

An informed consent process checklist

Below are sample questions from the “Documentation of the Informed Consent Process” checklist developed by the University of Pittsburgh in Pittsburgh, PA:

- List the persons present during the informed consent discussion.
- Who explained the details of study participation? Note approximate length of time of discussion.
- Were all risks and benefits of study participation presented to the subject (and family)?
- Were all questions answered to the subject’s (and family’s) satisfaction?
- Does the subject appear to understand all terms of participation and agree to enrollment? How is comprehension assessed?
- Was the consent document signed by all parties prior to the performance of any study-related procedures?
- Was a copy of the consent document provided to the subject?

The checklist also includes space to list the IRB number, principal investigator’s name and subject ID. It is signed and dated with time recorded by the investigator.