

**UNICEF / UNDP / World Bank / WHO
Special Programme for Research and Training
in Tropical Diseases (TDR)**

COLLABORATIVE RESEARCH PROJECT
SECTION A: GENERAL INFORMATION AND INSTRUCTIONS

DO NOT RETURN THESE INSTRUCTIONS WITH YOUR PROPOSAL FORM

I. PRACTICAL ADVICE

PLEASE READ THESE INSTRUCTIONS AND THE RELEVANT SCIENTIFIC WORKPLAN(S)
CAREFULLY BEFORE COMPLETING THE PROPOSAL FORM

As a first step in preparing a research proposal, first-time applicants may wish to write to the Director of the TDR Special Programme, giving a brief outline of the proposed research, rather than complete the proposal form at this stage. This will enable the TDR Secretariat to advise applicants on the relevance of their proposed research to TDR goals, as well as on the scientific and budgetary implications of the research. Subsequently, the proposal form could be completed in a way more appropriate for consideration by the relevant Scientific Steering Committee(s) / Task Force(s).

The following are frequent causes of delay in review or approval of proposals:

- omission of national clearance documents, if these are a national requirement;
- omission of proof of institutional and national ethical clearance, if the proposed research involves human subjects;
- inclusion of unacceptable budget items, such as salary of the Principal Investigator, unspecified travel, or institutional overhead expenses;
- omission of the signature of the Responsible Administrative Authority of the Institution;
- omission of letters from collaborators.

II. GENERAL INFORMATION

1. TDR's Objectives

The UNICEF / UNDP / WORLD BANK / WHO Special Programme for Research and Training in Tropical Diseases (TDR) has two interdependent objectives:

- to develop new methods of preventing, diagnosing and treating selected tropical diseases - methods that would be applicable, acceptable and affordable by developing countries, require minimal skills or supervision and be readily integrated into the health services of these countries;
- to strengthen - through training in biomedical and social sciences and through support to institutions - the capability of developing countries to undertake the research required to develop these new disease control technologies.

TDR activities are targeted at ten major tropical diseases: malaria, schistosomiasis, lymphatic filariasis, onchocerciasis, the trypanosomiasis (both African sleeping sickness and the American form, Chagas disease), leishmaniasis, leprosy, tuberculosis and dengue.

2. Scientific Steering Committees / Task Forces

TDR research is goal-oriented and applicants should be aware of the lines of research in which proposals are being sought. In particular, the relevant scientific workplans should be studied carefully to ensure that the proposed research falls within the current research priorities of the Programme. Applicants who have not specified their subject(s) of interest when requesting proposal forms will be asked to furnish this information to the TDR Communications Unit (see Section IV, Item 3 of this document) so that the appropriate scientific workplans and background documents may be sent to them.

3. Review of Proposals

Research proposals received by the TDR Secretariat are reviewed by a TDR Scientific Steering Committee or Task Force, which makes recommendations to the Director, TDR.

4. Funding of Approved Projects

Approved proposals are funded through a Technical Services Agreement between the World Health Organization (WHO) and the Institution responsible for the project. Funding is normally awarded on a yearly basis and may be renewed for up to three years, subject to availability of funds and to satisfactory progress.

Once an Agreement has been signed, any changes proposed in the approved plan of work or in budget allocations must be submitted to WHO/TDR for approval.

5. Principal Investigator and Institution

The ***Principal Investigator*** is the individual who is responsible to the Institution for all technical aspects of the work referred to in the Technical Services Agreement. The ***Institution*** is any legal entity, such as a research institute, university, ministry or research council, within which the Principal Investigator is working and to which he or she is responsible.

If the Principal Investigator leaves the Institution with which the Technical Services Agreement is made or ceases to actively direct the project, the ***Institution shall promptly inform the Director, TDR, of this fact***, in which case WHO/TDR shall have the right to terminate the Agreement. If another Principal Investigator is proposed by the Institution, the project may be continued provided the approval of WHO/TDR has been obtained.

6. Payments

The schedule of payments is specified in the terms of the Technical Services Agreement. Payments in excess of US \$100,000 are normally made in two or more installments. Payments may **not** be made to any account other than official Institutional accounts.

7. Funding Restrictions

The financial resources available to the TDR Special Programme are limited and it is therefore necessary to restrict funding for certain types of expenditures. Please note the following restrictions:

Salary support for the Principal Investigator: TDR policy does not permit salary support for the Principal Investigator other than in exceptional circumstances, which must be fully justified by the Institution's Responsible Administrative Authority.

Overhead, administrative or miscellaneous expenses: TDR will consider financial support for activities, services or materials such as "overhead", "administrative" or "miscellaneous" expenses, e.g., secretarial, clerical, book-keeper salaries, and office supplies and utilities, only if they are directly related to the project, and items are specifically identified. TDR funds may not be used for meetings unless specified in the Technical Services Agreement.

Equipment operating costs: Funds provided by TDR may not be used for the running, maintenance, repairs or insurance costs of permanent equipment not purchased with TDR funds or supplied directly by it, except as otherwise agreed with WHO/TDR. Such operating costs may be supported by TDR for equipment purchased with TDR funds.

Publication costs: Publication costs, including the preparation of manuscripts and illustrations, will be considered on an *ad hoc* basis when substantiated by the Principal Investigator.

Travel costs: Travel may be paid from TDR funds only if the travel is essential to the successful execution of the proposed work and itemized in the approved budget. TDR does not support travel for the purpose of attendance at scientific meetings.

Construction costs: TDR does not fund the cost of construction of new buildings or extensions of buildings, but will consider requests for modest alterations and modifications of existing premises, if such changes are essential to the successful execution of the proposed work.

8. Supplies and Equipment

Consumable supplies and equipment, including chemicals, reagents, animals, animal food and other special items, may be purchased for the approved project from TDR funds. Requests for major equipment will be considered if local arrangements for service and maintenance are available. Equipment acquired under a Technical Services Agreement with WHO/TDR normally becomes the property of the Institution. Only in exceptional circumstances and with the consent of the Institution and TDR may equipment be transferred from the Institution prior to the completion of the project. The Principal Investigator and the Institution are responsible for the care and maintenance of equipment provided, unless otherwise specified in the Agreement. WHO/TDR may require in the Agreement that it supplies equipment to the Institution instead of providing the Institution with the funds to make the purchase itself.

WHO is obliged to institute certain limitations on the time during which purchases of equipment may be ordered through the Organization with funds made available through a Technical Services Agreement. Accordingly, any balance of such funds which has not been used for purchases within the time specified by TDR (normally one year) will revert to WHO/TDR on 31 December following the year during which funds were awarded, unless special arrangements have been made with TDR. Hence, requests for purchases to be made by WHO should arrive in Geneva before 1 September of each year.

9. Annual Progress Reports and Final Reports

WHO/TDR requires the Principal Investigator to submit annual progress reports and a final report. These reports must be made on the official reporting forms, which will be sent to the Principal Investigator at the appropriate times. Progress reports comprise part of the project evaluation, and are essential for continued financial support of the project.

A final report must be submitted in the required format upon completion of the project. The final report should summarize the course of the research and give in some detail the positive and negative findings of the work in relation to the objectives of the relevant Scientific Steering Committee or Task Force. Annual progress reports and the final report must be signed by the Principal Investigator and the Chief Financial Officer of the Institution.

10. Financial Reports

A financial report (WHO form 782) on the use of funds, signed by the Principal Investigator and the Institution's Chief Financial Officer, must be submitted to WHO/TDR as part of the annual progress reports and final report. Interim financial reports shall be submitted to WHO/TDR upon request.

Financial reports are subject to audit by WHO's auditors or their designee at the discretion of WHO. In order to facilitate such financial reporting and audit, the Institution is required to keep accurate and systematic accounts and records of the project and to permit WHO to inspect these upon request.

11. Publications

Institutions and/or Principal Investigators may publish in any journal the results of work supported by the TDR Special Programme, although the responsibility for the direction of the work should not be ascribed to the Special Programme nor to WHO. However, in certain cases it may be advisable to maintain confidentiality for a period of time in order to promote the development of the results of the project into a useful health-related product (see Section II, Item 13 of this document).

All publications should have an acknowledgement as follows:

"This investigation received financial support from the UNICEF / UNDP / WORLD BANK / WHO Special Programme for Research and Training in Tropical Diseases (TDR)"

In the event of publication, one reprint or copy should be sent to TDR, unless another number is agreed upon.

12. Employer's Liability

When staff are paid from TDR funds, WHO/TDR does not assume any liabilities as an employer and the Institution's employees work under the Institution's normal regulations and discipline. Such staff are not entitled to describe themselves as staff members or employees of WHO nor of TDR.

13. Patent Rights

The intellectual property rights in any invention arising from the project belong to the Institution or, if WHO and the Institution so agree, the Principal Investigator. Thus, the Institution, or the Principal Investigator, may file applications for industrial property protection covering such inventions at its own expense. However, the Institution or the Principal Investigator, depending on who filed the patent application(s), shall provide Director, TDR, promptly with copies of all such patent applications filed and patents issued. If, in the opinion of WHO, the protection of the public interest will best be assured by the taking out of patents, and neither the Institution nor the Principal Investigator intends to do so, then WHO may request an assignment of the rights in the invention to itself for this purpose. In all cases, each party shall provide the other with its full cooperation to permit the effective exercise of the rights concerned.

In order not to prejudice the possibility of acquiring and exercising rights in the results of the project (which is often necessary to facilitate the development in the public interest of such results into a useful health-related product), confidentiality shall be maintained with respect to results that may be eligible for protection by intellectual property rights. Institutions and Principal Investigators are encouraged to consult WHO in cases of doubt about the need to maintain confidentiality.

The industrial or commercial exploitation of any tangible results or intellectual property rights arising from the project, including patent rights and the control of know-how, shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:

1. the general availability of the products of creative activity;
2. the availability of those products to the public health sector on preferential terms, particularly in developing countries;
3. the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual or other contribution to the research.

In order to promote the achievement of these objectives, all industrial or commercial exploitation of the above rights, as well as of any tangible products resulting from the project, may only be done in accordance with an agreement between the Institution and WHO.

With regard to technical information and/or patents relating to preparation and/or administration of techniques, apparatus or processes disclosed to WHO by the Institution, under projects for the purposes of which WHO has provided to the Institution medicines or devices made available to WHO under agreements with Third Party patent holders or their assignees, WHO may require that the Institution grant to such Third Party a non-exclusive license in respect of such technical information and/or patents developed by it. Such license shall be granted on a royalty-free basis or, if royalty is charged, at rates which shall be reasonable and non-discriminatory and shall be the subject of a separate agreement to that effect.

14. Research Involving the Use of Laboratory Animals or Captured Wild Animals

The Institution shall undertake that living vertebrate animals required for use in research pursued under a Technical Services Agreement with WHO/TDR will be handled in accordance with locally existing statutes and/or generally accepted principles for the humane treatment of animals, as embodied in the Guiding Principles for Biomedical Research involving Animals, published by the Council for International Organizations of Medical Sciences (CIOMS, Geneva, 1985). In all cases the avoidance of unnecessary suffering will be mandatory.

15. Research Involving Human Subjects

15.1 Ethical Aspects

It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO/TDR in accordance with the appropriate national code of ethics or legislation (refer to the TDR Guidelines for Ethical Clearance, available on request).

Funds may be used only to support investigations where:

- (a) the rights and welfare of the subjects involved in the research are adequately protected;
- (b) freely given, informed consent has been obtained;
- (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts at the Institution;
- (d) any special national requirements have been met.

The Principal Investigator must submit to WHO/TDR, together with the research proposal, the written approval of an appropriate Institutional Panel to carry out the proposed research involving human subjects. For countries with national ethical review bodies for research involving human subjects, written agreement from such a body must be submitted to WHO/TDR with the research proposal. In the absence of national ethical review bodies, the Principal Investigator shall be guided by the Declaration of Helsinki, as amended by the Twenty-ninth World Medical Assembly, in Tokyo, Japan, in 1975, and by the Thirty-fifth World Medical Assembly, in Venice, Italy, in 1983 (available upon request), and by the "Proposed International Guidelines for Biomedical Research Involving Human Subjects" (available upon request). WHO will, if so requested, advise scientists regarding the ethical aspects of planned research projects.

Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of human research carried out with funding from WHO/TDR. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. Furthermore, the Institution and the Principal Investigator shall protect the confidentiality of information relating to the possible identification of subjects involved in such research.

