

# CHART I

## A Comparison of Three Document Modes for Eliciting Informed Consent in Research

Provision Made for	Mode of Documentation		
	Written with Participant Signed Consent <sup>1</sup>	Written Investigator Signed Testimonial or Warrant of Consent	Investigator Written and Signed Notice to Complainant
Free Choice to document consent procedure by signature	Participant not free to choose only	Investigator and Participant not free to choose <sup>2</sup>	Investigator not free to choose
Unique identification required apart from signature	NOT REQUIRED	Both required apart from signature	NOT REQUIRED
Documented or other evidence of unique identification	1) Signature of parti- cipant only <sup>3</sup> 2) Possible fingerprints of both 3) Handwriting required of investigator for any amendment 4) Possible signature and fingerprints from auditor witness	1) Signature of both 2) Investigator lacks participants fingerprints 3) Handwriting required of investigator for any amendment 4) No auditor witness necessary	1) Signature of PI only 2) PI or representative fingerprints possible 3) No handwriting if separate from other forms 4) No auditor witness necessary

CHART I (Continued)

Provision of Complainant Information	No documentation or written notice required	Information on unique identity of PI and his/her agent when applicable provided but no notice provided	Formal notice and information on where complaint may be lodged provided
Provision for documentation of refusal	None	Required unless excepted	None
Provision for documenting informing procedure	None required	Whom read by and for	None required
Provision for documenting representative or auditor witness	Auditor witness only documented	Representative documented; no auditor witness required	Not documented
Written statement of required elements for being informed	Required	Required	Not required
Written statement of additional agreement	Not Required	Required	Not required
Written disclosure of Unique Identification Retained and Protection Provided for Uniquely Identifiable Information	Not Required	Required	Inapplicable

CHART I (Continued)

Possession of Documentation	By PI only (implied)	By Participant or both participant and Investigator	By Participant Only
Availability of Information on Who Performed Procedures Other than Eliciting Consent	Not Specifically Provided	Specific Provision Made	Specific Provision made
Access to Unique Identifiers or Information Uniquely Identified by Institutional Review Board	Rights of IRB not clearly defined but has broad review powers	Restricted to Explicit Agreement to provide confidential information	Inapplicable
Provision for Identifying Government Sponsor	None made since obliged to answer questions about procedure only	Obligated to provide on request only	Obligated to provide on request only

Footnotes

1. These comparisons are made using the present CFR. They are not all integral to the Written with Participant Signature documentation form. The form can be modified for some but not all comparison criteria.
2. An optional form might require only that the investigator document by signature that informed consent was elicited from a particular participant. This optional form probably is appropriate for some corporate actors and for much survey research when written documentation is required.
3. We make note of the fact that fingerprints are more difficult of recovery from paper than some other objects but much depends on conditions for both the paper and signatory. It is possible that anxiety and other factors attendant upon obtaining signed consent are more favorable to their recovery than is ordinarily the case and more likely for participants than investigators or their agents.