

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH) (<http://www.nih.gov/>)

National Science Foundation (NSF) (<http://www.nsf.gov/>)

Department of Energy (DOE) (<http://www.energy.gov/>)

Components of Participating Organizations

Fogarty International Center (FIC/NIH) (<http://www.fic.nih.gov/>)

National Institute of General Medical Sciences (NIGMS/NIH) (<http://www.nigms.nih.gov/>)

National Center for Complementary and Alternative Medicine (NCCAM/NIH) (<http://nccam.nih.gov/>)

Office of Dietary Supplements (ODS/NIH) (<http://dietary-supplements.info.nih.gov/>)

Directorate of Biosciences, National Science Foundation (<http://www.nsf.gov/dir/index.jsp?org=BIO>)

Office of Biological and Environmental Research, Department of Energy (<http://www.science.doe.gov/ober>)

Title: International Cooperative Biodiversity Groups (ICBG)[U01]

Announcement Type

This is a reissue of [RFA-TW-08-003](#).

Request For Applications (RFA) Number: RFA-TW-08-010

Catalog of Federal Domestic Assistance Number(s)

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Key Dates

Release Date: September 9, 2008

Letters of Intent Receipt Date: October 21, 2008

Application Receipt Date: November 20, 2008

Peer Review Date: March 2009

Council Review Date: May 2009

Earliest Anticipated Start Date: September, 2009

Additional Information To Be Available Date (Url Activation Date): N/A

Expiration Date: November 21, 2008

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The National Institutes of Health, the National Science Foundation, and the U.S. Department of Energy invite applications for the establishment or continuation of "International Cooperative Biodiversity Groups" (ICBG) to address the interdependence of biodiversity exploration for potential applications in health and energy, with investments in research capacity that support sustainable use of these resources, the knowledge to conserve them, and equitable partnership frameworks among research and development organizations in the U.S. and low and middle income countries.

- This FOA is operating under a pilot initiative for shorter applications than the regular NIH page allowances. See [Section IV.1](#) for application materials and details.
- **Mechanism of Support.** This FOA will utilize the U01 grant mechanism.
- **Funds Available and Anticipated Number of Awards.** We anticipate making 2-3 new and/or competing continuation grants. All NIH awards will be cooperative agreements using the U01 mechanism.
- **Budget and Project Period.** The Government is budgeting approximately \$2.5 million in FY 09 for the initial awards. An applicant may request a project period of up to five years and a budget for direct costs up to \$600,000 per year.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of Applications.** Only one application from any single institution will be reviewed. However, a single institution may submit an application as the lead institution and be a subcontractor (Associate Program) on another.
- **Resubmissions. Resubmissions are not permitted.** You may submit a new application from a previous ICBG competition provided it is responsive to the current FOA.
- **Renewals.** Renewal applications are permitted in response to this FOA.
- **Special Date(s).** This FOA uses non-standard due dates. See [Receipt, Review and Anticipated Start Dates](#)
- **Application Materials.** See [Section IV.1](#) for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-0088.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The National Institutes of Health, the National Science Foundation, and the U.S. Department of Energy (hereafter "the Government" or "the Participating Agencies") invite applications for the establishment or continuation of "International Cooperative Biodiversity Groups" to address the interdependence of biodiversity exploration for potential applications in health and energy, with investments in research capacity that support sustainable use of these resources, the knowledge to conserve them and equitable partnership frameworks among research and development organizations in the U.S. and low and middle income countries.

This competition of the International Cooperative Biodiversity Groups (ICBG) program, continues several new emphases that began with the previous RFA (TW-08-003), including an emphasis on microbial and marine organisms, some changes in target health areas, greater involvement of funded consortia with government contract resources, greater use of molecular and genomic tools, and the opportunity to integrate energy- related discovery research into projects.

Research and training focused on plant biodiversity continues to be of interest, especially that which may inform us regarding composition, safety and efficacy of botanicals that may be used or marketed as dietary supplements, or novel scientific

analyses of plants used traditionally as medicines. Information on the history of the ICBG program and previous competitions may be found at the following URL: http://www.fic.nih.gov/programs/research_grants/icbg/index.htm and <http://www.icbg.org/index.php>.

1. Pertinent background that establishes the need for this research

We are dependent on biological diversity for therapeutics, biotechnological tools, and new energy-relevant enzymes. Products originally identified from plants, animals and microorganisms are the basis for approximately 45% of the new chemical entities approved as drugs over the past 25 years. Continued increases in consumer use of unregulated botanical therapies in the U.S., often based on traditional uses from other countries, further elevates our need to understand health applications of biodiversity. Finally, we confront possibly dire consequences of global warming exacerbated by combustion of fossil fuels, and new biologically-based technologies are needed to develop alternative fuel sources and assimilate atmospheric CO₂.

However, advances in these areas are constrained, in part, by our reliance on less than 1% of the estimated 8-10 million species on the planet. Most of the structurally and pharmacologically diverse molecules we have developed are derived from compounds isolated from a few hundred species of plants and animals and microorganisms. Systematic and phylogenetic studies suggest that while there is a great deal of redundancy in nature, there is likely an enormous undescribed set of biologically active molecules awaiting discovery in both known and as yet undescribed taxa.

In the past 10 years, there have been many advances in the tools available to explore the planet's extraordinary biological diversity, particularly that of the microbial world. In parallel, we have made significant advances in the assay systems available to detect and characterize potentially useful biological activity, as well as in our technical ability to employ these molecules and biological processes to support health, agriculture and energy priority needs.

Ironically, we are today participating in one of the greatest mass extinction events the planet has undergone. The International Union for the Conservation of Nature estimates that approximately one quarter of the world's vertebrate species, half of the invertebrates, three quarters of the plants and an unknown but potentially very large portion of the world's microorganisms are threatened with extinction. As a result of this trend, the biological base for an extraordinary wealth of health, energy and agricultural innovations is disappearing.

The underlying causes of biodiversity loss are many and involve interwoven social, economic, technological and political elements. In developing countries struggling to meet the most basic human needs, efforts to protect biological diversity will be most successful where we can enhance our ability to use it sustainably. This includes both identifying new uses of diverse organisms and developing the local scientific capacity to study and take advantage of this diversity. Such investments provide both a practical and principled partnership framework to guide scientific research and will yield benefits to the global health, agriculture and energy communities as well as to local and national partners in collaborating countries.

At the nexus of these opportunities and threats there are urgent and simultaneous needs to explore and conserve the planet's biological and biochemical resources. The International Cooperative Biodiversity Groups program is an approach to these needs in an integrated model of collaborative international research and training.

2. Objectives of this research program

Each ICBG must develop a program to advance an integrated transdisciplinary scientific program that begins with exploration and characterization of biological diversity to:

2a) Discover and promote development of plants, animals, and micro-organisms and their molecular constituents toward human health therapeutic agents. While not required, an ICBG project may also incorporate microbial research toward energy applications;

Human health agents: Each ICBG will seek to discover potential therapeutic agents in: 1) disease areas of relevance to U.S.

populations, and 2) disease areas of particular relevance to the host country of the proposed ICBG partnership. In regard to the latter, you may wish to review the current and projected global burden of diseases described under the Disease Control Priorities Project (<http://www.dcp2.org/main/Home.html>). Research and training on HIV/AIDS therapeutics is of particular interest. Parasitic diseases, cardiovascular diseases, mental disorders, obesity and diabetes are also high priorities because of their growing health burden and our inadequate therapeutic and prevention options.

Therapeutic research objectives will be mainly oriented to the discovery and development of bioactive small molecules and peptides, but state of the art analysis of botanicals, including ethnomedically-indicated botanicals and botanical drugs of public health significance, is a welcome component of an integrated program.

Proposed bioassays and lead development strategies should have demonstrated disease relevance and include state of the art molecular, genetic, and biochemical approaches, as well as technologies appropriate to host country institutions. Investigators are encouraged to utilize a diversity of biological screens that provide information beyond basic toxicity to mammalian and microbial cells.

Groups are also invited to develop potential organisms or agents in support of biobased energy and climate goals of the DOE, as one component of an integrated research effort.

Energy/Climate goals: Novel microorganisms with potential to degrade cellulosic materials, assimilate CO₂ or generate biofuels are of great interest. In this regard, microorganisms from environments with high carbon turnover or capacities to degrade cellulose, hemicellulose or lignins, such as may occur in tropical forest soils and on sea floors, are of particular interest. DNA sequencing carried out on isolated microbes or microbial communities is expected to be a significant component of this research and resources to support this activity through the DOE Joint Genome Institute are described below under Cooperative Agreement Terms and Conditions of Award.

The search and collection of source organisms and materials should be guided by an explicit and formal analytical or theoretical framework based on phylogenetic, ecological and/or ethnomedical principles that maximize the potential for discovery of diverse and potentially useful organisms and/or molecular constituents. Further, the approach should provide a basis for post hoc review of the method's productivity in this regard. Applicants should provide a strong rationale for sample collections strategies, whether they are compound libraries or crude plants, animals, or micro-organisms.

Focal organisms for exploration:

Microbial organisms (inclusive of prokaryotes, virus, fungi, algae and protists) from terrestrial or marine sources as well as marine invertebrates are of greatest interest to the participating agencies in this competition for pharmaceutical and for bioinventory research. Terrestrial plants continue to be of interest for research and development related to therapeutic botanicals, including development of new analytical methods, ethnomedical and taxonomic research. Some targeted pharmaceutical research with plants will be allowed where these organisms present extraordinary scientific opportunities and are highly cost effective. Plant-associated microbes are of interest and carefully integrated exploration and analysis of these organisms in relation to their host plants and botanical preparations may provide new scientific insights as well as potential new health or energy related product candidates. Finally, plants often have a significant role in the inventory, conservation and resource management objectives described under b) and therefore you may want to consider novel ways of integrating them into your planned activities.

Other classes of organisms may be considered if they are strongly justified as offering novel opportunities for discovery of bioactive molecules. Grantees are encouraged to consider extracting high quality DNA samples from collected organisms and substrates ("metagenome") and storing these in the host country (and/or obtaining permission to use in the U.S. institution if resources are not present in the host country) for potential use in taxonomy, identification of associated organisms (such as microbial symbionts in terrestrial and marine plant and invertebrate collections), and genomic or metagenomic analysis of metabolic pathways from samples with interesting bioactivity.

2b) Undertake biodiversity inventory, and promote conservation and bioresource planning and policy in collaborating

countries;

Inventories of biological diversity must be designed and conducted to meet international standards for documentation and deposition in national and international museums and/or databases. Further, records of collections and identification information will be disseminated through appropriate internationally accessible internet sites, such as the Global Biodiversity Information Facility and the Encyclopedia of Life, GenBank and those of internationally recognized museums. All taxonomic groups are relevant and those proposed for inventory do not necessarily have to be the same as those analyzed for product oriented exploration, as outlined above. However, applicants should give careful thought to the potential synergies in expertise, data and cost-effectiveness if they overlap. Similarly, the choice of organisms and areas to study should reflect not only scientific value but their relevance to conservation planning.

Where possible and appropriate, bioinventory and the discovery/exploration research outlined above in objective 2a) should be integrated into a strategy that advances conservation and bioresource use planning, for example by engaging local government or non-governmental organizations in planning the creation of new protected areas or in strengthening the knowledge base for existing protected areas. Alternatively, you may wish to help develop a scientifically based sustainable use technology relevant to the scope of this FOA that enables host countries and/or communities to derive income from their biological resources without damaging the resource base.

2c) Train U.S. and developing country research scientists and transfer research tools related to the scope of the work of this FOA to collaborating research institutions in the developing world;

Examples of relevant areas of training could include systematics, geographic information science, ethnomedicine, natural products and medicinal chemistry, analytical chemistry, microbiology, pharmacology, genomic analysis, biotechnology, production methods, data management and quality control in botanical production, grant writing, and bioethics. Incumbent Groups should plan to advance the level of training of developing country scientists beyond initial efforts to include advanced field and laboratory work such as the development and conduct of locally appropriate bioassays, isolation and analytical chemistry, database development, ecology and biodiversity analysis and management techniques.

Research training supported through this award may take place in the host country or in the United States and may be linked to degree-earning programs. Training may include, but is not limited to: i) practical and applied short-term courses or workshops for professionals or technicians; ii) course work, laboratory, or field training in essential research skills for technical assistants, graduate degree candidates, or professionals; and iii) fellowships for one or more years for degree candidates or post-doctoral trainees to conduct research related to the goals of the Group. Training costs and plans must be specified in the text of the application and in the application's budget request.

Physical infrastructure support could include assistance for museums and laboratories, the supply of necessary equipment in these facilities, and the enhancement of biodiscovery capacity in the host country. Very limited renovation of existing facilities, but not construction of new facilities, is allowable under this FOA. All renovation of facilities must be strictly relevant to the research objectives of the Group and requires prior approval of FIC.

2d) Establish models for ethical and practical scientific collaboration with biogenetic resources;

As international collaborations involving genetic resources have become increasingly regulated and politicized over the past 15 years since the United Nations (U.N.) Convention on Biological Diversity came into force, the global scientific community has struggled to find ways to work that are both scientifically productive and responsive to local, national and international expectations.

The ICBGs have had a significant role in developing and testing new approaches to international collaborations among government, academic, industrial and not-for profit organizations, and local communities. The diverse objectives and integrated structure of research and training partnerships, contractual agreements, procedures for obtaining access, and design of benefit-sharing plans of the ICBGs have often become, in and of themselves, subjects of both policy analyses and academic study. The ICBGs have thus acquired a responsibility of experimenting with new approaches and disseminating

their lessons for the global community.

All collaborative activities undertaken under this award should be governed by formal, mutually developed agreements, as described in more detail below. Both the design and management of these “experiments” represent a significant investment of time in the politics of science and in policy formulation for ICBG investigators. Practical questions around the transaction costs associated with establishing a new partnership, measuring benefits that accrue to local and global interests, separating basic and commercial research for permit or contractual purposes, defining informed consent in a communal setting, and the impact of new regulations on host country scientists, research and public health, among others, pervade the international policy discussions but few lessons are available to inform these. ICBG investigators may wish to incorporate formal analysis and dissemination of their lessons, both successful and less so, to the academic and policy communities.

Applications for funding as an ICBG should stress creative, synergistic and cost-effective approaches to the above described objectives: a) exploration/discovery, b) biodiversity inventory/conservation, c) training/capacity-building and d) partnership model development. However, among these objectives, exploration/discovery of human health therapeutics is the leading edge of any successful ICBG, and applications will be evaluated accordingly. You are encouraged to contact the FIC Program Officials listed below to discuss how you may balance and integrate these complex objectives.

3. Composition of an International Cooperative Biodiversity Group

Groups should be multi-disciplinary, including individuals and organizations with expertise in various relevant disciplines of the biological and physical sciences, as well as areas such as economics and sociology, and may include those who have not collaborated in programs of this type in the past.

Groups will be international in scope with participation of developing country institutions to the greatest extent possible. Since it is unlikely that all of the required capabilities will be located within one institution, Groups likely will be multi-institutional as well.

While not mandatory, the active participation of the private sector is encouraged. Private sector partners may include companies, large and small, non-profit drug development organizations or a combination of these.

Groups should be multi-institutional in so far as multiple partners address the complex scientific objectives. Cost efficiencies through allocation of certain components of the work to private sector, U.S. Government and/or developing country institutions may be achievable.

Significant cost-savings should be achieved through careful and disciplined planning of research efforts as well as the size and nature of the participating team. For example, scientific strategies that reduce isolation chemistry required to achieve novel discoveries are encouraged. Furthermore, teams should be realistic in planning for the administrative burden of negotiating contractual agreements, communicating, developing reports and carrying out planning with large groups.

Applicants are encouraged to make explicit and potentially operational linkages to other projects funded by the participating agencies to maximize synergies and cost efficiencies. Examples include NSF/USDA Microbial Observatories, Biotic Surveys and Inventories, NIH funded National Cooperative Drug Discovery Groups (NCDDGs), FIC research training grants, and NIH screening and drug development contracts (described in Section VI, under Cooperative Agreement Terms of Award).

a) The composition of an ICBG is envisioned as follows:

i) A PI who is likely to also head an Associate Program.

ii) Associate Programs, each headed by an Associate Program Leader, in diverse scientific disciplines such as ecology, microbiology, cell biology, ethnobiology, sociology, anthropology, botany, zoology, pharmacology or chemistry, that may be appropriate to the realization of Group objectives. A predominance of developing country and U.S. institutions composing the Associate Programs is strongly encouraged. At least one of the Associate Programs must be located in a developing

country and directed by a scientist or program administrator in a developing country institution. Developing country scientists must be substantially involved in the overall program design. Developing countries are defined as low or middle income countries in the World Bank list of economies (see :

<http://siteresources.worldbank.org/DATASTATISTICS/Resources/CLASS.XLS>).

iii) A U. S. Government Project Coordinator appointed by the FIC Program Official to provide assistance to the Group. The Project Coordinator does not have a fiduciary role in management of the grant, but rather provides technical advice and may facilitate access to other government resources, such as contract based screening, to the Group.

b) The PI, in addition to providing scientific and administrative leadership, may head an Associate Program. Associate Program Leaders will be directly responsible to the PI. The formation of the Group, submission of the application in response to this FOA, the overall management of the Group, and the allocation of funds to the various Associate Programs based on anticipated needs, past performance and the overall Group needs at any given time will be the responsibility of the PI and the PI's institution in accordance with PHS policies. The PI will also be responsible for maintaining an integrated relational database of all the significant research and capacity-building activities of the Group as outlined under SPECIAL REQUIREMENTS.

c) The composition of the Group and its Associate Programs should depend on the talents required to accomplish its scientific and technical objectives as perceived by the PI and Associate Program Leaders. The major consideration in structuring an ICBG should be the maximum utilization of intellectual, physical, and financial resources to carry out the proposed research and capacity-building. If the Group includes more than one Associate Program on a specific topic, each should be capable of contributing high quality, necessary, and non-overlapping expertise.

d) An individual scientist or a single institution may be proposed as a PI in only one application. However, an individual scientist may be an Associate Program Leader in more than one application, or a PI and an Associate Program Leader on separate applications. If a scientist appears on more than one application, it is the responsibility of the PI to demonstrate in their applications that there are no scientific or budgetary overlaps or proprietary conflicts with each individual's proposed activities. Likewise, individuals currently receiving funding via contracts, grants, gifts, commercial arrangements, or Cooperative Agreements may be funded under this FOA providing that there is no scientific or budgetary overlap or proprietary conflict in funded activities.

Any Associate Program Leader must complete their portion of the overall application in detail even if no funds are requested for his or her specific project. Federal scientists from the funding agencies may participate in an ICBG as collaborators or consultants, but may not submit a formal application as an Associate Program Leader, assist in developing other portions of the application, or receive funds from this program. Such a government scientist must obtain appropriate clearances and include documentation in the application along with a letter of commitment, a current curriculum vitae. The PI must incorporate into the application, in the usual grant format, a full description of the project, including technical details and methodology. The participation of an intramural scientist is independent of and unrelated to the role of the Advisory Committee or the U.S. Government Project Coordinator as described under "Terms and Conditions of Award."

e) More than one Associate Program of a Group might be derived from a single institution. However, the varied talents and technologies required for the effective attainment of the objectives described in this FOA are not likely to be present in an individual institution. It is anticipated that the Associate Program Leaders within a Group will therefore likely be derived from several institutions.

f) No prescribed number of Associate Programs per Group is stipulated. However, the PI could experience difficulty in providing the desirable level of guidance, and Group members might communicate and collaborate less efficiently, if the Group were to contain more than five or six Associate Programs. In addition, to ensure the most effective use of budget resources and to minimize the burden of negotiating agreements and the management of data, the number of institutions collaborating in a Group should be considered carefully.

g) In forming Groups, potential PIs should remain cognizant of the need for communication, including regular meetings of

members and transfer in a timely manner of data and materials to Group members located in all the participating countries. A plan for communication and material transfer, including all permits and other legal documents required to assure this transfer, must be supplied. Regular telephone and internet based conferences can yield significant efficiencies in this regard.

h) Under the provisions of assistance via a Cooperative Agreement, the U.S. Government Project Coordinator will assist the ICBG and participate in the Group in a manner specified in "Terms and Conditions of Award," and carry out the scientific responsibilities required. The U.S. Government Project Coordinator will not conduct Associate Program activities.

4. Interests of Collaborating NIH Institutes and Centers and US Government Agencies

The Fogarty International Center (FIC) is dedicated to advancing Global Health through scientific research, training and partnerships with U.S. based and international organizations, and may support activities in any therapeutic or scientific area related to those goals. To this end FIC supports a diversity of research and research training grants that advance basic to implementation science with a particular focus on low- and middle-income countries. The ICBG program reflects the Center's core principles: pioneering discovery and filling gaps, promoting international training and collaboration, advancing global health research at the NIH and encouraging science for diplomacy.

The Office of Dietary Supplements (ODS) has interests in regard to organism collection and analysis, focus on molecular diversity, area protection, support of indigenous population enterprises, and publications. ODS is particularly interest in supporting continued basic research on indigenous plants and animals and their traditional uses whose metabolic constituents have potential use as dietary supplements as well as the development, validation, and dissemination of analytical methods for the determination of these constituents.

The National Center for Complementary and Alternative Medicine (NCCAM) is interested in the exploration and definition of promising opportunities to advance health through ethnomedical research, in particular through identification and study of potentially valuable traditional/indigenous health care practices that are in danger of being lost. In particular, NCCAM supports projects which (a) acquire a richer understanding of CAM whole medical systems and how they operate within their indigenous and dispersed settings; (b) advance understanding traditional/indigenous medical systems through international collaborative studies; and (c) contribute to the preservation of irreplaceable and valuable traditional/indigenous CAM knowledge and resources. NCCAM also supports basic, preclinical and clinical investigation of complex natural products. It will support studies of isolated constituents from complex natural products when the intent is to: (a) characterize and standardize whole products (e.g., botanicals), (b) compare the actions of single constituents with the complex product from which they are derived, (c) identify mechanisms of action for the whole product, or (d) better understand or optimize the production of the whole product.

The mission of the National Institute of General Medical Sciences (NIGMS) is to support basic biomedical research that is not targeted to specific diseases. NIGMS is interested in natural products research that contributes to an understanding of fundamental life processes and that creates a foundation for advances in disease diagnosis, treatment, and/or prevention. This could include the discovery of biological probes and/or drug leads where there is no effort to bias the discovery process toward a particular disease.

The National Science Foundation (NSF) supports basic research to promote discovery that advances the frontiers of knowledge, learning to sustain a broadly inclusive workforce, and research infrastructure through investments in instrumentation, facilities, and cyber infrastructure. NSF is participating in this FOA to further the discovery, description, and inventory of global species diversity, and to organize that information in efficiently retrievable forms that best meet the needs of science and society. NSF is interested in promoting new knowledge of biodiversity of plant, animal, and microbial diversity throughout the world, whether terrestrial, freshwater, or marine. NSF is also interested in promoting the broader impacts of this new knowledge through: its integration with teaching and training; the participation of individuals from groups unrepresented in science; the creation of new partnerships among institutions and countries; the enhancement to biodiversity infrastructure such as well-vouchered natural history collections, or stocks and cultures including associated databases; and the dissemination of this knowledge to the benefit of society.

The Department of Energy's (DOE) Office of Biological and Environmental Research is interested in novel microorganisms with the potential to degrade cellulosic materials, assimilate CO₂ or generate biofuels, as well as plants with novel forms of biomass potentially more efficiently convertible to biofuels. Microorganisms from environments with high carbon turnover or capacities to degrade cellulose, hemicellulose or lignins, such as may occur in tropical forest soils and on sea floors, are of particular interest. Additionally, opportunities will exist to have DNA sequencing carried out on isolated microbes or microbial communities at the DOE Joint Genome Institute, following satisfactory scientific and technical reviews.

Other federal partners in the ICBG program, including the Department of Agriculture's Cooperative State Research, Education and Extension Service (USDA CSREES), the National Cancer Institute, and the National Institute on Mental Health, continue to participate in the ICBG program, but are not planning to provide additional funds to support awards from this FOA.

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the NIH U01 award mechanism(s). The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

For the purposes of this FOA, the National Science Foundation and the U.S. Department of Energy will transfer funds to the NIH to co-support awards, except in the case of a DOE Federally Funded Research and Development Center (FFRDC) where the DOE portion of an award will be made directly by DOE. Decisions as to allocation of funds from different agencies in an ICBG award will be at the discretion of the Participating agencies. In all cases, the combined maximum allowable direct costs available from all participating U.S. government sponsors will not exceed \$600,000/year.

This FOA uses "Just-in-Time" information concepts. It also uses non-modular budget formats described in the PHS 398 application instructions (see <http://grants.nih.gov/grants/funding/phs398/phs398.html>). A detailed categorical budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application.

The funding opportunity is a cooperative agreement award mechanism. In the cooperative agreement mechanism, the Principal Investigator retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator, as described under the [Section VI. 2. Administrative Requirements](#), "Cooperative Agreement Terms and Conditions of Award". Plans to continue this program after the initially awarded period of performance are indefinite at this time.

An NIH award will be made only to the PI's institution, which will subcontract with the other participating institutions. All Group activities will be coordinated through the PI's institution. Applicants must comply with PHS policies concerning allowable costs. Note that foreign institutions, through subcontracts, are eligible for facilities and administrative (F&A) costs of up to eight percent. Questions about allowable costs may be directed to Mr. Bruce Butrum, Grants Management Officer, FIC.

Under the Cooperative Agreement, a relationship between the awardee and the Government is established in which the Group is responsive to the requirements and conditions set forth in the FOA. Specifically, the PI defines the details for the project in response to the FOA, retains primary responsibility for the performance of the Group, and agrees to coordinate with the assistance of the Government in all aspects of scientific and technical management of the project in accordance with the terms and conditions outlined under "Terms and Conditions of Award."

All policies and requirements that govern the grant program of the U.S. Public Health Service apply, in particular, PHS Grants

Policy Statement, DHHS Pub. No. (OASH) 90-50.000 (Rev), October 1, 1990.

2. Funds Available

The participating IC(s) including FIC, NIGMS, NCCAM, ODS and their agency partners NSF and DOE intend to commit approximately \$2.5 million dollars in FY 09 to fund two to three new and/or competing continuation grants in response to this FOA. An applicant may request a project period of up to five years and a budget for direct costs up to \$600,000 per year.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. The Government has no plans at present to reissue this FOA.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see [NOT-OD-05-004](#).

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
- Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- U.S. Territory or Possession
- Hispanic-serving Institution
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Other(s):
 - Eligible Agencies of the Federal Government

For profit institutions, Non-domestic (non-U.S.) Entities (Foreign Organizations and Regional Organizations) are eligible to participate as members of a Group but are not eligible to be the principal applicant organization.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current [NIH Grants Policy Statement](#).

3. Other-Special Eligibility Criteria

Applicants may submit a resubmission application from a previous ICBG competition. However, such an application must include an Introduction addressing issues raised in the previous critiques (Summary Statement) and be responsive to the priority areas of the current FOA.

Renewal applications will be permitted for this FOA. Renewal applications must include a progress summary in the Group Plan, as outlined below under Content and Form of Application Submission.

The NIH will review only one application, either renewal, or new, from any one institution. Therefore, you are encouraged to consult within your institution about other individuals who may be considering applying before developing one yourself.

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed in item (box) 2 of the face page of the application form and the YES box must be checked.

This FOA requires the submission of a single application for each proposed International Cooperative Biodiversity Group. Applicants should follow the instructions given in the Form PHS-398 (Rev. 4/2006) package unless otherwise indicated in this announcement or in supplemental instructions. Because of the multi-institutional nature of an ICBG and the special requirements in this FOA, additional instructions regarding format and some modifications are given to guide the writing of a comprehensive application. Furthermore, this FOA is operating under a pilot initiative to explore the value of shortened applications. As such, applicants are asked to deviate from the PHS 398 application instructions in the composition of the Biosketches, Research Plan, and Appendices as outlined below.

The application will be reviewed as a whole and, in addition, each Associate Program will be evaluated for its individual merit. Therefore, the application should contain separate sections for each Associate Program, preceded by a Group Plan section.

a) Group Plan

This section should contain the following portions of the PHS-398: Face Page; Description, Performance Sites, Key Personnel; Research Grant Table of Contents, Budget for Entire Period of Proposed Support, Research Plan, and Checklist. A 20-page limit applies to this Group Plan section individually and includes Items 2-5 as described in the PHS 398 form. This

page limit does not apply to the list of project publications achieved under a prior ICBG award. This list should go into an appendix.

Complete the FACE PAGE for the application as in a regular research grant application.

For the Group Plan section, KEY PERSONNEL should list the Associate Program Leaders and other key investigators for the whole Group. Do not use the pilot Multiple P.I. format pages of the PHS 398. The TABLE OF CONTENTS should number pages for the entire application consecutively, with the FACE PAGE as page one.

The BUDGET page in this section (Form Page 5) should reflect the consolidated TOTAL DIRECT COSTS, by category, of the entire proposed ICBG. A summary page of the TOTAL DIRECT COSTS, by Associate Program, by year, must be included on a separate page. The Group Plan section should also provide, from the applying institution, a Detailed Budget for the first twelve-month period and a budget for the entire proposed project period for direct costs for the management and coordination of Group activities through a Central Operations Office and all travel, including the cost of annual Group meetings and travel to the annual ICBG meeting of all Groups at NIH.

Often the various research tasks necessary to reach the Group's goals may need to be phased in, at least in part, in sequential fashion. For example, isolation chemistry will not likely begin until samples have been collected and samples with biologically-active constituents have been identified and verified. In such cases, the budgets for the individual Associate Programs should, logically, reflect an appropriate change in relative emphasis among tasks until an operational steady state situation is attained. Justification for phase-in budgets also should be provided.

Biographical Sketches: All Biographical sketches should be compiled alphabetically in the Group Plan Section and should not be repeated elsewhere. Individual biographical sketches may not exceed 4 pages. Do not include publications submitted or in preparation. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material. Follow all other instructions on the Biographical Sketch Format Page (PHS 398 reissued 11/2007) with the following modifications: Section B. Selected peer-reviewed publications are limited to 10 or fewer. With respect to the proposal, these 10 citations should include; (a) the most relevant, (b) the most significant, and (c) the most recent publications. Following each cited publication, the applicant should very briefly summarize the findings or achievements described in the publication that demonstrate relevance (familiarity with the field), and/or broad scientific impact, unless this is already apparent from the title. Summaries should not exceed 60 words each. Include Sections A and C as described in the Biographical Sketch Format Page.

Incumbent Groups must describe, within the research plan, the progress they have attained toward the original goals of their program, including a summary description of publications, trainees, significant molecules or species, conservation achievements and any other accomplishments of the Group. A comprehensive list of publications from prior ICBG support should be placed in an appendix.

Inasmuch as the PI may also function as an Associate Program Leader for his/her Associate Program, detailed budget information that duplicates information provided in the section describing the PI's Associate Program need not be included in the Group Plan Section.

The RESEARCH PLAN in the GROUP PLAN section should summarize and synthesize the associate programs to illustrate a coherent Group effort, e.g., how the projects are mutually reinforcing and how collectively they will further the goals of the proposed research. This should include a description of the interrelationships among members of the Group and how the data from the various associate programs involved in field and laboratory research will be integrated into a single relational database consistent with meeting the programmatic goals of this FOA. It is important to discuss any prior collaborative efforts among the investigators as evidence of the ability to work together in multi-disciplinary and/or international projects. As the Research Plan in the Group Plan is limited to 20 pages, it should emphasize the potential Impact or Significance of the ICBG on the research objectives: a) exploration/discovery, b) biodiversity inventory/conservation, c) training/capacity building, and d) partnership/model development.

The Group Plan section should not repeat details that are provided in the Associate Program sections, however, it should contain any additional information about the proposed PI or his/her institution that is evidence of the capability to carry out the scientific and administrative duties required in this FOA and the functions of the Central Operations Office.

The Group Plan Section must also include the following elements to be considered responsive to minimum requirements:

- i. A statement assuring compliance with the ICBG Program Principles for Access, Intellectual Property and Benefit-sharing detailed in this FOA.
- ii. A statement of acceptance of the provisions of "Terms and Conditions of Award," as described in that section of the FOA.

Finally, it is important that both the DESCRIPTION (project summary) and the relevant SPECIFIC AIMS in the Group Plan identify clearly all the therapeutic areas and other targets for the entire project.

b) Associate Programs

Each Associate Program section should begin with its own TITLE PAGE. The TITLE PAGE should state "International Cooperative Biodiversity Groups", the overall project title, and the PI at the top of the page. The Associate Program Leader, the Associate Program number within the group, and its general field(s) of study should be stated in the lower right hand corner.

Each of the Associate Programs should be numbered consecutively (i.e., AP 1, AP 2). Use Form PHS-398 for each Associate Program, but omit the FACE PAGE, TABLE OF CONTENTS, BIOSKETCHES and CHECKLIST for the individual AP. The remaining parts of the PHS-398 should be completed as in a normal grant application, detailing the proposed work of the Associate Program and, where relevant, the interactions with other Associate Programs within the Group. There should be only one CHECKLIST included at the end of the entire application.

A 10 page limitation applies to each of the individual Associate Program's Research Plans (items 2-5). It is important to focus attention on the potential Impact or Significance of the Associate Program in the 10 page Research Plan, while providing the essential methodological details and rationale for the approaches chosen. The Associate Program Training Plan, if relevant, should also be included within these 10 pages.

c) Appendices

Appendices may only be submitted on CD, as described below, but should be listed individually in the Table of Contents on the paper application and again on the CD. Appendices may include and should be organized generally along the following categories:

- i. List of publications from prior ICBG funding, if relevant.
- ii. All letters of agreement from Associate Program Leaders, Collaborators, and Consultants, both paid and unpaid.
- iii. A list of documents or actions that will be required to fulfill local institutional and governmental regulations in order to carry out the proposed work.
- iv. Completed or draft contracts and permits
- v. Letters of support from Government officials, community leaders or others, whose authority is relevant to the objectives outlined but who may not be considered research participants or collaborators.

vi. If internal or external advisory groups will be used in addition to those specified in this FOA, list their membership and describe their roles.

vii Important reprints that are not readily available to reviewers.

