Grand Challenges in Global Health

Sample Full Application Form

Online Application Fields

Page 1

Project Title: SAME AS LOI

Grand Challenge Number: SAME AS LOI

Sponsoring Institution Name: SAME AS LOI

Duration of Project (Number of Months):
Enter months in whole numbers – use only the format: 48

Type of Sponsoring Institution

- Select One -
University
Research Institute
Hospital
Other Nonprofit
Company (For-profit)
Government

Sponsoring Institution Tax Status and US Tax ID

- Select One -
170(c)(1) Government Unit (US)
501(c)(3) Private Foundation (US)
501(c)(3) Public Charity (US)
For-profit (US)
Foreign Government
Foreign Nonprofit
Foreign For-profit

US Tax ID Number (for US organizations only): _____

Type of Collaborating Institutions

Please select all types of collaborating institutions represented by your collaborators. For example and as shown below, if two of your collaborators work at Research Institutes and one works at a government agency, select Research Institute only once.

Research Institute
Government
- Select One -
- Select One -
- Select One -
- Select One -

Project Budget

Enter the Requested Total Cost (including all indirect costs) for each year of the project and the Requested Total Cost for All Years as shown in your budget spreadsheet.

For all of the currency entries below, enter in US Dollars
USE ONLY THE FORMAT: 1,000,000
DO NOT enter any decimals, spaces, words, or currency symbols.

Year 1 – Requested Total Cost:

Year 2 - Requested Total Cost (if applicable):

Year 3 –Requested Total Cost (if applicable):

Year 4 - Requested Total Cost (if applicable):

Year 5 - Requested Total Cost (if applicable):

Requested Total Amount for All Years (including indirect costs for all years):

NEWLY ENTERED TO REFLECT CHANGES SINCE THE LOI STAGE

Page 2

Changes in Contact Information

In this section please provide any changes, if applicable, to the contact information since the LOI application stage for the individuals listed in the section above.

Principal Investigator (previously submitted on LOI)

FIELDS OF CONTACT INFORMATION FROM LOI TO DISPLAY HERE
(Last Name, First Name, Middle Name, Prefix, Title, Address, Sponsoring Institution Name)

Changes to Principal Investigator Contact Information

Sponsoring Institution's Responsible Official (previously submitted on LOI)

FIELDS OF CONTACT INFORMATION FROM LOI TO DISPLAY HERE
(Prefix, Last Name, First Name, Middle Name, Title, E-mail, Phone, Fax)

Changes to Sponsoring Institution's Responsible Official Contact Information

Collaborating Researchers (previously submitted on LOI)

FIELDS OF CONTACT INFORMATION FROM LOI TO DISPLAY HERE
(Prefix, Last Name, First Name, Title, Sponsoring Institution Name)

Updates to Collaborating Researcher Information
(Previously identified collaborators with updated contact information – See below for additions and deletions)

Additions to Collaborating Researcher Information
(Please provide complete contact information for each)

Deletions to Collaborating Researcher Information
(Names of individuals who will no longer be collaborating on the project)

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Project Purpose

Please succinctly describe and summarize the purpose of the project including the following components, as applicable: the global health problem you are aiming to solve; the scientific/technical approach to be used to overcome the roadblock you are aiming at; the health condition/disease(s) it would address; and the populations most affected by the problem in the developing world. (Limit to 255 characters)

Example: To overcome the lack of an effective adjuvant by engineering a lipoprotein that will permit development of improved vaccines for the prevention of disease(s) or condition(s) XX, which affects Z% of the children in country YY (or the developing world).

Project Description

Please provide a brief description of your project in 150 words or less using lay terms (i.e., how the funds would be used to meet the project purpose as described above)

Program Summary

Please enter a copy of the Program Summary, Part I (2 page maximum) exactly as presented in Attachment A – Research Overview.

Meeting the Grand Challenge

Please enter a copy of the Meeting the Grand Challenge, Part IV (1 page maximum) exactly as presented in Attachment A – Research Overview.

Coding Definitions

The following information will be relevant to many but not all proposals. This information will be required only as appropriate to classify the targeted areas of the project. Please select up to three in each category below.

Disease/Health Condition Addressed (Three drop down boxes)
Please select up to three – one per box below.

- Select One -
Acute Respiratory Infections
African Trypanosomiasis
Cervical Cancer
Chagas
Dengue
Dracunculiasis (Guinea Worm)
Enteric Infections
HIV/AIDS
Herpes viruses
Hepatitis B
Hepatitis C
Hookworm
Human Papilloma Virus (HPV)
Leishmaniasis
Lymphatic Filariasis
Malaria
Measles
Meningitis
Micronutrient Deficiencies
Onchocerciasis
Poliomyelitis
Protein deficiency
Schistosomiasis
Sexually Transmitted Diseases
Tetanus
Toxoplasmosis
Trachoma
Tuberculosis
Vaccine Preventable Childhood Diseases
Other – Not Listed

- Select One -

- Select One -

Other Diseases Not Listed Above

Geographic Regions of the World Affected (Three drop down boxes)
Please select at least one

- Select One - Asia-Pacific Eastern Europe Latin America and Caribbean Middle East and North Africa North America Sub-Saharan Africa

- Select One -

- Select One -

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Required Proposal Attachments

FILE TYPES: All document attachments must be submitted in either Microsoft Word, RTF, or Adobe Acrobat PDF (the latter is preferred). No other formats can be read by reviewers and will not be accepted.

BUDGET TEMPLATE: Use only the standard budget template GCGHBudgetTemplate.xls sent to you by e-mail.

FILE NAMES: Your files must be named as follows:

Attachment A – Research Overview

Attachment B – Research Plan

Attachment C - Principal Investigator and Collaborator Bios

Attachment D - Budget Spreadsheet

IMPORTANT: Proposals will not be considered unless all four attachments are provided and completed in full.

Upload

The maximum size for all attachments combined is 5 MB. Please note that files with "exe", "com", "vbs", or "bat" extensions cannot be uploaded.

Title: Research Overview

File Name:

Upload

Important Proposal Requirements

1. Be sure to read the GCGH Full Proposal Review Criteria and ensure that all aspects of your proposal fully cover each topic. For example, all descriptions of the likelihood of solving the grand challenge must clearly describe the potential for implementation in the developing world, etc.
2. All of the information in Attachments A and B must be provided in the same format (section and titles) as shown in the proposal guidelines.
3. Attachment B - Research Plan must have a Table of Contents showing the major proposal sections with page numbering.
4. All pages must use 12 point Times Roman font and single spaced with 1 inch top, bottom, and side margins.
5. Do not include any multimedia presentations or an Appendix.
6. Web links are discouraged. Under limited circumstances, Web links to selected, critical information may be provided – however there is no assurance that reviewers will review these. For this reason, please be sure to include all necessary information in the body of your proposal.
7. Please consider that while some reviewers may be able to view color graphics, printed copies of proposals will be only in black and white. Please select and include graphics with this in mind.
8. Attachment documents A, B, and C must be provided in either Microsoft Word, RTF, or Adobe Acrobat PDF format (the latter is preferred). The project budget, Attachment D must be provided in Microsoft Excel format using the specified and downloaded template. No other formats will be acceptable or readable by reviewers.
9. It is the applicants' responsibility to ensure that all information relevant to their project is submitted, including all supporting documents that are mailed and signed by authorized sponsoring institution officials and all collaborating researcher(s). Applicants are also responsible for ensuring that proposals adhere to all stated page limits. **Incomplete or excessively long proposals and those that do not adhere to the stated file formats will not be accepted for review and will be returned to the applicant.**

Attachment A – Research Overview

Please be sure to read the "Important Proposal Requirements" section of this application prior to developing your proposal response. It is very important for you to address each of the following topics, noting the page limitations for each section.

I. Program Summary *(No more than two pages of narrative)*

This section is meant to serve as a concise executive summary of the project, including the key points of the project design, methods and plan. Provide an overview of:

- Your specific objectives and how they relate to the Grand Challenge you are addressing
- Research goals
- Major activities you plan to undertake to achieve them
- Milestones and timetable
- All locations where research will be conducted

This overview should correspond to the more detailed descriptions provided in later sections of the Research Overview and the Research Plan.

II. Goals, Objective and Outcomes *(Suggest no more than two pages)*

Using a copy of the table below, list the Goals, Objectives and Outcomes, and Major Activities and Outputs using the form provided. Note that your budget (Attachment B – Research Plan, section V.) must be organized to align resource requests with the stated Major Activities and Objectives described in this table. See the Glossary at the end for a definition of key terms.

Goal:	

Objectives & Outcomes (list as many as needed)

Objective	Indicator	Baseline	Expected Outcome
1.			
2.			

Major Activities & Outputs (list as many as needed)

Activity / Output (indicate objective #)	Indicator	Baseline	Expected Target Output(s)
1.			
2.			

III. Milestones and Decision Points *(Suggest no more than five pages)*

In concert with developing the Objectives, Activities and accompanying Budget tables required for Section II above, list and number in chronological order your proposed milestones, decision points and/or the major deliverables that you expect to provide during the grant period.

Present this as a project timeline, starting with the inception of the first activity and showing dates for each milestone and decision point. Create a table in text (not graphic) format, as shown in the sample below. Intermediate waypoints may be listed as subheadings under a main milestone if required (e.g., 1, 1a, 1b, 2, 2a, 2b etc.). The last column in this table must identify by number the "Objective(s) / Major Activities" from Section II above that pertains to each milestone/decision point/deliverable. Be sure to relate each milestone, etc. to the corresponding major budget element and time period.

You may also add a short Milestone Narrative below the table, to provide an expanded description of the milestones.

Format of Milestones, Decision Points and Deliverables (list as many as needed)

Milestone or Decision Point or Deliverable	Projected Start Date	Periodic Measurement Intervals	Projected Decision or Delivery Date	Linked Objective(s) and Major Activities
1.				
2.				
3.				

Sample Format of Milestones, Decision Points and Deliverables (list as many as needed)

Milestone or Decision Point or Deliverable	Projected Start Date	Periodic Measurement Intervals	Projected Decision or Delivery date	Linked Objective(s) and Major Activities
1. Build prototype	Month 1	Monthly	Month 15	Objective 1, Years 1-2
2. Successfully test and calibrate	Month 15	Monthly	Month 24	Objective 1, Year 2
2a. Verify data transmission and analysis	Month 25	Weekly	Month 26	Objective 1, Year 2

Milestone Narrative (as needed):

IV. Meeting the Grand Challenge *(No more than one page)*

Describe exactly how you envision that your project will solve the Grand Challenge you have chosen to address, or how the project is on the critical path to a solution. Describe whether the approach or technology is aimed at addressing the Grand Challenge as it relates to a single disease or condition, or could be more generally applied.

Describe with as much precision as you can how you believe the solution can be implemented in developing countries and what the impact will be. If your project is successful, what percentage of the problem being addressed would it likely solve, and in what time frame?

V. Innovation *(No more than one page)*

Describe the innovation and benefits of your proposed approach relative to the state of the art and alternative approaches. The innovation must be in the context of the Grand Challenge being addressed. Innovation in this context is not limited just to new scientific discoveries, technology platforms or approaches, but may also encompass news ways of integrating existing technologies or processes; or implementing existing ideas in new ways to provide a pathway to a solution for the problems being addressed.

Attachment B – Research Plan

Please be sure to read the "Important Proposal Requirements" section of this application prior to developing your proposal response. It is very important for you to address each of the following topics, noting the page limitations for each section.

Provide a Table of Contents with page numbers as a cover page for this section.

I. Detailed Technical Plan

(No more than 20 pages including figures, except for proposals involving complex consortia of more than three major partners, or budgets in excess of $10 million in total costs which may take 25 pages, if required.)

IMPORTANT: The detailed information in this section must clearly map to the objectives and outcomes, major activities, milestones and outputs, and time lines specified in Attachment A - Research Overview, sections I, II, and III.

A. Background

Describe and critically evaluate the state of existing knowledge and how your proposal will move it forward towards a solution of the grand challenge. Discuss competing approaches and related ongoing or previous work, both your own or that of others.

B. Preliminary Studies

Provide an account of any preliminary studies that principal investigator and collaborating researchers have carried out that are pertinent to the application.

C. Methods & Experimental Design

Describe the research design, methods and procedures to be used to accomplish the specific goals and major activities of the project. Include how the data will be collected, analyzed, and interpreted. Discuss the potential difficulties and limitations of the proposed plan and potential alternative approaches you will use to achieve your aims. Your research plan should respond to any suggestions and requirements that may have been transmitted to you from the review of your LOI. Your research plan should include clearly defined milestones and decision points, and should consider:

- When do you expect to complete key parts?
- Where do you expect to be year by year?
- What critical information will be needed to assess whether each milestone has been reached?

Describe how you will measure success in terms as quantitative as possible. You should reference the timeline provided under section A.

D. Project Team

Provide a brief description of the roles and responsibilities of the principal investigator and of each collaborating researcher. Please also describe the history of prior collaborations by members of the project team.

E. Management Plan

Describe how you plan to manage the project, including the participation of all the collaborators.

- How will you interact with each of the other participants and collaborators, and manage and coordinate the role those participants will play in the project?
- How will decisions be made, both programmatic and financial?
- How will resources be allocated?
- How will information flow be handled?
- How will you assure that the project remains focused on its objectives

This section also should address plans for identifying additional collaborators or partners as needed for completion of the project. Plans should indicate willingness in the first year to come to the Washington, D.C. area for a meeting of all grantees (P.I. and up to three key investigators) with the Grand Challenges in Global Health Scientific Board. Subsequent years should include a budget for two trips per year, an all grantee meeting and another more focused meeting to be determined by the needs of the projects. For budget planning purposes, assume one meeting will be on the east coast and one meeting on the west coast of the U.S. Actual meeting locations will be selected depending on the grantees selected, and may include non- U.S. venues.

F. Project and Product Maturation Plans

If appropriate, please indicate what kinds and levels of activities and resources would be required to propel the project, if successfully executed as written, further toward application and adoption at the end of the proposed grant. Is your project likely to result in a product that should eventually be developed and marketed? Please describe your plans for disseminating any innovation, including plans for engaging commercial partners and support. Describe any previous experience of your team in translating discoveries to health applications and making them broadly available.

G. Literature Cited

(This section <u>does not count against the page limit</u> for the Detailed Technical Plan)

List any critical references to your work or the work of others that support your arguments. References must include the title, names of all authors, book or journal,

volume number, page numbers, and year of publication. References should be limited to relevant and current literature.

II. Organizational Capacity *(One page or less per organization)*

Provide a brief description of the sponsoring institution's history, mission, and any activities in this field of endeavor and in relevant developing countries, if applicable. Describe previous experience in developing, implementing, and managing programs/research in the geographical and technical areas proposed.

If a consortium is submitting the proposal, please provide the same information described above (one page or less) for each organization in the consortium, as applicable.

III. Key Considerations

A. Plan for Managing Intellectual Property (IP) *(Please be precise and concise)*

Protection of intellectual property, and how it is managed, can play a key role in making inventions accessible to the developing world. Please answer the questions below, and provide a concise narrative summary of IP plans.

1. Is the proposed research likely to lead to any patentable or commercially exploitable results?

   Yes _____ No _____

   If yes, describe plans for allocating rights and assuring they will be consistent with the charitable purposes of the project and goal to benefit those most in need in the developing world. Briefly describe the strategies that you are likely to use to meet this objective.

2. Is the proposed project, either at its inception or at a foreseeable future point, likely to encounter any obstacles to the availability of materials or methods due to IP restrictions, or will it depend on the use of technologies, materials or other inventions that may limit availability in the developing world due to cost or other considerations?

   Yes _____ No _____ If yes, please enumerate the details and describe how you plan to overcome such hurdles.

3. Is the proposed research, in whole or in part, subject to any prior agreements with commercial, academic, or other organization, including other funding entities?

   Yes _____ No _____

   If yes, please explain and discuss how potential hindrances to adoption in the developing world will be avoided.

The answers and summary narrative for IP plans must cover the sponsoring institution as well as any collaborating institutions. Include how you will decide whether discoveries require IP protection**.** It is required that IP be dealt with in a manner that makes the invention available as widely as possible and that maximizes the possibility of benefit to the developing world. Applicants are required to choose patenting and licensing strategies that will result in the greatest good to the developing world. This will be required of grant award contracts.

If there is any intellectual property associated with materials you plan to use in your research, describe how you will assure that this does not adversely affect the availability and patentability of your research inventions and results.

IMPORTANT: This section and plan must be reviewed, approved and signed by both the sponsoring institution's official authorized to make commitments on behalf of the institution, and the sponsoring institution's technology transfer officer. A letter on institutional letterhead attesting to this approval must be provided by mail or fax.

B. Data Sharing Plan *(Please be precise and concise)*

Describe how you plan to make the products of your research available to others, including publication and sharing of data and materials. These plans must be consistent with your plans for intellectual property described above. Publication should be in journals readily available to investigators in the developing world. Open access journals are encouraged.

It is expected that, where public databases are available, data will be deposited in them expeditiously, but in no case later then the date of publication. Similarly, materials generated under GCGH grants are expected to be deposited in public repositories, where available, no later than the time of publication. Data or materials, for which public repositories are not available, should be made available to other researchers to the extent possible. If there are any costs associated with sharing materials, details should be given in this section and the total cost included in the budget.

C. Discussion of Ethical, Social or Cultural Implications of Research *(Please be specific and concise)*

Some Grand Challenges specifically identify ethical, social or cultural issues that must be considered in the research design. However, there may be additional issues, relating to those or other challenges, depending on the particular research strategy chosen. For example, the proposed solution to the Grand Challenge must be culturally acceptable as well as economically implementable in the developing world. If behavioral changes would be required, how will they be brought about in view of the notorious difficulty of making such changes? If human subjects are involved, how will informed consent be obtained in a way that meets international standards without violating cultural norms? Discuss any such issues raised by the research you propose and indicate how they will be dealt with so that the results of the research can be readily implemented to benefit people in the developing world.

D. Research on Human Subjects *(Please be precise and concise)*

Does this project involve human subjects research? If yes, grantees must adhere to the official regulations for human subjects in their country. For U.S. grantees these are the U.S. Government standards, including HIPAA (privacy) provisions, if applicable. For research outside of the U.S. all relevant Federal standards must be met. In the case of multi-national collaborations, the standards of the most restrictive country must be observed, unless these are incompatible with the laws and regulations governing the primary grantee. Please indicate which standards will be adopted and the rationale for choosing them.

1. Human Consent Form: If available, send a copy of your informed consent form in English. A final approved form will be required before any human subjects research can proceed.

2. IRB (Institutional Review Board) approval: If available, send a copy of your IRB approval. IRB approval for human subjects at all sites will be verified at the time of award or before human subjects research is initiated. If plans for use of human subjects are going to be indefinite at the inception of the grant, indicate the likely venues where such studies are to be conducted and the standards to be applied.

3. Clinical trials: If your project is anticipated to encompass a clinical trial as a part of the grant at some point in a future year, please indicate the strategy and circumstances you intend to follow, including which regulatory authority(ies) would be involved. Note that in general only Phase I trials will be supported under this program.

E. Animal Research *(Please be precise and concise)*

Does this project involve research on vertebrate animals? Grantees using animals in their research must adhere to the official regulations for animal welfare in their country. For U.S. grantees these are the U. S. Government standards. In the case of multi-national collaborations, the standards of the most restrictive country must be observed, unless these

are incompatible with the laws and regulations governing the primary grantee. Please indicate which standards will be adopted and the rationale for choosing them.

1. Institutional Animal Care and Use Committee (IACUC) approval: If available, submit your IACUC approval. IACUC approval will need to be verified at the time of award or before animal research can be initiated.

F. Other Sensitive Research *(Please be precise and concise)*

Does your research involve other areas that are subject to regulation or involve risk? For example: hazardous materials, Select Agents as defined under U.S. law, recombinant DNA, release of modified insect vectors or genetically altered plants into the environment. If yes, describe how you will address the regulatory or other requirements, and on what timeframes required approvals/permits will be acquired.

IV. Facilities & Resources Statement

Describe the facilities, resources and equipment available for the proposed research at all participating sites, in sufficient detail to guarantee that the infrastructure is there to allow the research to be carried out. Indicate the performance sites and for each describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. The sponsoring institution must vouch that these facilities and resources will indeed be available to the project if awarded.

V. Budget

The budget component of the grant proposal includes a Budget Spreadsheet (to be attached separately) and a corresponding Budget Justification. Together, they clearly link the funding you have requested to the major activities described in your proposal.

A. Budget Spreadsheet (Attachment D)

The Budget Spreadsheet is driven by the major activities described in the Research Overview and Research Plan sections of the proposal and will include all costs associated with these activities by year and in U.S. dollars. Please download and use the linked Budget Spreadsheet and adjust the template to accommodate the duration, size and scope of your project. The *major activity* worksheets will auto-populate the Total Project Costs worksheet. Definitions for the categories and budget line items are provided in the Budget Justification section listed below.

B. Budget Justification

The Budget Justification should describe the cost assumptions for each category and line item in the Budget Spreadsheet. Please indicate how the amount was determined for each of the categories relevant to your major activities.

1. Personnel

List personnel costs, excluding fringe benefits, for each requested staff position. FTE (full-time equivalency or percentage of effort for the proposed project) should be indicated for each position. Individually list key personnel (i.e. principal investigator, program manager, and other project staff) and group together administrative staff. The Budget Justification should include all positions with their base annual salary. Note that, for applications that include government laboratories, no salary can be claimed for U. S. government employees.

2. Fringe Benefits

List benefit costs related to personnel involved with the project, including pension contributions and other benefits provided to the employees. Please group the positions in the same manner as in the Personnel section (V.B.1.). The Budget Justification should include the description and rate of benefits for each position.

3. Travel

Include transportation costs by project personnel directly related to the major activities, including fares for all modes of transportation, lodging, meals, automobile expenses, mileage reimbursement, and per diem payments. Per diems should not exceed the U.S. rates for domestic travel or the WHO/UN or U.S. Department of State rates for international travel for the location. Travel can be grouped according to trip(s) as long as all cost assumptions are detailed in the justification. Air travel reimbursements will be limited to economy class tickets.

Your budget estimate for the first year should include a line item for a three day trip to the Washington, D.C. area for a meeting of all grantees (P.I. and up to three collaborating researchers) with the Grand Challenges in Global Health Scientific Board. Subsequent years should include a budget for two trips per year. For budget planning purposes, assume one meeting will be on the east coast and one meeting on the west coast of the U.S.

4. Equipment

Use of any equipment purchased with grant funds is limited to charitable purposes for the depreciable life of the equipment. This includes computers, printers, faxes, telephones, and laboratory equipment, vehicles etc. purchased or leased for use in the project. Applicants from for-profit entities wanting equipment with a depreciable life longer than the requested project period should consider other sources of funding, or leasing rather than purchasing, if possible. The Budget Justification should include an itemized list of equipment to be purchased and cost and depreciation assumptions. Items that cannot be considered research equipment (i.e., vehicles) should be justified in relation to the activity proposed, and all operating costs must be identified. For equipment to be

shipped to developing countries, applicants should request waiver of import fees where possible.

5. Supplies

Medical & Laboratory Supplies
Laboratory supplies, vaccines, drugs, pharmaceutical supplies, etc. The Budget Justification should include an itemized list of supplies to be purchased and all cost assumptions.

Other Supplies
Other non-personnel, project-related costs such as office supplies, postage, software, meeting costs, etc. The Budget Justification should include an itemized list of supplies to be purchased, individual meeting costs, and all cost assumptions.

6. Contracted Services

Include all agreements to be made with other entities and negotiated for an agreed upon price and specific deliverables over a specified period in relation to the activities proposed. The Budget Justification should include descriptions of the work to be performed, rates, and confirmation as to whether the contract is confirmed or projected.

7. Sub-Grants to Other Organizations

Identify funds that will be used to make grants to other organizations in furtherance of the project. The Budget Justification should include descriptions of the work to be conducted by the sub-grants and names of organizations, if known.

8. Consultants

List amounts paid to individuals for specific services and based on an agreed amount or agreed per diem rate including travel and other related expenses. Include fees paid to outside attorneys, accountants, or auditors. The Budget Justification should include descriptions of the work to be performed, rates, and confirmation as to whether the contract is confirmed or projected.

9. Construction and Renovation

Construction costs will not be allowed. Construction is generally defined as alterations that become an integral part of a facility and cannot be taken with you if you move. However, limited essential renovation funds may be requested, such as new electrical wiring or plumbing to accommodate new equipment.

10. Indirect Costs

Indirect costs include administrative expenses that are related to overall operations and are shared among projects and/or functions as they provide indirect benefit to those specific projects and/or functions. An indirect cost rate of up to 15% of direct costs minus equipment may be added without further justification or itemization. The same indirect cost limits apply to subgrants and subcontracts. The sponsoring institution may claim for itself indirect costs of $5,000 or 1%, whichever is less, of the amount on any subcontracts or sub-grants. No indirect cost will be allowed on grants to any U. S. government laboratories. However, subcontracts or sub-grants from government laboratories to non-government laboratories can claim 15% indirect cost.

11. Support from Other Sources

Include the name of other donor organizations contributing to your proposed project (committed and/or potential) and the respective grant amounts. You may also include "in-kind" support to be provided by your organization. The Budget Justification should include an explanation of the support to be provided, the form it will take (cash or in-kind) and whether or not the support is committed or potential.

Attachment C
Principal Investigator and Collaborator Bios

Please provide all of the following background information starting with the Principal Investigator and then for each Collaborating Researcher (if applicable) in the following specific format. The content of the first five sections per individual will not exceed two pages.

- **Last Name:**
- **Project Role:** *(either Principal Investigator or Collaborating Researcher)*
- **Positions Held:**
  Start with the most recent position and provide information for the last ten years: including period of employment (dates), organization, position title, and a brief description of the position's responsibilities.
- **Education:**
  - Degree
  - Year of Degree
  - Discipline
  - Institution
- **Publications:**
  Identify the five most important and relevant peer-reviewed publications. Include full reference with titles, authors, and journal source for each.
  DO NOT SUBMIT COPIES OF PUBLICATIONS.
- **Other Support:** *(not page limited, be comprehensive, but concise):*
  List all active research support to your laboratory that exceeds U.S. $50,000 per year. Briefly describe the purpose of each grant or contract and indicate any overlap with the project as proposed. Provide the annual budget amount and the number of remaining funded years.

