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

Post Approval Monitoring (PAM) Audit Checklist

Date of Audit: _____

Name of Research Compliance Auditor(s):_____

Principal Investigator: _____

School/Department: _____

IRB Project #: _____

IRB Project Title: _____

Is this a periodic compliance audit? Yes☐ No☐ N/A☐

If no, is this a for-cause audit? Yes☐ No☐ N/A☐

If N/A for both, please provide reason for audit:_____

Name of person(s) available during the on-site audit:

_____

_____

Key Personnel:

1. Are all study personnel up-to-date with their training in human subjects research (e.g., CITI, etc.)? Yes☐ No☐ N/A☐

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 documented and accounted for on the project (e.g., listed on the protocol synopsis, approved via the *Application for Change in Study Personnel* form and study amendment, etc.)? Yes☐ No☐ N/A☐

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Research Protocol:

1. Does the project have current IRB approval? Yes☐ No☐ N/A☐

2. Has the research been conducted in a manner which complies with the project description and procedures as approved by the IRB?
   Yes☐ No☐ N/A☐

3. Were all data collection instruments used by researchers approved by the IRB?
   Yes☐ No☐ N/A☐

4. Deviations documented / reported? Yes☐ No☐ N/A☐

5. Did subjects receive participation remuneration / payment schedule? Yes☐ No☐ N/A☐

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/stamped version? (check expiration date)? 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 How many subjects are/were completed / lost to follow up (LTF) / withdrawn (WD) to date?
_____

5. How many subjects were approved by the IRB in the protocol? _____

6. How many subjects were chosen for this review? _____

7. If applicable, did the subject initial/date each page of the consent form? (Not applicable if initials/date not included in the consent form.) 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 study representative?
Yes☐ No☐ N/A☐

A. If YES, who? _____

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☐

Comments:

_____
_____
_____
_____

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Eligibility Criteria:

1. Did each subject meet eligibility criteria? Yes☐ No☐ N/A☐
   If NO, were they excluded appropriately? Yes☐ No☐ N/A☐
   If NO, was a protocol deviation submitted to the IRB? Yes☐ No☐ N/A☐

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? Yes☐ No☐ N/A☐

   a. If YES, have all details been reported to the IRB? Yes☐ No☐ N/A☐

2. Reported / documented in a timely manner? Yes☐ No☐ N/A☐

Comments:

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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 recruit subjects approved by the IRB? Yes☐ No☐ N/A☐

3. If subjects received compensation, is there documentation? Yes☐ No☐ N/A☐

Comments:

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_____

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?

      Yes☐ No☐ N/A☐

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?

Yes☐ No☐ N/A☐

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

Yes☐ No☐ N/A☐

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 during 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☐

Comments:

_____

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_____

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Genetic Research:

1. Are samples being obtained in a manner consistent with the protocol synopsis?
   Yes☐ No☐ N/A☐

2. Are samples being used and stored in a manner consistent with the protocol synopsis?
   Yes☐ 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 manner consistent with the protocol synopsis? Yes☐ No☐ N/A☐

4. If samples were coded, were they coded in a manner consistent with the protocol 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

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Suggested Corrective and Preventative Action Plan(s)