SUBJECT RECORDS AND SOURCE DOCUMENTATION

GENERAL INFORMATION

Principal Investigator	
Study Title	
IRB Protocol Number	
Name of person completing checklist	
Type of Study *Please check all that apply:*	☐Drug ☐Genetic ☐Tissue/Sample Repository ☐Device ☐Medical Records/Database ☐Behavioral ☐Other: _____
Total # Enrollment*	#Approved: _____ #Enrolled to date: _____

* "***Enrolled***" *is anyone who signed a consent form.*

1. SUBJECT ENROLLMENT AND ELIGIBILITY

		YES	NO
1.1	Are the participant's informed consent form, informed consent process note, and HIPAA authorization form complete and on file? Reference: UAMS IRB Policy(ies) 15.1; 15.5; 13.3	☐	☐
1.2	Is documentation of an eligibility evaluation covering *all* of the inclusion/exclusion criteria mentioned in the protocol present? Reference: FDA Guidance: E6 GCP, Sections 4, 5.18.4, 6.5	☐	☐
1.3	Does the subject file indicate whether the subjects were included/excluded appropriately?	☐	☐
1.4	If any subjects that did not meet eligibility criteria were enrolled, was a protocol violation submitted to the IRB?	☐	☐
1.5	Does each subject's eligibility criteria documentation include dated signature/initials of the person obtaining the information?	☐	☐
Please use this space for additional explanation/comments			

2. SOURCE DOCUMENTS AND DATA COLLECTION FORMS

Review source documents (where you wrote it down first) and case report forms (CRFs), if any, to complete the following for each subject reviewed:

2.1	Are all protocol requirements verifiable from available source documentation? (Recommend going through the protocol step-by-step and assessing whether each step is documented.)	☐ YES	☐ NO
	If not, please explain:		
2.2	Are the case report forms (if any) completed?	☐ YES	☐ NO
	If the study uses CRFs and they are not completed, please explain:		
2.3	Do all source documents and CRFs include a subject identifier, the appropriate date, and signature of the person completing?	☐ YES	☐ NO
2.4	Are changes/cross-outs (if any) in subject files routinely initialed and dated?	☐ YES	☐ NO
Please use this space for additional explanation/comments:			

3. PROTOCOL VIOLATIONS/DEVIATIONS

Violations & Deviations		Date occurred	Date reported	Date of IRB Notification	IRB notification in subject file?	
					YES	NO
3.1	Number of major violations (impacting subject safety or data integrity) reported to IRB? _____				☐	☐
					☐	☐
					☐	☐
3.1.1	If any major violations/deviations have NOT reported to the IRB, explain why.					
3.2	Have all minor violations/deviations been logged and reported to the IRB according to Partners institutional guidelines (e.g. at continuing review)?				☐	☐
3.3	Any sponsor-approved protocol exceptions/deviations?				☐	☐
3.3.1	If yes, have they been reported to the IRB?				☐	☐
Please use this space for additional explanation/comments.						

4. ADVERSE EVENT (AE) REPORTING

(If there have been no AEs/SAEs check here ☐)

4.1	Have all AEs/SAEs been documented and reported per UAMS IRB policies?			☐ YES	☐ NO
4.2	Have all AE/SAE documentation been filed in this subject's study file?			☐ YES	☐ NO
4.3	How many SAEs have been reported to the IRB on this subject *since last continuing review?* _____	Date of event	Date of report	Date of approval	
4.4	Any AE/SAEs NOT reported to the IRB for this subject since last continuing review? ☐ YES ☐ NO	If yes, reason(s) for not reporting: ☐ Omission ☐ Expected mild to moderate events ☐ Unexpected mild to moderate events unrelated to study ☐ Other: _____ **Summarize events in next continuing review report*			
4.5	Have all AEs/SAEs been reported to the sponsor and/or FDA (where applicable)? *Clinical drug and device trials only*			☐ YES	☐ NO
Please use this space for additional explanation or comments.					

5. DRUG/DEVICE DISPENSING ACCOUNTABILITY

(If this is not a drug/device study, check here ☐)

5.1	Is there documentation of drug/device use for the subject?	☐ YES	☐ NO
5.2	If the study is blinded, is there documentation that each subject received the correct test article?	☐ YES	☐ NO
5.3	Who is responsible for shipping/receiving?	☐ Investigator ☐ Research Pharmacy ☐ Study Staff ☐ Other _____	
5.3.1	If investigator/study staff is receiving and dispensing drug, is a copy of the Outpatient Investigational Drug Responsibility Form on file?	☐ YES	☐ NO
5.3.2	Was a copy of the form sent to the pharmacy?	☐ YES	☐ NO
5.4	Are the shipping receipt and dispensing records complete and accurate?	☐ YES	☐ NO
5.5	Is there appropriate documentation for the return or destruction of drug/device?	☐ YES	☐ NO
5.6	Who dispenses study drug to the subject?	☐ Investigator ☐ Research Nurse ☐ Coordinator ☐ Other _____	
5.7	Has every instance of drug dispensing and by whom been documented in subject's study file? *If no, explain below*	☐ YES	☐ NO

5.8	Have there been any drug/device related errors to date?	☐ YES	☐ NO
5.9	Has study drug compliance been verified for each subject (i.e. subject took approximately the correct amount of the drug)?	☐ YES	☐ NO
Please use this space for additional explanation or comments.			