



SMALL RESEARCH GRANTS FOR PATIENT SAFETY

A resource for applicants

This resource is intended to assist researchers and practitioners in preparing their application for funding as part of the WHO Small Research Grants for Patient Safety. It provides information on the aims and objectives, access and eligibility criteria, application and assessment processes, ethics requirements, provision of funding as well as reporting and administration of grants.

The information is organized into two parts. Part one contains general information on the small grants initiative. Part two provides specific information on how to complete the application form. Please read this resource in full before completing the application.

For further information, please visit the website: www.who.int/patientsafety/research/grants/en

The final date for submissions is 30 September 2008.

For enquiries and to submit an application:

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Part I: Overview

1.1 About the WHO World Alliance for Patient Safety

The World Alliance for Patient Safety was launched in October 2004 by the Director-General of WHO. It aims to increase awareness and political commitment to improve patient safety, including policy and practice, in all WHO Member States. Research for Patient Safety is one of the key action areas of the Alliance. The Research Programme aims to foster patient safety research worldwide and to spread and use research findings and evidence to improve patient care.

1.2 About the Small Research Grants for Patient Safety

The Small Research Grants for Patient Safety aim to stimulate research in patient safety by providing seed funding for small well-defined, well-designed research projects, which focus on priority areas and can be achieved within 12-18 months. It is expected that this initiative will also contribute to building local research capacity and will help raise awareness about patient safety at both local and country levels. Specific objectives include:

- to increase research on patient safety by providing seed funding for 20–30 small research projects, to be initiated in 2009;
- to contribute to building local capacity for research on patient safety by providing grants to research institutions and research teams in developing countries and countries with economies in transition, especially to projects in which young researchers and those in early or mid-career are the lead investigators; and

- to promote the culture of patient safety by improving dissemination of research findings.

1.3 Funding available

In the first year, US\$ 500 000 will be allocated to fund 20–30 grants for studies to begin in 2009. Funding of between US\$ 10 000 and US\$ 25 000 per grant will be available. The amount is flexible, but the grant must be appropriately justified. The grant may be renewable if the first project is completed satisfactorily and if funding is available.

The grant will support the direct costs of research (see Conditions of Grants for more details) and is to be used within 12-18 months following the transfer of the first instalment. The project should commence within two months of the date specified in the Letter of Contract. In exceptional circumstances, an extension of the project and use of funds may be granted, subject to written approval from the World Alliance for Patient Safety.

1.4 Eligibility

Institution: Funding will be provided through an administering institution (host institution) which will be the fund holder and legal entity for contractual purposes. This ideally should be the main affiliated institution of the principal investigator. Other co-investigators must also provide details of their affiliated institutions. Eligible institutions include universities or other

research and academic centres, hospitals, community based organizations, non-governmental organizations, government departments and collaborating centres, for example. In all cases, the host institution will show proof of sufficient research capacity and of experience in managing and conducting research projects.

Researchers: Researchers at all stages of their careers are eligible to apply, although submissions from young researchers are especially encouraged.

Principal investigator: The principal investigator must be affiliated to a recognized institution in the country in which the research project will be conducted. He or she needs to demonstrate the ability to lead and complete a research project with similar characteristics to the project submitted. In the case of a multi-national research project, it will be encouraged that the study submit one or more investigators from each country.

Country: The focus of this programme are primarily researchers from developing countries or countries with economies in transition. Researchers from developed countries can, however, be co-investigators or collaborators. Researchers from developed countries are eligible to apply as principal investigators, but priority will be given to applications from developing countries and countries with economies in transition.

Collaboration: Collaborative research projects will be particularly encouraged. These may include collaboration between institutions in the same country, between countries within the same region or between developing/transitional countries and developed countries.

Special consideration will be given to applications that combine the efforts of researchers and clinicians, health care

professionals or policy-makers who are actively involved in the project.

1.5 Conditions of grant

The grant is to support the research project described in the application. It is cash-limited at the value stated in the contract. There is no scope for increasing the level of grant awarded. The fund is intended to contribute to the operational costs and not to substitute the salaries of the investigators. The expenditure must conform to the budget items outlined in the approved proposal.

The grants will be administered through the Technical Service Agreement. Appendix 1 provides details of terms and conditions of the grant.

Reports on expenditure (Financial reports) will be required at mid term and at the end of the project. The forms for these reports will be made available at the World Alliance for Patient Safety website.

1.6 Institutional approval

For all applications, evidence of approval and endorsement by the host institution is required. For applications selected for funding, the contractual arrangement will be negotiated between WHO and the host institution.

1.7 Project management

All applications must demonstrate a competent team and a sound project management structure that is necessary and sufficient to successfully implement the project. Applicants need to identify a project team, define their role and describe their relationships and collective responsibility.

1.8 Confidentiality

Unless otherwise indicated, information contained in the applications is regarded as confidential and will be treated as such

according to WHO requirements. Information comprising the names of successful grant applicants, their administering and/or collaborating institutions, the title of the research project and the funding awarded may be published in the Alliance website and/or annual report.

1.9 Ethics clearance

The World Alliance for Patient Safety requires the research it funds to be conducted in an ethical manner, which respects the rights of research participants and recognizes the responsibilities of the researchers. The principal investigators and the host institution are responsible for ensuring that ethical issues relating to the research project, if any, are identified and brought to the attention of the Alliance.

1.9.1 National Ethics Review Body

All research projects funded under this initiative must conform to the ethical requirements set by the relevant /appropriate national ethical review body. Evidence of ethics approval will be required. If the evidence of national ethics approval is not available at the time you submit the grant application, the evidence of your submission to the ethics review body should be provided along with statements indicating the date that the final approval will be available.

1.9.2 WHO Research Ethics Review Committee (ERC)

Research projects funded through this initiative must be approved by the WHO Research Ethics Review Committee (ERC). The Small Research Grants Manager will collate all research project protocols and coordinate the submission to the ERC.

Please ensure that your proposed project conforms to the requirements of the ERC. For your information, the WHO ERC has provided a range of resources which can be found at http://www.who.int/rpc/research_ethics/en/. Please consult these resources when preparing your applications:

- Guide for writing a Research Protocol (http://www.who.int/rpc/research_ethics/guide_r p/en/index.html)
- A practical guide for health researchers (http://www.emro.who.int/publications/pdf/health_researchers_guide.pdf)
- Guidance documents on seeking informed consent (http://www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf)
- Examples of informed consent form (http://www.who.int/rpc/research_ethics/informed_consent/en/)
- Checklist for Principal Investigator (http://www.who.int/entity/rpc/research_ethics/Checklist_for_PI.dot)

1.10 Available resources

Further information on this initiative, including the global priorities for research in patient safety, is available on the Alliance's website (www.who.int/patientsafety/research/en/).

1.11 Lodging and application and further information

The due date for submission is 30 September 2008. Applications submitted after the due date will not be considered. Completed applications can be sent by email to: Nittita Prasopa-Plaizier, email: pssmallgrants@who.int.

Part II: Completing an Application

2.1 Application Form

An application form is provided for the convenience of all applicants as well as of the reviewers and to enable appropriate comparison. **All applications are required to use the provided form and to provide all relevance information.** Applications that do not conform to this will not be considered.

The information in the application form is organized into three parts. Part one contains information on investigators and their affiliated institution. This section will be detached before distributing the applications to the reviewers. Part two contains detailed information on research proposal, which will be assessed for the scientific merit and policy relevance of the proposed project. Part three provides information on the project team and project plan, which will also be detached during phase one assessment.

2.1.1 Part I: - Administrative information

This sections include details of applicants i.e. principal investigators and co-investigators, administering institution and collaborating institutions. Please fill in all fields in this section. If the questions or items are not applicable, indicate "Not applicable".

2.1.2 Part II: - Research proposal

This section entails the study rationale and objectives, design, methods and data, expected outcomes and results dissemination. Please fill in all the fields. Where the questions are not relevant, indicate "Not applicable". Please provide precise and concise information. Care should be taken in

completing this section as the information will determine the scientific merit of the proposal.

2.1.3 Part III: - Project Management and organization

This section should describe the project team and how the project will be managed. The project team should comprise appropriate skill mix and distribution of roles and responsibilities. This should include research staff and administrative staff, if applicable. The composition of the project is an important selection criterion as the reviewers will assess if the applicants have sufficient and appropriate skills and resources to complete the project.

List all the relevant persons that will be part of the project team, their current position, their affiliate organizations and their proposed contribution to the project. For key project staff such as principal investigators, co-investigators, project manager (if different from the investigators) please provide a summary of their curriculum vitae (not more than 3 pages).

It is important to provide sufficiently detailed information on the project timeline. A template for planned timeline is provided for convenience. Please add items as appropriate.

Value for money is also a key selection criterion though it is difficult to assess. Thus, your budget should be as realistic and within the limit of the grant amount. As much as appropriate, please provide information on budget items and provide justification. You may provide references to other projects of similar size and design.

Part III: Application Assessment and Selection

3.1 Research priority areas

In late 2006, the World Alliance convened an expert working group to identify a set of priorities for patient safety research. Separate sets of global priorities have been defined for developing and developed countries as well as for countries with economies in transition.

A combined top ten priorities of all three levels of development are listed in Box 1.

You are strongly encouraged to use the priorities below as a guide when formulating the research questions for your proposal. Studies that correspond to the identified priority areas will be given higher priority. Justified local priorities will also be welcomed.

Box 1. Global research priorities of the World Alliance for Patient Safety

- Identification, design and testing of locally effective and affordable solutions
- Assessment of cost-effectiveness of risk-reducing strategies
- Counterfeit and substandard drugs
- Inadequate competencies, training and skills
- Maternal and newborn care
- Health care-associated infections
- Extent and nature of the problem of patient safety
- Lack of appropriate knowledge and its transfer
- Injection practices
- Blood products and blood practices
- Lack of communication and coordination
- Poor safety culture and blame-oriented processes
- Latent organizational failures
- Development of better safety indicators
- Devices and procedures that include human factors considerations
- Health information technology and information systems
- Patients' role in shaping the research agenda
- Adverse drug events and medication errors

3.2 Peer Review Process

The WHO Patient Safety Small Research Grants are awarded on a competitive basis. Applications will be evaluated via a peer review process to ensure a fair, equitable, and transparent assessment of their scientific and technical merit. The Research Programme of the WHO World Alliance for Patient Safety oversees, coordinates and manages the peer review process.

There are three steps in the process:

Firstly, the Research Programme will conduct an initial review of grant applications to ensure eligibility, completeness and accuracy of the information provided. An identification number (ID) will be assigned to each application to ensure confidentiality and anonymity. The identity of the researchers and their affiliated organizations will be detached from the application.

The second step is a peer-review assessment, which will be conducted independently and blindly by a panel of experts. Members of the review panel comprise experts in varying disciplines from different countries around the world covering all WHO regions. The review will be conducted into two phases. Phase one involves the assessment of the scientific merit, project management and policy relevance of the proposed study. Applications will be assessed according to the review guidelines using pre-determined criteria, which are available on the website. Each criterion consists of a number of questions to which the reviewers are asked to assign a score from 1 to 4, where 4 represents the most meritorious. In addition, the reviewers are also asked to provide comments on specific aspects of the proposal.

The applications will then be ranked and considered based on the total summed scores and the reviewers' comments. Proposals that

are not recommended for funding or those that require major modifications will not be given further consideration. Only proposals with high average scores and with positive recommendations from the reviewers will be selected for "Phase two" assessment.

Phase two involves an assessment of the capacity and ability of the principal investigators, the research team and the institutional facilities. Researchers must demonstrate that they have the necessary skills, experience, resources and institutional support to carry out and complete the project and deliver the outcomes as outlined in the proposal. At this stage, the identity of the researchers and their affiliated institutions will be provided to the reviewers to facilitate their assessment of the applications.

The applications will be ranked again based on the newly obtained scores. The outcomes of this process will inform the final selection. Selected applications will be submitted to the WHO Ethics Review Committee for final ethical clearance.

The final step in the assessment process is the ethical clearance by the WHO Ethics Review Committee. The Research Programme will work with the selected research team to facilitate this process. Only applications that receive approval from the WHO ERC will be recommended for funding.

3.3 Review Criteria

The grant selection review criteria comprise 3 components including scientific merits of the study, project management and organization.

Scientific merits of the study

- Relevance of the research questions
- Significance and originality
- Internal validity, methods and data

Project management an organization

- Project management and organization
- Facilities, resources, and environment
- Ethical consideration
- Budget and value for money

3.3.1 Scientific merits of the study

Relevance of the research questions

This is to assess whether the research questions correspond or have relevance to the research priorities identified by the World Alliance for Patient Safety (see Box 1 mentioned above) or priorities identified locally. For research questions linked to local priorities, you must demonstrate that the proposed questions are considered priorities by national authority. The reviewers will also assess the likelihood that the results of the study would be relevant for policy, organizational or managerial purposes, or clinical or patients' purposes. Please ensure that your proposal clearly states the research questions and the study objectives.

Significance and originality

This is to assess the contribution of the proposed project to the knowledge and practice relating to patient safety. The reviewers will assess evaluate whether the proposed study address an important problem or contribute to the advancement of treatments and interventions for patient safety or to clinical practice and health-care services. The reviewers will also evaluate the potential contribution of the study to the research methods and scientific knowledge. Please ensure that your proposal demonstrates the adequacy of the literature review, the sufficiency of the rationale, the importance and significance of the expected outcomes and the features of the project that demonstrate originality or innovation, if any.

Internal validity, methods and data

This is to assess whether the conceptual framework, design, methods and data analyses are adequately developed, well-integrated and appropriate to respond to the research questions. The reviewers will assess whether the key concepts and variables are clearly defined, the study population and the sample size are appropriate, adequate and justified, whether the analytical plan is adequate and corresponds to the research question, and whether the applicant acknowledges potential problems and considers alternative tactics or ways to minimize them. The information provided in this section will be essential for "Phase one" peer review assessment. Please ensure that your application contains sufficient, but concise and precise information.

3.3.2 Project management and organization

Investigators

This section will consider whether the principal investigators are qualified and sufficiently skilled and experienced to carry out the project, whether the composition of the project team is suitable in term of skills mix, delineated role, responsibility etc., and whether the investigators are knowledgeable about the subject area.

Project management

The project management section looks at the plans for organizing and carrying out the project in a satisfactory manner. Whether the management plans, timeline of the project, the flow of the project in terms of key events and products, and the personnel's time and resources are sufficiently allocated; whether roles, responsibilities and skills of the project team are well defined, and also whether the plan for result dissemination and data sharing are well-described and reasonable.

Facilities, resources, and environment

Some of the key questions here are: the resources of the administering institution and other study sites are adequate? Does the application have an endorsement of relevant authority such as the institution management and/or any other authority? Please enclose appropriate documentation of agreements among participants and collaborating organizations, if applicable. Please also enclose a letter from hosting organization as evidence of institutional support. Do the proposed studies benefit from unique features of the scientific environment or subject populations, or employ useful collaborative arrangements?

Ethical consideration

It is essential that the proposal addresses potential ethical issues. Where the study includes human subjects, the proposal will need to adequately describe the risks to subjects and approaches for protection. In these cases, the proposal needs to include an appropriate informed consent. All applications need to submit a resolution (or proof of submission to) by the corresponding local or national Ethics' body approval, according to the particular legislation of the country of the host institution.

3.3.3 Budget

Applicants are advised to ensure that the proposed budget is reasonable and adequate in relation to the proposed project. To that, budgets should be appropriately itemised and justified. The reviewers will look for good value for money. You should plan your budget realistically, itemise them clearly and sufficiently justify them. WHO may propose alternative budgets to successful grant applications.

3.4 Review by the WHO Ethics Review Committee

As mentioned previously, the purpose of this process is to ensure that the proposed projects conform with WHO ethical requirements and will be conducted in an ethically appropriate manner. Only applications that are approved by the WHO Ethics Review Committee will be considered for funding. Thus, you are advised to carefully consult with the WHO Ethics Review Committee requirements when preparing the proposal.

3.5 Review Process and Conflict of Interest

The assessment of the application is carried out independently and anonymously by each reviewer. The Research Programme will remove any information that may identify the study authors and/or corresponding institutions from the grant proposals prior to distributing them to the reviewers. This is an attempt to minimize the bias and conflict of interests among members of the review panel.

If however, the reviewers are or are becoming aware of the identity of the authors and/or of hosting institutions, they must contact the Research Programme and declare any possible conflict of interest or excuse themselves from reviewing that particular proposal.

Membership of the review panel does not disqualify ones from applying for a grant provided that their applications meet the grant eligibility criteria. If they so did, however, they must contact the Research Secretariat and disclose the details of the projects in which they are involved and their role within the project. They must not reveal the details of their applications to other members of the review panel to avoid any possibility of bias.

3.6 Unsuccessful Applications

WHO will communicate the outcome of the selection process related to all applications. Unsuccessful applications may be resubmitted to consecutive calls for proposals, providing that the application has been improved and taken into consideration the suggestions or the arguments of the review panel.

Applicants who disagree with the recommendations of the review panel may write to the Research Programme within three weeks of receiving the letter of resolution by WHO requesting additional review. Providing the arguments of the principal investigator are solid enough to respond to the queries of the review panel, the Research Programme will seek an additional independent review. No new nor amended research proposals will be accepted for this additional independent review.

3.7 Indicative Timeline for resolution of applications)

Indicative Timeline the Patient Safety Small Grants Programme - 2008-2009

Activity	Deadline
Programme launch	24 June 2008
Call for proposals	1 July 2008
Closing date for applications	30 September 2008
Peer review of proposals	October - November 2008
Communication of the review outcomes	December 2008
Applications reviewed by the WHO Ethics Review Committee	January - March 2009
Research projects commence	April - May 2009
Mid-term report due (six months after project commencement)	November 2009
Final report due (two months after project completion)	July - December 2010

Part V: Checklist

To facilitate the speedy review, before submitting your application, please ensure that you have completed all sections, answered the questions and provided all the required comments. The key items are summarized in the table below. A complete check list for principal investigator suggested by the WHO Ethics Review Committee is available at http://www.who.int/entity/rpc/research_ethics/Checklist_for_PI.dot.

	Have all your questions been answered and all sections completed? Are all of your responses correct?
	Are the details of your institution correct?
	Have you provided sufficient information to demonstrate that the selection criteria have been addressed?
	Have you provided sufficient information on budget items?
	Is the budget reasonable for your proposed project and has it been justified?
	Have you attached the required documents?
	Have all the necessary signatures been obtained?