Informed Consent Process Checklist

This checklist is to help researchers monitor the consent process to ensure that it follows the approved process in the protocol and covers all of the required components.

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Project Identification			
IRB protocol number		*Researcher Collecting Consent*	
Participant ID/Pseudonym		*Date of Consent*	

- ☐ Verify that the current IRB approved version of the Consent Form was used.
- ☐ Consent process took place in a private area (or as according to the approved Research Application).
- ☐ All of the participant's questions were answered.
- ☐ Participant is able to verbally express his/her understanding of what the research involves.
- ☐ Participant has had enough time, in their opinion, to make an informed decision.
- ☐ Both of the following occurred:
  - ☐ Printed name, signature, and date are accurately completed by participant and approved project team member.
  - ☐ Written consent was obtained prior to performing any research activities.

  –OR–
- ☐ Waiver of documentation of consent granted by the IRB.
- ☐ Special consent cases:
  - ☐ Not Applicable
  - ☐ Alteration of consent
  - ☐ Participant debriefing provided following study completion (for studies that involve deception)
  - ☐ HIPAA authorization obtained
  - ☐ Assent obtained
    - ☐ Electronically ☐Paper
  - ☐ Parental permission obtained
    - ☐Electronically ☐Paper
  - ☐ Consent obtained
    - ☐Electronically ☐Paper
- ☐ Signed Consent form retained by researcher and stored securely.
- ☐ A copy of the consent was given to the participant.

Notes about the consenting process including any information not included in the list above: