



MINUTES OF THE MEETING

(Date)

(Venue)

(Time)

1. ATTENDANCE

Present:

Absent:

2. CALL TO ORDER

3. DETERMINATION OF QUORUM

4. DISCLOSURE OF CONFLICT OF INTEREST (COI)

5. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING

6. BUSINESS ARISING FROM THE MINUTES OF THE LAST MEETING

Matters requiring CGHMC RERB action

7. STUDY PROTOCOL REVIEW

7.1. New Protocols for Initial Review

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary reviewers	
Technical Review	
Sponsor/ CRO	
Quorum Status	
Conflict of interest	

Assessment of Ethical Issues

Privacy and Confidentiality of data	
Protection Plan	
Vulnerability	
Risks	
Benefits	
ICF process and recruitment	
ICF including translation	

Recommendations

Decision

Approval/ expiration date



Frequency of continuing review (in case of approval)

7.2 RESUBMITTED PROTOCOLS FOR MODIFICATIONS

7.2.1.

Protocol code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Quorum status	
Conflict of interest	
Assessment of PI response to initial review	
Recommendations	
Decision	
Approval expiration date	
Frequency of continuing review (in case of approval)	
Protocol Code	

7.3 PROTOCOL AMENDMENTS

7.3.1.

Protocol Code	
Protocol Approval Date	
Amendment Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	



Assessment of amendment requested	
Recommendations	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

7.4 PROGRESS REPORT/CONTINUING REVIEW

7.4.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of progress reported	
Recommendations	
Decision	(Approved, Major Modification, Minor Modification, Disapproved)

7.5 FINAL REPORT

7.5.1.

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of final report	



Recommendations	
Decision	

7.6 PROTOCOL DEVIATIONS

7.6.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of deviation report	
Recommendations	
Decision	

7.7. EARLY STUDY TERMINATION

7.7.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of risks from early termination	
Recommendations	
Decision	



7.8. SITE VISIT REPORTS

7.8.1.

Protocol Code	
Protocol Approval Date	
Site Visit Date	
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of Site Visit report	
Recommendations	
Decision	(Uphold original approval with no further action, Request information, Recommend further action)

7.9. SAE/AE Reports

7.9.1.

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of SAEs reported	
SAE	
Submission Date	
Date of SAE	
Date of randomization	
Age	
Sex	



Country	
Nature of AE	
Co-morbidities	
Status	
Recommendations	
Decision	

7.10. QUERIES OR COMPLAINTS

7.10.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of query or complaint	
Recommendations	
Decision	

APPENDICES

8. REPORT OF RESULTS OF EXPEDITED REVIEW

8.1. NEW PROTOCOLS (MINOR RISKS)

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)



8.2. PROTOCOLS FOR MINOR REVISION

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

8.3. PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	
Date of Amendment Submission	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

9. OTHER MATTERS

10. ADJOURNMENT

Prepared by:

Approved by:

Signature over Name
CGHMC RERB SECRETARIAT
Date:

Signature over Name
CGHMC RERB Chair
Date: