CLINICAL TRIAL AND RESEARCH DIVISION
National Kidney and Transplant Institute

GUIDELINES FOR SUBMISSION OF RESEARCH PROTOCOL

1. No outside research studies will be conducted in this Institute if no National Kidney and Transplant Institute (NKTI) staff member is one of the lead investigators. Non-NKTI personnel can only conduct research in this Institute in collaboration with NKTI personnel who has a research background and is knowledgeable on the research topic.
2. All residents/fellows-in-training should submit a minimum of one (1) completed research paper per trainee before graduation or before the training ends at NKTI depending on the department's policy. It is a requirement for all before final clearance.
3. All researches done by residents/fellows-in-training should have consultant/s as their research adviser/s and co-investigator/s.
4. Fellows and residents-on-training can be co-investigators for investigator-initiated researches but not for pharmaceutical/sponsor-initiated research studies.
5. All research protocol will require submission to the Clinical Trial and Research Division (CTRD) for registration since the Research Committee needs to be aware of all researches being performed in the Institute. It will be the responsibility of the Department Training Officers and Department Research Coordinators (DRCs) to ensure that such researches are registered with the CTRD and approved by Institutional Review Board (IRB) prior to commencing the research.
6. Indicate in the protocol all the departments or sponsor/s or agency/ies involved in the study.
7. A valid GCP certificate is required to all investigators and co-investigators for submission of research proposals.
8. All research protocol needs Institutional Review Board (IRB) approval prior to commencement according to the following guidelines:
    a. The following studies will require approval from both Technical Review Committee (TRC) and Research Ethics Committee (REC):
        i. All interventional research
        ii. All pharmaceutical-funded or industry-initiated research
        iii. All multicenter/collaborative research
        iv. All off-label studies
        v. All research requiring direct patient contact such as interviews, surveys, questionnaires, home visits, and laboratory tests that requires blood extraction or if the patient is currently confined in the hospital or in Out-Patient Department (OPD) for consultation
    b. Researches composed solely of retrospective records or chart review will need REC approval before starting the research. A written approval from REC and CTRD is needed before the Medical Record Section can release the said charts.
    c. Case report and case series should be submitted to CTRD with patient consent form/s for registration.
    d. Meta-analysis/systematic review studies need registration to the CTRD and submission to REC for approval of exemption for review.
    e. Registry studies should have patient consent form and should be reviewed by both TRC and REC.

f. REC expedited review is needed for the following research protocols that pose at least minimal risk.
    1. Survey on non-sensitive nature: Questionnaire(s)/FGD that do not involve the collection of highly personal, sensitive or incriminating information; vulnerable populations; and/or impose a substantial burden on participants
    2. Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data

9. A signed Confidentiality and Anonymity Agreement (CAA) is needed for the following studies. The CAA forms of the CTRD and Medical Records Section will be signed by the Principal Investigator (PI) prior to data collection of IRB approved researches:
    a. Prospective studies needing documents from Medical Records Section such as admission charts, surgical technique records, etc.
    b. Retrospective studies
    c. Case series
    d. Case report
10. All research protocol needs Institutional Review Board (IRB) approval prior to research funding application from the Institute.
11. For collaborative or multicenter research studies:
    a. Identify all the collaborating institutions to the research project.
    b. Identify the consultants from all collaborating institutions to the research project. The consultant from NKTI must be one of the principal investigators in the project.
    c. Assign liaison officers from each collaborating agency who can be contacted at any time with regards the status of the study. Liaison officers may be persons other than the principal investigators. Include their contact numbers and update this information yearly as may apply.
    d. State the duties and responsibilities of the collaborating consultants.
    e. Based on the responsibilities of the collaborating parties, establish from the start the authorship criteria, which agency/investigator will have the rights to the paper (i.e. to what publication the completed paper will be submitted to), and acknowledgments.
    f. Clinical Trial Agreement (CTA) or Memorandum of Agreement (MOA) should be provided in three (3) copies (each copy for the following: investigator, hospital and pharmaceutical)
12. For research studies requiring approval from both Technical Review Committee (TRC) and Research Ethics Committee (REC):
    a. Submit the research protocol in three (3) hard copies and electronic copy to CTRD.
    b. Pay attention to the format for research protocol attached to this guideline. It is the sole responsibility of the primary investigator to ensure that they comply with the proper format. Non-compliance will result in delay in the review of their protocol.
    c. Submission of research protocol should be:
        i. Ten (10) working days before the scheduled TRC review (TRC is every first Mondays of the month)
        ii. On or before 16th day of the month for REC review (REC review is every last Wednesdays of the month)

d. The investigators should be informed prior to the scheduled IRB review in order to prepare them to answer any queries regarding the submitted research protocol.
e. It is the responsibility of the investigator to submit the approved TRC research protocol to REC for review.
f. The following fees will be charged to all industry-initiated researches submitted to CTRD for IRB review:
    i. A fee amounting to 25,000 pesos should be charged upon submission of the research proposal for review to the Technical Review Committee (TRC) and another 25,000 pesos for Research Ethics Committee (REC).
    ii. Payment of the TRC and REC fees should be made prior to calendaring the research proposal for review.
    iii. Once the research has been IRB approved, an administrative fee will be paid prior to initiation of the study. Attached is the administrative fee.
    iv. For Post Marketing Surveillance (PMS) Studies, the following fees will be paid –

For Post Marketing Surveillance (PMS) Studies	
Number of Patients	*Administrative Fee*
<30 Patients	P5,000.00
31-50 Patients	P8,000.00
51-70 Patients	P9,000.00
>70 Patients	P10,000.00

13. No research will be allowed to be conducted if disapproved by the IRB.
14. The following sanctions will be implemented for all researches that are not registered with the CTRD, or were not approved by the IRB, as outlined above:
    a. Such research paper will not be counted as part of the requirements for graduation for all residents- and fellows-in-training.
    b. Such research paper is not qualified for submission to the annual research forum contest of the Institute.
    c. Such research paper is not qualified for application for incentives.
15. For those fellows and residents who graduated but with research deficiencies during their training, they can do their research but with the guidance of consultant/s from their respective department as adviser/s and co-investigator/s.