List of All GCGH Full Proposal Attachments

Attachment A – Research Overview

Attachment B – Research Plan

Attachment C – PI and Collaborator Bios

Attachment D - Budget Spreadsheet

Proposal Template

Research Overview (Attachment A)

I. Program Summary

II. Goals, Objective and Outcomes

III. Milestones and Decision Points

IV. Meeting the Grand Challenge

V. Innovation

Research Plan (Attachment B)

I. Detailed Technical Plan

A. Background

B. Preliminary Studies

C. Methods & Experimental Design

D. Project Team

E. Management Plan

F. Project and Product Maturation Plans

G. Literature Cited

II. Organizational Capacity

III. Key Considerations

A. Plan for Managing Intellectual Property (IP)

B. Data Sharing Plan

C. Discussion of Ethical, Social or Cultural Implications of Research

D. Research on Human Subjects
   1. Human Consent Form
   2. IRB (Institutional Review Board) approval
   3. Clinical Trials

E. Animal Research
   1. Institutional Animal Care and Use Committee approval

F. Other Sensitive Research

IV. Facilities & Resources Statement

V. Budget

A. Budget Spreadsheet (Attachment D)

B. Budget Justification
1. Personnel
2. Fringe Benefits
3. Travel
4. Equipment
5. Supplies
   - Medical & Laboratory Supplies
   - Other Supplies
6. Contracted Services
7. Sub-Grants to Other Organizations
8. Consultants
9. Construction and Renovation
10. Indirect Costs
11. Support from Other Sources

PI and Collaborator Bios (Attachment C)

Required Supporting Documents to Be Mailed Separately Within 30 Days of Application Submission

Copies of signed versions of all of the following documents on institution letterhead must be received via mail within 30 days of application submission.

NOTE: Application processing will not be completed until signed versions of all required documents have been received. (The Principal Investigator will be sent an e-mail confirming receipt of each document).

Required Enclosures

Enclosure 1 – Approval of Sponsoring Institution's Responsible Official
A letter signed by both the Sponsoring Institution's Responsible Official and the Principal Investigator that states the following:

As the Sponsoring Institution's Responsible Official I have been provided with and have reviewed the Grand Challenges in Global Health application guidelines and the complete final submitted proposal of Request ID # ----------, Title:---------- PI: ----------.

This proposal is approved for submission by ----------(*name of institution*), which agrees to provide all of the resources and staff time specified in the proposal and to oversee the project to assure that all legal and contractual requirements are met.

Sponsoring Institution's Responsible Official Signature
Name
Title
E-mail address
Phone number

Principal Investigator's Signature
Name
Title

Enclosure 2 - Approval of Plan for Managing Intellectual Property (IP)
A letter signed by the Sponsoring Institution's technology transfer officer stating that they have reviewed and approved the Plan for Managing Intellectual Property (IP) as described in the proposal section III. A.

Enclosure 3 - Letters of Collaboration (only required for collaborations)
A signed letter of collaboration must be provided for each collaborating institution or individual . Each letter must specifically include the collaborator's role, contribution and anticipated level of effort.
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For commercial collaborators letters must be counter-signed by a corporate officer stating that the proposed collaboration has been approved within the company.

Optional Enclosures

Please submit the following enclosures if they are available at this time. All will be required prior to award.

Enclosure 4 - Human Consent Form *(If available at this time)*
The Sponsoring institution's consent form in English.

Enclosure 5 - Institutional Review Board (IRB) Approval *(If available at this time)*
The Sponsoring institution's IRB approval of the use of human subjects.

Enclosure 6 - Institutional Animal Care and Use Committee (IACUC) approval *(If available at this time)*

Please mail all supporting documents using this address and label format:

Grand Challenges in Global Health
Application Documents
Foundation for the National Institutes of Health
Natcher Building
45 Center Dr., Rm.3AN-44
Bethesda, MD 20892-6300

Request ID XXXX ß *Your proposal Request ID as shown on your full proposal invitation letter*

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THIS WILL HELP WHEN WE SCAN THESE DOCUMENTS

Please be sure to include all of the following information on an inside cover sheet:

- Sponsoring Institution Name
- Principal Investigator
- Grand Challenge Number
- Request ID Number

GCGH Full Proposal Review Criteria

The following criteria will be used in evaluating the application.

1. Likelihood of solving the Grand Challenge, including potential for implementation in the developing world.

Does this research have the potential to develop a scientific or technical breakthrough that can overcome one or more 'bottlenecks' in the path towards a solution of this Grand Challenge? Have the applicants correctly identified the most important problems and critical barriers? Have they proposed relevant scientific or technical approaches to remove the bottlenecks? Is there a well-reasoned critical path to the proposed solution? How much of the problem stated in the grand challenge would this proposal solve?

