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### What a signature means ...

As has been reiterated throughout our web site, the consent *form* provides information necessary for consent; the signature provides documentation that, at one point in time, the signer agreed to participate.

### Requirements

By regulation all that is required for a routine consent form is the signature and date of the person consenting or the legally authorized representative of that person.

IRC asks for the printed name of each person signing since signatures are often illegible.

Time should be included if the consent process is done the same date the study activity starts.

### Consentor/Consentee: A partnership

The consent process is often a partnership between the person giving the information (consentor) and the person giving consent (consentee). IRC endeavors to enhance the idea of a partnership. To this end, we prefer two signatures; the consentor and the consentee. The two people co-sign. Having both people sign as equal partners, each taking responsibility, can be documented in a signature box on the consent form.

	SUBJECT: I have read this, talked with the other person signing, and been satisfied with the answers to my questions. I agree to participate.	INVESTIGATOR OR DESIGNEE: I talked with the subject about this study, answered questions and believe that the information was sufficiently understood.
Signature		
Printed Name		
Date / Time		

### Others who might sign:

**Witness** - A witness is required if the consent document needs to be read to the subject who is otherwise capable of making an autonomous decision' e.g., a blind person, seriously dyslexic person, or illiterate person.

IRC discourages use of a witness in other circumstances. First, it makes it appear more legalistic than it is. Second, generally the function of the witness is not well defined and it seen as being more for defense (yes, this person signed this form) than for subject rights (watching the process to assure all information was fairly imparted.) If a witness must be used, the role of the witness should be described on the form.

Investigator - The regulations do not require investigators to sign the consent form. If the investigator line is included, it should be clear that the investigator will be present and will co-sign at the same time. If the investigator is not likely to be present and is signing to indicate that he or she reviewed the file and agreed the person was eligible, this can be done on a separate form or, at least, in a separate section with the purpose make clear.

Designee of investigator - Coordinators are often involved in the consent discussion and obtaining agreement. This often is preferred as it diminishes the potential for deferring to authority and as coordinators are often more adept at speaking lay language.

It is wise for anyone in this position to have the delegation in writing. The person gaining consent must have read the complete protocol.

Parent/Guardian - Although minors may have very strong opinions, they don't have the legal capacity to give their own consent. They can "assent" and their parent or guardian can give permission. The combination Assent + Permission = Consent

There are exceptions to this, however. The major exception is the Emancipated Minor who, according to the laws of the state, is considered to be an adult for many purposes. Before using this exception, the state law must be consulted.

LAR - Legally Authorized Representative - A signature line for an LAR should not be included on any consent form unless the involvement of people who cannot give their own consent has been approved. LARs are defined in most state laws either in the health code or the probate code.

Illiteracy - With effect on their expressions of autonomy, some people are functionally or fully illiterate. Many will pass unrecognized unless one is prepared to look for signs. Such a person will need to have everything read (translated) to them and may be able to sign only with a (witnessed) "X".

