VDSS IRB Guidance Document:
Procedures for Recording Minutes at Convened Meetings

I. Purpose:
   a. This guidance document establishes the process to take IRB minutes.
   b. This guidance begins when the meeting is called to order and ends when the minutes are finalized.

II. Background:
Federal policy for protection of human research subjects requires "Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution."[1] Additionally, the VDSS Administrative Code for Human Subject Research is in essence, a very close paraphrase of the federal policy.[2]

III. Responsibility: VDSS IRB.

IV. Procedure:
   a. Use the Minutes template to record minutes (enclosure).
   b. Record the date the meeting is held
   c. Record the place where the meeting is held
   d. Record the time the meeting is called to order.
   e. Record the total number of regular members on the current IRB roster and the number of members required for a majority[3]. A majority shall consist of the whole number greater than one-half of the number of regular members including at least one member whose primary concerns are in nonscientific areas. For example, if the board has 10 members, six, including one nonscientist, must be present for each vote.
   f. Complete the "IRB Member Attendance Table" (minutes' template).
   g. If IRB members are present by teleconference/telephone, indicate whether they received all pertinent material before the meeting and were able to actively and equally participate in all discussions.
   h. Complete the "Attendance Table – All others present at any time during the meeting" (minutes' template).
   i. Read the reminder notice about when members should recuse themselves.

[1] 45 CFR 46.115(2)
[2] 22VAC40-890-100A2
[3] 45 CFR 46.108(b)

j. Review minutes from previous meetings and record board decision and changes as appropriate.
k. Based on the purpose of the meeting, complete template items for new protocol(s), amendment(s), or continuing review(s), and/or etc.
l. If the purpose of the meeting is to discuss any of the issues listed below, summarize previous IRB actions, summarize the issue and record the board's discussion of the issue, summarize key information from oral reports presented by others present at the meeting.
    1. Unanticipated Problem Involving Risks to Subjects or Others
    2. Noncompliance
    3. Continuing Noncompliance
    4. Suspension of IRB Approval
    5. Termination of IRB Approval
m. If any item is not acted upon, record the reason[4].
n. If there were any controverted issues (IRB members expressed a difference of opinion), summarize the issue, label as a controverted issue, and summarize the resolution, if any.
o. If there were no controverted issues, so state.
p. Record the motion[5].
    1. For a motion of "Approve" or "Conditionally Approve" related to an initial or continuing review submission record:
        a. The approval period
        b. Whether research is Minimal Risk or greater than Minimal Risk
    2. For a motion of "approve with conditions" record the IRB's modifications required to secure approval and the reasons for those modifications. Further review by the IRB at a subsequent convened meeting is not necessary; rather, the IRB chair can ensure changes are made and issue the approval.
    3. For a motion of "Table" record the IRB's reasons and recommendations. In this case further review by the convened IRB is required at a future date after the required modifications are submitted by the investigator.
    4. For a motion of "Disapprove" record the IRB's reasons.

[4] For example: Loss of all non-scientific members, missing expertise, or meeting ended early due to fire alarm, etc.
[5] Reference: FQA "Approval of Research with Conditions: OHRP Guidance (2010)

5. For a motion of "Suspend" record the specific activities suspended and the IRB's recommendations, if any.
6. For a motion of "Lift Suspension" no other information needs to be recorded.
7. For a motion of "Terminate" record the IRB's reasons.

q. Record the vote as the numbers:
    1. "For": Voting for the motion.
    2. "Against": Voting against the motion
    3. "Abstain": Present for the vote, but not voting "For" or "Against"
    4. "Absent": Not present for reasons other than a Conflicting Interest
        a. Record the names of absent members (members in attendance at the meeting, but absent from the room for the vote)
    5. "Recused": Not present for discussion and voting due to a Conflicting Interest
        a. Record the names of recused members
    6. Record the time the meeting is adjourned.
    7. Minutes approval process:
        a. The Meeting Chair shall distribute the draft minutes to each IRB member who attended convened meeting and request comments/corrections/approval. After all comments/corrections have been received and posted to the minutes, the IRB Chair may use e-mail to ask the board to approve the minutes. If minutes are approved via e-mail, the chair shall provide to the members the recorded vote as outlined in item “q” above.
    8. Minutes of the IRB committee meeting will be directly used to generate written notifications of IRB decisions regarding the approval status of the research submission for dissemination to the listed principal investigator. If modifications to the minutes affect the approval status of a research study, the principal investigator will be notified.
    9. Approved minutes shall be included in the Annual Report to the Commissioner[6] and the IRB members.

V. References

[6] 22VAC40-890-90A

a. 45 CFR §46.103(4)
b. 45 CFR §46.115(a)(2)
c. 22VAC40-890-100

Date:
Place: VDSS, 801 East Main Street Richmond, VA, ____ floor, Room # ____

Call to order Time:
Total Members: _____ ; ____for a majority:

IRB Member Attendance Table

Present	Scientist (S) Non-scientist (N)	IRB Member	In person (I) Teleconference (TC) Telephone (TP)	Arrival Time	Departure Time (s)
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					

Voting Members Absent:

Attendance Table – all others present at any time during the meeting:

Name	Time arrived	Time departed	role during the meeting

The Chair reminded all board members to recuse themselves from deliberation and voting on any study submitted to the IRB in which they have a *potential or perceived* conflict of interest. This includes, but is not limited to: service as a principal investigator, co-principal investigator, sub-investigator: receiving funding from the study; serving in a supervisory or subordinate role with the principal investigator of the study; serving as a mentor/trainee relationship with the principal investigator; a family member of the principal investigator; working relationship for grants awarded by VDSS or a LDSS.

Review of Minutes from Previous Meeting(s):

Meeting Date	Accept as is	Accept with Revisions*	Revise & Resubmit*	*see minutes for revision
	☐	☐	☐	☐

Requested change to the minutes:

Requested change to the minutes:

A. **New Protocol(s)**:

Study Title:	
VDSS IRB #	Sponsor/Funder:
Investigator:	Primary reviewer(s):

N/A	Yes	No	Committee Review included, but was not limited to the following areas:
☐	☐	☐	Investigator included CV?
☐	☐	☐	Investigator has no conflict of interest that would compromise the integrity of the study?
☐	☐	☐	Does the study specifically target a vulnerable population?
☐	☐	☐	Written informed consent will be obtained from the subjects?
☐	☐	☐	This study enrolls children and written informed consent will be obtained from the child's parent or guardian?
☐	☐	☐	This study may enroll adults who are not competent to provide informed consent? (Written informed consent will be obtained from subjects' legally authorized representative).
☐	☐	☐	Consent document accurately describes the important aspects of the study?
☐	☐	☐	Consent document is written in a way likely to be understood by prospective subjects?
☐	☐	☐	The following revisions to the consent document are required for final study approval:
☐	☐	☐	Prospective subjects will be recruited from:

N/A	Yes	No	Committee Review included, but was not limited to the following areas:
☐	☐	☐	A research advertisement will be used?
☐	☐	☐	The following revisions to advertisement(s) is/are required for final study approval:
☐	☐	☐	This study provides reimbursement or payment to subjects for their participation in the study?
☐	☐	☐	The level and schedule of reimbursement/payment is reasonable in relation to study procedures?
☐	☐	☐	Subjects for whom the payment is likely to be coercive will be excluded from the study?
☐	☐	☐	Is there coercion or undue influence?
☐	☐	☐	Risks and discomforts of research participation were thoroughly evaluated?
☐	☐	☐	Risks are minimized by research design?
☐	☐	☐	Main risks of research participation are adequately summarized in the consent document?
☐	☐	☐	Participation in this research will not directly benefit research participants?
☐	☐	☐	This research may benefit people in the future?
☐	☐	☐	Risks of research participation are reasonable in view of potential benefits?
☐	☐	☐	Provisions to protect the privacy of subjects are adequate?
☐	☐	☐	Provisions to protect confidentiality of data are adequate?
☐	☐	☐	Are inclusion criteria clearly stated?
☐	☐	☐	Are exclusion criteria clearly stated?
☐	☐	☐	Is there a need for ongoing data monitoring for the purpose of identifying unexpected results that would indicate a need for study revision?
Discussion and Questions:			
Other Action Items:			
Controverted issues:			

Decision:	Approve ☐	Approve with Conditions ☐	Table ☐	Disapprove ☐
Vote:	Total Voting =	For =	Against =	Abstained =
		Absent =	Recused =	

Name(s) of voting members not in the room	Name(s) of voting members not present due to conflict of interest	Names of Members who abstained

B. **Amendment (s)**:

<table>
<tr><td colspan="3">Study Title:</td><td colspan="3"></td></tr>
<tr><td colspan="2">VDSS IRB #</td><td colspan="4">Sponsor/Funder:</td></tr>
<tr><td colspan="2">Investigator:</td><td colspan="4">Primary reviewer(s):</td></tr>
<tr><td>Action Items:</td><td colspan="5"></td></tr>
<tr><td>Discussion and Questions:</td><td colspan="5"></td></tr>
<tr><td>Controverted issues:</td><td colspan="5"></td></tr>
<tr><td>Decision:</td><td>Approve
☐</td><td>Approve with Conditions
☐</td><td>Table
☐</td><td colspan="2">Disapprove
☐</td></tr>
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C. **Continuing Review(s)**:

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D. **Potential Non-Compliance or Continued Non-Compliance**:

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E. **Suspension or Termination of IRB Approval**:

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F. **Potential Non-Compliance**:

Study Title:				
VDSS IRB #		Sponsor/Funder:		
Investigator:		Primary reviewer(s):		
Action Items:				
Discussion and Questions:				
Controverted issues:				
Decision:	Approve ☐	Approve with Conditions ☐	Table ☐	Disapprove ☐
Vote:	Total Voting =	For =	Against =	Abstained =
		Absent =	Recused =	

Name(s) of voting members not in the room	Name(s) of voting members not present due to conflict of interest	Names of Members who abstained

Adjourned Time: