**WKSH 358 - Protocol Assessment - Internal Review Process**

**Protocol Type:**

[ ] Exempt [ ] Expedited [ ] Full Board [ ]  [Check here if under “Continuing Review” status]

**Protocol Status: Check all that apply**

[ ] 1. The research is permanently closed to enrollment

[ ] 2. All participants have completed all research-related activities

[ ] 3. Collection of private identifiable information is completed

[ ] 4. Analysis of private identifiable information is completed

[ ] 5. The study did not collect private identifiable data

[ ] 6. None are applicable

NOTE: If items 1-4 or 1, 2 & 5 from Protocol Status are checked the research study may be closed using IRB Status/ Final Report Form in eProtocol.

IRB Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Classification: [ ] Faculty [ ] Master’s [ ] Doctoral, or Medical Student

[ ] Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Office Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Office Phone: \_\_\_\_\_\_\_-\_\_\_\_\_\_\_- \_\_\_\_\_\_\_\_\_\_ E-Mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@ \_\_\_\_\_\_\_\_\_\_\_\_\_

Other Investigators: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_;

Study Performance Location: On-campus Off-campus Lab facility Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **THIS SECTION TO BE COMPLETED BY QI MONITOR IN CONJUNCTION WITH PRINCIPAL INVESTIGATOR**

**Regulatory Review**

1. Initial IRB approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. If Expedited or Full Board review, most recent IRB approval action date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For QI monitor comments only:

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**Exempt study**

1. Review summary determination: Category(ies) \_\_\_\_\_\_\_\_\_\_\_\_\_

2. Was identifiable data collected? [ ] Yes [ ] No

If Yes,

1. Was the data stored safely, securely, and separate from personal identifiers?

 [ ] Yes [ ] No\*; If No, why?: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Was the code list/ link stored separately from the data?

 [ ] Yes [ ] No\*; If No, why?: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* + 1. Interactions with participants: [ ]  Yes [ ] No

If No, skip items 5-10. If Yes, check items 5-10.

4. There was a consent document/ process: [ ] Yes [ ] No

5. The consent document/ process disclosed the activities that involved research: [ ] Yes [ ] No

1. The consent document/ process disclosed the procedures that were to be performed: [ ] Yes [ ] No
2. The consent document/ process disclosed that participation was voluntary: [ ] Yes [ ] No
3. The consent document/ process disclosed the name and contact information for the investigator: [ ] Yes [ ] No
4. There are/ were adequate provisions to maintain the privacy interests of participants: [ ] Yes [ ] No
5. Total number of study participants:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	1. Total number of study participants approved at time of initial IRB review: \_\_\_\_\_\_\_\_\_\_\_\_\_
	2. Additional participants/ study locations approved by Addendum/ Modification request(s), if applicable: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. Current approved consent document in use, if applicable: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
7. Were study participants audio/ video recorded? [ ] Yes [ ] No

If yes, were the recordings stored securely, per the human research protocol? [ ] Yes [ ] No\*;

If No, why?: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. Was an IRB Status/ Final Report Form completed for the study? [ ] Yes [ ] No \* [ ] N/A

NOTE: If items 1-4 or 1, 2 & 5 from Protocol Status are checked the research study may be closed using Status/ Final Report Form

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**Expedited study or Full Board study**

1. Review summary determination: Category(ies) \_\_\_\_\_\_\_\_\_\_\_\_\_
2. Total number of study participants: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	1. Total number of study participants approved at time of initial IRB review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	2. Additional participants/ study locations approved by Addendum/ Modification request(s), if applicable:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Current approved consent document (s) in use: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Did consent document(s) have a Signature Block, (i.e. no waiver of written documentation of consent) [ ] Yes [ ] No

If Yes, were consent documents stored per human research study protocol? [ ] Yes [ ] No\*;

If No, why?: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Was identifiable data collected? [ ] Yes [ ] No

 If Yes,

* 1. Was the data stored safely, securely, and separate from personal identifiers?

 [ ] Yes [ ] No\*;

* 1. Was the code list/ link stored separately from the data? [ ] Yes [ ] No\*; If No, why?: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
1. Were study participants audio/ video recorded? [ ] Yes [ ] No

If Yes,

Were the recordings stored securely, per the human research protocol?