15.2 Blood Samples and Use of Drugs and Medical Devices

For projects involving taking of blood samples or other invasive procedures which might represent a risk of HIV infection, the Principal Investigator is responsible to ensure that appropriate measures are taken for sterilization of equipment in order to avoid transmission of microorganisms by syringes and needles in accordance with the recommendations adopted by WHO (WHO AIDS Series 9, WHO, Geneva, 1991). In addition, it is the responsibility of the Institution and the Principal Investigator to comply with national regulations pertaining to clinical studies of drugs or devices. WHO shall, upon request, arrange to make available such information in WHO's possession as may be required by national regulatory agencies.

16. National Requirements

In instances where national government approval is required, the Institution and Principal Investigator are responsible for obtaining any review and approval of proposed projects by national authorities, prior to formal submission of the proposal to TDR. A document indicating such approval must accompany the formal submission of the proposal to TDR.

III. INSTRUCTIONS FOR COMPLETING THE PROPOSAL FORM

Proposals for a TDR collaborative research project must be prepared in accordance with the instructions and guidelines given in this document. Please read all sections carefully before completing the proposal form (TDR/RP(B)/FORM/03).

All sections of the proposal form must be completed, and the page limits imposed for the various sections must be strictly adhered to. To permit efficient processing of your proposal, please do not write on the back of any page of the enclosed proposal form, nor on the back of any pages attached to it. Number any additional pages as instructed in the form itself.

The *curriculum vitae* of the applicant must be included in the proposal form. Please also attach the *curricula vitae* of any named scientist, trainee or fellow who would be involved in the project. Other formats containing the same information requested in Annexes A and B are acceptable but must not exceed the maximum page limitation of one page per individual. Please note that a complete list of publications is not required: ONLY the five most important publications over the last five years should be listed.

1. ADMINISTRATIVE INFORMATION (PART I OF THE PROPOSAL FORM)

Note: Selected information from Items 1.1-1.4 may be made available to the general public if this proposal is selected for funding.

1.1 Name and Address

First name(s) should be spelled out in full. Please give here the address at which you receive your professional correspondence, which may not necessarily be the same as the sponsoring Institution's address given in Item 1.6 of the proposal form.

1.2 Title of Project

The project title must not exceed the maximum of 120 characters.

1.3 Proposed Starting Date

The proposed starting date should be entered, bearing in mind that funds are normally transferred a few months after the date of the Steering Committee / Task Force meeting at which a proposal was recommended for approval. The estimated duration of the project should be indicated to a maximum of three years (beyond which a new research proposal is required).

1.4 Key to Steering Committees

Choose the Scientific Steering Committee or Task Force to which your proposal is being submitted, using the relevant key (refer to the list of acronyms in the Annex). If possible, please indicate the diseases relevant to your proposal.

1.5 Summary of Project

The summary must not exceed the space provided for Item 1.5 of the proposal form. It is recommended that this section be written after all others have been completed. Include in the summary the project's relationship to Scientific Steering Committee or Task Force objectives (as stated in the workplans); indicate why the project should be undertaken, rather than what is to be done; and mention any constraints that might interfere with completion of the project as planned.

1.6 Endorsement of the Proposal

ITEMS 1.6, 1.7, 1.8 and 1.9 OF THE PROPOSAL FORM MUST BE COMPLETED BEFORE THE PROPOSAL CAN BE PROCESSED.

The proposal must be endorsed by the Principal Investigator and the Responsible Administrative Authority of the Institution where the work is to be based. The Principal Investigator and Chief Financial Officer should also sign the budget summary (Part II of the proposal form).

Note that if the Principal Investigator is not a full-time employee of the Institution, the Responsible Administrative Authority should attach a signed statement specifying clearly the Principal Investigator's relationship with the Institution, and indicating the source of the Principal Investigator's salary.

1.7 Ethical Clearance of Proposals Involving Human Subjects

If any aspect of the proposed research involves human subjects (including collection of blood or other tissue samples from human subjects) then documents indicating institutional and, where applicable, national ethical approval **must** be annexed to the formal proposal submitted to TDR (see requirements in Section III, Item 4.3 of this document, and refer to TDR Guidelines for Ethical Clearance, available on request).

Note that the ethical approval is required from the authorities of the country where the material is to be collected (i.e. not necessarily the country in which the Principal Investigator is based).

1.8 National Government Clearance

A document indicating national approval of the proposal must also accompany the formal proposal submitted to TDR **if this is a national government requirement** (please refer to Section II, Item 16 of this document).

2. BUDGET (PART II OF THE PROPOSAL FORM)

Budget details should be itemized under the budget lines indicated in the budget table in Item 2.1 of the proposal form, bearing in mind that the amounts for the second and third years are only estimates.

2.1 Budget Details

Please recall the funding restrictions set out in Section II, Item 7 of this document.

All budgets must be submitted in US dollars. Budgets in other currencies are not acceptable. If any budget line requires funds in any other currency, indicate the reasons for this under "Budget justification", Item 2.4 of the proposal form, and give the conversion rate used.

The budget should relate directly to the planned activities and the costs of the resources required to carry out these activities. For example, a drug or vaccine trial could include visits to the subjects' homes to obtain better follow-up. Data analyses will also have to be provided. Such trials could be costed on a per patient basis by adding the activities and averaging the cost per patient. Costs, especially for laboratory-oriented research, could be broken down into total numbers of staff-months (e.g., technician, six staff-months), rental or purchase of equipment and its maintenance, purchase of supplies and chemicals, patient costs, transport for follow-up home visits, purchase of animals and their maintenance, etc. If additional space is needed for budget items, expand under "Budget justification", Item 2.4 of the form.

2.2 Other Support for the Proposed Research

ITEM 2.2 MUST BE COMPLETED FOR ALL PROPOSALS.

2.3 Amount Intended for Supplies and Equipment to be purchased by WHO through the WHO Trust Fund Mechanism

If the Institution so requests, some of the funds awarded for the research project may be held in a WHO Trust Fund for purchase by WHO of supplies and equipment for the proposed work. Although delivery of goods may take from 6 to 12 months from the time the order is placed, some institutions may wish to avail themselves of this service in order to overcome currency problems, prolonged delays in obtaining supplies, and lack of access to a wide variety of suppliers. In addition, WHO may be able to obtain discounts that might not otherwise be available to an institution.

WHO does not maintain stocks of supplies or equipment but must order them through commercial channels. The prices obtained are generally the most advantageous available. The average processing time from receipt of a request at WHO to shipment by the supplier is three months. Substantially longer periods are required if the merchandise is not immediately available from the manufacturer, or if the Institution has not provided a full specification of the required item.

If it is desired to take advantage of this service, indicate in the space provided (Item 2.3 of the form) the amount in US dollars intended for supplies and equipment to be purchased through the WHO Trust Fund mechanism, and complete Annex C (form WHO 5367E TDR). It should be noted, however, that WHO is unable to process requisitions totalling less than US \$500 and that **orders to be paid with funds in trust should arrive in WHO before 1 September following the year during which the Trust Fund was awarded** (please refer also to Section II, Item 8 of this document).

WHO may act only upon instructions from the Institution, duly signed by the Principal Investigator, as follows: the supplies and equipment to be purchased by WHO must be listed, **in order of priority**, on request form WHO 5367E TDR. If additional pages are needed, continue the list on additional sheets, using exactly the same format as in form WHO 5367E TDR. It is essential that you follow the instructions for completing that form. You are not required to order all supplies and equipment at once; each order will be handled separately upon receipt, until the funds are exhausted or the Trust Fund expires. However, one advantage of ordering everything at once is savings on freight charges.

Items to be ordered by WHO must also be included in the budget justification. When the Agreement is signed and returned, the sum to be kept in trust by WHO for purchase of supplies and equipment must be entered in the appropriate place in the Agreement. Please note that trust funds held by WHO for purchase of supplies and equipment may **not** be used for any other purpose.

After a purchase has been approved, you will receive a copy of the WHO Purchase Order. The delivery date shown on the Purchase Order is the estimated delivery date ex works, **not the date of delivery to the recipient**. Experience has shown this estimated date to be optimistic. If a shipment has not been received 60 days after this date and no explanation of the delay has been given, TDR should be informed of this fact.

