Initial Meeting

Date: _____ Name of Auditor: _____

Attendees (name/title): _____ / Principal Investigator

_____ /

_____ /

_____ /

1. Explain audit purpose

- ☐ Why protocol was selected and what are goals of review
- ☐ What to expect: Study Review, Final Meeting, Final Report and PI Response
- ☐
- ☐

2. Verify Sponsor and Funding Source

Approved: [insert sponsor and funding source on approved protocol submission materials prior to meeting]

Current Practice: *Ask PI/staff what is sponsor/funding source as open-ended question (avoid asking yes/no question such as, "is the sponsor____ and funding source____?").*

[insert PI response]

Changes/Notes: [describe any discrepancies between approved vs. current PI response, if any]

☐ No Change

3. Study design

Approved: [insert brief overview f the study design prior to meeting]

Current Practice:

Changes/Notes:

☐ No Change

4. Verify Subject Enrollment and anticipated Final Enrollment Number (N)

Approved N: _____ Enrollment reported at last IRB Continuing Review: _____

Actual Enrollment *Ask PI/staff what enrollment is to date as open-ended question (avoid asking yes/no question such as, "are __ subjects still enrolled?" or "have you exceeded approved N of__?"*

[insert PI response]

[insert auditor's notes during document review: do study/subject records verify PI response]

Changes/Notes: [describe discrepancies between approved/reported N vs. PI response & audit of study docs]

☐ No Change

- Do you expect to enroll N with the anticipated time frame? ☐ Yes ☐ No
- Do you feel that you have adequate resources/staff to conduct study safely? ☐ Yes ☐ No

If NO, please explain. Is there anything that would make a difference (e.g. resources)?

5. Verify Recruitment Process

Approved: [insert recruitment described on approved protocol prior to initial audit meeting]

Current Practice: *Ask PI/staff to describe current recruitment process and materials.*

[insert PI response]

[insert auditor's observations of recruitment practices based on study/subject document audit: do study/subject records verify PI response]

Changes/Notes: [describe any discrepancies between approved vs. current PI response, if any]

☐ No Change

6. Verify Informed Consent Process: who obtains consent, where and when

Approved: [insert informed consent process as described on approved protocol prior to initial meeting]

Current Practice: *Ask PI/staff to describe informed consent process; e.g. "walk me through process of how consent is obtained from subjects from start (giving info to point of enrollment)"*

[insert PI response]

[insert auditor's observations of consent practices based on study/subject document audit: do study/subject records verify PI response]

Changes/Notes: [describe any discrepancies between approved vs. current PI response, if any]

☐ No Change

Ensure PI/Staff know the following:

- ☐ Subjects/families must receive a copy of the signed consent/assent form(s)
- ☐ All signors must date their own signature – do not date another person's signature
- ☐ If consent is obtained on same day, specify in study notes

7. Verify where Signed Consents/Study Documents w/identifiers (PHI) are filed? Verify where Study Materials and Regulatory Study Documents are stored?

Approved:
Current practice:
Changes/Notes:
☐ No Changes

Ensure PI/Staff know the following:

☐ Institutional policy for storage of study documents
☐ Discuss "safe and secure" storage practices per good clinical practices

8. Have there been any Serious/Unanticipated Events, Deviations or Exceptions?

Reported Events:
Unreported/Notes:
☐ No Changes

Ensure PI/Staff know the following:

☐ Institutional Unanticipated Events reporting policy
☐ GCPs/best practices regarding reporting unanticipated events

9. Verify Data Safety Monitoring Plan

Approved:
Current Practice:
Changes/Notes:
☐ No Changes

Ensure PI/Staff know the following:

☐ Verify that all events requiring DSMB review were reporting according to IRB approved plan
☐ Institutional policy for Data Safety Monitoring Plans

10. Have there been any outside monitoring or review of this protocol?

☐ NO
☐ If YES, were copies of all outside monitoring reports/letters submitted to the IRB?

Ensure PI/Staff know the following:

☐ Copies of all outside monitoring formal reports/letters must be submitted to the IRB

11. If protocol expired, verify there was no research activity/enrollment during those times?

Expired periods: [note any periods protocol approval lapsed per IRB records]

PI Response: *If there were periods protocol expired, ask PI to describe research activity and enrollment process during these times – ask as open-ended question*

[insert PI response]

[insert auditor's observations of recruitment, enrollment and subject activities (of enrolled subjects) during expired time periods based on study/subject document review during audit]

☐ No Changes

Ensure PI/Staff know the following:

☐ Recommend to submit Continuing Review applications at least 2 months prior to expiration

☐ When protocol has expired or put on hold, all research activity/enrollment should stop, unless permission is granted from the IRB

12. Verify Research Staff and Training

☒	Approved Research Staff	Title/Role	Required Training
☐		Principal Investigator	☐
☐			☐
☐			☐
☐			☐
☐			☐
☐			☐

Is there anyone else who is not listed above that is currently involved in this protocol?

☐			☐
☐			☐
☐			☐

Ensure PI/Staff know the following:

☐ IRB policy: Multi-Center Research and Engagement in Research

☐ IRB policy: Education and Training – Investigator and Research Staff

☐ IRB policy: Communication of Staff Concerns Raised during Research

13. How is your relationship/communication with IRB? Have there been any unexplained delays, and/or overall turn-around time (> 14 days)?

14. What are your experiences, comments and/or feedback regarding:

IRB Office/Administrators

IRB Review Process

Clinical Trials Office

Research Pharmacy

Clinical Research Center

15. Are there any notable obstacles/frustrations to conducting research at [institution]?

16. Are there any notable strength that facilitate your research at [institution]?

17. Are there any resources or services that [institution] can provide that may facilitate research and/or encourage more investigators to conduct research?

18. Overall, what are your general thoughts/impressions about research at [institution]?

19. What are your expectations from this audit? What would you like to learn/improve upon?

20. Questions/Concerns/Comments

Ensure PI receives:

☐ Copy of Principal Investigator Responsibilities