

CONSENTING NOTE INSTRUCTIONS

PURPOSE

This tool is intended to assist the user in the consent process by providing a framework for documentation of the consent discussion and process in the participant files.

HOW TO USE

- Customize the consenting note template for your study.
 - Some items to consider:
 - Additional detail on the type of participant consent/assent/assent script combination used
 - Additional detail on the consenting process if using a Foreign Language (translated) participant consent/assent/assent script such as:
 - The form used was an IRB approved, certified translation
 - A translator was present or utilized during the consent process
 - The translator signed the consent form as a witness
 - Which forms were provided for the participant to take with them – i.e. the participant was assented in English, the parent/LAR was consented in Spanish, the participant received copies of the signed forms as well as an unsigned copy of the assent form in Spanish for reference.
 - Additional detail on the consenting process if the participant is illiterate
 - The consent form was read to the participant and by whom
 - A witness was present, and their signature was included on the consent form
 - Electronic file – AEHR
 - Participant Binder - with the consent/assent/assent script
- Establish a plan for use, train study personnel on that plan
- Use per plan, complete periodic reviews to confirm that the process is taking place as planned
- Revise the process as needed

GOOD PRACTICE RECOMMENDATIONS

- Use the tool for initial consent as well as throughout the study, as consent forms are updated and participants are re-consented.