



MINUTES OF REGULAR MEETING

Date of Meeting:

Time of Meeting :

Venue of Meeting: IEC Conference Room, AKMRC

ATTENDANCE

IEC Members	Position/ Area of Responsibility
	Chair/ Medical
	Co-chair/ Non-medical; Non-scientific
	Member/ Medical
	Member-Secretary/ Non-medical; Non-scientific
	Non-affiliated Member/ Scientific
	Affiliated Member/ Non-medical; Non-scientific
	Non-Affiliated Member/ Medical; Scientific
	Lay Member/ Non-medical; Non-scientific

1. DETERMINATION OF QUORUM

The IEC Secretary declared that a quorum was present, with _____ members, inclusive of non-Institutional and _____ non-scientific/lay members in attendance.

2. CALL to ORDER and CONFIRMATION OF QUORUM

The IEC Chair, upon confirming a quorum, called the meeting to order at

3. DISCLOSURE OF CONFLICT OF INTEREST

The IEC Chair called for the disclosure of Conflict of Interest (COI) in any of the study protocols scheduled for deliberation in the meeting.

<The following member<s> inhibited from participation in the deliberations during the meeting for the following reasons>:

Name of IEC Member	Reason(s) Given
<Title, Name, Surname>	Being <Principal Investigator for the study > < TITLE> <PTN>



4. READING AND APPROVAL OF THE MEETINGS OF THE LAST MEETING

Date of Last Meeting :

Time of Last Meeting :

Venue of Last Meeting: IEC Conference Room, AKMRC

The IEC Chair presided over the discussion of the minutes of the last meeting. The minutes were corrected, and approved as amended.

5. BUSINESS ARISING FROM THE MINUTES

6. PROTOCOL REVIEW

6.1. FULL REVIEW

6.1.1 INITIAL REVIEW

PROTOCOL 1	PTN <number>
Date of Submission:	Date Received:
Title	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Previous Approval from other Technical/Ethics Review Committees	<Name of Technical /Ethics Review Committee> < Approval Start and End Date>
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest
Scientific Soundness (refer to IEC FORM 2C/V1/2012)	Comments
1. Study Objectives 2. Background Information/Data 3. Study/Sampling Design 4. Use of Control Arm/Placebo 5. Inclusion/Exclusion/Withdrawal Criteria 6. Statistical/Data Analysis Plan 7. Specimen Collection, Processing, Storage Procedures 8. Facilities/Infrastructure at Study Site 9. PI Qualification, Competence, Experience 10. Contribution to science, research capacity, health care, treatment 11. Benefit to Local Communities	
Ethical Soundness (refer to IEC FORM 2C/V1/2012)	Comments
1. Privacy/Confidentiality Safeguards 2. Involvement of Human Participants 3. Involvement of Vulnerable Populations	



<ol style="list-style-type: none"> 4. Voluntary, non-coercive recruitment 5. Participant Selection 6. Risk-Benefit Ratio 7. Informed Consent process 8. Language of the Informed Consent/Assent Forms 9. Translation(s) of the Informed Consent/Assent Forms 10. Specific Informed Consent Provisions (as specified in the Protocol Assessment Form) 	
Conclusions and Recommendations	
Action Taken APPROVAL MAJOR MODIFICATION (<i>which require Full Board deliberation</i>) MINOR MODIFICATION (<i>which can be expedited at the level of the Chair</i>) DISAPPROVAL	

6.1.2. RESUBMISSIONS (*protocols with MAJOR corrections/modifications*)

PROTOCOL 1	PTN <number>
Date of Initial Review	Date of Resubmission: Date Received:
Title	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Rreview:	Primary Reviewers:
Quorum Status	Conflict of Interest
Assessment of the Responses (<i>refer to submitted IEC Form 2H/V1/2012</i>)	
Conclusions and Recommendations	
Action Taken APPROVAL MAJOR MODIFICATION (<i>which require another Full Board deliberation</i>) MINOR MODIFICATION (<i>which can be expedited at the level of the Chair</i>) DISAPPROVAL	

6.1.3. REQUIRING CLARIFICATORY INTERVIEW

PROTOCOL 1	PTN <number>
Date of Initial Review	Date of Clarificatory Interview:
Title	
Principal Investigator	
Sponsor/CRO	



Primary Reviewers	
Quorum Status	
Conflict of Interest	
Assessment of the Responses	
Conclusions and Recommendations	
Action Taken REQUEST INFORMATION (<i>specify</i>) RECOMMENDED FURTHER ACTION (<i>specify</i>)	

