION 3 - OTHER ISSUES ***

RESEARCH WITH MINORS

Federal regulations specify that minors deserve special care and protection as human subjects. This includes all children under the age of 18. All of these research projects require full committee review.

- Did you provide an assent form? Assent is required for children age 5 and up. It should be in language appropriate for the age group. If you are using a range of ages you will need separate assent forms. Typically you should group ages 5-6, 7-9, 10-12 and 13-17.
- Did you provide a consent form for the parent/guardian allowing the child to participate in the study?
- Is the assent form written in language the child can understand?
- Did you provide this language in the assent form?
"You do not have to participate even if your parent gave permission for you to do so."
- Did you provide this language in the parental consent form?
"My child will also be asked to participate. He /she does not have to participate, or he /she can withdraw at any time, even if I have given my permission."
- Did you remember that research involving participants at New York City public schools, must be approved by the NYC Department of Education IRB?

Please note that the concept of "passive consent" is not acceptable. Passive consent is providing parents with information regarding the study and asking them to return a form only if they do **not** want the child to participate with instructions that say that if the form is not returned the child **will** participate in the research.

RESEARCH WITH COGNITIVELY OR MENTALLY IMPAIRED PERSONS

Federal regulations specify that cognitively or mentally impaired adults deserve special care and protection as human subjects. The category of cognitively or mentally impaired includes, but is not limited to, people suffering from mental retardation, neurological diseases and disabilities affecting judgment, mental disorders producing delusion or confusion, and/or dementia. All of these research projects require full committee review.

- Does the informed consent process address the need to preserve participant decision-making autonomy?
- Did you show that you have made every possible attempt to seek the informed consent of the participant as well as the informed consent of the participant's proxy? As a general rule, all adults regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment?
- Did you assure that potential participants are fully informed about the voluntary nature of their participation, and that they remain free to withdraw at any time, even when proxy consent has been obtained?
- Are both participants and their proxies fully informed about the risks, costs, and risk/benefit ratio of the study?
- If there is evidence of serious mental disability that would impair reasoning or judgment, did you explain how you will assess competency?
- Did you include a description of appropriate psychological or medical screening criteria for competency and indicate how and when you will use them?

RESEARCH WITH PRISONERS

Federal regulations specify that research which involves prisoners deserve special care and protection as human subjects. At Hunter, the category of prisoners includes, but is not limited to, prisoners, parolees and those on probation. All of these research projects require full committee review.

The following research is normally permissible:

- a. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
- b. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.
- c. Research on conditions particularly affecting prisoners as a class.
- d. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.

The following criteria must be met:

- Are any possible advantages accruing to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for mailings in the prison, of such a magnitude that his/her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison impaired?
- Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?
** For prisoners, minimal risk is the probability and magnitude of **physical or psychological** harm that is normally encountered in the daily lives or in the routine medical, dental or psychological examination of **healthy persons**.
- Are the procedures for the selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? Unless the principal investigator provides justification in writing to the IRB for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
- Is the information presented in language which is understandable to the subject population?
- Are there adequate assurances that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole; each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole?
- Did you add to the consent form a statement that participants should *not discuss open cases*? This includes cases pending in the criminal justice/judicial system as they may be subject to subpoena.

*** Note: Research that is conducted or supported by HHS must be certified by OHRP. The IRB Office will aid in certification, after the protocol is approved.**

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

- Do you use individually identifiable health information created by a covered entity? No Yes
- Do you use or disclose health information that has been created by or obtained from HIPAA-covered entities, such as hospitals, physicians' offices, or social service and mental health agencies?
 No Yes
- If you answered yes to the last question, have you attached a HIPAA Waiver Application or a HIPAA Research Authorization? No Yes
- Are you using key personnel that are not affiliated with CUNY? No Yes
- If you answered yes to the previous question, have you attached a Subject Information Confidentiality Agreement for each non-CUNY key personnel? No Yes
- Do you have a completed and signed Data Use Agreement between yourself and the covered entity? (see Section 2 on Data Use Agreements)

SPECIAL RELATIONSHIPS

Clients, students or staff of Hunter College or any other agency or institution may feel they HAVE TO or MUST participate in a study if their practitioner, teacher or supervisor asks them. It is recommended that teachers not use class time to complete interviews or questionnaires. It is also preferable, if possible, to avoid having teachers, staff or practitioners recruit their own workers, students or clients directly for your study. If you are asking staff/teachers to recruit participants on your behalf, it is preferable for the staff/teacher not to know if the worker/students have actually participated. Here are ways to handle that:

- a) they could provide information to the clients/students asking them to contact the researcher directly;
 - They could get permission from the client/students to give client names to researcher. You, the researcher, would then contact them directly;
- b) If staff must or cannot help but know who participates, it must be stated in the recruitment script and consent form that the participant's participation is still voluntary, and there will be no withdrawal of services or other penalties if they choose not to participate.
 - Be sensitive to the impact of group pressure when recruiting participants in a group session, public meeting or class setting. To minimize, the researcher (or someone else) could distribute cards to the potential subjects, asking people interested in participating to write down their contact information, and then the researcher can contact them. Collect the cards from everyone so no one in the group will be overtly aware of who volunteered. Alternatively, the researcher can distribute a recruitment flyer, which asks the potential subjects, in writing, to contact the researcher.

RESEARCH WITH GROUPS

It is important to convey to the participants in focus groups, that they should not discuss what is said in the group outside of the group.

- Did you include the following statement or similar appropriate language to the consent form:
"To protect the privacy of the group members, please refrain from speaking to others about what is said within the group."
- Did you include a statement that group members will know what the subject says and therefore confidentiality cannot be guaranteed?

ANONYMITY AND CONFIDENTIALITY

Anonymity is the state of a person being anonymous or unidentified. The identity of the person is not known to the researcher.

When a researcher promises confidentiality to participants, they have agreed to a bond of trust. The researcher knows who the participants are but has committed to and has the responsibility to keep the information private.

Confidentiality does not mean the participants are anonymous. These words are not interchangeable. Confidentiality means that the researcher can identify the participants and/or the responses of the participants. A study can be conducted where the data is confidential but not anonymous. Conversely, if the data is anonymous, it more than likely will be kept confidential.

To determine if you should use the term anonymous, as a rule of thumb, ask yourself, "Will I know who participated in the study?" If the answer is yes, the study is not anonymous.

- Valid informed consent requires:
 - (1) **Disclosure** of relevant information to prospective participants about the research;
 - (2) their **comprehension** of the information, and
 - (3) their **voluntary agreement**, free of coercion and undue influence, to research participation.
- Consent forms should be in the second person voice. Listed below are elements that should be included. The model that appears uses a block format to make it easier to read, though this format is not mandatory. The following elements must be included in the consent form.
- This template uses standard language for normal adults with a relatively high literacy level (8th Grade). For some populations (cognitively or mentally impaired, children, non-native English speakers and those with lower literacy levels) you will need to alter the language.
- If you alter the standard language, please be sure to explain how and why this was done.
- You can check the reading level of a document in Microsoft Word. (Click on Tools, then Options, then the Spelling & Grammar tab, then click the box 'Show readability statistics.' Check the document as you normally would and the readability statistics will appear.)

ELEMENT	EXAMPLE
<p>Purpose And Background</p> <p>This section should present the introduction to the study, indicating who is conducting the research, stating the aim of the study, giving a brief summary of the background or reason for the project, and explaining why the individual has been asked to participate.</p>	
<ul style="list-style-type: none"> • Who is the researcher? • What is the researcher's affiliation with Hunter College? • What the study is about? • Criterion for Participation • How did the researcher find and/or select this participant? • Number of Anticipated Participants • A statement of voluntary participation 	<p>Sarah Brown is a graduate student in the Department of Health Sciences at Hunter College. She is conducting a study about how nurses deal with stress. You are being asked to participate in a study which explores how nurses experience and cope with stress in their roles. You have been identified as a possible participant because you are a nurse who has worked in the field for five years or more and you are over the age of 18. It is anticipated that 30 individuals will participate in this study. Participation in this study is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are entitled.</p>
<p>Procedures</p> <p>Each procedure should be discussed preferably in the sequence in which it occurs. If the study involves screening procedures, these should be mentioned first and identified as tests that will determine eligibility to participate in the study. This section should clearly state what will be done to the individual as a result of participation in the study, and, where appropriate, how this differs from standard treatment or practice or what would happen to the individual if he/she did not participate in the study.</p>	
<ul style="list-style-type: none"> • What will the participants be asked to do? Will it be interviews, focus groups, etc. • Where will it take place? • Expected duration of the participant's participation. How long will it take? 	<p>You are being asked to participate in an in-person interview. During the interview you will be asked questions about your day-to-day experiences as a nurse. The interview will take place at a mutually agreed upon public location and will take about one hour.</p>
<p>Risks and/or Discomforts</p> <p>The risks and/or possible discomforts of all study procedures should be listed and explained in this section. It is best to describe the risks of each procedure in a separate point and arrange them according to severity and the likelihood of occurrence. Where appropriate, the precautions that will be taken to avoid certain outcomes from occurring should be indicated and what will be done should they occur. It is important to consider the emotional impact of the research on the people who are your research participants, even if the study is of a seemingly impersonal subject matter. PLEASE NOTE: There is always the possibility of harm to the participants, even if remote and minor. Examples of types of risks to participants are: <u>Physical</u> – risk of heart attack if project involves participants working out on a treadmill; <u>Psychological</u> – survey questions remind participants of traumatic or emotional events; <u>Social</u> – disclosure of individual responses could lead to a loss of community standing; <u>Legal</u> – survey questions may be self-incriminating; <u>Economic</u> – disclosure of individual responses could result in loss of employment.</p>	

<ul style="list-style-type: none"> • Indicate risks • Indicate what the participant should do if he/she is bothered or upset as a result of participation. • Include a statement about the participant's ability to not answer any question. 	<p>The study may raise difficult issues about stress in your life. In the event that this happens, the researcher has a list of resources that you may contact for assistance should you need them. You can choose to not answer any particular question. You may also stop the interview process at any time.</p>
<p>Benefits</p> <p>Any potential direct benefits to the participant should be described. In behavioral research there typically are no direct benefits.</p>	
<ul style="list-style-type: none"> • Indicate the Benefit(s) to the participant. Note that accumulating knowledge that might help to understand a problem or change a policy in the future is <u>not</u> a benefit to the participant and should not be advertised as such. 	<p>There are no direct benefits. However, participating in the study may increase your knowledge of stress as it relates to nurses.</p>
<p>Alternatives</p> <p>This section should discuss any alternatives to participation in the study. If the study involves only normal, healthy volunteers, and thus the only alternative is to decline participation in the study, this need not be mentioned in a separate section because the individual's right to choose not to participate will be made clear in the last section of the form. If the study involves the use of a student's class time, alternatives that the child will be given if they choose not to participate must be detailed.</p>	
<ul style="list-style-type: none"> • Indicate Alternative 	<p>None</p>
<p>Financial Considerations</p> <p>This section should state the total dollar amount that the participant will be paid for participation in the study, and should give any other relevant information such as pro-rating if a participant does not complete the study. If appropriate, a payment schedule should be included in this section. Participants should not be required to complete the entire study in order to be reimbursed.</p> <p>Participants should be informed how payment will be made (e.g., in cash, by check) and when they will be paid (e.g., immediately after the interview, approximately six weeks after completion of the study or one-third upon completion of the first of three phases of the study). It is important that this information be clear and complete. If there will be no payment or reimbursement to participants for study participation, this information should be stated in this section.</p>	
<ul style="list-style-type: none"> • <i>Indicate Payment</i> 	<p>You will receive \$10 for your participation. Even if you do not complete the entire interview, you will still receive the \$10.</p>
<p>Privacy and Confidentiality</p> <p>Indicate how confidentiality in the study will be maintained. If there are limits to confidentiality this must be spelled out.</p>	
<ul style="list-style-type: none"> • Tell participants how the data will be collected. • Explain how and where the data will be handled and stored. • State when and how data will be destroyed. • Tell participants what will happen to the data that is collected. • Indicate if anyone will know if they have participated in this study, and if so, who will know. 	<p>The researcher will tape record the interview with your permission. You will be given a separate form to indicate your permission. No one but the researcher and her faculty advisor will listen to the tapes. The tapes will use identifying codes. Your name will not appear on the transcripts. Tapes will be destroyed after interviews are transcribed. No personal identifiers can be linked to the data. All materials will be kept in a locked file cabinet in the faculty advisor's locked office to which only the researcher and her faculty advisor have access. The data will be stored for a minimum of three years. After that,</p>

