

Informed Consent Process Self-Assessment

Protocol Information

Study Title:
 PI Name:
 UAMS IRB No.:
 Review Date:
 Person Completing:

Informed Consent Forms (ICFs)

How many versions of the ICF has the IRB approved to date?		
List version numbers/dates and approval dates here	Version number/date	Date approved by IRB
Are the version numbers and dates correct on each version? Y/N		Comment: If any are incorrect, add a note to file to correct the date if form is no longer in use; submit a corrected form to the IRB for approval if the form is still in use
Do the version number and date printed on each form match those listed in the corresponding IRB approval letter? Y/N		Comment: If either the version number or date does not match what's listed in the approval letter, request a corrected approval letter from the IRB
Is a copy of each approved ICF version on file? Y/N		Comment: Store the current approved ICF separately from the versions that are no longer in use.

Review of Informed Consent Process Documentation – Studies Enrolling Adults

Review minimum of 10 percent of enrollment; review of 100 percent enrollment is strongly recommended.

Subject ID	ICF Version Used	Subject or LAR signature, date, and time	Witness signature, date, and time	Person Obtaining Consent (POC) signature, date, and time	PI signature, date, and time	Are all signatures except PI timed within 10 minutes of each other?	Are there any extraneous marks or highlighting on the consent form?*	Is a complete informed consent process note present?	Are any discrepancies, problems, or special circumstances** discussed in the informed consent process note?
		Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
		Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
		Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
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		Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
		Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
		Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
		Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>

* Extraneous marks change an approved version of the consent form to an unapproved version.

** In addition to the required elements, the informed consent process note can contain a description of items such as the reason a legally authorized representative was required, an explanation of why any signature times are discrepant, and any other details relevant to a particular subject’s informed consent process.

Review of Informed Consent Process Documentation (Studies Enrolling Children)

Review minimum of 10 percent of enrollment; review of 100 percent of enrollment strongly recommended.

Subject ID	ICF Version Used	No. of parent signatures required	Parent signature(s), date, and time	Witness signature, date, and time	Person Obtaining Consent (POC) signature, date, and time	PI signature, date, and time	Signature times (except PI) within 10 minutes of each other?	Is child's assent appropriately documented?	Any extraneous marks on the consent or assent forms?*	Is a complete informed consent process note present?	Are any discrepancies, problems, or special circumstances discussed** in the informed consent process note?
			Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date: Number:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
			Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date: Number:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
			Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date: Number:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
			Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date: Number:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
			Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date: Number:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>
			Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date: Number:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Sig: Y <input type="checkbox"/> N <input type="checkbox"/> Date:	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>

Did any pediatric subject turn 18 or emancipate while on study? (Minor subjects must be reconsented after reaching age 18 or emancipation.) Y N
 If "yes", was the subject reconsented using the current adult consent form? Y N

* Extraneous marks change an approved version of the consent form to an unapproved version.

** In addition to the required elements, the informed consent process note can contain a description of items such as the reason a legally authorized representative was required, an explanation of why any signature times are discrepant, and any other details relevant to a particular subject's informed consent process.

Pediatric

Consent Process Overview

1. Was any subject consented using a process that differed from the IRB-approved process?	Y <input type="checkbox"/>	N <input type="checkbox"/>	
2. Were any subjects consented using an invalid (never approved or outdated) ICF?	Y <input type="checkbox"/>	N <input type="checkbox"/>	
3. Was any subject missing a consent form?	Y <input type="checkbox"/>	N <input type="checkbox"/>	
If question 1,2, or 3 is answered "yes", was a protocol violation filed with the IRB?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Report date:
4. Are all required signatures present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	
5. Do all required signatures appear authentic?	Y <input type="checkbox"/>	N <input type="checkbox"/>	
If either question 3 or 4 is answered "no", was a protocol violation filed with the IRB?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Report date: