

## **Frequently Asked Questions**

As of May 28, 2004

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### **Submission Due Dates**

#### When is the full application due?

Full applications including all required proposal attachments must be submitted online on the following revised schedule. This will enable a higher level of support during the final days of submission. We have staggered the deadline across several days based on the order in which applicants were sent reviewer feedback.

Monday, June 7 - 5pm USA EDT	GC 13, 14
Tuesday, June 8 – 12noon USA EDT	GC 1, 2, 3
Tuesday, June 8 - 5pm USA EDT	GC 7, 8, 9
Wednesday, June 9 - 12noon USA EDT	GC 4, 5, 6
Thursday, June 10 - 12noon USA EDT	GC 11, 12
Thursday, June 10 - 5pm USA EDT	GC 10

NOTE: USA EDT time is the same as Washington, DC time

#### When are all of the additional required supporting documents due?

Signed versions of the required supporting documents on institutional letterhead must be sent separately by mail and received by FNIH no later than July 7, 2004. All of these supporting documents must be:

- § Sent in a <u>single envelope</u> using the address label format shown on the full application instructions
- § <u>Unstapled</u> to facilitate our scanning

### Principal Investigator and Collaborators

Should we list a single principal investigator, or as long as there is a single sponsoring institution are we able to list multiple PIs within the consortium? FNIH requires that a single principal investigator is appointed who will have overall responsibility for the grant and will be the principal point of contact for the project team with FNIH. Having a single point of contact promotes consistency in communications and project management.

# Will proposals with collaborators from developing countries have an advantage in terms of the chances of the proposal being funded?

We encourage collaborations that will enhance the research or that are essential for project success. However, there is no absolute requirement for collaborations with investigators from developing countries. Proposals will be reviewed using the criteria described in the full application.

Since our project involves five investigators and three institutions, should we structure our application as a program project (effectively five different projects) or as a single project with four sub-contractors or co-investigators?

Your application should be structured as a single integrated project. The project may have a number of related objectives within an overall goal, and should have a timeline and milestones. Instructions for this are included in the Full Application Instructions available at: http://www.gcgh.org/subcontent.aspx?SecID=363

# Could you clarify when a letter from a collaborator and/or a collaborating institution is needed?

There should be a letter of collaboration from every collaborating investigator who is not part of the PIs group, as well as from every consultant. If the collaborator is at a different institution from the PI, and if the collaboration will involve substantial commitment of resources and facilities from the collaborating institution (for example space or equipment), then the collaborating institution should countersign the letter of collaboration to indicate they will make the resources available and are prepared to manage any subgrant that may be awarded to them.

### Attachment C – PI and Collaborator Bios

For the PI and collaborator bios, how much detail should be provided about the "other support"?

Provide the purpose or title of the grant, the agency that awarded the grant, the amount awarded and the number of years of funding remaining.

What is the definition of a collaborator with respect to the need for bios? You should provide a bio for all key individuals who are making significant intellectual contributions to the project.

Should I list just my 5 most important and relevant publications in my bio, or should I list all publications and highlight the 5 most important?

You should list ONLY the 5 most relevant publications.

### Changes from the LOI

May we make slight changes to the project title of the full grant application (without changing the basic concept), or should we use the same title that was used in the LOI?

It is important to keep the titles the same for proposal tracking purposes. However, if the LOI title no longer reflects the project, then please contact us and we will make the necessary change in the database.

# We want to propose a different principal investigator for the full application. Is this possible?

Yes, this is possible, but requires our prior approval. We have to make some changes in our proposal tracking and online application system to allow the new PI to submit. Your current PI must send a written request to FNIH (via email) to make this change.

# I have identified excellent additional scientists to join our consortium of collaborators but didn't list them as collaborators in the LOI. Will there be a problem if I add new collaborators?

This is not a problem. We encourage you to assemble the best possible team. You may add or subtract collaborators as needed.

#### Can I make changes to the total budget amount proposed in my LOI?

Yes, you may change your budget from what was proposed in the LOI. We recognize that in the course of six months your plans will have evolved.

# How much can we change the scope of the project from what we originally proposed in the LOI?

Your full application must represent the same topic and the same goal as described in your LOI. However, it is expected that your ideas will have evolved in the six months since you submitted the LOI. Your scope may have broadened or contracted, you may have added or subtracted collaborators and the budget requirements may have changed. These kinds of modifications are acceptable.

### **Submitting the Online Application**

Where can I find the latest version of the full grant application instructions and the budget spreadsheet template?

These are available at: http://www.gcgh.org/subcontent.aspx?SecID=363

What is the Web link (URL) for the full application page? https://www.grantreguest.com/SID 373

#### How do I send someone the URL to the full application page?

Send the Web link (URL): https://www.grantrequest.com/SID 373

Do not copy and paste the URL from the Web page itself since that URL is different and will not work.

#### Which Web browsers are supported?

- § Netscape 7.02
- § Opera 7.11
- **§** Safari 1.0 (v85)
- § IE 5.5 (Mac and PC)
- **§** IE 6.0 (PC)

#### Are there any special browser configuration issues I need to be aware of?

Aside from using one of the browsers listed above, you must make sure your browser is configured to support cookies. Also be sure to close all browsers before viewing the grant application form. Otherwise, your browser may display a locally stored older copy of the application you were viewing previously.

#### Can I save my work and complete the application later?

Yes, you can use the [Save and Finish Later] button at the bottom of each page of the online application. When you return, go to the "Open" section of the Homepage and select the link to the proposal you were working on.

# How can I make a copy of the application before it is submitted? This will be important for the purpose of review and approval.

Before submitting your final application you can view and print it by selecting the <u>Printer Friendly Version</u> option on the top right of any screen. This will enable you to review and print your work in progress.

#### I get the following message when I click on the URL:

Your browser is not configured to support cookies. In order to access this online application form, you must adjust your browser settings to allow cookies.

This message would be generated under two conditions.

<u>Incorrect URL</u>: If you simply copy and paste the URL from the form to another browser window (or if someone sends you a link that was copied from the form) you will get this error. Please use the following URL instead: <a href="https://www.grantrequest.com/SID">https://www.grantrequest.com/SID</a> 373

<u>Browser Configuration</u>: This can be fixed by configuring your browser to support cookies.

In Internet Explorer v6.0 this setting is found on the Tools à Internet Options à Privacy à Advanced. You can then change the option to support cookies.

In Netscape Navigator v7.0 this setting is found at Edit à Preferences à Privacy & Security à Cookies à Enable Cookies

#### Can I open and edit more than one application at a time?

No, you must save and exit your browser before opening another application. Otherwise, your browser may display information from the application you were previously viewing and you may end up saving the information in the wrong application.

Is there a way to change the name of the online grant application form as it appears on the online application homepage?

No, this is not possible at this time.

How can I view a copy of the LOI that we submitted back in January?

Go to <a href="https://www.grantrequest.com/SID\_373">https://www.grantrequest.com/SID\_373</a> and log in. Then go to the submitted application section at the bottom of the page and click on <a href="https://www.grantrequest.com/SID\_373">Letter of Intent - Grand Challenges in Global Health</a>.

I get the following message when I click on a link to my application from the home page:

The application form that you began is no longer being accepted. You may begin a new form. We apologize for the inconvenience.

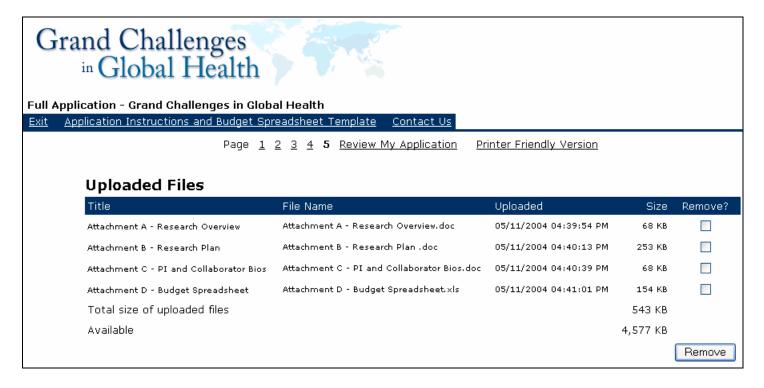
Please contact us at <a href="mailto:grandchallengesgh.org">grandchallengesgh.org</a> or call us at either 301-402-4976 or 301-402-4968.

#### How long will it take to upload my application attachments?

This time will vary depending upon the speed of your Internet connection, the size of the uploaded file, and the number of other researchers uploading files at the same time. If you're using a high-speed connection then it may take up to 3-4 minutes. If you're using a dial-up connection it could take much longer. You can see if the file is uploading by watching the upload meter at the bottom right corner of your browser screen. Please do not use your computer until after the file uploads completely.

#### What should the file upload box look like after all attachments are uploaded?

After you have uploaded all required proposal attachments A-D, the Uploaded Files box at the top of the online application Page 5 should look just like the image below. Please note that the file Title and the File Names are the same.



#### How will I know if my final online submission was received?

You will see an onscreen message describing that your submission was received right after you click on the [Submit] button. You will also receive an e-mail acknowledgement with a copy of the information that was entered online. If you submit your application on June 7, 2004 (the final submission deadline) it may take several minutes for you to submit your application and all attachments.

### NEW! Can I include figures or other material as additional attachments?

No, only the 4 required attachments will be visible to reviewers. All figures must be included within these 4 required attachments.

### **Objectives, Activities and Milestones**

I have a management core and/or a facilities core. Should I describe these as separate activities in the budget?

Yes, by all means make these components of your project a separate activity. Indicate how these activities intersect with the other parts of your application.

# Can you please provide some examples to show how I should fill out the Objectives and Activities table?

We've developed and posted examples of two completed Objectives and Activities tables on the GCGH Web site at <a href="http://www.gcgh.org/subcontent.aspx?SecID=363">http://www.gcgh.org/subcontent.aspx?SecID=363</a>
These are hypothetical examples that illustrate the general approach to completing this table. Please note that these should not be interpreted as literal examples.

What is the difference between objectives/outcomes, activities/outputs, and milestones/deliverables in sections II-III of Attachment A. Do these subheadings represent a hierarchy, or are they different groupings of the various tasks described in the grant? Is there perhaps an example to follow?

Objectives/outcomes, activities/outputs, and milestones/deliverables are all related and represent different ways of describing your plans.

Objectives/outcomes are the key aims in your proposal, or the sub goals under your overall goal. For example, a proposal may have one goal: making an HIV vaccine. Within that you may have several objectives: creating the vaccine, studying immunogenicity, conducting phase I trials, conducting phase II trials etc. Each objective should have an end point or outcome and this should be tied to your timetable and milestones.

Activities/outputs are the various separate steps under your objectives. For example creating the vaccine may require several steps: isolating the antigen, adding various parameters, assessing purity, etc.

Milestones/deliverables relate to your timetable and indicate when certain parts of the research will be completed. The deliverable may be an experimental results or an actual product.

Also please see the Glossary of Terms on the last page of the Full Application Instructions for definitions of these terms.

### **Tables**

Do I need to use 12 point Times Roman font for tables such as the Objectives and Activities tables?

No, you can use smaller Times Roman font so long as it is easily legible.

My Objectives and Activities tables are going to be longer than 2 pages. Can I exceed the limit?

Yes, the 2 pages are a suggested limit and you can use more pages if needed. You are free to reformat the table to make it more compact, so long as it remains readily legible.

### Intellectual Property

# What model does FNIH prefer for handling intellectual property that may arise from GCGH grants?

FNIH will not hold patents or licenses on any inventions produced by GCGH grants. FNIH also does not have a preferred model for handling inventions. Each situation should be evaluated on its own terms and the best course of action chosen to meet the overall objectives of GCGH, which are to benefit the developing world. FNIH will ask grantees to report any inventions and will work with grantees to arrive at the best course of action.

# In the IP management plan (Key Considerations - Section III. A.) of the proposal, is a formal agreement signed by all parties to the application required, or simply the outline of a plan that is agreed to by all parties?

A formal signed agreement is not required at the time of application but may be required before an award is made. The applicant institution should submit a description of the plan that has been agreed to by all participants.

# How does the FNIH IP policy differ from the standard practice of universities under Bayh-Dole?

FNIH expects the grantee organization (and/or collaborating institutions as appropriate) to be the holder of any patents, as it is under Bayh-Dole. However, we also expect that patenting and licensing will be managed in such a way that the benefits of the invention will accrue to the developing world. How this is achieved will depend on the invention. It is the responsibility of the sponsoring institution, i.e. the PI institution, to negotiate an appropriate understanding with the subgrantee institutions.

If a grant is made, the sponsoring institution will be responsible for overseeing IP issues. Grantees will be required to report any inventions under GCGH grants to the FNIH, which in turn will assist grantees in developing a mutually acceptable plan for the invention.

### **Clinical Trials**

# My project calls for phase I clinical trials in the third year. Do I have to have all my paperwork for the trials completed at the time of application?

No, it is not necessary to have all the paperwork, such as consent forms and IRB approvals, completed at the time of application if your human subjects research does not begin until later in the grant. However, you should describe your plans in as much detail as you know at the time of application. No research involving human subjects will be allowed until all approvals have been obtained.

We are proposing a project that includes an initial animal test phase followed by human trials. However, the human trials would depend on the results from the animal tests. Should we provide a comprehensive plan that includes the human trials which are contingent on earlier success in the animal test?

Include a description of your plans for the human studies, but make clear that they are contingent on successful completion of the animal studies. Make sure your milestones and budget also reflect this.

For animal and human studies, will we need to have obtained IRB approvals before submitting our proposal or can those be obtained at a later date (before funding starts)?

For animal and human studies the final approvals can be submitted at a later date if they are not yet available at the time you submit your application. However, please submit any approvals that you have in hand with the application.

### **Co-Funding or Complementary Funding**

I have funding from another organization that is complementary to the funding from GCGH that I am applying for. Is this permissible?

Yes, complementary funding is allowed. However, you will have to explain clearly how the activities funded by the other organization differ from those you are applying for from the GCGH.

Is there an expectation of co-funding from the applicant organization?

No, there is no expectation for co-funding. However, the limitation on indirect costs may in effect result in some contribution from the applicant organization.

### **Subgrants from Federal Agencies**

The applicant organization is a federal agency. We have several collaborators who are not in federal laboratories. What is the best way to make sub-grants to them? Will FNIH make separate awards for the collaborators?

No, FNIH will not make separate awards. You will need to work with your agency to develop a mechanism for transferring funds to your collaborators.

### **Planning Grants**

Is funding available to support the cost of the proposal development? No, funds are not available from FNIH for this purpose.

### **Budget**

Are we required to use the GCGH Budget Template or can we use our own format?

You must use the GCGH Budget template. No other format will be accepted.

# Where should I put the budget justification? Should it be inserted into the fields in the spreadsheet?

No. Please submit your budget justification as part of Attachment B – Research Plan.

# The budget spreadsheet has just one line for sub-grant budgets. Isn't detail required for these budgets?

Yes, detail is definitely required and should be included in the budget justification. You should indicate how much is for salary, supplies, equipment, etc. as part of the justification. An optional tab has been added to the budget spreadsheet for use with subgrant budgets.

Does FNIH use the same cost principles for determining indirect cost as NIH? No, FNIH does not use federal cost principles. For the purposes of GCGH, any allowable cost that can be attributed to a project can be claimed as a direct cost. Costs that cannot be attributed to a project are indirect costs and these are limited to 15%.

My organizations' indirect cost rate far exceeds 15%. Is this rate negotiable? No, the rate is not negotiable. However, you are not obliged to use the federal cost principles when deciding what costs are appropriate to charge as direct vs. indirect costs. You may charge as direct costs any cost that can be directly attributed to your project. This may include a number of costs that would not be allowed as direct costs when applying for an NIH grant, for example office support.

# Would you please clarify the PI's limit of \$5,000 or 1% of indirect costs per subgrant?

The amounts for each subgrant are for the entire period of the grant. That is, \$5,000 or 1%, whichever is less, per subgrant.

# We have a number of subgrants and are not sure how to calculate the indirect costs for the sponsoring institution and the subgrants.

The sponsoring institution can claim indirect costs at 15% of its direct costs, minus equipment, subgrants and subcontracts. In addition, for each subgrant or subcontract, the sponsoring institution can claim an indirect cost of \$5,000 or one percent of the total cost of the subgrant or subcontract over all years of the project, whichever is less.

Subgrantees or subcontractors can claim indirect costs at 15% of their direct cost (minus equipment and subcontracts, if any).

For contracts with service providers, the full cost may be claimed as a direct cost without further breakdown. However, the budget justification should explain how the amount was arrived at.

Salaries and fringe benefits are treated differently in my company from the way they are in academia. For example, individual salaries are not itemized but are grouped by category of employee. Fringe benefits also include items not included in academia, such as vacation pay, burden, etc. How should I fill in the budget pages?

Fill in the budget pages using the closest relevant figures your company can supply and explain in the budget justification exactly how these figures were arrived at. The reviewers and FNIH staff need to be able to understand how you arrive at your amounts.

# What will be the disbursement schedule of funds to grant recipients? How shall we prepare our budgets, i.e., semi-annually, annually, achievement of outcomes/objectives?

To prepare your budget, you must use the spreadsheet that has been provided to you. This spreadsheet asks for your budget by activity and year. Awards will likely be made in annual increments or by milestones, depending on the project.

#### How should budget line items be entered?

The budget worksheet has been designed using Excel's outline feature to make it easy to enter budget line items. Click on the plus sign • at the far left so that the worksheet will expand and reveal the hidden rows. You can now enter budget line items. See the Equipment example below.

+	63		
	64	Equipment	18,000.00
	65	Item/ Qty	
	66		
Г٠	67	Microscope	10,000.00
•	68	Centrifuge	8,000.00
l ·	69		
l ·	70		
•	71		
•	72		
•	73		
l ·	74		
l ·	75		
•	76		
•	77		
•	78		
	79		
1	80		
_	81		
	82	Supplies - Medical and Laboratory	0.00
	83	Item/ Qty	
	84		
+	100		

In the budget, can I group supplies into categories such as tissue culture supplies, glassware, growth media, etc. similar to what is done in NIH grant applications?

Yes, it is appropriate to group your supplies in this way. If there are any unusually expensive items, such as a particular chemical, please list them separately.

My project includes a number of items that are program wide activities, such as administrative activities, including costs of relevant personnel and shared resources. Can I create a special activity for these for budget purposes? Yes, it would be appropriate to create a "core" activity for such program wide items.

For purposes of calculating indirect cost, what is the definition of equipment vs. supplies? Is there a dollar cut-off that differentiates between them?

You can consider items below US \$5,000 to be supplies, and items over US \$5,000 to be equipment for purposes of indirect cost calculation.

Where in the spreadsheet should I enter costs such as patient care costs that are not included in the current headings?

You can add additional categories to the spreadsheet as needed, by adding lines and headings.

I have more than five major activities. Can I add additional activity sheets to the budget spreadsheet?

Yes, you can add as many additional activity sheets as you need. Note that all the formulas on the "Total Budget" page will have to be modified to accommodate the new sheets.

How do the "Major Activities" in the budget spreadsheet relate to the Activities in the Objectives and Activities tables?

The major activities in the budget spreadsheet will generally correspond to your objectives. However, if any of the activities under your objectives are substantial in terms of budget, you can break them out in a separate sheet to make clear the costs involved. The budget breakdown should be guided by the nature of your project.

However you break down the budget, be sure to make clear how the major activities in the budget relate to the objectives/ activities and milestones.

I will be contracting with a provider organization to conduct IND-enabling preclinical studies. These providers are not willing to do the work with a 15% indirect cost cap. Can an exception be made for this situation?

This is a special situation. You can consider the total cost of this service as a direct cost to your grant and enter it in the contract line. Explain in the budget justification how the cost is arrived at.

### **Funding**

When will a decision be made about the funding of my proposal? We anticipate a decision will be made in December 2004.

When is the earliest possible starting date if my GCGH proposal is funded? We anticipate making the first awards at the beginning of 2005.

### **Resubmission of Applications**

If my application is not funded, will there be an opportunity to resubmit? There are no plans for another solicitation at this time.

### **Follow-up Questions**

How can I contact FNIH Grand Challenges in Global Health staff if we have more questions?

Please contact us at grants@grandchallengesgh.org or call us at 301-402-4968.

#### What number do I use to reference my grant application?

Please be sure to use the Request ID number as shown on the first page of the full application invitation letter that we sent to you on March 11, 2004.