***REVISED***

This Program Announcement expires on November 27, 2002, unless reissued.

PLANNING GRANTS: NATIONAL PROGRAMS OF EXCELLENCE IN BIOMEDICAL COMPUTING (PRE-NPEBC)

Release Date: June 29, 2000 (Supercedes May 30, 2000 version)

PA NUMBER: PAR-00-102

National Cancer Institute
National Center for Complementary and Alternative Medicine
National Eye Institute
National Heart, Lung, and Blood Institute
National Human Genome Research Institute
National Institute on Aging
National Institute of Alcohol Abuse and Alcoholism
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute on Drug Abuse
National Institute on Deafness and Other Communication Disorders
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Library of Medicine

Letter of Intent Receipt Date: October 27, February 27, and June 27 annually
Application Receipt Date: November 27, March 27, and July 27 annually
(Solicitation begins with the November 27, 2000, receipt date and ends with the November 27, 2002, receipt date.)

PURPOSE

Participating Institutes and Centers of the National Institutes of Health (NIH) invite applications for P20 planning grants that lead to the establishment of National Programs of Excellence in Biomedical Computing. Susequent to this program announcement, a series of solicitations will be issued by participating NIH Institutes and Centers to invite applications for National Programs of Excellence in Biomedical Computing (NPEBC) awards.

There exists an expanding opportunity to speed the progress of biomedical research through the power of computing primarily in areas concerning management and analysis of data and modeling biological processes. The NIH is interested in establishing NPEBC to promote research and developments in biomedical information science and technology that will support rapid progress in areas of scientific opportunity in biomedical research. As defined here, biomedical computing or biomedical information science and technology includes database design, graphical interfaces, querying approaches, data retrieval, data visualization and manipulation, data integration through the development of integrated analytical tools, synthesis, data archiving, data exchange, tools for electronic collaboration, and computational research including the development of structural, functional, integrative, and analytical models and simulations. The NPEBCs are also intended to create an infrastructure of excellence in biomedical information science and technology that will support and promote multidisciplinary research and provide the environment in which to train a new generation of researchers.

NPEBCs are intended to:

- Promote bio-informatics and bio-computational research that enables the advancement of biomedical research;
- Develop useful and interoperable informatics and computational tools for biomedical research;
- Establish mutually beneficial collaborations between biomedical researchers and informatics and computation researchers; and
- Train a new generation of bio-informatics and bio-computation scientists.

NPEBC will provide a formal framework through which scientific synergy can occur on a stable and continuing basis, and will provide: 1) an organizational structure specifically designed to facilitate intellectual cross-fertilization between seemingly disparate groups of investigators; 2) core facilities to support research activities; 3) developmental funds for feasibility testing of new projects; 4) career development opportunities for new and established investigators; and 5) a broad range of educational activities, from formal undergraduate and graduate programs to courses and seminars for students and researchers, visiting scientists program or other types of training, cross-training, or educational approaches. NPEBC are expected to promote multidisciplinary research and are not intended to support institutional information infrastructure.

This PA describes the three-year, P20 Planning Grant for National Programs of Excellence in Biomedical Computing (pre-NPEBC). It is clear that there is a range of areas in biomedical computing that might potentially benefit from the establishment of NPEBC. Given the emerging nature of the field of biomedical computing, it is not clear at this point that all institutions that might be interested in establishing NPEBCs in the various areas of opportunity are ready to submit coherent programs that would qualify as ready for a National Program of Excellence designation. The planning phase provided by this mechanism will allow Institutions that have most of the separate scientific components necessary for creating a cross-disciplinary research and training program in biomedical computing to plan and create the organization required for a NPEBC. Responsive groups would include those that have a limited track record of performing interdisciplinary research and training in biomedical information science and technology or require extensions of existing collaborations among interdisciplinary scientists. Institutions that do not require a planning phase are encouraged to submit directly in response to forthcoming solicitations for NPEBC.

In recognition of the critical importance of integrating computing expertise with biomedical research, applications responsive to this solicitation will be required to have a Principal Investigator (PI) with expertise in either computing or biomedical research as well as a Co-Principal Investigator (Co-PI) from the complementary field. The planning activities should emphasize the interface between informatics/computing and biomedical research and should be structured to meet the needs and level of maturity of the ongoing efforts. Planning activities may take place in a single or multiple phases. For example, an application could propose a first phase to allow for formal establishment of an organizational and operational structure of the pre-NPEBC, and a second phase to provide the time and funds for the initiation of multidisciplinary Development projects, development of courses and other training opportunities, and for these newly-formed groups to complete recruitment efforts necessary for bringing in critical expertise.

Pre-NPEBC awardees will be expected to compete for a NPEBC award (see below) that will be competitively reviewed, in part, on the organizational and scientific progress made during the planning stage. Successful applicants in the current solicitation may apply for NPEBC at any point during the life of the pre-NPEBC award. Groups that do not require planning activities can compete directly for NPEBC in the area of interest without submitting an application to this solicitation.

Solicitations for NPEBC awards will be issued in areas of interest to individual or groups of NIH Institutes or Centers. Subject-specific NPEBC solicitations will be issued in a time frame

considered appropriate for the field of biomedical information science and technology they are intended to support. Such solicitations are likely to be issued beginning shortly after the release of the current pre-NPEBC solicitation and continuing over the next several years. Successful applicants in the NPEBC initiatives will have ongoing multidisciplinary research that integrates biomedical research and information technology.

The National Human Genome Research Institute will support NIH biomedical computing activities through its Centers of Excellence in Genomic Science (CEGS) program. A program announcement inviting P20 and P50 grant applications for CEGS is available in the NIH Guide as PAR-00-096.

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 program announcement (PA), Planning Grants: National Programs of Excellence in Biomedical Computing (Pre-NPEBC), 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/ .

ELIGIBILITY REQUIREMENTS

Applications for P20 Pre-NPEBC grants may be submitted by domestic non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals and laboratories, units of state or local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

Each of the lead investigators including the PI, Co-PI, and Project Leaders must be established investigators as evidenced by scientific contribution and/or funding. Applicants must therefore clearly define the scientific areas to be represented within the Pre-NPEBC, and for each scientific area, one or more investigators must be identified as assuming a leadership role.

MECHANISM OF SUPPORT

Support of this program announcement (PA) will be through the National Institutes of Health (NIH) P20 Exploratory Grant Mechanism. These exploratory studies may lead to NPEBC.

Responsibility for the planning, direction, and execution of proposed projects will be solely that of the applicant. The total project period for a P20 application submitted in response to this PA may not exceed 3 years.

An applicant planning to submit an application for this PA requesting $500,000 or more in direct costs for any year is advised that NIH policy requires an applicant to obtain agreement for acceptance of both any such new application and/or any subsequent amended application. Refer to the NIH Guide for Grants and Contracts, March 20, 1998, which is available on the Internet at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-030.html.

To obtain agreement, an applicant must contact IC program staff (listed under INQUIRIES) before submitting the application; i.e., as plans for the study are being developed. Furthermore, the applicant must obtain written agreement from IC staff that the IC will accept the application for consideration for award.

## FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available in FY 2000 for the first year of support for awards under this PA will be approximately $10 Million. Because the nature and scope of the research proposed in response to this PA may vary, it is anticipated that the size of the awards will vary also. The number of awards and level of support will depend upon receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of individual participating Institutes and Centers of the NIH, the award of grants pursuant to this PA is contingent upon the anticipated availability of funds for this purpose. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and the availability of funds.

## BACKGROUND

Computing and computational tools have become increasingly important in enabling progress in biomedical research. In recognition of the critical role computing will play in biomedical research, the NIH Director commissioned a Working Group on Biomedical Computing to:

Investigate the needs of NIH-supported investigators for computing resources, including hardware, software, networking, algorithms, and training. It should take into account efforts to create a national information infrastructure, and look at working with other agencies (particularly

NSF and DOE) to ensure that the research needs of the NIH-funded research community are met.

It should also investigate the impediments biologists face in utilizing high-end computing, such as a paucity of researchers with cross-disciplinary skills. The panel should consider both today's unmet needs and the growing requirements over the next five years (a reasonable horizon for extrapolating the advances in the rapidly changing fields of computing and computational biology).

The result of the deliberations of the Working Group on Biomedical Computing is a report entitled "The Biomedical Information Science and Technology Initiative (BISTI)" which can be viewed at the following site: http://www.nih.gov/welcome/director/060399.htm. A primary recommendation of the BISTI is that the NIH should establish National Programs of Excellence in Biomedical Computing (NPEBC) devoted to basic and applied research as well as developing education and training opportunities to promote discovery in biomedical computing. The promotion of the interface of biomedical information science and technology with biomedical research should result in new digital and electronic tools that will have substantial impact on broad areas of biomedical research.

The Institutes and Centers of the NIH acknowledge the wisdom of this recommendation and are offering support thorough the current solicitation for planning grants leading to the development of potential NPEBC. As outlined in the BISTI and endorsed by the participating Institutes and Centers of the NIH:
Distinguishing features of the NPEBC would include:
o A range of work, from fundamental discoveries to useful tools in biomedical computing.
o A plan for disseminating the results of the research-and-development effort, so that others can take advantage of the data that is produced, the tools that are created, and the science that is discovered.
o A full menu of education, ranging from formal undergraduate and graduate programs to courses and seminars for students and working researchers, visiting-scientist programs, "total-immersion" programs, one-week or two-week intensive-training programs, and other innovative programs to help spread the knowledge gleaned in the course of research. That training would underline the scientific effort within the Program.

RESEARCH GOALS AND OBJECTIVES
This solicitation targets support for the development of infrastructures of excellence in biomedical information science and technology that will support and promote multidisciplinary research and

provide the environment in which to train a new generation of researchers. The targeted infrastructures should foster multidisciplinary teams focused on fundamental research in biomedical computing science and technology, as well as the development and application of new biocomputing tools, for a particular area(s) of scientific opportunity in biomedical research. The teams should reflect mutually beneficial collaborations between biomedical researchers and informatics and computation researchers.

Support is specifically for planning activities and pilot research projects leading toward the development of organization and infrastructure competitive for support as a NPEBC. The NPEBC will focus on advances in biomedical computing in the context of enabling progress in a compelling area(s)of biomedical research. Activities proposed in response to the current solicitation should target the establishment of a research and communications infrastructure that would promote new discoveries in biocomputing and the dissemination of new related tools, as well as a range of training opportunities that would promote a new generation of scientists that span the interface of biomedical research and computing.

Programs may target one or multiple areas of biomedical computing that will enable progress in biomedical research. Specific research areas in informatics or computational science include, but are not limited to:

- Research on databases, querying approaches, and information retrieval
- Research on data visualization
- Computing algorithms and new analysis and statistical methodologies for social science research related to areas of biomedical interest, such as population aging
- Research on new approaches to data integration
- Research on the development of models or simulation environments
- Development of models or simulation environments

The development of biocomputing and informatics tools is anticipated to be a part of the pre-NPEBC research efforts. To that end, core resources and expertise available through the pre-NPEBC may be expended toward that end. The dissemination of the results of the associated research-and-development efforts, including the data that is produced, the tools that are created, and the science that is discovered, is strongly encouraged. Pre-NPEBC are not intended to support the development costs required for creating a fully robust form of the tool, comparable to a commercial product. Tools of interest include but are not limited to:

- Tools for data collection
- Tools for archiving large data sets
- Analysis tools for interpretation of large data sets

- Platform-independent translational tools for data exchange
- Tools or models to promote interoperability
- Web-based linkage tools for data sharing
- Tools for electronic communication

Areas of biomedical research likely to be critically dependent on biocomputing advances include but are not limited to:

- Behavioral science
- Biological rhythms
- Biomedical imaging
- Cell biology
- Clinical research
- Clinical trials
- Developmental biology
- Drug design at the molecular and cellular levels
- Dynamic modeling of retirement
- Dynamic modeling of health, chronic disease, and disablement
- Endocrinology
- Environmental science
- Epidemiology
- Genetics
- Genomics/proteomics
- Immunology/inflammation
- Medical genetics
- Morphology
- Neurobiology and cognitive science
- Pharmacology
- Physiology
- Population biology
- Structural biology
- Substance abuse research
- Surgery and virtual tools
- Temporal patterns

Pre-NPEBCs will provide Institutions with the resources to set in place all of the components that would make them eventually competitive for a NPEBC grant. The success of a Pre-NPEBC will ultimately be determined by the quality and dedication of the investigators involved in the project.

An appropriate Pre-NPEBC Director with expertise in the area of biomedical computing or biomedical research must be selected, as well as a Co-Director with expertise in the complementary field. In addition, the institution must assemble a multidisciplinary leadership team of investigators who are committed to the success of the Pre-NPEBC. This group of investigators will be responsible for the definition of the research goals and objectives of the Pre-NPEBC, as well as ongoing activities. The lead investigators must each represent a major scientific component that will be involved in the Pre-NPEBC, and each must have demonstrated scientific accomplishment, but they do not need to demonstrate prior interactive research amongst themselves.

During the course of the Pre-NPEBC award, the leadership team will be responsible for the design and implementation of planning activities that will lead to a formal framework through which scientific synergy can occur on a stable and continuing basis, and will provide: 1) an organizational structure specifically designed to facilitate intellectual cross-fertilization between seemingly disparate groups of investigators; 2) core facilities to support research activities; 3) developmental funds for feasibility testing of new projects; 4) career development opportunities for new and established investigators; and 5) a broad range of educational activities, from formal undergraduate and graduate programs to courses and seminars for students and researchers, visiting scientists program or other types of training, cross-training, or educational approaches.

The planning activities should emphasize the interface between informatics/computing and biomedical research and should be structured to meet the needs and level of maturity of the ongoing efforts. Planning activities may take place in a single or multiple phases. Planning activities should address the following elements:

o Establishment of an Organizational Structure - The applicant group will define and implement a structure for a Pre-NPEBC. Organizational activities must occur, during which the group will be expected to define:

1. The organizational and operational structure of the Pre-NPEBC. This will include planning for a Scientific Steering Committee, composed of both internal and external senior investigators, who will be responsible for the overall scientific direction of the Program, as well as mechanisms for involving a dynamic group of investigators at all levels of experience. The Scientific Steering Committee should include expertise in areas of biomedical computing and biomedical research relevant to the focus of the Pre-NPEBC. Applicants should not invite or select specific members of the Scientific Steering Committee prior to application, but provide a list of the types of investigators or expertise they would select.
2. A plan for interactive Pre-NPEBC activities that will occur regularly over the entire course of the award. These interactions will be determined by the applicants, and emphasis will be placed on

establishing creative, productive interactions. In addition the interactive activities should be geared towards promoting the cross-fertilization between fields of information science and technology and biomedical research.
3. A description of the core facilities necessary to support the scientific goals of the Pre-Program. Access to equipment and resources is often a problem, especially for multi-disciplinary programs. The establishment of core resources dedicated to Pre-NPEBC-related Development Projects will provide this access. Initially, Pre-NPEBC core resources may simply be extensions of existing laboratories or facilities, and the definition of a core resource would vary considerably depending on the Development projects to be selected, existing facilities, and the scientific focus of the Pre-NPEBC.
4. A model of the process for the selection, monitoring, funding and, if necessary, termination of Development Projects to be implemented.5. A plan for developing a full range of educational activities, from formal undergraduate and graduate programs to courses and seminars for student and researchers, visiting scientists program or other types of training, cross-training, or educational approaches.

o Initiation or expansion of Developmental Projects – The applicants should select two to three highly interactive Developmental Projects for research support. For more established groups selection of these projects may occur prior to submission of the proposal. For groups requiring an initial planning process to define the Developmental Project selection process examples may be provided in the application, with final selection during the course of the Pre-NPEBC. These projects will be geared toward determining project feasibility, proof of principle, and acquisition of preliminary data. At least one of the pilot studies must demonstrate newly established collaborative efforts between two or more groups of investigators. Additional evelopmental Projects may either be newly established collaborations or significant extensions of ongoing collaborations. Projects must span the interface of biomedical research and biomedical information science and technology. Given the expanding needs in biomedical research for advances in these areas, consideration should be given that approaches and technologies can ultimately be generalizable, scalable, extensible, interoperable, and use sophisticated computational resources. The informatics research component as reflected in the proposed pilot projects should be future-oriented and seek to exceed the current state-of-the-art.

The P20 application should contain no more than three five-page descriptions of the Developmental Projects selected or examples of possible Development Projects. These projects will not be reviewed as traditional research projects. Rather, the proposed Development Projects will serve as an indication of the priorities to be focused on by the group, a reflection of the decision-making abilities of the scientific leadership, the ability to stimulate mutually beneficial

collaborations between informatics and computation researchers and biomedical researchers, and the initial ability of the group to interact productively and scientifically. When the P20 groups submit their NPEBC application, it is expected that the Development Projects will have generated sufficient data for meaningful interpretation. The results acquired during this phase will be a critical focus of the NPEBC review, since these results will be an important indication of how successfully the Pre-NPEBC group functioned to implement innovative research.

SPECIAL REQUIREMENTS

Funded Pre-NPEBC groups will be required to include in their first non-competing renewal (annual reports) 1) a description of the activities that occurred; 2) the organizational and operational structure that was implemented including a detailed description of the process for selecting Development projects, and decisions regarding the establishment of core facilities; 3) a description of each of the Development projects that have been initiated, and the progress made on each of those projects; 4) a description of progress toward developing a range of educational opportunities in biomedical computing. Subsequent non-competing renewals will be required to include a detailed report of organizational and operational activities as well as a progress report for each of the ongoing Development projects.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

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 biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided 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 429B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994, and are available on the Internet at http://grants.nih.gov/grants/guide/notice-files/not94-100.html .

Investigators may also obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

## INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research conducted or supported by the NIH unless there are scientific or ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

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" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html. Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

## URLS IN NIH GRANT APPLICAION OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary for the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

## LETTER OF INTENT

Prospective applicants are asked to submit by the deadlines given on the first page of this announcement a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the PI, the name of the Co-PI, the identities of other key personnel and participating institutions, and the number and title of the PA in response to which the application may be submitted. 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 Institute staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to the program staff contact listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: grantsinfo@nih.gov. Application kits are also available at the following URL: http://grants.nih.gov/grants/forms.htm

SPECIAL INSTRUCTIONS FOR PREPARATION OF THE APPLICATION

All applications must be submitted on the form PHS-398 (rev.4/98).

Budget:

Applicants should submit separate detailed budgets (Form Page 4-DD) for the planning activities, the individual Developmental Projects, and core facilities required for the initial Developmental Projects, and a single summary budget for the entire proposed period of support (Form Page 5-EE). The budgets should appear in the following order:

Planning Budget (use Form Page 4-DD) should include all of the costs required for planning activities. Examples of acceptable planning costs would be salary support for the PI, co-PI,and key personnel involved in organizing the Pre-NPEBC, costs associated with planning meetings, and other relevant planning related organizational costs. An annual meeting of all investigators funded through this program will be held to share planning progress and research insights that may enable further progress in the program. Applicants should request travel funds in their budgets for the principal investigator and one additional senior investigator to attend this annual meeting.

Individual Developmental Project Budgets (use Form Page 4-DD) should detail the costs associated with individual selected Developmental Projects or approximate budgets for example Developmental Projects. Budgets should indicate salary support for investigators involved in the Development Projects, costs associated with equipment, supplies and use of core facilities designed to support the Development Projects.

Individual Core Budgets should detail the costs associated with establishment of individual core services required to support the selected individual Development Projects. If the Developmental

Projects presented are examples, examples of cores required for those projects should be used for budget estimates. Budgets should include salary support for core staff, as well as costs associated with equipment and supplies.

Biographical Sketches and Other Support:

All applications should describe the scientific and administrative experience of key personnel and should include and follow the PHS-398 form instructions for Biographical Sketches and Other Support information. In this case, key personnel includes the Pre-NPEBC PI, co-PI, each of the investigators identified as a primary scientific project leader, and each of the investigators involved with a submitted Development Project.

Resources:

This section is to include a detailed description of the quality and variety of scientific resources available to accomplish the scientific goals of the Pre-NPEBC.

RESEARCH PLAN (not to exceed a total of 35 pages):

A) Major Research Objectives (8-10 pages).

This section should concisely describe the Pre-NPEBCs major research objectives, and should include descriptions of each of the scientific areas to be involved in the Pre-NPEBC, how they will be integrated, and the unique scientific opportunities that will be addressed. Applicants should address the opportunity offered by the selected research area for biomedical information science and technology to promote advances in a compelling area of biomedical research. The description of the PI and co-PI chosen to lead the Pre-NPEBC should include their scientific qualifications and a demonstration of administrative and scientific leadership abilities. The application should also address the complementary nature of the expertise of the PI and co-PI with respect to expertise in biomedical computing and biomedical research. For each major scientific subdivision, an experienced investigator that will assume responsibility within the Pre-NPEBC must be identified. Senior investigators must demonstrate a strong track record of scientific accomplishment, and a willingness to effectively collaborate, and the application should clearly define the role that each of these investigators will play in Pre-NPEBC activities. For each participating investigator, a short description of his/her ongoing research and its potential relevance to the Pre-NPEBC is required.

B) Organizational Activities (8-10 pages)

This section should include an example (model) of an organizational structure for the Pre-NPEBC. This model will not be a final structure, since that will be determined during the course of the planning activities. Instead, applicants should provide a detailed description of the activities that will take place. Activities to be completed during the course of the program include:a) Finalization of an organizational structure of the Pre-NPEBC. This structure will include the description of the appropriate constitution of relevant committees (not specific members), composed of both internal and external senior investigators, who will be responsible for the overall scientific direction of the Program.
b) Establishment of ongoing, interactive, multidisciplinary activities, such as seminars, workshops, forums, etc.
c) Determination of the process for the selection, implementation, monitoring, and if necessary, termination of Development Projects to be initiated. Include a discussion of appropriate timing for and planned approaches to facilitating the transition of these projects to independent support and completion.
d) Definition of the core facilities necessary to support the scientific goals of the Pre-NPEBC, how these core facilities will be maintained, how the decision to add or terminate a core facility will be made, and how resources will be allocated to the selected Development projects.
e) Establishment of a plan for developing a broad range of educational activities, from formal undergraduate and graduate programs to courses and seminars for student and researchers, visiting scientists program or other types of training, cross-training, or educational approaches.
f) Since the P20 Planning Grants are designed to support the organization of a multidisciplinary group, it is expected that the critical mass of investigators already exists at the Institution. Recruitment of one or two investigators in defined scientific area(s) may be required. If this is the case, applicants must identify the particular scientific area(s), and describe and justify recruitment plans in detail.

