

The Ideal: Informed consent consists of:

- the transmission of all relevant information to a potential subject
- who has legal capacity to consent and
- the ability to reach an autonomous decision,
- in a format understandable to that person,
- careful consideration of the issues by the person using
- necessary time and resources,
- a chance to ask questions and have them answered, and
- agreement.

The ideal is rarely achievable. Our goal is to constantly work toward it.

There is so much to say about consent that it had to be further sub-divided.

- 3.4.1. Codes of Ethics
- 3.4.2. Process
 - 3.4.2.A. Advertising (first part of process)
- 3.4.3. Elements of Information
 - 3.4.3.A. Comparison ICH-Common Rule – FDA
- 3.4.4. Documentation
 - 3.4.4.A. Template
 - 3.4.4.B. Boilerplate language
 - 3.4.4.C. A 1 page form
- 3.4.5. Signatures - Illiteracy
- 3.4.6. Problems
 - 3.4.6.A. Proxy
 - 3.4.6.B. Waiver
 - 3.4.6.C. Translation
- 3.4.7. ---
- 3.4.8. ---
- 3.4.9. GUIDE to INFORMED CONSENT
 - 3.4.9.A. Power Point slides

