

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 majority³. 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)

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

- 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 reason⁴.
- 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 motion⁵.
 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)

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

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 Commissioner⁶ and the IRB members.

V. References

⁶ 22VAC40-890-90A

Approved DDMMYYYY

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

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

Approved DDMMYYYY

VDSS IRB Minutes Template

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)
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					

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.

VDSS IRB Minutes Template

Review of Minutes from Previous Meeting(s):

Meeting Date	Accept as is	Accept with Revisions*	Revise & Resubmit*	*see minutes for revision
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

VDSS IRB Minutes Template

N/A	Yes	No	Committee Review included, but was not limited to the following areas:			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A research advertisement will be used?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The following revisions to advertisement(s) is/are required for final study approval:			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This study provides reimbursement or payment to subjects for their participation in the study?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The level and schedule of reimbursement/payment is reasonable in relation to study procedures?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Subjects for whom the payment is likely to be coercive will be excluded from the study?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there coercion or undue influence?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Risks and discomforts of research participation were thoroughly evaluated?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Risks are minimized by research design?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Main risks of research participation are adequately summarized in the consent document?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Participation in this research will not directly benefit research participants?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This research may benefit people in the future?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Risks of research participation are reasonable in view of potential benefits?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Provisions to protect the privacy of subjects are adequate?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Provisions to protect confidentiality of data are adequate?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are inclusion criteria clearly stated?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are exclusion criteria clearly stated?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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 <input type="checkbox"/>	Approve with Conditions <input type="checkbox"/>	Table <input type="checkbox"/>	Disapprove <input type="checkbox"/>
			Vote: Total Voting =		For =	Against =
		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	

VDSS IRB Minutes Template

B. Amendment (s):

Study Title:				
VDSS IRB #		Sponsor/Funder:		
Investigator:		Primary reviewer(s):		
Action Items:				
Discussion and Questions:				
Controverted issues:				
Decision:	Approve <input type="checkbox"/>	Approve with Conditions <input type="checkbox"/>	Table <input type="checkbox"/>	Disapprove <input type="checkbox"/>
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	

VDSS IRB Minutes Template

C. Continuing Review(s):

Study Title:				
VDSS IRB #		Sponsor/Funder:		
Investigator:		Primary reviewer(s):		
Action Items:				
Discussion and Questions:				
Controverted issues:				
Decision:	Approve <input type="checkbox"/>	Approve with Conditions <input type="checkbox"/>	Table <input type="checkbox"/>	Disapprove <input type="checkbox"/>
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	

VDSS IRB Minutes Template

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

Study Title:				
VDSS IRB #		Sponsor/Funder:		
Investigator:		Primary reviewer(s):		
Action Items:				
Discussion and Questions:				
Controverted issues:				
Decision:	Approve <input type="checkbox"/>	Approve with Conditions <input type="checkbox"/>	Table <input type="checkbox"/>	Disapprove <input type="checkbox"/>
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	

VDSS IRB Minutes Template

E. Suspension or Termination of IRB Approval:

Study Title:				
VDSS IRB #		Sponsor/Funder:		
Investigator:		Primary reviewer(s):		
Action Items:				
Discussion and Questions:				
Controverted issues:				
Decision:	Approve <input type="checkbox"/>	Approve with Conditions <input type="checkbox"/>	Table <input type="checkbox"/>	Disapprove <input type="checkbox"/>
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	

VDSS IRB Minutes Template

F. Potential Non-Compliance:

Study Title:				
VDSS IRB #		Sponsor/Funder:		
Investigator:		Primary reviewer(s):		
Action Items:				
Discussion and Questions:				
Controverted issues:				
Decision:	Approve <input type="checkbox"/>	Approve with Conditions <input type="checkbox"/>	Table <input type="checkbox"/>	Disapprove <input type="checkbox"/>
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: