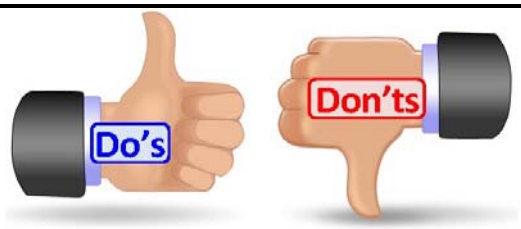
CONSENT FORM



1. Use the current IRB-approved version

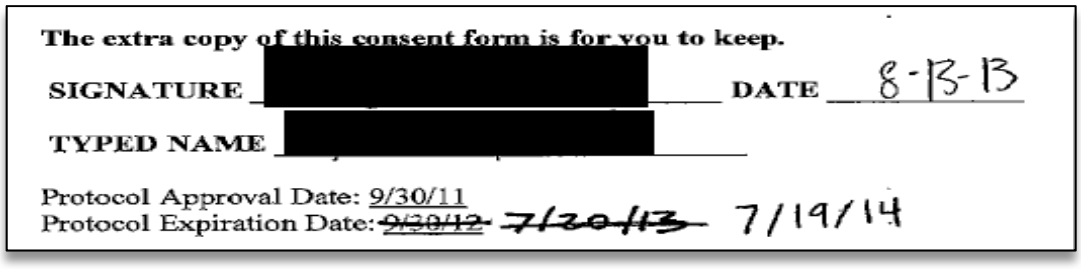
- ✓ **DO** use the consent form templates on the IRB website, when drafting your study consent form, for the most current regulations and suggestions.
- ✓ **DO** update your consent form, when you change study procedures and/or identify new risks to participants.
- ✓ **DO** obtain IRB approval before using a revised consent form.
- ✓ **DO** keep all original signed consent forms with research study records.

DO print current approved consent forms from eProtocol dashboard, as needed.

Don't use expired consent forms.

Don't use old consent forms to save trees.

Don't alter approved consent forms.


The extra copy of this consent form is for you to keep.

SIGNATURE [redacted] DATE 8-13-13

TYPED NAME [redacted]

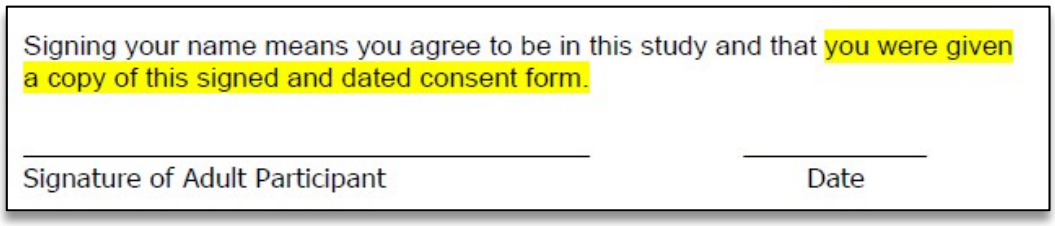
Protocol Approval Date: 9/30/11
Protocol Expiration Date: ~~9/30/12~~ ~~7/30/13~~ 7/19/14

Don't use consent forms without IRB approval and expiration dates.
(Contact IRB Manager, ASAP, if dates are incomplete.)

IRB Use Only
Approval Date: Monthname dd, 20yy
Expiration Date: Monthname dd, 20yy

DO verify that each participant is given a signed *and* dated copy of the consent form at the time of initial consent. (Required by FDA and California Experimental Subject's Bill of Rights)

Don't omit this step; it is "Best Practice" *and* required as above.


Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

2. Ensure all items are completed

DO verify that participant answers all questions on the consent form.

Don't leave consent form questions incomplete.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

Are you participating in any other research studies? _____ Yes _____No

DO verify that participant follows consent form instructions - or consider modification of the consent form, if appropriate.

Don't confuse initials with checkmarks.

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

I give consent to be audiotaped during this study.
Please initial: X Yes ___No

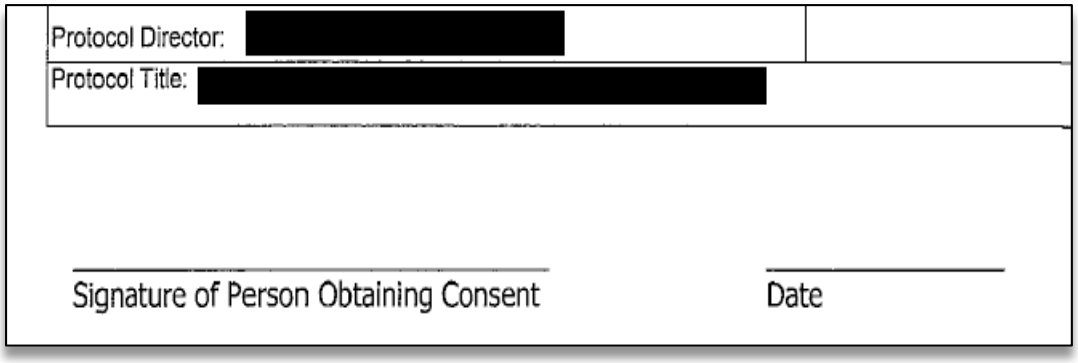
I give consent to be videotaped during this study:
Please initial: X Yes ___No

I give consent for tapes resulting from this study to be analyzed for research purposes.
Please initial: X Yes ___No

3. Get all necessary signatures and dates

DO verify that person obtaining consent (POC) has signed, when applicable.

Don't omit signature (or date signed) by POC.



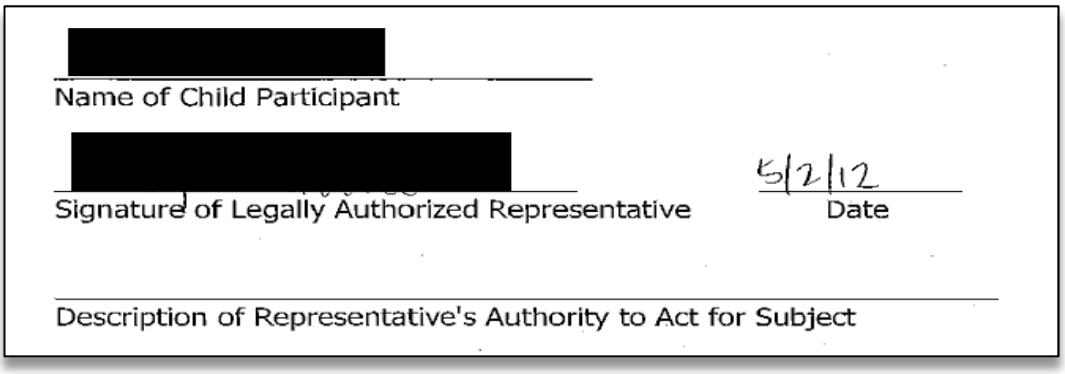
DO verify that signers complete ***all applicable lines*** on consent form.

– *If the participant or the LAR (Legally Authorized Representative) is non-English speaking, (during the short form consent process with a translator) the Person Obtaining Consent (POC) must ensure that:*

1) *the LAR's Description of Authority is completed and;*
2) *responses to all questions or options on the consent form are documented and initialed by the POC, per the participant's/LAR's wishes, as they are understood during the consent process.*