Does the proposed approach contain novel concepts, novel integration of existing approaches, or novel implementation strategies that are likely to result in a clear improvement over what is currently known/available/being done? Is the proposed solution likely to be implementable in the developing world? Will it have a significant impact beyond the immediate question being asked if successful? Will it provide a durable solution? Do the applicants have a vision of how the work they propose is on a critical path to implementation of a solution of the health problem being addressed?

2. Technical approach, including appropriateness of the timetable and milestones.

Is the technical approach based on sound scientific reasoning? Does it take into account the current state of the art? Does it promise a significant step forward in our understanding? Is the research appropriately designed to meet the overall goals? Are the objectives and major activities correctly selected? Are the timetable and milestones appropriate and realistic and will they provide a useful basis for the management of this project? Is the scope and scale realistic and achievable?

3. Qualifications of the investigators, including appropriateness of collaborative efforts and availability of space and resources at the sponsoring institution and other performance sites.

Are the Lead Investigator and collaborators appropriately trained and experienced to direct and conduct this research? Is there appropriate representation from all the expertise areas needed for successful conduct of the study? Are the investigators knowledgeable about the settings in which the solution would be implemented? Is the applicant organization able to take responsibility for this work? Do the applicant organization and the collaborating sites have the space and resources necessary to carry out this project? If applicable, have consultants and collaborators appropriate to assure success of this work been identified? Does the project include appropriate collaboration with scientists from developing countries that are confronted with the health problems that are being addressed?

4. Appropriateness of the plan for financial and programmatic management.

Are the plans for managing the scientific and financial aspects of the project adequate? Will the communications strategies assure that all collaborators are working in concert? Is the decision making process going to serve the nature of the project and will it assure that resources are allocated wisely and efficiently? Does the PI have the necessary authority to lead the project? Do the investigators indicate willingness to engage in collaborative activities with others as the opportunity or need arises?

5. Technology maturation plans.

Do the investigators have an appropriate vision for how their discoveries can lead to practical applications in the developing world? If the project is likely to develop a product that could be developed and marketed by the end of the project period, have the investigators made adequate plans for how this might be brought about? Have the investigators correctly considered plans for dissemination of any innovation?

The following aspects will be evaluated and recommendations made, but not scored. These topics will be the subject of negotiations and verification. No award will be made unless a satisfactory agreement is reached, regardless of the merit of the proposal.

A. IP plan

Does the IP plan serve the objectives of GCGH?

B. Sharing plan

Does the sharing plan adequately serve the objectives of GCGH?

C. Ethics plan

Have the applicants adequately addressed any ethical concerns raised by their research or by the potential application of the results?

D. Human subjects/ animal research/ other sensitive research

Are human subjects and animals used in the research adequately protected? Are other potentially hazardous aspects of the research addressed correctly?

E. Appropriateness of the budget and cost/benefit ratio.

Is the budget realistic for what is proposed? Is the project duration reasonable? Is the potential impact worth the investment? Are there any budget items that should be adjusted up or down? Is the distribution of resources among collaborators appropriate?

Glossary of Terms

Activities: Processes necessary to achieve the objectives and ultimately meet the goal of the project. Each major activity should be linked to the budget worksheet.

Baseline: The numerical/scientific/technical starting points in terms of relevant knowledge and state of the work at the inception of the project.

Indicators: the specific milestones and ways (quantity, quality, timeliness, technical achievement or performance characteristics etc.) that you will measure and interpret results to determine if progress is being made.

Milestones: Defined points of measurable achievement and progress on a critical path which must be successfully met before proceeding further with the project.

Objectives: The desired project end points that contribute to achieving the stated goal. Objectives should be specific, measurable, achievable, relevant, and time-based.

Outcomes: The expected specific project impact in terms of changes and results. What will change, by how much, in what time frame? Intermediate outcomes are the results of meeting the project objectives; long term outcomes are the significant changes that the project ultimately hopes to accomplish (i.e., health impact).

Outputs: Tangible results from the linked activities, such as the actual work or experiments, subjects tested, technical capabilities, etc. achieved, to reach specific milestones.

Target: The date by which you expect to accomplish your objective(s), along with quantitative and qualitative measures that the project is aiming to achieve. Intermediate targets may be used for reporting annual milestones. For example, in a clinical trial, important dates might be final protocol approval, opening of accrual, completion of accrual, analysis of data, etc. In basic research or technical development projects, measurements might be expressed as rates or numbers (such as progress toward meeting specific technical performance characteristics, acquisition of compounds, sequences, antigens; submission of a patent; obtaining a specific set of replicate results, etc).

Ver. 5/12/04