

## **DEVELOPMENT AND CONDUCT OF RESEARCH**

### ***Who should do research in KEMRI?***

There are four main categories of people who are duly permitted to carry out research in the Institute. These are:

- i Research Officers
- ii Technologists and
- iii Visiting scientists
- iv Research associate scientists

### ***General Conditions for Appointment of Visiting Research Scientists***

The Institute recognises the need to co-operate and interact with other organizations in carrying out its research activities. One way of encouraging this collaboration is through participation in joint research activities with other research organizations and institutions and also encouraging the scientists in the Institute to participate in such activities with others outside the Institute. The Institute also recognises three categories of collaborating research personnel, namely, (i) the self-supporting, (ii) the non-self-supporting, and (iii) the partially-supported, visiting scientists.

The following guidelines are therefore provided to foster collaboration for mutual benefit:

Visiting scientists are appointed by the Director of the Institute under the following conditions:

1. All visiting scientists must be prepared to work in research areas of national priority and within the mandates approved by the Institute.
2. All collaborative research work must be geared to realising maximum benefits to the country and the Institute.
3. Unless otherwise stipulated in the terms of their appointment, the Institute is not responsible for costs in respect of passages for visiting scientists.
4. All collaborative research programmes must provide comprehensive training arrangements of Kenyans both locally and outside the country and all visiting research scientists must be prepared to impart training to their collaborating research personnel in the Institute.
5. All visiting research scientists must provide the Director of the Institute with their academic and professional qualifications as well as their past employment record for their applications to be processed through the Board of Management before their appointment.
6. All equipment and materials brought by visiting research scientists for the purpose of conducting research in the Institute will remain the property of the Institute at the expiry of the collaborative arrangement. The maintenance costs of such equipment will however, be born by the collaborating organization during the time of such an arrangement.
7. All reports and any other documentation sent to the sponsoring organization must be copied to the Director, KEMRI for his information.
8. All publications arising from work conducted in the Institute or in collaboration with the Institute must conform with the KEMRI requirements on publications and must be in this regard be cleared by the Director, KEMRI.
9. All collaborating organizations should send a budget of their research work within the Institute before the beginning of each financial year to the Director, KEMRI.

10. All appointments of staff on collaborative research programmes must be authorised by the Director, KEMRI.
11. All visiting research scientists will, for administrative and other reasons, be appointed within one of the Research Centres of the Institute and will be accountable to the Director, KEMRI through the Directors of their respective Research Centres.
12. All scientific inventions with market potential made through collaborative research work should be jointly patented among the individual scientists responsible or their sponsoring organizations, whichever is applicable, and the Institute.
13. At the end of their appointments all visiting research scientists should make a comprehensive report of their work in the Institute to the Director, KEMRI.
14. A visiting non-Kenyan scientist is obliged to have Kenyan counter-parts as collaborators who shall be at the level of not less than a technologist. Similarly, the visiting scientist must include in all his publications emanating from projects in the Institute Kenyan co-authors who must be at a level of not less than a technologist. In either case, where a local counterpart or co-author is not available, the Director of the Research Centre will automatically assume these roles unless the Centre Director identifies one of the Centre staff or some other suitable person to play these roles. Research associate scientists are persons who, by permission of the Director of KEMRI, have access to the use of Institute's research facilities while they remain in their own institutions or places of work. This category also includes students working on their research projects.

#### ***Non-resident Persons from Outside the Institute***

People who are not employees of the Institute or who are not appointed visiting scientists may be permitted to carry out research at the Institute under the following provisions:

- i. They may develop research collaborative projects with the bona fide research staff of the Institute, provided they possess academic qualifications at the level of technologists and above.
- ii. Such persons must attach their curriculum vitae to such a project proposal developed jointly with a KEMRI research staff.

#### ***Development of Research Projects***

- i. Research project proposals are expected to be initiated by individuals or groups at the Research Centres.
- ii. A research project proposal intended for consideration by the Institute's Committees must be written with the following components and should be arranged in the following sequence:

#### ***Guidelines for Writing Project Proposals***

1. TITLE OF THE PROJECT: This should be concise and not longer than 30 words.
2. INVESTIGATORS AND INSTITUTIONAL AFFILIATIONS: Non-KEMRI investigators should include their *curriculum vitae*.
3. ABSTRACT: It should provide a concise summary of the background, justification, objective, work planned, nature of results expected, and their significance. This should be structured as one paragraph in NOT MORE THAN 200 WORDS.
4. INTRODUCTION/BACKGROUND: This should be a historical and/or scientific background to the project proposal with literature citations. The literature cited should be listed at the end of the proposal document with the full names of the

authors, the title of the publication, the journal/book, the year, volume, beginning and end pages of the article.

*[THIS SECTION SHOULD NOT EXCEED ONE A4 SIZE PAGE USING 12 PTS TIME NEW ROMAN FONT OR SIMILAR]*

5. JUSTIFICATION FOR THE STUDY: This section should give a short justification of the significance of the proposed research, emphasising how the results will provide new knowledge in the particular field, and why it will be important for national or international development.

*[NOT MORE THAN HALF PAGE OF A4 SIZE SINGLE SPACING]*

6. STATE THE NULL HYPOTHESIS: Where applicable.

7. (a) GENERAL OBJECTIVES: The main aim should be given clearly. *[NOT MORE THAN TWO SENTENCES]*

(b) SPECIFIC OBJECTIVES: This section must clearly and unambiguously state the objective(s) of the project. These must be achievable objectives and not statements of the methods to be carried out. The objectives should be written in short concise sentences, and each not consisting of more than two sentences.

*[NOT MORE THAN FOUR SPECIFIC OBJECTIVES SHOULD BE GIVEN]*

8. DESIGN AND METHODOLOGY:

(a) Study site (geographical)

(b) Study populations

i. Criteria for inclusion of subjects

ii. Criteria for exclusion of subjects.

iii. Rationale for animal use and justification for animal species chosen.

(c) Sampling

i. Sample size determination.

ii. Sampling procedure.

(d) Procedures

i Description of the type of data to be collected and collection procedures to be followed.

ii. Provisions for data verification, and validation in the field and laboratory (where applicable).

The structure of this section will be determined by the specific nature of the study. If it is a clinical study, it should specify such things as study site, patient selection, inclusion and exclusion criteria, summary of the procedures to be used, etc. If it is laboratory and/or field study, it should specify the study site, materials, procedures to be used preferably in bullet form, etc. Where appropriate, calculation of the subject/patient population should be shown. The instruments to be used in surveys, clinical studies, questionnaires, should be appropriately mentioned in the text and copies of such instruments should be attached to the proposal document in the form of Appendices. Similarly, the INFORMED CONSENT FORMS AND EXPLANATIONS should be attached as Appendices.

*[THIS SECTION SHOULD NOT EXCEED ONE A4 PAGE SINGLE SPACING USING TIMES NEW ROMAN 12 PTS OR SIMILAR].*

9. DATA MANAGEMENT:

(a) Data Storage.

i. Provision for database management incorporating how data will be stored before and after analysis.

ii. Description of devices to be used for storage, i.e. type of computer, software to be used in data entry, checking and management.

(b) Data Management (where applicable)

Data Analysis - The statistical techniques to be applied in the analysis to meet the requirements of each of the specific objectives and hypotheses to be tested.

This section should concisely describe how the data obtained will be processed, calculated or computed. If a computerised method is to be used, it should specify which software(s) will be used and HOW it will be used. Such statements like "The results will be entered in a computer" without any further explanation will not be accepted. Where results will be processed in the form of tables, a short form of such tables should be given with the headings.

*[THIS SECTION SHOULD NOT ME MORE THAN HALF OF A4 PAGE SINGLE SPACING]*

10. TIME FRAME/DURATION OF THE PROJECT:

- (a) Pilot study (where applicable)
- (b) Definitive study
- (c) Data analysis
- (d) Report preparation

The total period planned for the project should be stated in months or years, followed by a breakdown of the stages implementation.

