Informed Consent

[This is a consent sheet that includes all of the required information that research participants are required to know before giving consent.]

Protocol Title: ………………………………………………….

Please read this consent document carefully before you decide to participate in this study.

Purpose of the research study: The protocol’s “purpose of research” text or study aims often works well here.

Who is conducting and funding the study: State who the study director(s) are – and if external funding has been obtained, state who is funding the study.

What you will be asked to do in the study: Describe what you are asking the participant to do. This includes how you will collect data (e.g., interview, focus group, self-administered questionnaire), what topics will be included in the data collection, when and where data will be collected.

Time required: Specify the amount of time required for participation and any information about scheduling, if relevant.

Access to Existing Records: State whether you are requesting access to any other information (e.g., medical records)

Longitudinal Study: If you are conducting a longitudinal study, you must inform the participant about all planned data collection. You must state that participating in the baseline data collection does not obligate the participant to participate in any of the subsequent data collection. State that they can decide at that time whether or not they want to participate in the next wave of data collection.

Risks and Benefits: Text from the protocol’s “risks and benefits” section often works well here.

Compensation: if any compensation will be offered to participants, state exactly what they will receive and when.

Confidentiality: Explain how confidentiality will be assured and maintained. State where the data will be stored and who will have access to the data. State who will be able to see the list linking names and study ID numbers,

Your identity will be kept confidential to the extent provided by law. Your information will be assigned a code number that is unique to this study. The list connecting your name to this number will be kept in a locked file [specify where] and only the Study Director and other researchers will be able to see the list. When the study is completed and the data have been analyzed, the list will be destroyed. Study findings will be presented only in summary form and your name will not be used in any report.

If there are any limits to confidentiality, state them very clearly. These include breaking confidentiality if a participant informs you that they are planning commit self-harm or harm someone else, or in the case of a report of child abuse or neglect. State that you will have to break confidentiality and exactly what will happen in these circumstances.
Anonymity: If you are offering anonymity, you should omit the section on confidentiality, and instead state:

Your identity in this study would be anonymous. It will not be possible to know who chooses to participate in this study and who did not. It will also not be possible to know who completed which questionnaire.

Voluntary participation: State that participation is voluntary and that there is no penalty for not participating. Describe the lack of penalty in terms that are relevant to your study.

Your participation in this study is completely voluntary. If you choose not to participate in this study, this will have no effect on the services or benefits you are currently receiving. You may refuse to answer any of the questions we ask you and you may stop or end the interview at any time.

Right to withdraw from the study: State that the participant may withdraw from the study at any time without consequences.

You may choose to stop participating in the study at any time. This will have no effect on FILL IN WITH RELEVANT WORDING, E.G. the services you receive from NAME OF AGENCY.

For online surveys, state that they can choose to stop completing the survey and not submit the part they already completed.

Recording: If you will be audio- or video-recording the interview or focus group you must state this. Also state whether agreeing to be recorded is required for study participation, or whether the participant can choose to not be recorded. Also state that the participant can request that the recording be stopped at any time during the interview or focus group, either permanently or temporarily, as appropriate to your study. State who will have access to the recordings, where they will be stored, and when they will be destroyed. State that they will not be used for any purpose other than the research study. If you will be transcribing the recording, state that a typewritten version will be created. State that no names or other information that could be used to identify the participant will be included in the typewritten version. State that anything that could possibly indicate the identity of the participant will not be included in the typewritten version or will be disguised.

Who to contact if you have questions about the study: (List your contact information here.)

Who to contact about your rights as a research participant in the study:

Michele Kuchera, IRB Manager
Phone: 718-817-0876 E-mail: IRB@fordham.edu

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

If you agree to participate in this study please sign on the next page. Thank you.
There are directions on the next page for participants of anonymous studies.

Agreement:
I have read the procedure described above. I voluntarily agree to participate in the procedure and I have received a copy of this description. IF RECORDING IS USED AND REQUIRED FOR PARTICIPATION, ADD: I understand that this (interview/focus group) will be (audio-/video-)recorded.

Name (Printed) ____________________________________________

Signature: ________________________________________________

Date: ____________________

Principal Investigator: _____________________________________ Date: ____________________

IF RECORDING IS USED BUT IS OPTIONAL, ADD: I agree to allow this interview to be (audio-/video-) recorded. I understand that I can request that the recording be stopped at any time.

Signature: ________________________________________________

IF ANONYMITY IS USED IN THIS STUDY, DO NOT INCLUDE THE SIGNATURE LINES. INSTEAD, STATE:

Your completion and return of the questionnaire indicates your consent to participate in this study.