Foreign Organizations (Non-domestic (non-U.S.) Entity)

NIH policies concerning grants to foreign (non-U.S.) organizations can be found in the NIH Grants Policy Statement at: http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600260.

Applications from foreign organizations must:

- Request budgets in U.S. dollars.
- Contain detailed budgets. See [NOT-OD-06-096](#).

In addition, for applications from foreign organizations:

- Charge back of customs and import fees is not allowed.
- Every effort should be made to comply with the format specifications, which are based upon a standard U.S. paper size of 8.5" x 11" within each PDF.
- Funds for up to 8% Facilities and Administrative (F&A) costs (excluding equipment) may be requested. See [NOT-OD-01-028](#), March 29, 2001.
- Organizations must comply with Federal/NIH policies on human subjects, animals, and biohazards.
- Organizations must comply with Federal/NIH biosafety and biosecurity regulations. See [Section VI.2.](#), "Administrative and National Policy Requirements"

Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.

3. Submission Dates and Times

Applications must be received on or before the receipt date described below ([Section IV.3.A](#)). Submission times N/A.

3.A. Receipt, Review and Anticipated Start Dates

Letters of Intent Receipt Date: October 21, 2008

Application Receipt Date: November 20, 2008

Peer Review Date: March 2009

Council Review Date: May 2009

Earliest Anticipated Start Date: September, 2009

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the

information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in [Section IV.3.A.](#)

The letter of intent should be sent by email to:

Joshua Rosenthal, Ph.D.
Deputy Director,
Division of International Training and Research
Fogarty International Center
National Institutes of Health
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220
Telephone: 301-496-1653
Email: joshua_rosenthal@nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the research grant applications found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

Personal deliveries of applications are no longer permitted (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html>).

3.C. Application Processing

Applications must be **received on or before the application receipt date(s)** described above ([Section IV.3.A.](#)). If an application is received after that date, it will be returned to the applicant without review. Upon receipt, applications will be evaluated for completeness by the CSR and responsiveness by the Fogarty International Center (FIC). Incomplete and non-responsive applications will not be reviewed.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

Information on the status of an application should be checked by the Principal Investigator in the eRA Commons at: <https://commons.era.nih.gov/commons/>.

4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

Pre-award costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm.

All activities at the foreign site(s) will be restricted until cleared by the U.S. State Department.

All collections of biodiversity specimens at the foreign site(s) and associated research on collected material will be restricted until cleared by NIH staff following review of collection permits and other documents demonstrating achievement of prior informed consent and mutually agreed terms as outlined below in Section VI, 2 under Principles for Accessing Genetic Resources.

Direct your questions about financial or grants management matters to:

Elizabeth C. Cleveland
Grants Management Specialist
OD, Fogarty International Center, NIH
Building 31, Room B2C29
31 Center Drive
Bethesda, MD 20892-2220
Phone # 301-451-6830
Fax # 301-594-1211
E-mail: clevelande@mail.nih.gov

6. Other Submission Requirements and Information

SPECIAL REQUIREMENTS

1. Award Monitoring and Evaluation

Progress of each funded Group will be monitored and evaluated using semi-annual technical progress reports prepared by the Group. Detailed reporting instructions will be provided to grantees upon receipt of award or by request. Part of this reporting process will rely on grantee cooperation with an ICBG Data Coordinating Center that will be supported under a contract from the Government. Evaluation of productivity and accomplishments of Groups will utilize diverse criteria including scientific publications, new species, new lead compounds, new energy-related resources (where relevant), new analytical or production methods, other new inventions or discoveries and appropriate intellectual property (e.g., patents), trainees, courses, local income-generating activities, institutional and policy changes and conservation or health policy impacts.

The U.S. Government Project Coordinator or the FIC Program Official, with advice from the Advisory Committee, may also

elect to conduct site visits or enlist the technical assistance of external consultants to review progress and work with investigators to suggest mid-course changes or recommendations for non-competitive renewal of awards.

2. ICBG Global Data Center

To ensure the integrity of collaboration within groups and the ability of the Government to monitor and facilitate progress of the ICBGs, minimum data elements, formats and standards for a subset of data will be required from each Group. Grantees will be required to maintain an integrated relational database for bioinventory (e.g. species name and collection site) and drug discovery (e.g. bioassay results and compounds isolated) and to provide a subset of these data on a regular basis to a Global Data Center serving all groups. All grantee data will be treated as proprietary, confidential and the property of the grantees and their collaborators except where otherwise indicated by the grantees. The Data Center will also serve a variety of data analysis, data management, literature access, outreach and training needs of the funded groups. To facilitate coordination of data entry and to provide data access at multiple sites within a single ICBG, the Global Data Center can host a Group server and provide secure web-based functionality if requested by the PI. The Government will choose a software package to consolidate these data and will seek to use a system that Groups can easily use or with which Groups can integrate their own data management systems. You are encouraged to discuss this issue with the FIC program managers. Allocation for a data manager to coordinate data entry and analysis and to interact with the Global Data Center should be included in the budget.

3. Genetic Resources Access, Intellectual Property and Benefit-Sharing

Because the discovery of bioactive agents from natural sources is one objective of this effort, along with ensuring that an equitable economic benefit accrues to developing country organizations or communities associated with ICBG research, it is essential that applicants develop appropriate plans for access to genetic resources and contractual agreements for the treatment of benefits and any applicable intellectual property that may arise. The importance of carefully planned and executed approaches to access and benefit-sharing is a function of both their integral relationships with the goals of this program and the rapidly changing regulatory environment in many countries as they respond to the U.N. Convention on Biological Diversity. The development of these plans and agreements is frequently complex, challenging and time-consuming because multiple institutions and countries are involved, often with very different objectives, perceptions and expectations, and occasionally from very different legal environments.

In the application, each applicant Group must, therefore, provide a detailed description of its approach to prior informed consent, intellectual property and the sharing of benefits from ICBG-sponsored research, consistent with meeting the programmatic goals of this FOA. Descriptions should encompass both the conduct of collaborative research activities and the nature of contractual agreements among the collaborators. The research plan and contractual agreements among Group members must be designed such that they address the ICBG "Principles for Access, Intellectual Property and Benefit-Sharing" detailed in this FOA (see Section VI.2.) Draft or completed contracts or permits (subject to the 50 page total page limit) may be included in appendices, as described above.

If these are not completed before the time of award, awardees will have one year from the date of their award to provide signed copies of locally appropriate evidence of prior informed consent and formal agreements specifying the rights and responsibilities of each Group member institution. Applications that represent continuation from previous ICBG awards must also provide updated, revised or new evidence of prior informed consent and agreements by the end of the first award year. The above applies to all research carried out under this FOA, including any that may involve U.S. Government laboratories. Failure to provide these documents may impact budget and constrain activities in subsequent years, or result in termination of the award.

MINIMUM REQUIREMENTS FOR APPLICATION

Applications to the International Cooperative Biodiversity Groups must meet a set of minimum requirements, listed below, in order to be considered by the peer review panel. These requirements are each described elsewhere in this FOA and should be addressed in the relevant portions of the application or as detailed below.

1. Identify a single PI from a U.S. eligible institution who will be responsible for the application, for Group research and technical activities, and for the disbursement of funds in support of Group activities.
2. Structure the Group to include at least one Associate Program located within and led by a developing country institution that hosts the ICBG.
3. Identify the PI's institution that will assume legal and financial responsibility and accountability for the use and disposition of funds awarded on the basis of this FOA; show availability of personnel and facilities capable of performing and supporting the administrative and scientific functions of this ICBG including data management.
4. Present, for each Associate Program, research, technical approaches, and detailed budget requirements.
5. Provide a description of the Group's plan for assuring legal and appropriate access to genetic resources, treatment of intellectual property and sharing of benefits that may result from US Government funding of the proposed work. The application requires, at a minimum, an authoritative outline of the legal and policy requirements of the collaborating country and descriptions of the agreements to be developed among all Group members and their institutions, including local community organization representatives as appropriate.
6. Present letters of support for the project from: 1) the relevant host country Government agency(ies), acknowledging the multiple objectives of the program and its coincidence with national and local laws and policies; and 2) at least one representative investigator from each participating institution, indicating his or her ability to conduct the proposed research and training within the budgets and timeframes of the project and the intellectual property framework of the ICBG program and the proposed project.