*[NOT MORE THAN HALF A PAGE]*

11. ETHICAL CONSIDERATIONS

- (a) Human Subjects

In all investigations involving human subjects, the following guidelines should be observed:

- i . "First, do no harm."
- ii . Direct benefit to study subjects or community should exist.
- iii. Informed consent by subjects and/or community leaders including possible benefits, risks and inconveniences (the protocol should be accompanied by a consent-seeking information sheet and informed consent form). See Appendix I.
- iv. Indicate the method of maintaining confidentiality of information obtained during the study.
- v. In case of new drugs and/or procedures to be used on human subjects, any possible side effects, untoward reactions and results of previous use even in animals should be stated.

- (b) Animal Subjects.

In all investigations involving animals, the following guidelines should be observed:

- i . Methods to minimise pain and distress must be specified;
- ii. If applicable, a strong justification must be made for not using proper drugs to alleviate pain and distress;
- iii. If applicable, the method of euthanasia should be specified.

12. EXPECTED APPLICATION OF THE RESULTS: This section should summarise briefly the importance of the expected results and their potential use or application.

*[NOT MORE THAN HALF A PAGE]*

13. REFERENCES

- (a) In the text, use numbering citation method.
- (b) In the References page, use the following citation system:

1. Adungo, NI, Mahadevan S, Mulaya NL, Situbi AP and Githure JI: Comparative determination of *Plasmodium falciparum* sporozoite rates in Afrotropical *Anopheles* from Kenya by dissection and ELISA. *Annals of Tropical Medicine and Hygiene* 1991; 85: 387-394.
2. Okong'o-Odera EA, Abok K, Wamachi A, Mumo J and Koech DK. Analysis of diagnostic potential of *Leishmania donovani* antigens. In: *Proceedings of the 12th Annual Medical Scientific Conference, 4-8 February 1991, Nairobi, Kenya. 1992, pp. 271-278.*

The literature citations should be provided in full detail, preferably using the numbering style, but in any case, each reference cited in the project proposal must be listed giving: the names of the authors, the full title of the publication, the year of publication, the volume if it is a serial or authors and publishers if it is a book, the beginning and end pages of the article.

- 14 . BUDGET: The budget section should be written in three parts:
- a. Budget Summary which should list the major components of the budget, e.g. Travel, Staff emoluments, Equipment, etc.
  - b. Detailed Budget which should give the break down of each of the sub-sections of the budget summary. The total in (a) and (b) should be the same.

The item costs should be given in US dollars ( a stable currency), but at the end, the total equivalent in Kenyan Shillings at the time of writing the project, should also be given.

- (a) Personnel, salaries and benefits disbursement
- (b) Patient costs, travel, food and/or supplies
- (c) Major equipment itemised; minor aggregated
- (d) Supplies
- (e) Travel and accommodation:
  - i. Local or field travel
  - ii International/Local conferences
- (f) Transportation, vehicle repairs, insurance, etc.
- (g) Operating expenses, postage, printing, etc.
- (h) Animals: acquisition, food, cages, etc.
- (i) Consultancy fees
- (j) Contingency funds (15% including inflation)
- (k) Institutional administrative overheads: 15%

15. JUSTIFICATION OF THE BUDGET:

A short paragraph (NOT MORE THAN HALF A PAGE) should give a justification for the items intended for the project and the cost estimates given.

*[THE BUDGET SECTION SHOULD NOT BE MORE THAN TWO AND A HALF PAGES]*

16. APPENDICES

- (a) State the role of each participating investigator.
- (b) Attach the relevant documents:
  - Curriculum vitae of each non- KEMRI investigator
  - Case record and data collection forms
  - Informed consent advice and forms

***Procedure for Submission of Project Proposals***

i .A completed research proposal is reviewed by the Centre Scientific Committee, after which it is forwarded to the Scientific Steering Committee by the Centre Director with the *Forwarding Form* (See Appendix II) duly completed and his certification that the project proposal has been duly reviewed by the Centre Scientific Committee and has been found to be scientifically sound and to fall within the mandates of the Centre. *A project proposal that has not been reviewed by a Centre Scientific Committee will NOT be accepted by the Scientific Steering Committee.*

ii. A project proposal duly forwarded by the Director of a Centre will be reviewed and approved by the Scientific Steering Committee provided:

