



NKTIREC FORM 6.1: MINUTES OF THE MEETING

National Kidney and Transplant Institute Research Ethics Committee
Minutes of the Meeting
(Date), (Venue), (Time)

1. NOTICE OF MEETING

- 1.1 1st notice of meeting: verbal reminder at the time of previous meeting dated
- 1.2 2nd notice of meeting: via SMS AND SUBMISSION OF MINUTES AND AGENDA TO REC MEMBERS (one week prior to Board meeting) dated
- 1.3 3rd notice of meeting: 3 days prior to meeting via SMS All of the above to be written on the agenda and minutes with proof of notice as encoded in computer which will be traced dated

ATTENDANCE

PRESENT:

ABSENT:

DATE OF MEETING: <dd/mm/yyyy>

TIME OF MEETING

VENUE OF MEETING

- 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
- 7. RE-SUBMISSION AND RESPONSES FROM PREVIOUS MONTHLY MEETINGS
- 8. PROTOCOL REVIEW
 - 8.1 New Protocols

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal investigator	
Primary reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of interest	
ASSESSMENT OF SCIENTIFIC SOUNDNESS	<ul style="list-style-type: none"> 1. Objectives/Expected output 2. Literature review 3. Research design 4. Sampling design, sample size 5. Inclusion criteria, exclusion criteria, withdrawal criteria 6. Data collection and processing plan



	7. Specimen collection and processing 8. Statistical and data analysis plan 9. PI qualifications 10. Suitability and choice of site Duration of participant involvement
ASSESSMENT OF ETHICAL ISSUES	1. Conflict of Interest and Transparency: 2. Privacy and confidentiality including data protection plan 3. Vulnerability 4. Risks and safety monitoring plan 5. Benefits 6. Compensation 7. Community Considerations 8. Dissemination or data sharing plan Documentation of collaborative study and TOR
ASSESSMENT OF INFORMED CONSENT FORM ISSUES	1. Informed consent process and recruitment: 2. Informed Consent Form (ICF) (including translation)
Conclusion and recommendations	
Decision	
Approval expiration date	
Frequency of continuing review	

8.2 PROTOCOL FOR CLARIFICATORY INTERVIEW

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of Protocol	
Recommendations	
Decision	

8.3 PROTOCOLS FOR MODIFICATION

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>



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	

8.4 PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of amendment requested	
Recommendations	
Decision	

8.5 CONTINUING REVIEW

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Continuing Review Report Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	



Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of progress reported	
Recommendations	
Decision	
Approval expiration date	
Frequency of continuing review	

8.6 FINAL REPORTS

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Final Report Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Final reported	
Recommendations	
Decision	

8.7 PROTOCOL DEVIATIONS

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Protocol Deviation Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	



Assessment of Deviation report	
Recommendations	
Decision	

8.8 EARLY STUDY TERMINATION

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Study termination	
Recommendations	
Decision	

8.9 SITE VISIT REPORTS

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Site visit report	
Recommendations	
Decision	

8.10 SAE/AE REPORTS

8.10.1 ONSITE SAE

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>



Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of SAE's reported	
SAE I	
Submission Date	<dd/mm/yyyy>
Date SAE	<dd/mm/yyyy>
Date of Randomization	<dd/mm/yyyy>
Age	
Sex	
Country	
Nature of AE	
Co-morbidities	
Status	
Recommendations	
Decision	

8.10.2 OFF-SITE SUSAR

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
SUSAR I	
Assessment of SAE's reported	
Status	
Recommendation	
Decision	

9. REPORT OF RESULTS OF EXPEDITED REVIEW

9.1 STUDY PROTOCOLS FOR INITIAL REVIEW



Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	
Date of Action Taken	<dd/mm/yyyy>

9.2 RESUBMITTED PROTOCOLS FOR MINOR REVISION

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	
Date of Action Taken	<dd/mm/yyyy>

9.3 PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Date of Amendment Submission	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	
Date of Action Taken	<dd/mm/yyyy>



9.4 CONTINUING REVIEW APPLICATIONS

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	
Date of Action Taken	<dd/mm/yyyy>

9.5 PROTOCOLS EXEMPTED FROM ETHICAL REVIEW

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Date of Action Taken	<dd/mm/yyyy>

10 QUERIES AND COMPLAINTS

11 NOTIFICATIONS

12 OTHER MATTERS

13 ANNOUNCEMENT OF NEXT MEETING

14 ADJOURNMENT

15 CUT-OFF DATE

Prepared by:

Approved by:

Signature over Name
NKTIREC Member Secretary

Signature over Name
NKTIREC Chair

Date:

Date: