**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 If 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_