IRB Study Number_____

Informed Consent Self-Assessment Form

Date of 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 and dates and approval dates here	Version numbers and dates		Date approved by IRB
Are the version numbers and dates correct on the form for each version?	Y ◯ N ◯	Note:	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 numbers and dates printed on each form match those listed in the corresponding IRB approval letter?	Y ◯ N ◯	Note:	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 ◯	Note:	Store the current approved ICF separately from the versions that are no longer in use.

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Review of Informed Consent Process Documentation

Review minimum of 10 percent of enrollment but review of 100 percent of enrollment strongly recommended

Subject ID	ICF Version and Date Used	Subject or LAR Signature and Date	Person Obtaining Consent (POC) Signature and Date	Is the subject signature date and POC signature date the same date or close to the same date if using email consenting	Are there any extraneous marks or highlighting on the consent form?*	Is a complete informed consent process note present?	Consent process note adequately discusses any discrepancies, problems, or special circumstances that occurred in the informed consent process ? **	Comments (If any of these answers are no write a note to file to explain why)
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	
		Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	Y ◯ N ◯	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 elements are discrepant, and any other details relevant to a particular subject's informed consent process.

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Consent Process Overview

1. Was any subject consented using a process that differed from the IRB-approved process?	**Y** ◯	**N** ◯	
2. Were any subjects consented using an invalid (never approved or outdated) ICF?	**Y** ◯	**N** ◯	
3. Was any subject missing a consent form?	**Y** ◯	**N** ◯	
• **If question 1, 2, or 3 is answered yes, was a protocol deviation reported to the IRB**	**Y** ◯	**N** ◯	**N/A** ◯
4. Are all required signatures present?	**Y** ◯	**N** ◯	
5. Do all required signatures appear authentic?	**Y** ◯	**N** ◯	
• **If question 4 or 5 is answered no, was a protocol deviation reported to the IRB**	**Y** ◯	**N** ◯	**N/A** ◯

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** 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 elements are discrepant, and any other details relevant to a particular subject's informed consent process.