Checklist for the Informed Consent (or Assent) Process

This checklist helps to assure that all components of the consent process are addressed, and in the proper order. Adapt to your own study as needed

Study Name: _____ Participant ID: _____

Items Addressed	Comments
☐ List persons present during the informed consent process and the consent signee.	Persons Present: Signee Name:
☐ List the person who explained the details of the study participation.	Name:
☐ Discussed purpose of research and procedures.	
☐ Discussed risks and benefits of study participation.	Questions asked and answered:
☐ Discussed alternatives to research.	
☐ Discussed that participation is voluntary and participants may withdraw at any time.	
☐ Discussed issues of confidentiality.	
☐ Discussed potential study-associated costs.	
☐ Assessed if family appears to understand all terms of participation and agree to enrollment. (parent and child if assent is needed)	Demonstrated through: ☐ Talk back method ☐ Q&A ☐ Other _____
☐ The consent document was signed prior to the performance of any study-related procedures.	
☐ An unsigned copy of the consent was provided to the participant, including investigator/research team contact information.	

Investigator or IRB-approved delegate who conducted the consent process and completed this form.

Signature:	Date:	Time: AM/PM

Created by Pat Karausky RN, BSN,CCRC, Clinical and Translational Science Institute, University of Pittsburgh