1. **Use the current IRB-approved consent!**

✓ **DO** use the consent form templates on the IRB website, when drafting your study consent form, for the most current regulations and suggestions.
✓ **DO** update your consent form, when you change study procedures and/or identify new risks to participants.
✓ **DO** obtain IRB approval before using a revised consent form.
✓ **DO** keep all original signed consent forms with research study records.
✓ **DO** print current approved consent forms from the iRIS system, as needed.
✓ **DO** verify that each participant is given a signed and dated copy of the consent form at the time of initial consent.

× **Don’t** use expired consent forms.
× **Don’t** use old consent forms to save trees.
× **Don’t** alter approved consent forms.

2. **Ensure all items are completed in the consent form.**

✓ **DO** verify that participant answers all questions on the consent form.
✓ **DO** verify that participant follows consent form instructions - or consider modification of the consent form, if appropriate.

× **Don’t** leave consent form questions incomplete.
× **Don’t** confuse initials with checkmarks or “X”s.

× **Don’t** include consent instructions that you do not follow; it **may be** considered noncompliance.

3. **Get all necessary signature and dates.**

✓ **DO** verify that **person obtaining consent** has signed, when applicable.
× **Don’t** omit signature or date signed by **person obtaining consent**.
DO verify that signers complete all applicable lines on consent form.

DO explain, if needed, that Legally Authorized Representative for a child is parent or guardian.

Don’t leave representative’s authority to act undocumented or it may not be considered valid.

TIP

Use sticky tabs or highlighting to indicate all pages that need signatures and/or other responses from signer, so POC can quickly check the consent form for completeness, before giving the signer a copy.

DO verify participant enters date of signing at the time of consent. This is “Best Practice” and required by FDA regulation 21 CFR 50.27(a).

Don’t enter dates for participants – they must write it themselves.
**DO** verify signature **dates** are complete, formatted as consistent with your study SOPs, and legible.

**DON’T** ignore ambiguous dates (Ju = June or July?). Explain them, if needed.

4. **Using PHI? Ensure HIPAA Research Authorization is signed & dated.**

PIs should be utilizing the combined ICF/RA for all new studies initiated after April 1, 2015. For all older active studies, please ensure that the ICF is converted to the new ICF/RA at the time of Continuation Review.

**DO** verify that the participant signs and dates the ICF/RA, otherwise it is not valid and you will not be allowed to use the data.

5. **Consent is a Process, not just a document.**

**DO** train the research staff about the consent process before beginning a study.

_The principal investigator is responsible_ for ensuring that each research participant voluntarily gives informed consent before that individual participates in any research activities.

_The principal investigator is ultimately responsible_, even when delegating the task of obtaining informed consent to individuals who are trained and knowledgeable about the research. (Don’t forget to use a Delegation of Authority Log to ensure appropriate individuals are obtaining informed consent.)

_Informed consent is more than just a signature on a form;_ it is a process of information exchange. Institutional Review Boards (IRBs), principal investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. So, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the participant throughout the research.

For more information about Informed Consent and Assent, see the HSPP Policy Manual, Chapter 12.