Research Plan Page Limitations

A 20-page limit applies to the Group Plan section individually and includes Items 2-5 as described in the PHS 398 form. This page limit does not apply to the literature cited section or the list of project publications achieved under a prior ICBG award.

A 10 page limitation applies to each of the individual Associate Program's Research Plans (items 2-5), The Associate Program Training Plan, if relevant, should also be included within these 10 pages. The literature cited section is not included in this page limitation.

Appendix Materials

All paper PHS 398 applications submitted **must** provide appendix material on CDs only. Include five identical CDs in the same package with the application. (See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-031.html>.)

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the required page limitations may be delayed in the review process.

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value of, and advance research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in Resource Sharing section of the application. See http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.

(a) *Data Sharing Plan*: Investigators seeking \$500,000 or more in direct costs in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are

encouraged to discuss data-sharing plans with their NIH program contact. See [Data-Sharing Policy](#) or <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources, or state appropriate reasons why such sharing is restricted or not possible. See [Sharing Model Organisms Policy](#), and [NIH Guide NOT-OD-04-042](#).

(c) *Genome-Wide Association Studies (GWAS)*: Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-088](#), and <http://grants.nih.gov/grants/gwas/>.

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

Specific Instructions for Foreign Applications

All foreign applicants must complete and submit budget requests using the Research & Related Budget component found in the application package for this FOA. See [NOT-OD-06-096](#), August 23, 2006.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications that are complete and responsive to the FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Center for Scientific Review (CSR) and in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by appropriate national advisory councils or boards of participating sponsors.

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

Program considerations include geographic distribution, match between program emphases and interests of funding partners, as well as perceived special opportunities in a given application. Importantly, funding decisions will take into account the ability to comply with the terms and conditions of award, including the Principles of Access and Benefit-sharing described in Section VI.2, below.

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a meritorious priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? What is the potential impact of the project on human health, biodiversity conservation and, where appropriate, the development of new biobased products such as biofuels? Will it measurably advance the scientific capacity of the host country(ies) and contribute to sustainable economic opportunities?

Approach: Is the conceptual framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

- Is there a rigorous and well developed plan to discover and analyze health therapeutic agents from biodiversity?
- Are the other goals of the ICBG integrated conceptually and operationally with the therapeutic research?
- Is there likely to be strong multidisciplinary cooperation among associate programs and potential for synergy of activities toward the goals of the program?
- Are the plans for intra-Group communication and data-sharing adequate to meet the objectives of this program and do they account for the special requirements of an international collaboration?
- Is the training plan for building scientific capacity for biomedical, biodiversity, and energy research adequate and appropriate to local and international scientific needs beyond the specific targets of the proposed work?
- Is the extent and level of developing country participation and documentation of local community involvement appropriate and sufficient to achieve the project's objectives? Is the plan for treatment of intellectual property and benefit-sharing likely to meet the objectives of the program?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Does the PI and Associate Program leaders have a track record of success relevant to this FOA and demonstrated past support from NIH, NSF, DOE or other sponsors?

- Does the Group have the ability and commitment, as measured by previous success, to cooperate with and train developing country nationals in the scientific and technical disciplines considered critical to meeting the objectives of

the proposed programs?

- Does the PI have administrative experience and competence in the development, implementation, and management of comprehensive research programs, and has the applicant institution demonstrated commitment to support these activities?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? Does the proposed work take place in a country or region that is a priority for biodiversity conservation and economic development efforts, and does it take advantage of the unique biological and intellectual resources of that country or region? Would the genetic resource access and benefit-sharing policies and procedures of the host country facilitate development of the proposed project?

- Are the physical facilities and research and training resources available adequate? Is there sufficient evidence of the availability and competence of the institutions involved to carry out all required legal, fiscal and policy responsibilities?

2.A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Resource Sharing Plan(s)

When relevant, reviewers will be instructed to comment on the reasonableness of the following Resource Sharing Plans, or the rationale for not sharing the following types of resources. However, reviewers will not factor the proposed resource sharing plan(s) into the determination of scientific merit or priority score, unless noted otherwise in the FOA. Program staff within the IC will be responsible for monitoring the resource sharing.

- Data Sharing Plan. [http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm]
- Sharing Model Organisms. [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>]
- Genome Wide Association Studies (GWAS). [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>]

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](#).

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official (designated in item 12 on the Application Face Page). If a grantee is not email enabled, a hard copy of the NoA will be mailed to the business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also [Section IV.5. Funding Restrictions](#).

2. Administrative and National Policy Requirements

PRINCIPLES FOR ACCESSING GENETIC RESOURCES, THE TREATMENT OF INTELLECTUAL PROPERTY AND THE SHARING OF BENEFITS ASSOCIATED WITH ICBG-SPONSORED RESEARCH

In developing both research plans and appropriate intellectual property agreements, it is important that all involved understand the differences between patent coverage and benefit-sharing agreements. While legal protection of the right to commercialize an invention is generally accomplished through the patent system, agreements among collaborators are generally required to designate the terms of partnerships including, among other things, the licensing of an invention and the sharing of any financial benefits that accrue from it.

The conduct of ICBG-sponsored research and the agreements among the collaborators must address the following principles to be eligible for funding.

1. Disclosure to and informed consent of host country stakeholders

a) Plans to collect samples for drug discovery or for other potentially commercializable agents should be vetted with the appropriate national government authorities of the host country and with any other organizations they, you or your partners deem appropriate at the earliest stage of planning and once again, formally, before any collections take place.

b) Where national governments do not have clear regulations to guide informed consent procedures, activities should follow a two phase approach to distinguish basic and commercial research. Basic research intended primarily for publication, including collecting and analyzing biodiversity, including bioassay and chemistry work, may be considered "basic" research for the purposes of this program. If, at any time, researchers intend to file a patent application based on this work or to send a sample for testing to an industrial partner, the research will be deemed to immediately be entering the commercial realm for the purposes of this program and must follow all the requisite permit and contract standards of the host country.

c) Arrangements for the use of traditional knowledge or the collection of samples from the lands of local peoples should be based upon full disclosure and informed consent of those peoples. Under best practices such arrangements develop as a partnership with early and ongoing full participation of community representatives in project design.

d) Indigenous concepts of intellectual property should be respected. If, for instance, cooperating indigenous groups, on the basis of religious or other concerns, object to specific uses, widespread dissemination or other treatments of the knowledge or resources they provide, these concerns should be respected in the conduct of ICBG projects.

e) The process of disclosure and informed consent should be as inclusive and formal as is possible and culturally appropriate. The best practice is the development of written agreements with a community following complete and formal mutual agreement and understanding of the Group's goals and methods. Presentations by scientists to host country stakeholders should provide realistic descriptions of the type, amounts and probabilities of benefits, as well as any costs or risks that may accrue to cooperating communities or organizations. Arrangements with individuals who cooperate or provide information should be based upon prior community-level agreements whenever possible or appropriate.

2. Clear designation of the rights and responsibilities of all partners.

a) This is principally done through the design of adequate contractual agreements. Agreements should be among all collaborating organizations, whether or not they are recipients of government funds. These may include commercial drug developers, source country and U.S. research institutions, and indigenous and local peoples whose resources, biological or intellectual, are utilized in the research process.

b) It is strongly recommended that all parties to agreements have separate, competent legal counsel to represent their interests.

c) Useful contractual tools for the designation of rights and responsibilities include material transfer agreements, research and development agreements, license options agreements, know-how licenses, benefit-sharing agreements, and structured trust funds.

d) Unless stipulated otherwise in agreements among source country institutions and their collaborators, biological samples and associated information collected under ICBG-sponsored research is the property of the source country institutions. For those discoveries subject to 35 USC 200-212 (Bayh-Dole Act), inventorship and ownership will be consistent with applicable laws, and the US Government retains "march-in" rights to require licensing if the inventing organization(s) fail to pursue development of the process or invention or discovery (e.g. process), as described in the "Terms and Conditions of Award."

e) The ownership and compensation terms of first generation and subsequent inventions based upon a lead discovered in ICBG work should be clearly stipulated in agreements, consistent with applicable laws.

f) Agreements should specify that the basic goals of the collaboration include biodiscovery for therapeutic, agricultural and/or energy-related agents, economic development, and the conservation and sustainable use of biological diversity.

g) Agreements should also indicate how a sustainable source of materials for follow-up analysis of a lead compound will be developed, and should preferentially use the participating country and/or communities as the first source of raw or processed materials.

3. Protection of inventions using patents or other legal mechanisms.

a) Non-profit organizations (including universities) and small business firms retain the rights to any inventions resulting from U.S. Government contracts, grants, or Cooperative Agreements consistent with the Bayh-Dole Act and its implementing regulations (35 USC 200-212; 37 CFR 401). PL 96-517, through regulation as well as applicable Executive Order, extends to businesses of any size the first option to the ownership of rights to inventions made in the performance of a federally-funded contract, grant, or Cooperative Agreement. All group members, therefore, including businesses of any size, might be full

partners in the research of the Group and in rights to file patents for any inventions resulting therefrom as specified in the Group's research agreement, consistent with applicable laws. This includes communities organized into or represented by an appropriate legal entity.

b) The specific intellectual property arrangements among the institutions may vary and could include joint patent ownership, exclusive licensing arrangements, etc., consistent with the Bayh-Dole Act. Valuable intellectual resources that may not be patentable, such as traditional medicinal techniques, may require alternative protection methods. You are encouraged to develop an arrangement that best suits the particular circumstances of your Group.

4. Sharing of benefits with the appropriate source country parties.

a) Benefits that emerge from an ICBG should be considered thoughtfully by the Group, and may include financial benefits from a commercial relationship or product, as well as training, targeted research to address local priorities, and the establishment of long-term partnerships, among other types, consistent with applicable laws.

b) Equitable distribution of financial or other benefits that flow from a commercial relationship or product should accrue to all those who contribute to the relationship or product, whether they are members of the consortium or not, including research institutions and local or indigenous people who provide useful traditional knowledge, consistent with applicable laws.

c) Benefits should flow back to the area in which the source plant, animal or microorganism was found, in such a way that they at least indirectly promote conservation of biological diversity.

d) The selection of beneficiaries must be justified in terms of program goals, as well as local and international laws and customs.

e) Benefits should be structured such that they are appropriate to the needs of the communities and the resources of the other collaborators. For example, trust funds managed by a community or community-project board may be more effective in support of conservation and health or education services than cash payments to a single individual or authority.

e) Ideally, compensation begins flowing early in the collaboration through initial payments, training, equipment or services, to provide near-term conservation incentives.

5. Information flow that balances proprietary, collaborative and public needs.

a) Agreements and research plans should anticipate potential tension between the traditional scientific ethic of public access to information, including publication of results, and the understandable desire of indigenous or commercial partners for confidentiality of information with potential commercial value, pending protection through patenting or other means. While proprietary needs often require at least temporary confidentiality, research results should not be withheld which would unduly compromise the goals of the program, e.g., beyond those which are likely to be commercialized or would harm the interests of project stakeholders in identifiable ways.

b) Sharing of information among collaborating organizations should be an ongoing and regular process and should be as complete as possible to maximize efficiency of research and equity in partnerships while recognizing the proprietary concerns of those partners. Reporting back to collaborating communities, where relevant, on significant project developments should be a regular and expected component of the project.

6. Respect for and compliance with relevant national and international laws, conventions and other standards.

a) Relevant international conventions, such as the U.N. Convention on Biological Diversity and national laws regarding study, use and commercialization of chemical, genetic, biological and cultural resources, should be observed rigorously in the development of agreements and the conduct of research.

b) An essential goal of this program is to develop models for sustainable and equitable commercial use of biodiversity-rich ecosystems. As such, ICBG research agreements and activities should, wherever possible, go beyond the minimum legal standards regarding international research collaborations, looking to codes of conduct and other standards for guidance. In this regard you are encouraged to review the U.N. Biodiversity Convention's Bonn Guidelines on Access and Benefit-sharing: <http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf>.

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the Notice of Award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

2.A.1. Principal Investigator Rights and Responsibilities

The Principal Investigator will have the primary responsibility for planning, directing, and executing the proposed project and ensuring that the Group is responsive to the requirements and conditions set forth in the FOA. Assistance via Cooperative Agreements differs from that of grants in that, in addition to programmatic and administrative stewardship responsibilities, the U.S. Government, in awarding the Cooperative Agreement, anticipates substantial scientific involvement during performance of the project. However, the Group must define its objectives and its approaches to attain these objectives in accord with its own interests, scientific creativity, capabilities and perceptions. In this process, Groups are invited to use novel and effective approaches to the interdependent program areas of exploration and discovery, biodiversity inventory and conservation, training and capacity-building, and partnership model development. The Group must develop the details of the program design following the guidance given in this FOA. It is the primary responsibility of the PI to state clearly the objectives of the Group, to direct the research and other activities stipulated in the application, and to ensure that the results obtained are properly disseminated and published. It is anticipated that decisions will be reached by consensus of the Group under the leadership of the PI and that the U.S. Government Project Coordinator will have the opportunity to offer input to this process.

Each project is expected to contribute to the achievement of three classes of benefits: 1) health and agricultural or bioenergy benefits through the exploration of chemical and genetic properties of biodiversity; 2) benefits in the understanding and conservation of biological diversity; and 3) enhanced scientific and economic capacity of the host country. The following three sections describe responsibilities of the awardee relating to the realization of these benefits.

Grantee organizations and their domestic and foreign partners retain custody and rights to all proprietary data and intellectual property that emerge and develop from their research, as outlined in the section, "Principles for Access, Intellectual Property and Benefit-sharing."

The US Government will retain the option to cross-file or independently file an application for investigational clinical trial [e.g. an Investigational New Drug Application (INDA) or an Investigational New Device] to the U. S. Food and Drug Administration of any invention resulting from these U.S. Government-supported cooperative agreements. It is the responsibility of the PI to submit to the U.S. Government Project Coordinator and FIC Program Official, and the ICBG Global Data Center upon request, data and reports generated by the Group or any of its members required for cross-filing purposes. Such reports will include background information, methods, results, and conclusions. They will be subject to approval and revision by Government staff and may be augmented with test results from other Government-sponsored projects prior to submission to the appropriate regulatory agency.

The awardee will retain custody of and rights to the data. Molecular discovery data shared with the U.S. Government and its contractors will be presumed to be confidential until otherwise indicated or agreed upon. Significant findings emerging from ICBG-funded research must be published in a timely fashion in peer-reviewed scientific journals except in cases in which clear proprietary concerns are present. Publications or oral presentations of work done under this agreement will require appropriate acknowledgment of joint support from the NIH, NSF, and/or DOE under this FOA.

Projects must comply with all national and international regulations regarding collection, import/export and use of biological specimens. All requisite permits for inventory collections and for product oriented research collections from the relevant government organizations will be procured in advance of collection activities and copies must be provided to the FIC Program Official. Requests to collect species that have been declared threatened or endangered by the Convention on International Trade in Endangered Species (CITES) must be particularly well-justified, and all regulations regarding these species must be scrupulously followed.

Awardees will have up to one year to provide evidence of prior informed consent and completed, signed agreements sufficient to conduct the research activities proposed in the application. Extensions or exceptions will be few and may only be granted by the FIC Program Official, in writing.

Collection of biological materials for inventories, assays, chemical analyses or commercial development must be conducted with close attention to the potential impact of collection on natural populations of target or associated organisms.

For projects that will have substantial interactions with indigenous and local communities, Groups are advised to develop formal, well-documented consultations with indigenous community leaders and respected local Non-Governmental Organizations during project planning and periodically thereafter. Seeking the advice or participation of social scientists and development organizations with local expertise is also advisable during this process.

In the licensing of a product for advanced development and/or commercial production, the licensee must be required to use the participating country and/or communities as the first source of raw or processed material, subject to the negotiation of mutually agreed terms.

In the enhancement of scientific infrastructure, project managers must specifically consult with participating country officials to assure that the enhanced research capabilities can be sustained after completion of the project, using locally available resources. Equipment procured will be of U.S. source and origin where possible. Major equipment procurements that are not from U.S. sources or origins must be justified in writing and are subject to U.S. Government approval.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

2. A.2. NIH/Participating Agencies Responsibilities

A US Government Project Coordinator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. Additionally, an FIC Program Official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The U.S. Government shall assist in the activities of the ICBG principally through the U.S. Government Project Coordinator and the FIC Biodiversity Program Official. The FIC Program Official shall be the primary Government contact with the PI for issues relating to program administration, funding and policy.

The U.S. Government Project Coordinator will be the primary Government contact with the PI for scientific and technical issues. The Project Coordinator will be appointed by the Government. During performance of the award, the Project Coordinator may provide appropriate assistance in the design of activities, in the identification of and access to NIH and other scientific resources. In all cases, the role of the Project Coordinator will be to assist and facilitate, and not to direct activities.

The U.S. Government Project Coordinator, as well as any other Group member, may assist in research planning; may suggest studies within the scope of the Group's objectives; may present to the Group findings from published sources or from grant or contract projects in support of these suggestions; may participate in the design of project activities and experiments as agreed to by the Group; and may participate in the analysis of results.

