ARRIVING AT A CONSENSUS ON CONSENT PROCESS DOCUMENTATION ACROSS THE SYSTEM
It became apparent that consent process documentation was **not** universally practiced across the System.
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.
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.
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 in 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.

SEE FDA vs ICH…
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
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
The consent process documentation should include at the minimum the following topics:

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