- a. That the project proposal has been properly written according to the criteria set by the Committee (see below), and it fulfils all the criteria in its entirety;

- b. That where a proposal will involve humans or animals, it has been duly cleared by the Ethical Review Committee and/or Animal Care and Use Committee.
- iii. In cases where ethical approval is required, the approval of a manuscript will remain pending until ethical clearance is received from the Ethical Review Committee.
- iv. All project proposals approved by the Scientific Steering Committee are submitted to the Scientific Programmes Committee for ratification. *A project proposal is considered officially approved when the Scientific Programmes Committee has accepted it.*
- v. Addendum or extensions to an approved project proposal should not be made. If during the implementation of an approved project proposal, the investigators have found that some work has to be done as a complement to the existing one, and which is not covered by the original project proposal, then this item should be handled as a new project proposal and should be written as such, giving the likages. This project proposal should be treated like any other research proposal of the Institute.

**Time Schedule for Submission of Proposals**

- 1. The Scientific Steering Committee has six scheduled meetings in a year. These meetings are held in the *first week of: JANUARY, MARCH, MAY, JULY, SEPTEMBER and NOVEMBER.*
- 2. The Ethical Review Committee and the Animal House and Care Committee also meet similarly to examine proposals approved by the SSC for ethical issues.
- 3. A project proposal for consideration by the SSC must reach the Secretary of the SSC by the 15th of the month preceding the date of the meeting. (See the table below). Investigators are expected to ensure that their project proposals have been processed by the respective Centre Scientific Committees in order for the proposal to be submitted to the Secretary before the deadline.

Meetings	Meeting Dates of the SSC	Deadlines for Proposal Submission
1	January	December 15
2	March	February 15
3	May	April 15
4	July	June 15
5	September	August 15
6	November	October 15

- 4. The decision of the SSC on a project proposal is communicated to the Principal Investigator of the project through the Director of the Research Centre.
- 5. *ALL communications to the SSC concerning project proposals should be directed to the Secretary of the SSC through the respective Director of the Centre concerned.*

**Funding of Research in KEMRI**

Funding of research projects at the Kenya Medical Research Institute comes from two main sources:

- 1. Kenya Government funding (approx. 40%)
- 2. Funding from research projects (approx. 60%)

The development of suitable, fundable projects becomes an essential aspect of sustaining health research at the Institute. The following are the guidelines for processing of research grants awarded to the research staff of the Institute:

### ***Procedure for Receiving Research Grants***

1. The Director, KEMRI is the accounting officer of the Institute. Therefore all research grants awarded to a member of staff of the Institute must be sent to the Director KEMRI for disbursement.
2. A research officer who receives a research grant should provide the following details to the grants office in the KEMRI Secretariat through the Director of the Research Centre:
  - a. The letter of award from the donor
  - b. The details giving the conditions of the award and any other pertinent details.
  - c. The technical services agreement
  - d. The approved project proposal which contains the detailed breakdown of the budget.
3. The grants office will open an operational account to which the cheque will be paid on receipt of the grant from the donor.
4. As soon as the grant is received the grants office will immediately advise the Principal Investigator as specified in the SSC-approved proposal. If the research grant is in foreign currency, the grant office will calculate the local currency equivalent at the existing bank rate and advise the grant recipient accordingly. It is expected that prospective research grant recipients should make regular enquiries to the grants office regularly to ensure that there is no undue delay in starting the research project.
5. A grant recipient who is receiving a research grant for the first time will be advised on the disbursement procedures at the grants office.
6. All imprest requests to the grants office by Principal Investigators should be made through the Director of the Centre, and such requests should NOT be made on the last working day of the week especially if the investigator intends to start utilising the funds from the weekend.
7. All Directors of Centres should be acquainted with the terms of award of all the research project grants in their respective Research Centres and to be able to ensure that the funds are used according to the budget approved by the SSC.
8. The grants office will rationalise the disbursement of the research grant in conformity with the time frame given in the project proposal, and any deviation from this should be certified by the Director of the Centre.