



Consent and Short Forms: Who Must Sign?

<i>If the Study Subject...</i> ↓	Subject (or Legally Authorized Representative) Signs	Person Obtaining Consent Signs	Witness Signs	
Understands language of Consent	Consent*	Consent	N/A	➔ <i>Subject Receives Signed Copy of Consent</i>
Does not understand language of Consent	Short Form + Bill of Rights** <i>(in subject's language)</i>	Consent	Short Form and Consent	➔ <i>Subject Receives Signed Copy of Short Form, Bill of Rights** and Consent</i>
Is capable of providing consent but has a condition that impairs consent documentation (e.g., illiteracy, blindness)	Consent* <i>(makes "mark", if possible)</i>	Consent	Consent	➔ <i>Subject Receives Signed Copy of Consent</i>
	<i>On consent form, note the method used for communicating with the subject and the means by which subject communicated agreement</i>			

Dates on Consent and/or Short Forms:

Subject or Legally Authorized Representative (LAR) signature and date on the Consent or Short Form does not have to match the date that the Person Obtaining Consent signs. No study-related procedures may be performed until the Subject or LAR has signed the Consent and/or Short Form.

Remember: if consent is obtained on the same day that the subject's involvement in the research study begins, the subject's medical records/case report form should also document that consent was obtained prior to participation in the research (*FDA-regulated research*).

*if consent includes California Subject Bill of Rights, subject must sign Bill of Rights (1st page) and consent (last page)

** Bill of Rights, if applicable (check if English version of consent includes Bill of Rights on 1st page)