

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

PROJECT DEVELOPMENT GRANT
SECTION A: GENERAL INFORMATION AND INSTRUCTIONS

DO NOT RETURN THESE INSTRUCTIONS WITH YOUR PROPOSAL FORM

I. 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 trypanosomiases (both African sleeping sickness and the American form, Chagas disease), leishmaniasis, leprosy, tuberculosis and dengue.

Proposals for support of full-scale research projects under a TDR Scientific Steering Committee or Task Force should be submitted on the Collaborative Research Proposal form (TDR/RP(B)/FORM/03). Separate proposal forms and instructions must be used for TDR Research Capability Strengthening Grants.

The workplans of TDR's Scientific Steering Committees, also available upon request, describe current research priorities and the lines of research in which projects are being sought by the Programme.

2. Project Development Grant

The Project Development Grant is designed to assist scientists of developing countries in formulating technically sound research proposals suitable for consideration for financial support by the various TDR Scientific Steering Committees and Task Forces. The funds may be used for three purposes:

- to seek the advice of recognized experts in the preparation of a research proposal on a subject area of interest to TDR;
- to gather baseline or other preparatory data;
- to initiate preliminary research.

The grant is open only to scientists who are nationals of developing countries and who are interested in pursuing research on one or more of the TDR target diseases.

3. Review of Proposals

Research proposals submitted for support under a Project Development Grant are reviewed by technical experts and the Director of TDR.

4. Funding of Approved Projects

Project Development Grants are limited to a maximum of US\$10,000. Approved proposals are funded through a Technical Services Agreement between the World Health Organization (WHO) and the Institution responsible for the project. Funding under a Project Development Grant is awarded on a 'once only' basis and may **not** be renewed.

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

Payments are made as specified in the Technical Services Agreement. 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 only for activities, services or materials clearly itemized and justified in the approved budget included within the proposal. Requests for "overhead", "administrative" or "miscellaneous" expenses, e.g. secretarial, clerical, bookkeeper salaries, and office supplies and utilities, **will not normally be permitted** 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.

Publication costs: Publication costs, including the preparation of manuscripts and illustrations, are not normally funded.

Library support Limited costs for library support for projects in developing countries may be considered, if justified.

Travel costs: Travel may be paid from TDR funds only if the travel is essential to the successful execution of the proposed work and is *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.

8.1 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 October of each year.

8.2 Visiting Experts

Funds for visiting experts may be requested, with clear indication of the field(s) of competence sought, the duration of stay (up to a maximum of one month per visit) and the name of the visiting expert's local counterpart. These funds may be managed by the Institution or kept in an account with WHO (see next paragraph) during the period for which the funds have been awarded. Any balance of such funds which has not been used for visiting experts 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 payments to be made by WHO for visiting experts should *arrive* in Geneva *before* 1 October of each year.

The Institution should assume full responsibility for administrative arrangements for visiting experts, including decisions on their selection, recruitment and length of stay. If reasons beyond the Institution's control (e.g. national currency regulations) make it impossible for the Institution to purchase the necessary airline tickets or pay the expenses of the visiting expert(s), TDR will review the matter and may agree to set up a Visiting Experts Account for the Institution in WHO. In the latter case, the Institution shall be responsible for all preliminary arrangements for the visit (i.e. handling all correspondence with the expert(s), arranging the dates of the visit, obtaining necessary visas and any required government clearances). TDR's function shall be limited to purchasing the travel tickets and, if necessary, making per diem payments from the Institution's Visiting Experts Account in WHO. Regardless of whether the funds are managed by the Institution or by WHO, each visiting expert must submit a report on the visit before or soon after he or she leaves the Institution. A copy of the visiting expert's report must be submitted to TDR.

9. Final Technical Report

Upon completion of the project, the Principal Investigator shall submit a final report to the Director, TDR. This report must be prepared on the official reporting form, which will be sent to the Principal Investigator at the appropriate time. 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 disease control.

The Principal Investigator should submit a full research proposal for review by the relevant Scientific Steering Committee within a maximum of six months from their receipt of the expert's report.

10. Financial Report

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 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 I, 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 intellectual 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 the 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.

In some instances, because of the nature of the research work being funded by WHO, it should be appropriate for WHO to retain rights other than those provided in the general conditions of the standard form of the Technical Services Agreement (TSA). It may also be appropriate where WHO is the organizer of a series of individual research projects as part of a larger programme, that WHO exercise rights as part of an agreement with a commercial enterprise to develop those results into a final product. In such cases, it is necessary for WHO to hold the intellectual property rights in the results of the work, or at least to have a non-exclusive license in the rights relating to the results. For example, WHO has become increasingly involved in testing compounds of commercial enterprises, and the conditions of the TSA, which grant the institution rights in the results of the testing, constitute an inappropriate contractual basis for funding such work. In the cases mentioned above, the general conditions of the standard TSA form will be amended by an overriding letter of agreement.

14. Research Involving the Use of Laboratory 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.

II. INSTRUCTIONS FOR COMPLETING THE PROPOSAL FORM

Proposals for support of a research project under a Project Development Grant 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/PDG(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. Please do not use pages larger or longer than those of 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

Enter here the proposed starting date of the project, and its proposed duration in months.

1.4 Key to Steering Committees

If applicable, 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 disease control; 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 16, 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 I, Item 15 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 I, Item 16 of this document).

2. BUDGET (PART II OF THE PROPOSAL FORM)

2.1 Budget Details

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

Budget details should be itemized under the budget lines indicated in the budget table in Item 2.1 of the proposal form. 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 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 percentage of time (e.g. technician percentage of time), 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.

2.2 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 2.1 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). The amount entered for supplies and equipment 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 and equipment to be ordered locally should include, if applicable, local PFI charges. 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 October following the year during which the Trust Fund was established** (please refer also to Section I, Item 8.1 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.

2.3 Visiting Experts

Visiting experts are to be recruited directly by the Institution receiving the grant. However, if the Institution is unable to recruit directly, the Institution may request, with appropriate justification, that TDR identify and/or assist in making arrangements for visiting experts. If this request is granted, the value of the Technical Services Agreement will be reduced by the amount to be used for this purpose. Please refer also to details given in Section I, Item 8.2 of this document).

It shall be understood that the assignment of a visiting expert does not create any employer/employee relationship as between the visiting expert and the World Health Organization, and that the Organization is not responsible for any loss, accident, damage or injury suffered by the visiting expert or any person claiming under the visiting expert arising in and out of the execution of his or her work in any manner.

Funds retained in WHO that are designated for visiting experts but not requested **90 days before the end of the contract period will revert to WHO**.

3. PROJECT DESCRIPTION (PART III OF THE PROPOSAL FORM)

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

3.1 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 present status of scientific knowledge relevant to the project and ongoing research within the Institution, TDR and elsewhere. It may be appropriate here to outline preliminary results. Please indicate if the proposal relates to the workplans and priorities of the relevant Scientific Steering Committee or Task Force.

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

3.2 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.

If any aspect of the proposed work involves human subjects, the proposal must be reviewed and approved by an independent institutional ethical body prior to formal submission of the proposal to TDR.

Proposals involving human subjects should also be sent for review and clearance through the national authority (usually the Ministry of Health) for the regulation of human experimentation, if such a body exists within the country, prior to formal submission of the proposal to TDR. **The document(s) of approval must be attached as an annex to the proposal.**

For all protocols or projects involving human subjects:

- Include a statement of the ethical considerations involved. The research protocol should indicate that the principles of the Declaration of Helsinki, amended as stated in Section I, Item 15.1 of this document, are complied with.
- Indicate the benefits and any known risks or inconveniences to the subjects involved in the study.
- Describe precisely the information which will be conveyed to potential subjects of the study and the manner, oral or written, by which this information is to be conveyed. Examples of information to be given to potential subjects include: aims of the research; descriptions of experimental procedures; any known short- or longer-term risks; possible discomfort; anticipated benefits from the procedures to the subject or others; expected duration of the study; alternative methods of treatment available if the study involves a treatment procedure; and the freedom of the subject to withdraw from the study at any time. If a written consent form is to be used, attach a sample. The name(s) and status of the project staff member(s) who give(s) this information to potential subjects and who ascertain(s) that it is understood and that the consent is given freely by the subject, must be included.
- Fully justify any form of reimbursement (e.g., transportation costs) proposed for subjects participating in the project; where payments are involved, specify amounts, manner and timing. Please recall that TDR policy does not allow payments to subjects 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 research.
- Indicate how the confidentiality of all information obtained during the course of the study, relating to participants included in the study, will be maintained.

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.

III. SUBMISSION OF PROPOSALS

1. Deadlines for Submission of Proposals

Proposals for a Project Development Grant may be submitted at any time of year.

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/>**