6.1.4. PROTOCOL AMENDMENT APPLICATIONS (*with MAJOR Amendments that can affect the scientific and/or ethical acceptability of the protocol*)

PROTOCOL 1	PTN <number>
Date of Approval:	Amendment Submission Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of the Requested Amendment (<i>refer to submitted IEC FORM 3A/V1/2012</i>)	
Conclusions and Recommendations	
Action Taken APPROVAL MAJOR MODIFICATION (<i>which require Full Board deliberation</i>) MINOR MODIFICATION (<i>which can be expedited at the level of the Chair</i>) DISAPPROVAL	

6.1.5. CONTINUING REVIEW APPLICATIONS

PROTOCOL 1	PTN <number>
Date of Approval:	Continuing Review Application Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of the Study Progress (<i>refer to submitted IEC Form 3B/V1/2012</i>)	



Conclusions and Recommendations

Action Taken

UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION
REQUEST INFORMATION (*specify*)
RECOMMENDED FURTHER ACTION (*specify*)

6.1.6. FINAL REPORTS

PROTOCOL 1	PTN <number>
Date of Approval:	Final Report Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of the Final Report (<i>refer to submitted IEC Form 3C/V1/2012</i>)	
Conclusions and Recommendations	
Action Taken	
APPROVAL REQUEST INFORMATION (<i>specify</i>) RECOMMENDED FURTHER ACTION (<i>specify</i>)	

6.1.7. SAE and SUSAR REPORTS

PROTOCOL 1	PTN <number>
Date of Approval:	SAE/SUSAR Report Submission Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of SAE/SUSAR Report (<i>refer to submitted IEC FORM 3G/V1.2012</i>)	
Conclusions and Recommendations	
Action Taken	
UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (<i>specify</i>) RECOMMEND FURTHER ACTION (<i>specify</i>) FORWARD TO SAE SUB-COMMITTEE	



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6.1.8. SITE VISIT REPORTS

PROTOCOL 1	PTN <number>
Date of Approval :	Site Visit Report Submission Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of Site Visit Report (refer to submitted IEC FORM 3F/V1.2012)	
Conclusions and Recommendations	
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (specify) RECOMMEND FURTHER ACTION (specify)	

6.1.9. NON-COMPLIANCE (DEVIATION/VIOLATION) REPORTS

PROTOCOL 1	PTN <number>
Date of Approval :	Non-Compliance Report Submission Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of Non-Compliance Report (refer to submitted IEC FORM 3D/V1.2012)	
Conclusions and Recommendations	
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (specify) RECOMMEND FURTHER ACTION (specify)	

6.1.10. EARLY STUDY TERMINATION APPLICATIONS

PROTOCOL 1	PTN <number>



Date of Approval	Early Termination Application Submission Date <dd/mm/yy> Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of Risks from Early Termination (refer to submitted IEC FORM 3E/V1.2012)	
Conclusions and Recommendations	
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (specify) RECOMMEND FURTHER ACTION (specify)	

6.1.11. QUERIES AND COMPLAINTS

PROTOCOL 1	PTN <number>
Date of Approval:	Query/Complaint Receiving Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of Query/Complaint (refer to submitted IEC FORM 3I/V1.2012)	
Conclusions and Recommendations	
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (specify) RECOMMEND FURTHER ACTION (specify)	

6.2. EXPEDITED REVIEW

6.2.1. INITIAL REVIEW

PROTOCOL 1	PTN <number>
Date of Submission:	Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Previous Approval from other Technical/Ethics Review Committees	<Name of Technical /Ethics Review Committee>



