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1			STITUTIONAL REVIEW E	-
2		Minutes of the Meeting SPH.IRB-00 20		
3		(Form 6.1)		
4			Date	
5				
6				
7	ATTEN	NDANCE:		
8				
		ent IRB Members and Staff:	Present Guest	Absent:
		e, position, expertise,		
		nedical, affiliated/non- ated, male/female		
		e, position, expertise,		
		nedical, affiliated/non-		
		ated, male/female		
		e, position, expertise,		
		nedical, affiliated/non-		
	affili	ated, male/female		
9 10 11	PROCEEDINGS:			
12	١.	Opening Prayer		
13		Led the opening prayer.		
14	١١.			
15		Dr. Jaime Manila called the meeting to order at		
16		III Determination of the Overse		
17	III. Determination of the Quorum			
18 10	The Chair declared a quorum with members from the different sectors present:			
19 20	N/	IV. Approval of the Agenda		
20				nproved and seconded by
22		Upon the motion ofthe agenda was approved and seconded by The IRB passed the agenda: SPH.IRB-00 - 20 .		
23		The IND passed the agenua. SPH.IND-UU 2U		
24	V.	Reading and Approval of th	e Minutes of the Previo	ous Meeting

25	Upon the motion of	the minutes of the previous meeting was approved
26	and it was seconded by	Thus, the IRB passed the Minutes of the Meeting:
27	SPH.IRB-00 20	
28		

- 29 VI. Business Arising From the Minutes of the Meeting
- 31 VII. Disclosure of Conflict of Interest among Members:

33 VIII. Protocol Review

34 35

30

32

A. New Protocols for Initial Review of Full Board.

IRB Protocol #			
Protocol #			
Protocol Title:			
Principal Investigator:			
Primary			
Reviewers:			
Name of Sponsor:			
Documents:			
Date of submission			
Specify elements of	<mark>elements of</mark>	<mark>findings</mark>	recommendations
<mark>review (under</mark>	<mark>review</mark>		
<mark>lssue)</mark>			
i. Scientific review			
ii. Ethical Considerations			
iii. ICF Review			
III. ICF Review			
Summary of		1	I
Findings and			
recommendations			
Decision:			
Documentation of			

36

37

B. Review of SJREB Protocols

IRB Protocol #	
Protocol #	
Protocol Title:	

Principal			
Investigator:			
Primary			
Reviewers:			
Name of Sponsor:			
Documents:			
Date of submission			
Specify elements of	<mark>elements of</mark>	<mark>findings</mark>	recommendations
<mark>review (under</mark>	review		
<mark>lssue)</mark>			
i. Scientific review			
ii. Ethical			
Considerations			
iii. ICF Review			
<mark>Summary of</mark>			
Findings and			
recommendations			
Decision:			
Documentation of			
voting			

C. Report on the Results of the Expedited Review

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

D. Exempt from Review Protocols

IRB Protocol #	
Protocol #	
Protocol Title:	

Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

E. Resubmission:

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Date of initial	
submission	
date of initial	
review	
Date of	
resubmissions	
Documents:	
Issue:	
Decision:	

F. Amendments:

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Documents:	
specify the	
amendment	
type of	
<mark>amendment</mark>	

Issue:	
Decision:	

G. Progress Reports.

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

H. Early Termination Report.

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

I. Application for Continuing Review

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	

Documents:	
Issue:	
Decision:	

J. Final Reports

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Date of permanent	
closure of the	
study/research	
Date when the	
final report was	
received:	
Documents:	
Issue:	
Decision:	

K. SAE Reports

Reports	
IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Sponsor:	
Documents:	
indicate the	
elements of	
review	
i.e. type of	
SAE/SUSAR,	
indicate onsite,	
relatedness to	
intervention,	
outcome of SAE on	
the participant,	

how SAE was	
managed	
Issue:	
Decision:	

57 L. Protocol Deviations and Violations

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

58

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M. Site Visit

60 61

N. Queries and Complaints

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	

Primary	
Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

O. Appeal

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

P. Reports on Negative Events (RNE)

IRB Protocol #	
Protocol #	
Protocol Title:	
Principal	
Investigator:	
Primary	
Reviewers:	
Sponsor:	
Documents:	
Issue:	
Decision:	

Q. Other Reports

 IRB Protocol #

 Protocol #

Principal	
Investigator:	
Sponsor:	
Documents:	
Issue:	
Decision:	
70	
71 72 IX. Other Matters	
72 IX. Other Matters 73	
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75	
76	
77 X. Adjournment:	
78 There being no matters to discussed, the meeting adjourned at	
79	
80	
81 Prepared By:	
82	
83	
84 IRB Member- Secretary	
85	
86 Attested by:	
87	
88	
89 IRB Chair	