HUNTER COLLEGE

HUMAN RESEARCH PROTECTION PROGRAM (HRPP) OFFICE
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NEW YORK, NY 10065
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http://www.hunter.cuny.edu/IRB

IRB PROTOCOL SUBMISSION GUIDANCE

NOTE: *This form should be reviewed in its entirety. Attention to these elements will facilitate the CUNY UI-IRB's review of your protocol. Please review before submitting your package on Ideate.*

SECTION 1 - **ITEMS REQUIRED FOR AN IRB PROTOCOL**

APPLICATION

- Did you complete the CUNY Ideate application? You must answer **all** questions asked in the format requested. Not adhering to the questions or format will result in error messages, as your application will not be able to be submitted if incomplete.
- Did you summarize your research question(s) and their significance? **DO NOT ATTACH YOUR WHOLE RESEARCH PAPER.**
- If seeking an Exempt review, did you select the type of review within the "Summary" tab?

KEY PERSONNEL INFORMATION

- Did you include all key personnel in the IRB application? Key personnel are defined as the Principal Investigator, Co-Investigators and research personnel who interact directly with human subjects or have access to private information related to human subjects during the course of a research project. Key personnel also include faculty sponsors/advisors who provide direct oversight of research with human subjects or research using private information about human subjects.

EVIDENCE OF TRAINING

- Did you complete the Collaborative Institutional Training Initiative (CITI) and link a copy of the certificate to your application? For further instructions, please refer to our website under the "How to apply" link. Training can be completed at: www.citiprogram.org.
- The CUNY UI-IRB requires the Social and Behavioral course or Biomedical course, depending on the nature of the PI's studies.
- 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 the "Forms" section of our website? You may also use the template below, under 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.
- You can request a waiver of documentation of consent or a complete waiver of consent upon completion of your application. A *waiver of documentation* means that you are consenting the subject orally, but you are **not** documenting the process with papers that the PI and/or subject can review and sign. A *complete waiver* means that you are not asking the individuals permission at all. You are not providing documentation, not requesting a signature, not providing the subject with any information written or orally. This often happens when a PI is doing data analysis and the subjects' contact information is not available because the data is de0identified or when returning to a previous project where the subjects have consented and you are not changing any of the parameters of the research.

INSTRUMENTS

- Did you include your research instrument (questionnaire, interview protocol, record review summary sheet/data extraction 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 (screenshot or link to survey) and review the requirements on the education and training link on our website? The relevant language for online surveys needs to be inserted in the consent form.

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?

    a. You can contact participants by use of flyers, postcards, advertisements, press releases, brochures, verbal exchanges, and postings on the Internet.
    b. 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.
    c. For in-person contact, a recruitment script should be an introduction which the researcher will use with potential participants to introduce the study.
    d. For telephone contact, a recruitment script should be a 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....*"
    e. 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? You may attach this as a separate document that will be given to participants or included on the consent form.
- 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 which exempt category your protocol qualifies for and justify why your protocol meets the exempt criteria? If your study does not apply to any of the exempt categories- an expedited or full-board submission should be submitted, instead.
- 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 AUDIOTAPE OR VIDEOTAPE

- Did you include the procedures as to how you will audio-tape or video-tape the participants (under procedures) on the consent form and in the application?

- Did you include a checkbox at the end of the consent form giving participants the option to be audio recorded/video recorded?

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?

- Please see the revised translation policy below from the CUNY Policies and Procedures:

Translations of Consent Documents (Section 9.8.1)

When an investigator expects to enroll non-English speaking subjects, the investigator must submit translations of the English language consent form into all languages spoken by the expected subject population. Translations must be performed by one of the following:

- *A certified translator; OR*
- *A bilingual member of the research team, who is fluent in both English and the language of the non-English speaking subject.*

For translations performed by a certified translator, a certificate of translation must accompany the IRB submission.

For translations performed by a bilingual member of the research team, an explanation of the translator's qualifications must be included with the IRB submission.

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 an expedited or full-board review, depending on the risk level of your study.

- 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 their child to participate in the study (parental permission form)?
- 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? *Conditional approval will be granted until the DOE approval letter is submitted to the Hunter College HRPP office.*

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 their 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 an expedited or full-board review, depending on the risk level of your study.

- 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 an expedited or full-board review, depending on the risk level of your study.

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 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 earnings 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 CUNY HRPP 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?

- 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?

- If you answered yes to the questions above, have you attached a HIPAA Waiver Application or a HIPAA Research Authorization from the HIPAA-covered entity?

- Are you using key personnel that are not affiliated with CUNY?

- If you answered yes to the previous question, have you included them to the key personnel section of the IRB application?

- Do you have a completed and signed Data Use Agreement between yourself and the covered entity?

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 their 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 Tool, 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.)

<table>
<tr><th>ELEMENT</th><th>EXAMPLE</th></tr>
<tr><td colspan="2">Purpose And Background

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.</td></tr>
<tr><td>• 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</td><td>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.</td></tr>
<tr><td colspan="2">Procedures

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.</td></tr>
<tr><td>• 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?</td><td>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.</td></tr>
<tr><td colspan="2">Risks and/or Discomforts

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: Physical – risk of heart attack if project involves participants working out on a treadmill; Psychological – survey questions remind participants of traumatic or emotional events; Social –disclosure of individual responses could lead to a loss of community standing; Legal – survey questions may be self-incriminating; Economic – disclosure of individual responses could result in loss of employment.</td></tr>
<tr><td>• Indicate risks</td><td>The study may raise difficult issues about stress in your life. In the event that this happens, the researcher has a list of resources</td></tr>
</table>

• 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.	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.

Benefits

Any potential direct benefits to the participant should be described. In behavioral research there typically are no direct benefits.

• 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.	There are no direct benefits. However, participating in the study may increase your knowledge of stress as it relates to nurses.

Alternatives

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 <u>choose not to participate must be detailed.</u>

• Indicate Alternative	None

Financial Considerations

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.

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.

• *Indicate Payment*	You will receive $10 for your participation. Even if you do not complete the entire interview, you will still receive the $10.

Privacy and Confidentiality

Indicate how confidentiality in the study will be maintained. If there are limits to confidentiality this must be spelled out.

• 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. • Briefly describe how the confidentiality of private information will be protected, i.e.,	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, 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

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/police, etc.)." ™ 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 fill extend permitted by law." ™ Do not use this language if you are using anonymous surveys.	mandated to report to the proper authorities suspected child abuse, and any indications that you are in imminent danger of harming yourself or others.
Withdrawal The following statement must appear in the consent form:	
• Include a statement about discontinuing the study	You may discontinue participation at any time without penalty or loss of benefits or services to which you are entitled.
Contact Information The contact information should read as follows:	
• "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 CUNY Research Compliance Administrator at (646) 664-8918, if you have questions regarding your rights as a subject or if you feel you have experienced a research-related injury." **Or alternately** "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 CUNY Research Compliance Administrator at (646) 664-8918, 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."	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 CUNY Research Compliance Administrator at (646) 664-8918, if you have questions regarding your rights as a subject or if you feel you have experienced a research-related injury.
Signatures	
• <u>For a waiver of signed consent</u> (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" • <u>For a signed consent form</u> • 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*