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

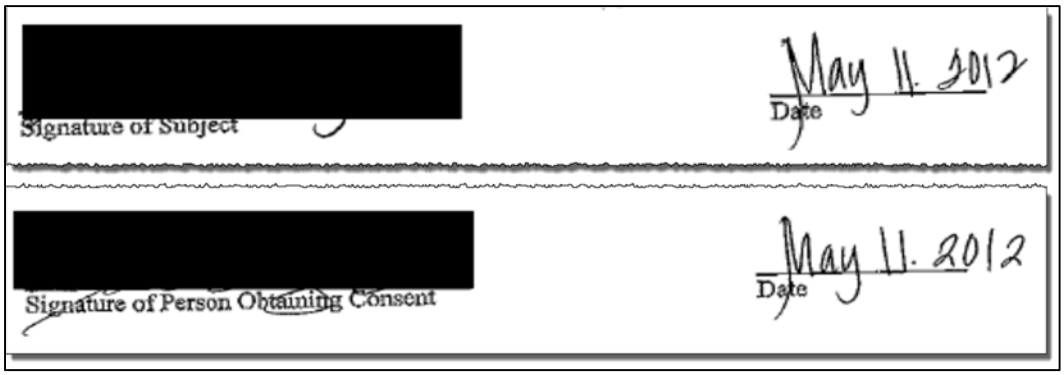
Don't leave representative's authority to act undocumented.



3. Get all necessary signatures and dates

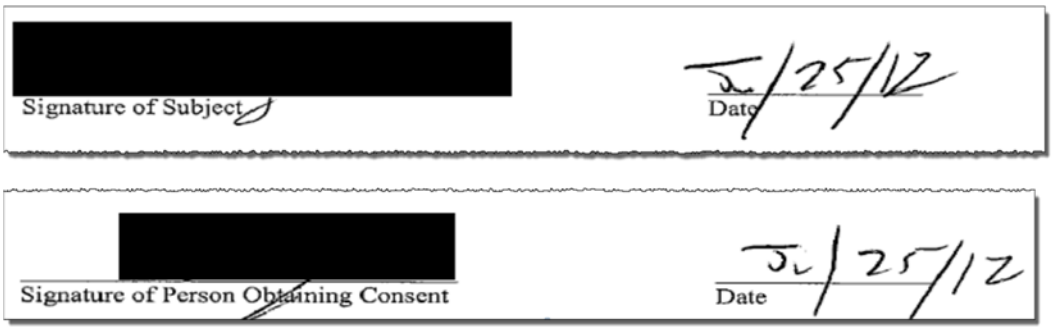
DO verify ***participant enters date of signing*** at the time of consent. This is "Best Practice" and required by FDA regulation 21 CFR 50.27(a).

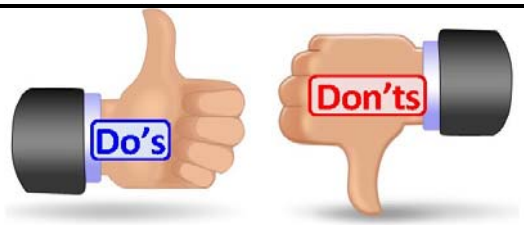
Don't enter dates for participants – they must write it themselves



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 Auth is signed & dated

DO verify that participant signs and dates ***HIPAA Authorization***, if applicable, before using protected health information (PHI).

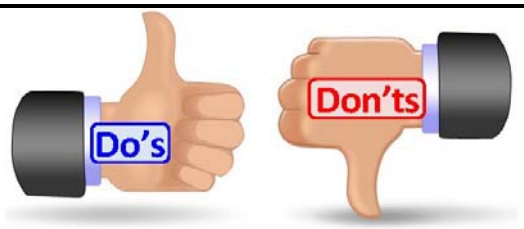
Don't use participants' data, if signed HIPAA Authorization is not obtained, as required.

Don't use participants' data if the HIPAA Authorization has expired.

Your authorization for the use and/or disclosure of your health information will expire January 1, 2020.

_____ _____

Signature of Participant Date



5. Consent Process

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

DO train newly hired research staff about the ***consent process.***

DO enter all staff who are authorized to obtain consent, for clinical studies, on the study's Delegation of Authority Log.

The principal investigator is responsible for ensuring that each research participant voluntarily gives informed consent before that individual participates in any research activities.
The protocol director/principal investigator is ultimately responsible, even when delegating the task of obtaining informed consent to individuals who are trained and knowledgeable about the research.

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. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the participant throughout the research.

TIPs

- ✓ ***Use sticky tabs*** 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.
- ✓ Keep all original signed consent forms with research study records.

More information:
See HRPP Policy Manual Chapter 12 **Informed Consent and Assent**