<ul style="list-style-type: none"> • Briefly describe how the confidentiality of private information will be protected, i.e., coding of records, limiting access to the study records, not using any individual identifiers in publications or reports resulting from the study. • Limits to confidentiality – This language is necessary in almost all instances regardless of subject matter. “If the researcher becomes concerned that you are a danger to yourself or others, she/he will alert (counselor, agency director/polic e, etc.).” <ul style="list-style-type: none"> ❖ If you are talking to professionals or key informants about their feelings, this language is required. ❖ You need not use this language with professionals or other key informants if you are asking about organizational or professional practices. Instead, use the phrase, “The information you disclose will be kept confidential to the fullest extent permitted by law.” ❖ Do not use this language if you are using a nonymous surveys. 	<p>all materials may be destroyed. As long as the data exists it will be kept secured. The information will be used to produce a paper for a graduate research project. Only aggregate data will be reported in any reports or publications derived from this research. All identifying information about you and others who participated will be omitted or disguised. The researcher is mandated to report to the proper authorities suspected child abuse, and any indications that you are in imminent danger of harming yourself or others.</p>
<p>Withdrawal</p> <p>The following statement must appear in the consent form:</p>	
<ul style="list-style-type: none"> • Include a statement about discontinuing the study 	<p>You may discontinue participation at any time without penalty or loss of benefits or services to which you are entitled.</p>
<p>Contact Information</p> <p>The contact information should read as follows:</p>	
<ul style="list-style-type: none"> • “If you have questions about the study, you can contact the researcher, (name of researcher at (xxx) xxx-xxxx or his/her faculty advisor (name of faculty advisor) at (xxx) xxx-xxxx. You should contact the Hunter College IRB Office at (212) 650-3053, if you have questions regarding your rights as a subject or if you feel you have experienced a research-related injury.” <p style="text-align: center;">Or alternately</p> <p>“If you have questions about the study, you can contact the researcher, (name of researcher at (xxx) xxx-xxxx or his/her faculty advisor (name of faculty advisor) at (xxx)xxx-xxxx. “You should contact the Hunter College IRB Office at (212) 650-3053, if you have questions regarding your rights as a subject or if you feel you have been harmed as a result of your participation in this research.”</p>	<p>If you have questions about the study, you can contact the researcher, Sarah Brown at (555) 555-5555 or her faculty advisor Joe Black (555)555-5577. You should contact the Hunter College IRB Office at (212) 650-3053, if you have questions regarding your rights as a subject or if you feel you have experienced a research-related injury.</p>

Signatures

- For a waiver of signed consent
(i.e., use of an Information Sheet rather than a consent form)
The last paragraph should read:
"The information you provide is anonymous. No one will know how you responded to these questions. Please do not put your name or other identifying information on the questionnaire to assure anonymity. By completing and returning the instrument you are giving consent"
- For a signed consent form
- The last paragraph should read:
"I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form for my records and future reference." (Note: this statement should be in the first person.)
- This should be followed by lines for the participant's printed name, his or her signature and the date of signature.
- This should be followed with the signature of person obtaining consent. This provides participants with a record of who explained the study to them. This should include the printed name of the specific individual obtaining consent, his or her signature and the date of signature.

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form for my records and future reference.

Participant's Name _____ *Signature* _____ *Date*

Researcher's Name _____ *Signature* _____ *Date*

PLEASE INDICATE WHICH ITEMS YOU HAVE INCLUDED WITH YOUR APPLICATION

<input type="checkbox"/> CONSENT FORM(S) # _____	<input type="checkbox"/> ASSENT FORM(S)
<input type="checkbox"/> RECRUITMENT FLYER/ LETTER/ EMAIL	<input type="checkbox"/> PARENTAL PERMISSION
<input type="checkbox"/> FORM FOR PERMISSION TO AUDIO TAPE	<input type="checkbox"/> HIPAA RESEARCH AUTHORIZATION
<input type="checkbox"/> FORM FOR PERMISSION TO VIDEO TAPE	<input type="checkbox"/> DEBRIEFING SCRIPT
<input type="checkbox"/> INTERVIEW PROTOCOL	<input type="checkbox"/> RECRUITMENT ORAL SCRIPT
<input type="checkbox"/> DATA TRANSFER SHEET (FOR STUDIES INVOLVING USE OF EXISTING DATA)	<input type="checkbox"/> SAMPLE RECORD (FOR STUDIES INVOLVING USE OF EXISTING DATA)
<input type="checkbox"/> LETTER FROM COOPERATING AGENCY or IRB APPROVAL FROM ANOTHER INSTITUTION	<input type="checkbox"/> REFERRALS/ RESOURCE LIST
<input type="checkbox"/> UNAFFILIATED INVESTIGATOR FORM	<input type="checkbox"/> SUBJECT INFORMATION CONFIDENTIALITY AGREEMENT
<input type="checkbox"/> DATA USE AGREEMENT	<input type="checkbox"/> OTHER: _____
<input type="checkbox"/> INSTRUMENT(S) # _____ LIST ITEMS: _____	

I certify that I have read, completed and addressed all items in the IRB Protocol Coversheet.

Principal Investigator
 Date: _____

Co-Principal Investigator/ Faculty Advisor
 Date: _____

Co-Principal Investigator/ Faculty Advisor
 Date: _____

Co-Principal Investigator/ Faculty Advisor
 Date: _____

**** IRB Protocol Forms, Manuals and FAQs may be downloaded from:**
<http://www.hunter.cuny.edu/IRB>