Institutional Review Board
Sponsored Programs Office, Buckham Hall B-206
1300 Elmwood Avenue, Buffalo, NY 14222
Federalwide Assurance ID#: 00007126

INVESTIGATOR'S CHECKLIST FOR HUMAN PARTICIPANTS COMPLIANCE

Investigators are encouraged to use this checklist when submitting a protocol. These items represent what the IRB considers when reviewing protocols.

- ✓ **Project Description**: The description of the project must be written in layperson's terms. Language used should be 6th to 8th grade level. Avoid using technical/scientific terminology. Explain the procedures/process of the project and what you are trying to accomplish.
- ✓ **Subject Recruitment and Selection**: You must indicate all criteria for selection of participants, including where and how you are obtaining participants. Give details on the recruitment process. Provide a script and the procedure for recruiting. (One of the things the IRB reviews is equitable selection of participants.) Include copies of any fliers or announcements you may be using.
- ✓ **Confidentiality or Anonymity**: Provide details on the procedures you will use to protect the confidentiality or anonymity of participants. Remember that confidentiality of participation should be included with the protection of the data obtained.
- ✓ **Procedures to be used**:

_____ *Questionnaires:* Submit copy of all questionnaire(s).
_____ *Interviews:* Submit copy of interview script.
_____ *Video Recording:* Provide information on procedures to be used for storage and disposal of video and images.
_____ *Observation:* Provide information on whom and what you are observing. Will there be any interaction with these participants?
_____ *Records Review*: Provide information on records you will be reviewing; include specifically what data you will be extracting from these records. You must obtain permission from the site where these records are located and also consent from the participants; indicate in the consent form exactly what information you will be obtaining. Also, if you are not directly extracting the data, you must indicate who is and the procedures to be followed to maintain confidentiality.
_____ *Secondary analysis*: Are individuals identifiable in your data? Is this information

identifiable through links, such as coded information or pseudonyms? Include where you are getting this information from and if you have received permission. If identifiable, you must provide procedures to maintain confidentiality.

_____ *Tasks*: Provide exact details on what is expected of participants and what you are to gain from their performing this task. Indicate if there is any risk involved, how much, and how you plan to minimize the risk. Also include the length of time to complete the task. This should be included in the consent form also.

_____ *Deception*: You must provide a justification for needing the deception. Provide a "debriefing" for participants and indicate when the debriefing will take place. The debriefing must clearly explain the deception and why it was necessary. Indicate if there is any additional risk to participants due to the deception and how you plan to minimize the risk.

- ✓ **Informed Consent**: In general, signed consent should be obtained from all participants prior to their participation, unless a justification is provided as to why there would be additional risk placed on participants. Include the process you plan to use to obtain consent. Anonymous, innocuous questionnaires may not require a signed consent form, however a written cover page with all the standard consent information needs to accompany the questionnaire. A statement that returning the completed questionnaire indicates consent to participate should be included on the questionnaire or cover page.
- ✓ **Third parties**: When an investigator obtains private identifiable information about an individual for research purposes from someone else without direct contact with the individual, that individual may be considered a "secondary subject." As with human participants, consent must be obtained from the third parties. There are circumstances where written consent may be waived with justification.
- ✓ **Consent Form**: A copy of the form should be given to participants for future reference. (If deception is involved, you cannot use a consent form, since participants are not fully informed. However, you must provide participants with an "information sheet" which contains the standard consent information. See Informed Consent template on the Sponsored Programs Office website and in the RF SUNY PACS IRB library for required format.