Study Title: Click here to enter text.

VDSS IRB Study Number: Click here to enter text.

Principal Investigator (PI) Name: Click here to enter text.

PI Title and Organization: Click here to enter text.

PI E-Mail Address: Click here to enter text.

PI Telephone Number: Click here to enter text.

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| --- |
| Study Progress Report |

1. Is the study under review by another IRB [ ]  Yes [ ]  No

If study is under review or recently approved by another IRB, identify the IRB Click here to enter text.

Also, provide a copy of the study approval

1. Provide a brief project summary:

Click here to enter text.

1. Any changes in study sponsor? [ ]  Yes [ ]  No

If yes, explain the change and provide name and contact information for new sponsor

Click here to enter text.

1. Number of potential VDSS subjects screened Click here to enter text.
2. Number of potential Non-VDSS subjects screened Click here to enter text.
3. Number of subjects enrolled at VDSS study sites 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 subjects enrolled at Non-VDSS study sites 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 subjects dropped out of study, VDSS study sites Click here to enter text.

Reasons for drop-out Click here to enter text.

1. Number of subjects dropped out of study, Non-VDSS study sites Click here to enter text.

Reasons for drop-out Click here to enter text.

1. Number of subjects lost to follow-up, VDSS study sites Click here to enter text.
2. Number of subjects lost to follow-up, Non-VDSS study sites Click here to enter text.
3. A brief summary of any amendments to the study approved by the VDSS IRB since the IRB’s initial review or the last continuing review, whichever is later: Click here to enter text.
4. Describe any new and relevant information, published or unpublished, since the last IRB review, especially information about risk associated with the research:

Click here to enter text.

1. Since initial IRB approval or the last continuing review, have there been any changes in the study protocol?: [ ] Yes [ ] No

If yes, describe the changes:

Click here to enter text.

1. Any changes in study personnel? [ ]  Yes [ ]  No

If yes, submit the study personnel form

1. Any unanticipated problems?: [ ] Yes [ ] No

If yes, provide a summary of the problem(s):

Click here to enter text.

1. Any adverse events?: [ ] Yes [ ] No

If yes, provide a summary of the event(s):

Click here to enter text.

1. How many subjects have withdrawn from the study since the last IRB review: Click here to enter text.

Explain the reasons for withdrawal: Click here to enter text.

1. Summarize any complaints about the research from subjects or others since the last IRB review:

Click here to enter text.

1. Are there any proposed modifications to the informed consent document?

[ ]  Yes [ ]  No

If yes, provide a track changes Microsoft Word version of the proposed change(s). Otherwise, include in this submission, a copy of the VDSS IRB approved consent document.

1. Is there any other information related to risks to subjects? [ ] Yes [ ] No

If yes, describe the risk and risk reduction procedures:

Click here to enter text.

If yes, have subjects been informed about the risk(s)? [ ] Yes [ ] No

If subjects have not been informed about new risks, why not and when will they be informed? Click here to enter text.

|  |  |
| --- | --- |
| Print the name of the person who completed this formClick here to enter text. | E:MailClick here to enter text. |

|  |  |
| --- | --- |
| PI Signature | DateClick here to enter a date. |