ARRIVING AT A CONSENSUS ON CONSENT PROCESS DOCUMENTATION ACROSS THE SYSTEM

CHRISTUS Health®
Research and Academics

Office of Human Subjects Research Protection Program

IMPROVEMENT AREA

It became apparent that consent process documentation was ***not*** universally practiced across the System.

TO CORRECT THAT…

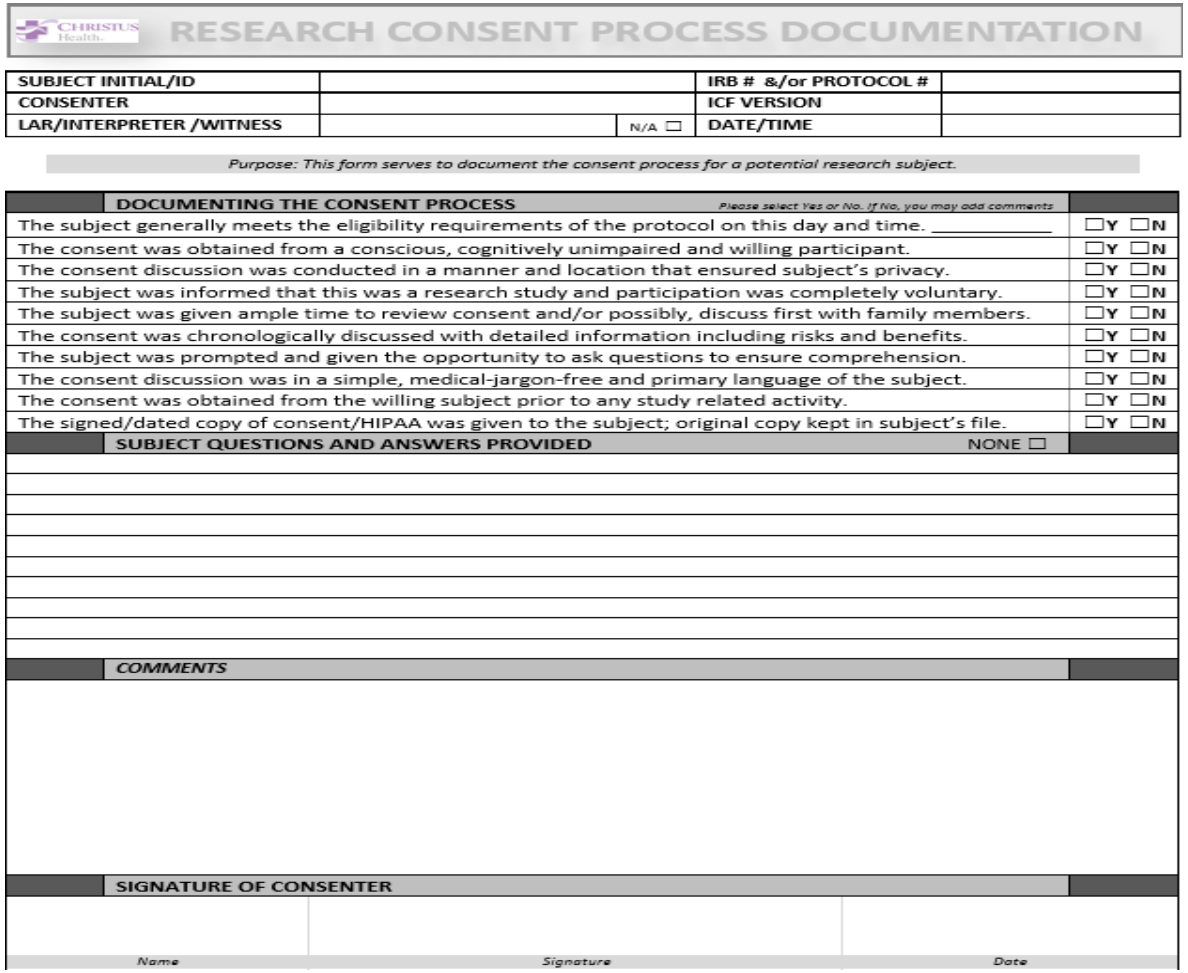
- The System Director of Research instructed the compliance auditor to develop a form to capture consent process.
- The CIIACC and regional leadership reviewed the form and made valuable changes.
- The form was also reviewed by the CRCs/RNs. They made valuable recommendations and shared their respective version of the consent process forms they use.

