Submission of this report is appropriate only if all of the following have been accomplished. If not, submit the Continuing Review form.

1. All subjects have finished their final follow-up activities (such as phone calls, post-card contacts, or long term follow up required by the protocol) are completed,
2. The sponsor has indicated that the study is closed at your site, and
3. All data analysis is completed.

[ ]  Check, if all criteria above are true

1. Study Title Click here to enter text.
2. Sponsor Name: Click here to enter text.
3. VDSS IRB Study Number: Click here to enter text.
4. Principal Investigator (PI) Name: Click here to enter text.
5. PI Email Address Click here to enter text.
6. Number of VDSS potential subjects screened Click here to enter text.
7. Number of Non-VDSS potential subjects screened Click here to enter text.
8. Total number of VDSS clients enrolled Click here to enter text.

 Female Click here to enter text. Male Click here to enter text.

 Asian/Pacific Islander Click here to enter text. Black, Non-Hispanic Click here to enter text.

 Caucasian, Non-Hispanic Click here to enter text. Native American/Alaskan Click here to enter text.

 Other/Unknown Click here to enter text. Hispanic Click here to enter text.

1. Number of VSDD subjects dropped out of study Click here to enter text.
2. Reasons for drop-out Click here to enter text.
3. Number of Non-VSDD subjects dropped out of study Click here to enter text.
4. Reasons for drop-out Non-VDSS subjects Click here to enter text.
5. Total number of subjects enrolled other study sites? Click here to enter text.
6. Number of subjects lost to follow-up Click here to enter text.
7. Were there any medical, legal, or practical difficulties that have been encountered in the study aside from adverse events? For example, difficulties would include complaints of subjects, logistic problems, or any difficulties that may pertain to the rights of subjects.

 [ ]  Yes [ ] No

 If yes, describe Click here to enter text.

1. Were there any adverse events encountered during this study?

 [ ]  Yes, Number Click here to enter text. [ ]  No

1. Have all adverse events been reported to the VDSS IRB? [ ]  Yes [ ] No

 If you answered “No”, submit the adverse event report form

1. Did you experience any problems with the consent process? [ ]  Yes [ ] No

 If yes, explain. Click here to enter text.

1. Were there any subject complaints? Yes [ ]  No [ ]

If yes, describe Click here to enter text.

1. Submit a brief summary of study results. Discuss any changes in procedures and anticipated risks or benefits. Also, you are reminded that Virginia legislative mandate (§32.1-162.19E) requires results of completed studies be summarized in the VDSS annual report and made available to the public on the VDSS IRB web page. As soon as practicable, please submit to the VDSS IRB a copy of the project’s final report[[1]](#footnote-1). Click here to enter text.

|  |  |
| --- | --- |
| PI Signature | Date signedClick here to enter a date. |

1. A report is not required if project information is exempt from disclosure under the Virginia Freedom of Information Act ($2.2-3700 et seq.). [↑](#footnote-ref-1)