



**NATIONAL KIDNEY & TRANSPLANT INSTITUTE**  
**RESEARCH ETHICS COMMITTEE**

**NKTIREC FORM 3.1: COVER LETTER FOR ALL SUBMISSIONS TO THE NKTIREC OFFICE**

NKTI REC PROTOCOL NO.:
TITLE OF PROTOCOL:
PRINCIPAL INVESTIGATOR:
DATE OF SUBMISSION:

TYPE OF SUBMISSION: PLEASE CHECK THE APPLICABLE ITEM:

INITIAL SUBMISSION     PROSPECTIVE     RETROSPECTIVE     EXEMPT FOR REVIEW

*FOR PROSPECTIVE STUDIES AND CLINICAL TRIALS:*

- *PLEASE FILL OUT NKTI REC FORMS*
  - NKTIREC FORM 3.2: APPLICATION FOR PROTOCOL REVIEW**
  - NKTIREC FORM 3.3: PROTOCOL SUMMARY SHEET**
  - NKTIREC FORM 3.4-A: PROTOCOL EVALUATION**
  - NKTIREC FORM 3.4-B: INFORMED CONSENT EVALUATION**

*FOR RETROSPECTIVE STUDIES:*

- *PLEASE FILL OUT NKTI REC FORMS*
  - NKTIREC FORM 3.4-A: PROTOCOL EVALUATION**
  - NKTIREC FORM 3.9: APPLICATION OF WAIVER OF CONSENT**
- *ATTACH STUDY PROTOCOL*

*FOR META-ANALYSIS, SYSTEMATIC REVIEW OR OTHER STUDIES APPLYING FOR EXEMPT FOR REVIEW:*

- *PLEASE FILL OUT NKTIREC FORMS:*
  - NKTIREC FORM 3.10: LETTER FOR APPLICATION FOR EXEMPT FROM REVIEW**
  - NKTIREC FORM 3.11: CHECKLIST FOR EXEMPTION OF REVIEW**
- *ATTACH STUDY PROTOCOL*

- ✓ *PLEASE ATTACH LETTERS OF REQUEST TO DEPARTMENT/ SECTION HEADS FOR ACCESS TO LOGBOOKS/MEDICAL RECORDS OF PATIENTS INCLUDED IN STUDY.*
- ✓ *PLEASE ATTACH CV AND GCP CERTIFICATES OF ALL INVESTIGATORS FOR ALL INITIAL SUBMISSIONS.*

**PLEASE CHECK THE APPLICABLE ITEM:**

RESUBMISSION: PROTOCOL VERSION #: \_\_\_\_ ICF VERSION # \_\_\_\_

- *PLEASE FILL OUT NKTIREC FORM:*
  - NKTIREC FORM 3.8: REVIEW OF RESUBMITTED PROTOCOL**
- *ATTACH STUDY PROTOCOL WITH HIGHLIGHTED REVISIONS*

RESPONSE TO REC DECISION OR QUERY; *PLEASE ATTACH A COPY OF THE REC DECISION*

<input type="checkbox"/> AMENDMENT <ul style="list-style-type: none"><li>➤ PLEASE FILL OUT NKTIREC FORM: <b>NKTIREC FORM 4.2: PROTOCOL AMENDMENT REVIEW</b></li><li>➤ ATTACH STUDY PROTOCOL WITH HIGHLIGHTED REVISIONS</li></ul>
<input type="checkbox"/> SERIOUS ADVERSE EVENT REPORT (SAE) <input type="checkbox"/> SERIOUS UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR) <ul style="list-style-type: none"><li>➤ PLEASE FILL OUT APPLICABLE NKTIREC FORM: <b>NKTIREC FORM 4.1-A- SERIOUS ADVERSE EVENT/S REPORT</b> <b>NKTIREC FORM 4.1-B- STANDARD ADVERSE DRUG EVENT/S REPORT</b> <b>NKTIREC FORM 4.1-C- SAE SUMMARY REPORT</b></li></ul>
<input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> CONTINUING REVIEW REPORT; <b>NOTE:</b> <ul style="list-style-type: none"><li>➤ PLEASE SUBMIT THIS REPORT AT LEAST 30 DAYS BEFORE DATE OF EXPIRATION OF PROTOCOL APPROVAL.</li><li>➤ PLEASE FILL OUT NKTIREC FORM: <b>NKTIREC FORM 4.3: CONTINUING REVIEW REPORT</b></li><li>➤ PLEASE ATTACH A PROGRESS REPORT WITH THIS SUBMISSION.</li></ul>
<input type="checkbox"/> PROTOCOL NON-COMPLIANCE/VIOLATION/DEVIATION <ul style="list-style-type: none"><li>➤ PLEASE FILL OUT NKTIREC FORM: <b>NKTIREC FORM 4.5: PROTOCOL NON-COMPLIANCE/ VIOLATION/DEVIATION SUMMARY REPORT</b></li></ul>
<input type="checkbox"/> EARLY STUDY TERMINATION; <ul style="list-style-type: none"><li>➤ PLEASE FILL OUT NKTIREC FORM: <b>NKTIREC FORM 4.6: EARLY STUDY TERMINATION</b></li></ul>
<input type="checkbox"/> FINAL REPORT: <ul style="list-style-type: none"><li>➤ PLEASE FILL OUT NKTIREC FORM: <b>NKTIREC FORM 4.4: FINAL REPORT</b></li><li>➤ ATTACH STUDY PROTOCOL</li></ul>
<input type="checkbox"/> REQUEST/QUERY/COMPLAINT RECORD: <ul style="list-style-type: none"><li>➤ PLEASE FILL OUT NKTIREC FORM: <b>NKTIREC FORM 8.0: REQUEST/QUERY/COMPLAINT RECORD</b></li></ul>
<input type="checkbox"/> OTHERS PLEASE SPECIFY:

**FOR ALL SUBMISSION TO NKTIREC, INCLUDE THE FOLLOWING:**

- COVER LETTER ADDRESSED TO REC CHAIR
- HARD COPY AND ELECTRONIC COPY OF THE STUDY PROTOCOL AND ALL RELATED DOCUMENTS

**TO BE FILLED UP BY REC OFFICE:**

TYPE OF REVIEW:  FULL BOARD REVIEW; DATE OF MEETING: \_\_\_\_\_

EXPEDITED; DATE RECEIVED BY PRIMARY REVIEWERS: \_\_\_\_\_

ACTION TAKEN : \_\_\_\_\_

DATE : \_\_\_\_\_

REVIEWERS : \_\_\_\_\_

-----NOTHING FOLLOWS-----