 [ ] Yes [ ] No\*; If No, why?:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Were the recordings erased/ destroyed, per the human research protocol and consent document? [ ] Yes [ ] No\*; If No, why?:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Did the PI receive any complaints or reports of unanticipated problems from study participants? [ ] Yes [ ] No\*;

If Yes, were the complaints reported to the IRB? [ ] Yes [ ] No\*; If No, why?;

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. Did any study participants withdraw from the research? [ ] Yes [ ] No

If yes, how many and what were the reasons for participant withdrawal?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Were informed consent forms completed and on file under separate study file?

[ ] Yes [ ] No, but required\* N/A (Waiver of Documentation of Consent; skip 9 a-j)

If Yes,

a. Total number of anticipated subjects/participants to complete a Consent Form: \_\_\_\_\_\_\_\_\_

b. Total number of enrolled subjects/participants who completed a Consent Form: \_\_\_\_\_\_\_\_\_\_

c. Discrepancies in the number of subjects/participants identified:

 [ ] Yes\* [ ] No; If Yes, explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_d. Was the content of the informed consent form administered to the subjects/participants the same as the content approved by the IRB for that time period? Yes No\*; If No, why?: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_e. Were informed consent forms signed and dated by the subject/participant or the subject/participant’s legal representative (parent or legal guardian)?

 [ ] Yes [ ] No, but required \* [ ] N/A [Waiver of Documentation of Consent]

f. Were informed consent forms signed and dated by the individual obtaining informed consent? [ ] Yes [ ] No, but required \* [ ] N/A

g. Were there more than one (1) informed consent form(s) approved by the IRB for the study?

 [ ] Yes [ ] No

h. Was the informed consent form (or consent forms) translated to another language?

 [ ] Yes [ ] No

 If Yes, which language(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

i. Were the translated version(s) of the informed consent form reviewed/approved for use by the IRB? [ ] Yes [ ] No\*

 j. Were informed consent forms obtained from each subject/participant PRIOR to the start of study procedures, including screening procedures to determine eligibility?

 [ ] Yes [ ] No\* If No, why? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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k. Did a Waiver or Alteration of the Consent Process (i.e. deception: the study misled or withheld information from participants) apply to the protocol? [ ] Yes [ ] No

a) If Yes, were the study participants debriefed at the end of research activities using the approved IRB debriefing statement? [ ] Yes [ ] No\* If No, why? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Number of Continuing Reviews approved by the IRB? \_\_\_\_\_\_\_ [ ] N/A

If applicable, list approval dates: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Was there a lapse in IRB approval between approved protocol expiration date and the Continuing Review approval date? [ ] Yes [ ] No

If Yes,

1. Were any subjects/participants enrolled during the elapse in IRB approval date?

 [ ] Yes [ ] No

1. Was a protocol deviation submitted to the IRB due to the elapse in approval dates?

[ ] Yes [ ] No

c) Were any study related activities conducted during the lapse in IRB approval? [ ] Yes [ ] No If Yes, is there any documentation on file to support that those activities were approved by the IRB? [ ] Yes [ ] No\* [ ] N/A

1. Number of Addendums/Modifications approved by the IRB? \_\_\_\_\_\_\_ N/A

If applicable, list approval dates: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_;\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Were all Addendums/Modifications submissions and IRB approval letters on file?

 [ ] Yes [ ] No

1. Were there changes to the protocol that should have gone to the IRB for review but did not?

 [ ] Yes \* [ ] No N/A I[ ] f Yes, explain why? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Were there changes to the study design or other study documents (e.g. # of participants, study sites) that should have gone to the IRB for review but did not?

 [ ] Yes \* [ ] No [ ] N/A

 If Yes, explain why?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

15. Were lab tests required under the study? [ ] Yes [ ] No

 If Yes, was a copy of lab results on file for each applicable subject/project participant?

 [ ] Yes [ ] No; If No \*, why? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

16. a) Were specimens collected from subjects/participants? [ ] Yes [ ] No

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1. Were specimens received from a repository, a hospital or any other medical facility?

