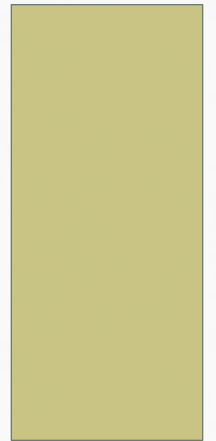


CONSENT SIGNATORIES

PATRICK HERBISON, MEd, CIP



CODE OF FEDERAL REGULATIONS
TITLE 36: PARKS, FORESTS, AND PUBLIC PROPERTY
CHAPTER I: NATIONAL PARK SERVICE
PART 2: RESOURCE PROTECTION, PUBLIC USE AND RECREATION
SECTION 2.14: SANITATION AND REFUSE



CONSENT SIGNATORIES GUIDANCE DOCUMENT

CONSENT SIGNATORIES	Regular Consent	Surrogate Consent (Use OHR-8B as signature page)	Assent (Always used with parent / guardian consent)	Parent / Guardian Consent (Used with assent)	Subject is Physically Unable to Sign (e.g. paralyzed)	Subject is Illiterate (Full consent form is presented verbally)	Subject is Blind (Must use braille consent or reading device)	Short Form Process – English Speaking Subjects	
								Short Form	Summary
Subject	X		X		X (Makes mark if possible)	X (Signs or makes mark)	X		
Person Conducting Consent Interview (May be Inv. unless otherwise specified)	X	X		X	X	X	X		X
Investigator	X	X		X	X	X	X		X
Impartial Witness (May not be study personnel)					X	X	X	X	X
Parent / Guardian / Legal Representative / Surrogate		X		X					

CONSENT SIGNATORIES GUIDANCE DOCUMENT

CONSENT SIGNATORIES	Translations – Full Consent Form (Written Form is in Other Language)		Translations – Short Form Process - Investigator / Study Personnel Does Not Speak Other Language		Translations – Short Form Process - Investigator / Study Personnel Speaks Both Languages and Acts as the Translator	
	Investigator / Study Personnel does not speak other language	Investigator / Study Personnel speaks both languages and acts as the translator	Short Form (Written Form is in Other Language)	Summary	Short Form (Written Form is in Other Language)	Summary
Subject	X	X	X		X	
Person Conducting Consent Interview (May be Inv. Unless Otherwise Specified)	X	X		X		X
Investigator	X	X		X		X
Impartial, Bilingual Witness (May be translator but not study personnel)	X		X	X	X	X
Translator (If not study personnel, may act as impartial witness)	A translator is needed but doesn't sign unless also acting as the impartial witness.		A translator is needed but doesn't sign unless also acting as the impartial witness.	A translator is needed but doesn't sign unless also acting as the impartial witness.		

NOTES

- The person obtaining consent and the investigator can be the same person (unless otherwise specified).
- The investigator does not have to be present:
 - But should be present if the study is high risk.
 - And if not present, should be available if the subject has questions.
- Witnesses must be impartial (not study personnel).
- Assent is always used with parental / guardian / surrogate consent.

NOTES

- The short form process (oral consent with a short form and a summary) is best used for unexpected, non-English speaking subjects.
- The translator (if needed) can be study personnel (FDA does not approve of 'on-the-fly' translations of English documents).
- For the short form process, if the translator is study personnel, an impartial, bilingual witness is also required.
- If the translator is not study personnel, s/he may act as the impartial witness.
- If the translator and the impartial, bilingual witness are 2 different people, the translator doesn't have to sign the consent.

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TAKE AWAY

- When reviewing studies (OHR-2, Parts E, F, H) the guidance document is available if necessary.

QUESTIONS?

- The 'Consent Signatories Guidance' document is available on the OHR website:
- http://www.jefferson.edu/university/human_research/irb-reference-documents.html



IRB Reference Documents

▶ Contact Us

- IRB Fee Schedule
- Federalwide Assurance
- Guidance for Staffing of Personnel
- Statement of Compliance
- Guidance for IRB Voting Criteria
- Consent Signatories Guidance

