

Office of Research Compliance (in affiliation with the North Texas Regional Institutional Review Board)

Post Approval Monitoring (PAM) Audit Checklist

Da	te of Audit:			
Na	me of Research Compliance Auditor(s):			
Pri	incipal Investigator:			
Sc	hool/Department:			
	B Project #:			
IR	B Project Title:			
		X 7	No No	N/A N/A
If I	N/A for both, please provide reason for audit:			
Na	me of person(s) available during the on-site audit:			
Ke	ev Personnel:			
1.	Are all study personnel up-to-date with their training in human subjects etc.)?	s researc Yes		
2.	Is a conflict of interest form on-file for all key personnel on the study?	Yes	No	N/A
3.	Have all research personnel working on the project been appropriately accounted for on the project (e.g., listed on the protocol synopsis, appro Application for Change in Study Personnel form and study amendment	oved via	the	_



Research Protocol:

1.	Does the project have current IRB approval?	Yes	No N/A	4
2.	Has the research been conducted in a manner which complies with the and procedures as approved by the IRB?	project	descriptior	1
		Yes	No N/A	4
3.	Were all data collection instruments used by researchers approved by			. —
		Yes	No N/A	4 <u></u>
4.	Deviations documented / reported?	Yes	No N/A	4
5.	Did subjects receive participation remuneration / payment schedule?	Yes	No N/A	4
Со	Comments:			

Consent / Assent Process:

For the consent forms and documentation reviewed, complete the following questions:

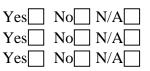
1.	Is a written consent form required?	Yes No N/A
	a. If required, did the subject sign the consent form prior to entry	? Yes No N/A
	b. If required, was it the current and correct IRB-approved/stamp expiration date)?	ed version? (check Yes No N/A
2.	Is a verbal/online consent process required (not written)?	Yes No N/A
	a. If verbal/online, was the IRB-approved script used?	Yes No N/A
	b. If verbal/online, was the subject's consent documented?	Yes No N/A

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3.	How many subjects are/were enrolled to date?	
4.	How many subjects are/were completed / lost to follow up (LTF) / with	thdrawn (WD) to date?
5.	How many subjects were approved by the IRB in the protocol?	
6.	How many subjects were chosen for this review?	
	If applicable, did the subject initial/date each page of the consent forn tials/date not included in the consent form.)	n? (Not applicable if Yes No N/A
8.	Did each subject sign/date his/her own consent form on the signature	page? Yes No N/A
9.	Was there a research team member acknowledgement on the signature	page?
		Yes No N/A
10	. Did anyone not approved by the IRB to consent subjects sign as a stu	dy representative?
	A. If YES, who?	Yes No N/A
11	. Are there any unexplained date discrepancies?	Yes No N/A
	A. If YES, describe:	
12	. Were invalid consent forms used?	Yes No N/A
13	. Did each subject receive a copy of the consent form?	Yes No N/A
14	. Was the consent process witnessed (audited) on-site?	Yes No N/A
Со	mments:	



Eligibility Criteria:

Did each subject meet eligibility criteria?
If NO, were they excluded appropriately?
If NO, was a protocol deviation submitted to the IRB?



Comments:

Adverse Events / Serious Adverse Events / Unanticipated Problems/Complaints:

	1. Have there been any adverse events (AE), serious adverse events (SAE), unanticipated problems, complaints, or subject withdrawals while conducting this research?				
1	, 1 , J		Yes No N/A		
	a. If YES, have all details	been reported to the IRB?	Yes No N/A		
2.	Reported / documented in a	a timely manner?	Yes No N/A		
Со	Comments:				



Recruitment/Materials:

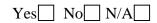
1. Were subjects identified and recruited according to the methods approved by the IRB?

		Yes No N/A
2.	Were the advertisements and/or the recruitment materials used to recruby the IRB?	iit subjects approved Yes No N/A
3.	If subjects received compensation, is there documentation?	Yes No N/A

Comments:

Recordkeeping/Security:

- 1. Where are the consent forms and applicable study related data maintained?
 - a. If applicable, does this align with the storage methods outlined in the protocol?

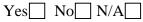


- 2. Are study related records maintained and organized in a manner that allows for easy retrieval of documents and/or does the study file demonstrate that the PI is able to maintain accurate, complete, and current records? Yes No N/A
- 3. Pertaining to <u>hard copy</u> documents, were security measures in place to protect the privacy of the subjects and confidentiality of the information in the study documents as stated in the protocol synopsis (e.g., locked cabinet, coded, etc.)? Yes No N/A
- 4. If the researchers proposed to collect the data anonymously, has the anonymity been maintained in the physical and/or the electronic records? Yes No N/A
- 5. If applicable, is electronic data stored on a secure and password protected computer?

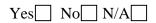
Yes No N/A



6. Is access to computer, electronic files, and physical files limited to appropriate study personnel?



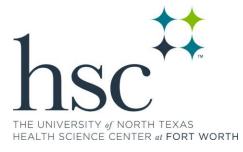
7. Was the research data stored/disposed of as described and approved by the IRB?



Comments:

Continuing Review:

1.	Is the Principal Investigator able to locate and/or provide information about the project's study expiration date?	Yes No N/A			
2.	Have there been any lapses in IRB approval?	Yes No N/A			
	a. If YES, did the PI report any research activity that was performed du	uring the lapse?			
		Yes No N/A			
3.	Were there any changes to the approved project since the last continuing review?				
		Yes No N/A			
	a. If YES, was a revision submitted to the IRB?	Yes No N/A			
4.	Have there been any new findings to change the risk benefit ratio?	Yes No N/A			
Со	Comments:				



Genetic Research:

1.	Are samples being obtained in a manner consistent with the protocol s	· ·	
		Yes	No N/A
2.	Are samples being used and stored in a manner consistent with the pro-	<u> </u>	nopsis? No N/A
3.	Is written consent required?	Yes	No N/A
4.	Were subject identifiers collected?	Yes	No N/A
	a. If so, were they collected in a manner consistent with the protocol	synopsis	?
		Yes	No N/A
	b. Is the identifying information being stored and maintained in a ma	nner con	sistent with
	the protocol synopsis?	Yes	No N/A
4.	If samples were coded, were they coded in a manner consistent with the	ne protoc	ol synopsis?
		Yes	No N/A
5.	Is there a secondary use of the samples?	Yes	No N/A
	a. If so, is there IRB approval for these uses?	Yes	No N/A

Comments:



Auditor's Finding(s) / Suggestion(s):

□ No finding(s) or determination(s) noted

☐ Met Compliance Criteria: No issues or findings

- □ Non-Compliance Deficiency: Failure to follow the regulations governing human subjects' research, North Texas Regional IRB policies and procedures related to human subjects research or the requirements or determinations of the IRB
- □ Serious Non-Compliance Deficiency: Increases risks to subjects; adversely affects the rights, welfare or safety of subjects; compromises the scientific integrity of the research, or compromises the integrity or effectiveness of the North Texas Regional IRB Human Research Protections Program
- Continuing Non-Compliance: A pattern of repeated noncompliance that indicates an inability or unwillingness to comply with governing human subject's research regulations, North Texas Regional IRB policies and procedures or the requirements or determinations of the IRB



Suggested Corrective and Preventative Action Plan(s)