2.4 Budget Justification

The budget should clearly reflect the planned activities and the costs required. Justify each and every budget line, stating how the cost figures were derived in relation to the activities to be undertaken. Pay particular attention to major or unusual items. Use a **maximum** of two additional pages, if necessary, writing on **one side only** and numbering them as instructed on the form. The following information should be provided for the various budget lines:

Personnel: For each person, give name (if known), position and salary requested, including percentage for fringe benefits if such benefits represent actual costs to the employer of benefits paid to the employee. Please note that TDR funds only research personnel and not administrative staff. Please recall that salary support for the Principal Investigator will be considered only in **exceptional** circumstances (please refer to funding restrictions under Section II, Item 7 of this document). Remember to attach the *curricula vitae* of all named research personnel.

Supplies List separately the costs of the various categories of expendable supplies (e.g., laboratory reagents, glassware, field supplies). The amount entered for supplies to be ordered through the WHO Trust Fund mechanism should include 20% for packing, freight and insurance (PFI) charges. Similarly, the amount entered for supplies to be ordered locally should include, if applicable, local PFI charges.

Equipment: Give general justification for minor equipment and identify any piece of equipment costing more than US \$1000 (major equipment) and justify its purchase in relation to the work proposed. Give strong technical justification for your choice of equipment costing over US \$10,000. The amount entered for equipment to be ordered through the WHO Trust Fund mechanism should include 20% for PFI charges. Similarly, the amount entered for equipment to be ordered locally should include, if applicable, local PFI charges.

Animals Specify species, number, purchase costs and costs of maintenance.

Patient Costs Explain the nature of the costs (e.g., transportation, drugs for field trials) and method of calculation. Please note that the Special Programme does not support payment to patients as inducement to participate in research programmes, nor does it provide support for the costs of normal medical care of patients participating in TDR-supported studies.

Travel: Include in this item the costs of local transportation and field research expenses necessary for carrying out the proposed research. List separately the costs of transportation, *per diem* (indicate *per diem* scale paid by the Institution) and any other costs (specify). Please recall that TDR does not support travel for the purpose of attendance at scientific meetings.

Other Expenditures: Itemize under this budget line any other expenditures required for the proposed work.

3. PROJECT LINKS AND TRAINING OPPORTUNITIES (PART III OF THE PROPOSAL FORM)

Complete all items in this section, which must not exceed the single page provided in the proposal form.

3.1 Collaboration with other Scientists and Research Institutions

Please give the names and institutional affiliations of all proposed collaborators, including links with industrial groups (if any).

Indicate both the potential and need for such collaboration within the project, and describe the type of collaboration envisaged. This may include direct collaboration with scientists and institutions in other countries, and training for scientists from tropical developing countries. Please indicate those aspects of the project suitable for such training, and their duration.

In all cases, collaboration must be based on mutual agreement between the parties concerned. Please attach letters of confirmation from scientists and institutions with whom collaboration is proposed. On request, the TDR Secretariat will advise applicants of scientists and institutions potentially interested in collaborating in this way.

3.2 Links with other projects supported by TDR

Indicate here the links that would be established with other TDR research projects (if any). If the proposal is based on, or forms a continuation of a previous or existing TDR project, give the title and identification number of that project.

4. PROJECT DESCRIPTION (PART IV OF THE PROPOSAL FORM)

Describe the project in the order given (refer to the guidelines below). Continue on a maximum of three additional pages, if necessary, writing on one side only and numbering them as instructed in the form.

4.1 Objectives and Rationale

State clearly the objectives of the project and indicate the hypotheses to be tested and questions to be answered. Show how the research relates to:

- the workplan and priorities of the relevant Scientific Steering Committee or Task Force. Identify the gap(s) in knowledge which the proposed research will fill.
- the present status of scientific knowledge relevant to the project (including brief survey of relevant literature). It may be appropriate here to outline preliminary results.

Indicate how accomplishment of the research objectives may contribute to improved disease control.

4.2 Experimental Design and Methods

Provide information on experimental design and methods, including statistical methods, to a level of detail which will permit critical evaluation by experts. Indicate an approximate time schedule for each part of the proposed plan of work.

4.2.1 For Laboratory Studies

The following should be clearly outlined:

- experimental design;
- statistical design and proposed analysis;
- methods (with relevant bibliographic references);
- resources.

