

Instructions:

Please complete this form and attach it to the Protocol Closure Request submitted using the electronic system.

Please reference the Guidance section of the website for additional information

GENERAL INFORMATION

Principal Investigator: Enter PI Name

Person Completing Form: Enter Name

WVU Protocol Number: Enter protocol #

Sponsor Number (if applicable): Enter Sponsor #

REQUEST FOR CLOSURE

1. Indicate the final status of the study:

Select the status of the study

If the study was closed due to an unforeseeable circumstance, please explain below:

[Click here to enter text.](#)

ENROLLMENT

2. What did the research involve? Select all that apply and indicate the total numbers enrolled by the WVU researchers.

Participants.....Total number of participants enrolled by WVU: Enter total # subjects

Medical Records.....Total number of records reviewed by WVU: Enter total # records

Samples.....Total number of samples collected by WVU: Enter total # samples

3. Were any participants withdrawn by the Principal Investigator (PI) or the Sponsor?

Yes.....How many were withdrawn? Enter # withdrawn by PI/Sponsor.

No

Briefly state the reason(s) why the PI withdrew the participant(s).

[Click here to enter text.](#)

4. Did any participant stop participating during the study or withdraw their participation?

Yes,.....How many participants stopped participating? Enter # withdrawn

No

Briefly state the reason(s) why the participant(s) withdrew.

Click here to enter text.

FINDINGS

- 5. Please summarize any preliminary or conclusions from the research. Also, please attach any additional pertinent information, findings, or publications.**

Click here to enter text.

PROTOCOL MONITORING

- 6. If the study was monitored or audited during the last year, please indicate by whom:**

- Not applicable
- Sponsor or designated monitor
- Federal agency or accrediting body
- WVU IRB audit or QIP
- Other

Please provide a brief description of the findings or attach the report(s). Be sure to note the monitoring/auditing bodies in this description.

Click here to enter text.

FINAL NOTE

Please be sure that all reportable events have been reported to the WVU IRB or the IRB of record.

If your study is sponsored by an external source, attach confirmation correspondence for closure.