Center for Clinical and Translational Science

CONSENTING CHECKLIST INSTRUCTIONS

PURPOSE

This tool is intended to assist the user in documenting the consent process by providing a framework for the consent discussion and process with the potential study subject.

HOW TO USE

- Complete the form header by adding the Participant's Initials, ID code and date of birth. Add the visit date and study title.
- The study team member consenting the participant should complete the body of the form as follows:
    - Document the type of consent and version reviewed with the participant
    - Complete each section by responding to the questions as outlined.
    - Complete the additional notes section as needed
    - Sign and date the form

GOOD PRACTICE RECOMMENDATIONS

- If using the checklist, it should be printed and completed as a source document at the time of consent.
- Use the tool for initial consent as well as throughout the study, as consent forms are updated and revised and participants are re-consented.
- Utilize the Additional Notes section of the form for clarification and or documentation of any special circumstances at the time of consent such as the presence of a witness
- Be sure to customize the template to make it study-specific.