Indicate whether trained staff, facilities and methods are already available and, if not, the nature of the support requested with respect to:

- personnel;
- training;
- equipment;
- other resources (e.g., cold rooms, small animal facilities).

4.2.2 For Clinical Studies (other than clinical trials)

Clearly describe:

- the study protocol;
- the criteria for subject selection;
- all procedures to be carried out on human subjects;
- the provision for care and surveillance of subjects;
- the clinical facilities available for the study.

If laboratory studies are also involved, provide the information requested under Section III, Item 4.2.1 of this document (see also Item 4.3)

4.2.3 For Clinical Trials

Protocol design Outline clearly and include:

- type of trial (e.g., controlled, double-blind);
- number of treatment groups;
- characteristics of the study population and each group therein;
- nature and frequency of observations;
- proposed agent or drug;
- statistical design and analyses;
- inclusion and exclusion criteria;
- assumptions on which sample size has been calculated.

(See also Section III, Item 4.3 of this document)

Protocol operation Describe how the trial will be carried out and include:

- *Criteria for subject selection:*
Describe the origin of the study population (e.g., schoolchildren, village residents, medical students, nurses, laboratory assistants). Specify in detail all characteristics required for participation in each observation or treatment group (e.g. age limits, special physical or physiological requirements, such as height, weight, haemoglobin levels, disease conditions where these are being studied). Provide in detail the specific contraindications for admission to the study.
- *Admission procedure:*
Attach a copy of the admission form, showing details of history to be taken, physical examination and laboratory tests.
- *Subject allocation:*
State the method of allocation to the observation group or treatment group, e.g., random allocation using random table, open allocation (physician's choice, subject's choice).
- *Criteria for discontinuation:*
of individual subjects in study: specify all conditions that would require dropping a subject from the study (e.g., specific side-effects, loss of follow-up);
of the study itself: the criteria for premature termination of the study should be spelled out, e.g., lower than 94 per cent confidence limits for cure or prevention rates in an efficacy study or for side-effect rates in a study on safety.
- *Follow-up:*
Attach a copy of the follow-up form showing details of history, physical examination and laboratory tests.

4.2.4 For Field Studies

Indicate the type of study, e.g., cross-sectional survey, longitudinal study (prospective or retrospective), control trial.

Describe the study area, including description of, or reference to, geography, climate, seasonality of transmission, etc. Identify the target populations or population groups.

Give any available epidemiological information related to the disease(s), including the control measures and their effects (if applicable).

Describe the sociological and cultural background of the human population involved. If it is intended to seek their active cooperation, indicate ease of linguistic communication or language training needs, as well as how the proposed studies will be explained to them.

Indicate the estimated duration of:

- planning and preparation phase (pretesting in questionnaires, purchase and organization of material and logistics);
- actual data collection in the field;
- compilation of data from laboratory studies (serology, etc.);
- data analysis.

Describe methods:

- method of definition of the population, cohort or sample (e.g., mapping and census, randomization);
- methods of evaluation of intervention measures (i.e., pre-/post-intervention comparison/control group or areas);
- detailed methods of data collection and validation (e.g., standardized questionnaires, physical examination, serological tests);
- methods of data recording (e.g., laboratory books, direct recording on computer-oriented records);
- methods of data analysis (e.g., computing facility and tools for analysis).

Field studies of vectors or reservoir hosts should clearly indicate the environmental characteristics of the study site, giving, where relevant, the correct taxonomic determinations of the organisms involved.

Indicate available personnel and equipment (i.e., vehicles, permanent apparatus).

Indicate laboratory facilities required to support the study and their availability.

4.3 Ethical Considerations for Projects Involving Human Subjects

For all protocols or projects involving human subjects:

Any proposal that is supported by WHO and involves human subjects will be reviewed by the WHO Secretariat Committee on Research Involving Human Subjects (SCRIHS). This includes any proposal which involves

- (a) human subjects,
- (b) biological material obtained from human subjects,
- (c) accessing records from human subjects or
- (d) obtaining information from human subjects such as in questionnaires or social science research

Submission of the proposal to SCRIHS remains the responsibility of the **WHO Responsible Officer**, but a well prepared proposal saves a lot of the Secretariat time and can go for a review faster.

The core documents in any submission are the following:

1. Research Proposal
2. Associated Study Instruments (Survey Instruments, Questionnaires, FGD Guides, In depth interview guides etc) both in English and the local language.
3. Patient Recruitment material (e.g. leaflets or flyers that will be used to recruit participants both in English and the local language)
4. Informed Consent Forms (Information Sheet and the Consent Certificate) in English and the Local Language (*templates for clinical research, clinical trials, focus group discussion are available on the TDR website: www.who.int/tdr/grants/grants/ethical.htm*)
5. National or Institutional ethics approval

The following are important in drug or vaccine trials

1. Drug Package inserts (where applicable)
2. Trial drug related information where applicable
3. Adverse event reporting forms (where applicable)
4. Any other related documents

4.3.1 Checklist

The checklist, which is available on the TDR website: www.who.int/tdr/grants/grants/ethical.htm, has been prepared to guide you in preparing your proposal in the manner recommended by SCRIHS. Please remember to provide all necessary documentation and annexes. The protocol should provide the necessary information and details to comply with the questions proposed in the checklist. Also remember to attach any necessary explanations either in the proposal or relevant accompanying documents.

List all drugs, vaccines and diagnostic or other procedures to be used, regardless of whether these are registered, unregistered, new or already in current use, in the country in question or elsewhere. For drugs or vaccines which are widely used, provide the proprietary names, composition, doses to be administered and the name and address of the manufacturer.

For new drugs, vaccines or agents being used for the first time in human subjects or still at an early stage of clinical study, or being used by a new route or dose schedule, state the chemical composition of the drug, the source of the drug to be used in the study, amount present per dose and the tests undertaken to establish and control the quality of the drug to be administered.

The Principal Investigator should describe concisely the main pharmacological actions of the compounds to be used and provide appropriate safety data including results of studies already conducted in human subjects, if these are available. For new drugs, this type of information is required not only for the active compounds but also for the vehicle or carrier, e.g., an adjuvant in the case of a vaccine.

For chemical or biological products which are to be used in the general environment, e.g., biological methods to control disease vectors, state clearly any potential risks involved to human populations and to other environmental components. Indicate the measures planned to evaluate possible environmental changes and include any necessary national clearance document.

4.4 Critical Assessment and Possible Limitations of Approach in Relation to Project Objectives

Outline here your own critical assessment of the approach taken and its possible limitations in reaching the project's objectives.

IV. SUBMISSION OF PROPOSALS

1. Deadlines for Submission of Proposals

To guarantee review of a research proposal at a given meeting of a TDR Steering Committee or Task Force, it should be received in Geneva at least two calendar months before the date of that meeting. Applicants should consult the schedule of Steering Committee / Task Force meeting dates enclosed with the proposal form.

2. How to Apply

The original plus two copies of the completed proposal form should be submitted to TDR; a further copy of the proposal should be retained for your records. Complete information is essential for rapid consideration of proposals. Please ensure that all required signatures have been obtained and that any additional documentation, such as national or ethical approval(s), are annexed to the original proposal form. Proposals should be submitted by mail, courier or fax to:

**Office of the Director
Special Programme for Research and Training in Tropical Diseases (TDR)
World Health Organization
1211 Geneva 27, Switzerland
Fax: +41 22 791 4854
Email: tdrgrant@who.int**

All researchers applying for TDR grants are requested to send a copy of their proposals to the WHO Representative in their country. This will allow Representatives to keep abreast of projects and research progress in their countries, and help them to assist more effectively in any administrative or logistical problems that may arise.

Electronic submissions of application forms (by email to tdrgrant@who.int) are accepted, however, the Investigator must follow-up by sending the two pages which require original signatures:

- the responsible Administrative Authority (institutional endorsement), and
- the Chief Financial Officer and Principal Investigator (budget page).

3. Further Information

Further information can be obtained on request from:

**Communications Unit
Special Programme for Research and Training in Tropical Diseases (TDR)
World Health Organization
1211 Geneva 27
Switzerland
Telephone: 41 22 791 3725
Fax: 41 22 791 4854
Email: tdr@who.int
Web: <http://www.who.int/tdr/>**