VDSS IRB Guidance Document: Checklist of Materials Required for IRB Review

I. Overview

This guidance document outlines the materials investigators should assemble and include with their applications for IRB review in order to provide sufficient information for the IRB to make specific determinations regarding the risks, potential benefits, informed consent, and safeguards for human subjects. The *IRB submission forms provide additional guidance on what to include in the submission packet.*

II. Initial Review

The following materials are **required** for initial review of **all types of research**:

☐Completed IRB Initial Review Application

☐Recruitment and Screening materials (if applicable)

☐Informed Consent Documents(s) (if applicable)

☐Request for waiver of informed consent (if applicable)

☐Request for waiver of documentation of informed consent (if applicable)

☐Study protocol/research plan/evaluation plan

☐Evidence of review by another IRB to include approval notice (if applicable)

☐Request for VDSS IRB to defer to another IRB review (if applicable)

☐Survey, questionnaires, interview materials and/or other materials related to interactions/intervention with human subjects to include investigator-authored measures (if applicable)

Sponsored Research

☐Detailed Sponsor's Protocol/research plan/evaluation plan

☐Relevant Grant Applications or Contracts

☐For federally supported Multi-center trials: Federally approved Consent Forms and Protocol/research plan/evaluation plan

Other

☐Any additional documentation the investigator(s) deems pertinent

III. Continuing Review

☐Completed Continuing Review Application

☐Any relevant multi-center reports (if applicable)

☐Currently approved and any proposed recruitment and screening materials (if applicable)

☐Currently approved and any proposed informed consent document(s) (if applicable)

☐Any additional pertinent documentation

IV. Amendments to Approved Research

☐Completed Amendment application

☐Relevant modified study documents

☐Recruitment materials, screening materials, and consent documents (if applicable)

☐Any additional documentation requiring IRB review and approval

V. Responses to IRB Correspondence

☐Investigator's response to IRB requires

☐Revised consent documents, screening and recruitment materials (if applicable)

☐All other modified study documents

☐Any additional pertinent documentation