[ ]  Yes [ ] No

 If Yes to either 16 (a) or (b) above, are there departmental policies or procedures that establish:

 i. Who can use or have access to such specimens? [ ] Yes [ ] No

 ii. How to store and/or maintain such specimens? [ ] Yes [ ] No

 iii. Procedures relating to the disposition of such specimens, if not defined on the protocol methodology or the provider? [ ] Yes [ ] No

 If Yes to 16. i-iii, were such procedures followed by Investigator/study team?

 [ ] Yes [ ] No

c) Were specimens labeled in such a way that can be removed /disposed of in accordance with the terms listed in the informed consent form, protocol or consistent with provider requirements? [ ] Yes [ ] No [ ] N/A

17. Was this study part of a sponsored activity?\*: \_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] Yes [ ] No

If Yes,

1. Provide the sponsor name:

[ ] DHHS unit (other than NIH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] DoD [ ] FDA

[ ] NIH [ ] NIJ [ ] NSF [ ] Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Federal flow through (if known)

1. Were the project research ID# and the sponsor name listed in the IRB application?

 [ ] Yes [ ] No [ ] N/A

c) Was the project a multi-year effort? [ ] Yes [ ] No

d) Were there human subject activities conducted EACH year of the project? [ ] Yes [ ] No

18. Is the study more than minimal risk? [ ] Yes [ ] No

**If Yes to 22, was there a Data Safety Monitoring Plan (DSMP) approved by IRB for this study?** Data Safety Monitoring Plan (DSMP): The DSMP is the process for reviewing data from an ongoing study to monitor the progress of the research and the safety of the subjects/participants. A DSMP makes adequate provision for monitoring the data collected to ensure the safety of subjects/participants.

[ ] Yes [ ] No [ ] N/A

If Yes, list protocol section/page where found: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

19. Was an IRB Study Closure Request Form completed in eProtocol for the study?

 [ ] Yes [ ] No \* [ ] N/A

NOTE: If items 1-4 or 1, 2 & 5 from Protocol Status are checked the research study may be closed using IRB Study Closure Request Form eProtocol.

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**Clinical trial study**

1. Were all relevant communications (e.g. study meeting notes, letters, e-mails) etc. maintained in a separate study file? [ ] Yes [ ] No\*; If No, explain why:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Were subjects/participants screened for involvement in the study based on IRB’s approved inclusion/exclusion criteria?

 [ ] Yes [ ] No [ ] N/A

3. Was there an eligibility checklist that documents the inclusion/exclusion criteria for each enrolled subject?

 [ ] Yes [ ] No [ ] N/A

* + 1. Were there any **UNANTICIPATED EVENTS (UEs)** or **ADVERSE EVENTS (AEs)** resulting from the study performance (other than data safety)? [ ] Yes [ ] No

**An Unanticipated Event** (UE) (also known as an **Adverse Event (**AE), is any incident, experience, or outcome that meets all of the criteria listed below. It usually requires a significant, safety-related change in the protocol such as revising the inclusion/exclusion criteria, or including a new Data Safety Monitoring Plan or Informed Consent Form. NOTE: An individual UE or AE occurrence identified by a QI Program staff member or expressed by the Investigator to the QI Program staff member (meaning an occurrence that only involves one (1) subject/participant) may not necessarily meet the criteria listed below. As an isolated event, its implication for the study may not necessarily be understood or considered significant, unless such UE/AE have caused an aggravated impact/change in the subject’s health status (in comparison to what it was prior to the subject’s participation in the study), or if death occurs.

**Criteria: A UE/AE must be:**

 • Unexpected (not anticipated, per information contained in the approved protocol)

 • Related or possible related, and

• Increases the risk of harm to subjects/participants, or others.

1. Were ALL UEs/AEs reported to the IRB in writing? [ ]  Yes [ ]  No\*
2. Was an Addendum/Modification to the protocol required by the IRB in regard to the UE(s) /AE(s)? [ ] Yes [ ] No

If Yes, list Addendum/Modifications(s) approval date(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_