	< Approval Start and End Date>
Type of Review:	Primary Reviewers
Quorum Status:	Conflict of Interest:
Scientific Soundness (refer to IEC FORM 2C/V1/2012)	Comments
<ol style="list-style-type: none"> 1. Study Objectives 2. Background Information/Data 3. Study/sampling Design 4. Use of Control Arm/Placebo 5. Inclusion/Exclusion/Withdrawal Criteria 6. Statistical/data Analysis Plan 7. Specimen Collection, Processing, Storage Procedures 8. Facilities/Infrastructure at Study Site 9. PI Qualification, Competence, Experience 10. Contribution to Science, research capacity, health care, treatment 11. Benefit to Local Communities 	
Ethical Soundness (refer to IEC FORM 2C/V1/2012)	Comments
<ol style="list-style-type: none"> 1. Privacy/Confidentiality Safeguards 2. Involvement of Human Participants 3. Involvement of Vulnerable Populations 4. Voluntary, non-coercive recruitment 5. Participant Selection 6. Risk-Benefit Ratio 7. Informed Consent process 8. Language of the Informed Consent/Assent Forms 9. Translation(s) of the Informed Consent/Assent Forms 10. Inclusion of Specific Provisions in the ICF 11. Specific Informed Consent Provisions (<i>as specified in the Protocol Assessment Form</i>) 	
Conclusions and Recommendations	
Action Taken APPROVAL MAJOR MODIFICATION (<i>which require Full Board deliberation</i>) MINOR MODIFICATION (<i>which can be expedited at the level of the Chair</i>) DISAPPROVAL	

6.2.2. CONTINUING REVIEW APPLICATIONS (*for expedited protocols*)

PROTOCOL 1	PTN <number>
Date of Approval:	Continuing Review Application Date: Date Received:



Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of the Study Progress (refer to submitted IEC Form 3B/V1/2012)	
Conclusions and Recommendations	
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (specify) RECOMMENDED FURTHER ACTION (specify)	

6.2.3. PROTOCOL WITHDRAWAL

PROTOCOL 1	PTN <number>
Date of Submission:	Date of Withdrawal Application/Letter : Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of the Reasons for Withdrawal	
Conclusions and Recommendations	
Action Taken APPROVAL REQUEST INFORMATION (specify) RECOMMENDED FURTHER ACTION (specify)	

6.2.4. FINAL REPORTS (for expedited protocols)

PROTOCOL 1	PTN <number>
Date of Approval:	Final Report Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of the Final Report (refer to submitted IEC Form 3C/V1/2012)	



Conclusions and Recommendations
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (<i>specify</i>) RECOMMENDED FURTHER ACTION (<i>specify</i>)

6.2.5. NON-COMPLIANCE (DEVIATION/VIOLATION) REPORTS (*for expedited protocols*)

PROTOCOL 1	PTN <number>
Date of Approval :	Non-Compliance Report Submission Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of Non-Compliance Report (<i>refer to submitted IEC FORM 3D/V1.2012</i>)	
Conclusions and Recommendations	
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (<i>specify</i>) RECOMMEND FURTHER ACTION (<i>specify</i>)	

6.2.6. EARLY STUDY TERMINATION APPLICATIONS (*for expedited protocols*)

PROTOCOL 1	PTN <number>
Date of Approval:	Early Termination Application Submission Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status:	Conflict of Interest:
Assessment of Risks from Early Termination (<i>refer to submitted IEC FORM 3E/V1.2012</i>)	
Conclusions and Recommendations	
Action Taken	



UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION
REQUEST INFORMATION (*specify*)
RECOMMEND FURTHER ACTION (*specify*)

6.2.7. QUERIES AND COMPLAINTS (*for expedited protocols*)

PROTOCOL 1	PTN <number>
Date of Approval:	Query/Complaint Receiving Date: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
Quorum Status	Conflict of Interest
Assessment of Query/Complaint (<i>refer to submitted IEC FORM 3I/V1.2012</i>)	
Conclusions and Recommendations	
Action Taken UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION (<i>specify</i>) RECOMMEND FURTHER ACTION (<i>specify</i>)	

7. REPORT ON APPROVED PROTOCOLS

7.1 Protocols with MINOR Modifications (*Expedited at the Level of Chair*)

PROTOCOL 1	PTN <number>
Date of Initial Review:	Date of Resubmission: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:
Type of Review:	Primary Reviewers:
IEC Chair's Decision : APPROVAL	

7.2. Protocol Amendments Expedited at the Level of the Chair (*amendments that are MINOR or administrative in nature*)

PROTOCOL 1	PTN <number>
Date of Initial Review:	Date of Amendment Submission: Date Received:
Title:	<Version Number, Date>
Principal Investigator:	Sponsor/CRO:



Type of Review:	Primary Reviewers:
IEC Chair's Decision : APPROVAL	

8. OTHER MATTERS

9. ADJOURNMENT

The meeting was adjourned at _____ :

Prepared by:	
_____	_____
<i>IEC Secretary's Signature Over Printed Name</i>	<i>Date</i>
Checked and Approved by:	
_____	_____
<i>IEC Chair's Signature Over Printed Name</i>	<i>Date</i>