When appropriate and with prior knowledge of the Advisory Committee to the Government Project Coordinator, U.S. Government laboratories or contractor laboratories may be available for training related to the specific research efforts of the ICBG. Prior written approval from the laboratory director must be obtained. With the exception of database training provided by the ICBG Global Data Center, funding for this training must be within the ICBG's approved budget.

The Project Coordinators for all ICBGs will participate in the Technical Advisory Group (TAG) for the ICBG Program. The FIC Program Official chairs the TAG and will make all final programmatic and budgetary determinations on behalf of the U.S. Government.

The Group is encouraged to make full use of NIH contract-based resources in drug discovery and development to facilitate screening and development of important lead compounds discovered from the funded ICBGs. These resources should not be used for primary screening of extracts. The intent is to broaden the scope of discovery which may be limited within one Group's technical capabilities and budgetary constraints and maximize the chance of success in lead development. For example, the NCI's Developmental Therapeutics Program has available contract resources in compound libraries, screening, in vivo testing, formulation, pharmacology and toxicology. Similar resources are available through the NIMH, as well as other components of the NIH not listed on this FOA. The Groups are encouraged to access these and other resources through RAID, RAND, and DDG programs (<http://www.dtp.nci.nih.gov>) and (<http://nihroadmap.nih.gov/raid>).

A more detailed list of such resources is available through the FIC ICBG website: http://www.fic.nih.gov/programs/research_grants/icbg/index.htm. All samples transferred to the U.S. Government resources for evaluation should have a completed Material Transfer Agreement with sample originator retaining the intellectual property. The Groups should contact ICBG Technical Advisory Group representative(s) from participating agencies and institutes or the FIC Program Official regarding potential use of this support. The Groups are also encouraged to make full use of the resources at NIH Roadmap Programs for compound testing and evaluation. In addition, all Groups are encouraged to establish workable sample and other resource sharing agreements to facilitate the maximum exposure of samples to additional disease areas not covered in one Group's research plans if these efforts may advance the goals of the overall ICBG.

The Department of Energy, Office of Environmental and Biological Research will provide to funded ICBGs free sequencing of whole genomes of microbes that may be relevant to cellulose degradation, CO₂ assimilation or bioenergy production. Each sequencing project will need to be evaluated for both mission relevance and technical feasibility. If this service is to be included in your project you are strongly encouraged to consult the DOE representative listed in Section VII for requirements and incorporate these plans into the application.

These "Terms and Conditions of Award" require that the U.S. Government Project Coordinator approve the following: reports intended for inclusion in INDAs and Clinical Brochures; redistribution, outside the ICBG, of biological and chemical materials received from the U.S. Government; and dissemination of research or project findings resulting from the use of such materials to assure conformity to existing confidentiality agreements with suppliers.

Data Access and Standards

The US Government will have access to all data generated under this Cooperative Agreement and will periodically review the data for program management purposes. The US Government may elect, following consultation with grantees, to publish summary results from program activities to fulfill its responsibility to disseminate lessons learned from the program.

Minimum data quality and format standards will be developed in consultation with awardees. Awardees will be required to maintain an integrated relational database of inventory and drug discovery activities and to provide these data on a regular basis to an ICBG Global Data Center serving all groups. Grantee data will be treated as proprietary, confidential and/or the property of the grantees and their collaborators except where otherwise agreed upon between the Government and the Awardees.

Sequence data provided by the DOE will allow for a limited period of confidentiality (not to exceed 6 months from first assembly into contigs), after which it must be deposited and annotated in GenBank or another publicly accessible database.

Groups are encouraged to submit published chemical and extract data, or non-published data as desirable, to the PubChem public database maintained by the NIH (<http://pubchem.ncbi.nlm.nih.gov/deposit/deposit.cgi>).

2.A.3. Collaborative Responsibilities

The PI is responsible for organizing meetings of all Group members, at least once per year, to review progress, plan and design research and technical activities, and establish priorities. The FIC Program Official, Project Coordinator, and members of the Technical Advisory Group (TAG) will attend these meetings, when possible. You should attempt to coordinate the timing of these meetings with the Government's representatives.

In addition, the PIs from each ICBG will meet every year at the NIH Campus to share findings and lessons with each other and the ICBG TAG. Following these meetings, a subset of the TAG will meet individually with each ICBG to discuss prioritization of leads and to facilitate lead development. At least two of the yearly network meetings during the five-year duration of awards under this FOA should include Associate Program Leaders from each Group, as appropriate, and all available TAG members to share important information, review the overall progress of the program and establish future priorities. Applicants should budget for these meetings from grant funds.

2.A.4. Arbitration Process

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and HHS regulations 45 CFR Part 16.

3. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (<http://grants.nih.gov/grants/funding/2590/2590.htm>) and financial statements as required in the NIH Grants Policy Statement.

Awardees will be required to submit a semi-annual report each year in addition to the annual progress report. Reports will include tabular data using table formats provided by the sponsoring agencies as well as tables generated from a semi-annual data submission to the Global Data Center. Two hard copies and a CD of each semi-annual and annual report should be sent to the FIC Program Official.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Joshua Rosenthal, Ph.D.
Deputy Director,
Division of International Training and Research
Fogarty International Center
National Institutes of Health
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220
Telephone: 301-496-1653
Email: joshua_rosenthal@nih.gov

Flora Katz, Ph.D.
Program Officer
Fogarty International Center
National Institutes of Health
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220
Telephone: 301-402-9591
Email: katzf@mail.nih.gov

For questions related to specific areas of interest of funding partners:

NCCAM

Marguerite Klein, M.S. R.D.
Program Officer
National Center for Complementary and Alternative Medicine,
Division of Extramural Research and Training
National Institutes of Health
6707 Democracy Blvd., Suite 401
Bethesda, MD 20892 (for express delivery 20817)
Telephone: 301-402-5860
Email: kleinm@mail.nih.gov

ODS

Joseph M. Betz, Ph. D.
Program Director
Office of Dietary Supplements
National Institutes of Health
6100 Executive Blvd., MSC 7517
Suite 3B01

Bethesda, MD 20892-7517
Telephone: 301-435-2920
Email: BetzJ@OD.NIH.GOV

NIGMS

John M. Schwab, PhD
Program Director
Division of Pharmacology, Physiology and Biological Chemistry
National Institute of General Medical Sciences
National Institutes of Health
Bldg 45, Room 2As.43A
Bethesda, MD 20892
Telephone: 301-594-3827
Email: schwabj@mail.nih.gov

NSF

Matthew Kane, Ph.D.
Program Director,
Division of Environmental Biology
National Science Foundation
4201 Wilson Blvd., (Rm 635)
Arlington, VA 22230
Telephone: 703-292-7186
Email: mkane@nsf.gov

DOE

Daniel Drell, Ph.D.
Program Manager
Biological Systems Sciences Division
SC-23.2/Germantown Bldg
Office of Biological and Environmental Research
Office of Science
US Department of Energy
1000 Independence Ave., SW
Washington, DC 20585-1290
301-903-4742 (phone)
Email : daniel.drell@science.doe.gov

2. Peer Review Contacts:

Dan Gerendasy, Ph.D.
Scientific Review Administrator
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, RM 3212 (MSC 7808)
BETHESDA, MD 20892-7843 (use 20817 for overnight mail)
Telephone: (301) 594-6830
Email: gerendad@csr.nih.gov

3. Financial or Grants Management Contacts:

Elizabeth C. Cleveland
Grants Management Specialist
OD, Fogarty International Center, NIH
Building 31, Room B2C29
31 Center Drive
Bethesda, MD 20892-2220
Phone # 301-451-6830
E-mail: clevelande@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Policy for Genome-Wide Association Studies (GWAS):

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-](#)

088. For additional information, see <http://grants.nih.gov/grants/gwas/>

Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

Required Education on the Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

Human Embryonic Stem Cells (hESC):

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

NIH Public Access Policy Requirement:

In accordance with the NIH Public Access Policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>) investigators must submit or have submitted for them their final, peer-reviewed manuscripts that arise from NIH funds and are accepted for publication as of April 7, 2008 to PubMed Central (<http://www.pubmedcentral.nih.gov/>), to be made publicly available no later than 12 months after publication. As of May 27, 2008, investigators must include the PubMed Central reference number when citing an article in NIH applications, proposals, and progress reports that fall under the policy, and was authored or co-authored by the investigator or arose from the investigator's NIH award. For more information, see the Public Access webpage at <http://publicaccess.nih.gov/>.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, internet addresses (URLs) **must** be used for **publicly** accessible on-line journal articles. Unless otherwise specified in **this** solicitation, Internet addresses (URLs) should **not** be used to provide any **other** information necessary for the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some

cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: <http://www.lrp.nih.gov>.

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