THE CONSENSUS

It was agreed that:

- All sites are required to document the consent process.
- Adopting the developed form is not mandatory.
- Sites with inadequate or without consent process documentation forms may adopt the one developed.
- Sites using their own respective versions may keep using it as long as it captures the major elements.

RESEARCH CONSENT DOCUMENTATION



RESEARCH CONSENT PROCESS DOCUMENTATION

SUBJECT INITIAL/ID		IRB # &/or PROTOCOL #	
CONSENTER		ICF VERSION	
LAR/INTERPRETER /WITNESS	N/A ☐	DATE/TIME	

Purpose: This form serves to document the consent process for a potential research subject.

DOCUMENTING THE CONSENT PROCESS *Please select Yes or No. If No, you may add comments*	
The subject generally meets the eligibility requirements of the protocol on this day and time. _____	☐Y ☐N
The consent was obtained from a conscious, cognitively unimpaired and willing participant.	☐Y ☐N
The consent discussion was conducted in a manner and location that ensured subject's privacy.	☐Y ☐N
The subject was informed that this was a research study and participation was completely voluntary.	☐Y ☐N
The subject was given ample time to review consent and/or possibly, discuss first with family members.	☐Y ☐N
The consent was chronologically discussed with detailed information including risks and benefits.	☐Y ☐N
The subject was prompted and given the opportunity to ask questions to ensure comprehension.	☐Y ☐N
The consent discussion was in a simple, medical-jargon-free and primary language of the subject.	☐Y ☐N
The consent was obtained from the willing subject prior to any study related activity.	☐Y ☐N
The signed/dated copy of consent/HIPAA was given to the subject; original copy kept in subject's file.	☐Y ☐N

SUBJECT QUESTIONS AND ANSWERS PROVIDED NONE ☐

COMMENTS

SIGNATURE OF CONSENTER		
Name	*Signature*	*Date*

IT IS IMPORTANT

It is important because:

- The importance of consenting subjects the right way, every single time cannot be overstated.
- Proper documentation is one of this industry's best practices.
- It proactively answers possible questions about a core process like consenting. Example, during sponsor monitoring visits when you are present, or long after study ends at FDA inspections when you may not be present to answer questions.
- Though not required in regulations, it is highly recommended.

ICH GCP SAYS…

- ***1.27 …*** obtaining and documenting informed consent of the trial subjects.
- ***1.31 …*** material to be used in obtaining and documenting informed consent of the trial subjects.
- ***4.8.1…*** In obtaining and documenting informed consent, the investigator should..
- ***4.8.2 …*** communication of this information should be documented.

SEE FDA vs ICH…

FDA

- FDA has no regulations concerning delegation of consenting although it is discussed in the FDA Information Sheets.
- FDA only requires that a copy of consent be provided to subject.
- If consent is obtained the same day that the subject's involvement is the study begins, the subject's medical records/case reports form should document that consent was obtained prior to participation in the study.

ICH

- ICH allows the delegation of the informed consent process to a designee.
- ICH recommends the person conducting the informed consent process sign and date the consent form
- ICH recommends that the subject receive a signed and dated copy of the consent form

IN SUMMARY

- Consent documentation begins with ensuring that the right consent form is signed and dated by all parties.
- More than just a signature on a form
- Process of information exchange that may include:
  - Subject recruitment materials
  - Verbal instructions
  - Reading and signing the Informed Consent
  - Q&A sessions and measures of subject understanding

…YOUR MINDSET…

Consenting should be:

- Ongoing
- Interactive process
- Different for every subject
- Different for every study
- Considered essential for study success
- Using an IRB approved ICF every time
- Used to provide clear definition between where SOC leaves off and research begins
- A re-assessment of subject's understanding with each visit

DOCUMENT THESE

- *Language*
- *Copy*
- *Voluntary*
- *Eligibility*
- *Understanding*
- *Privacy*
- *Questions*
- *Prior*
- *Time*
- *Details*

The consent process documentation should include at the minimum the following topics :