C) Development Projects (may not exceed 15 pages total)

When the P20 application is submitted, it must contain no more than three five-page descriptions of Development Projects or examples of Developmental Projects to be implemented in the Pre-NPEBC. These projects should be geared toward determining project feasibility, proof of principle and acquisition of preliminary data. These development studies must demonstrate collaborative efforts between two or more groups of investigators with a focus on biomedical computing in the context of areas of scientific opportunity in biomedical research. Each of these examples should include:

1) Title
2) Investigator names, and areas of scientific expertise
3) Specific Aim(s)
4) Background and Significance. Included in this section should be a description of the unique scientific opportunity made possible by this collaboration.
5) Research Design and Methods

D) Institutional commitment (1-2 pages)

Examples of Institutional support could be contribution to the support of salaries and/or equipment and reagent purchases required by investigators during the Phase II planning stage. The Institution could also make a commitment to the Program to provide common laboratory and/or administrative space, both during the planning phase and in the event that a successful NPEBC grant is awarded. If recruitment of investigator(s) is necessary, the Institutions plans for this effort, and clear demonstration of its commitment must be included.

The PA title and number must be typed on line 2 of the face page of the application form, and the YES box must be marked.

Submit a signed and complete original of the application, including the Checklist, and five signed and legible photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

Applications must be received by the application deadline dates given on the first page of this solicitation. If an application is received after that date, it will be returned to the applicant without review. The Center for Scientific Review (CSR) will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by the program staff within the relevant Institute or Center. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIH in accordance with the review criteria stated below. As part of the initial merit review, a process may be used by the initial review group in which applications receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the relevant institute advisory board.

Review Criteria

The five criteria to be used in the evaluation of grant applications are listed below.

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. The reviewers will comment on the following aspects of the application in their written critiques 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 by the reviewers in assigning the overall score weighting them as appropriate for each application.

1. Significance.
o Will the program provide significant advances in the selected areas of research?
o Will the research provide foundations or infrastructure for other research?
o Will the research advance human health directly or indirectly?
o Will the Pre-NPEBC have a significant effect on the concepts or methods that drive this field?
o Does the program bring in new ideas and new personnel and resources, or is it an aggregate of existing facilities?

2. Approach.
o Is the conceptual organizational and operational framework reasonable and appropriate to the aims of the project?
o Does the program integrate biomedicine and biomedical information science and technology?

o Does the program incorporate both fundamental discovery and the development of useful tools?
o Does the program take into consideration issues related to standardization of data input; interoperability of database design; and data retrieval, exchange, visualization, manipulation and integration?
o Is there a viable strategy for developing a menu of education opportunities, ranging from formal programs to courses and seminars, visiting scientist programs, etc?
o Is there a clear plan for defining sharing of responsibilities among investigators and between institutions (if more than one institution is involved)?
o Does the applicant acknowledge potential problem areas and consider alternative tactics?
o Does the proposed approach support the possibility of the Pre-NPEBC being ready to compete for a NPEBC Grant within the time frame of the proposed planning period?

3. Innovation.
o Does the Pre-NPEBC employ novel approaches or methods for facilitating scientific interaction?
o Do the proposed Development projects establish new, multidisciplinary collaborations, and are the projects original and innovative?
o Does the Pre-NPEBC group challenge existing paradigms or develop new methodologies or technologies?
o Does the program plan to use high-end computing?

4. Investigators.
o Are the Pre-NPEBC PI, co-PI, and lead investigators appropriately trained and well suited to the organizational and scientific responsibilities associated with this project?
o If there are plans to recruit investigator(s), are those plans reasonable and necessary and can those efforts be completed in a timely manner, such that the recruited investigator(s) can make meaningful contributions to the Pre-NPEBC?

5. Environment.
o Is there evidence of significant scientific commitment of the institution to fulfilling the objectives of the Pre-NPEBC?
o Does the scientific environment in which the work will be done contribute to the probability of success?
o If collaborative arrangements are proposed, is there a convincing demonstration that these interactions will be consistent enough to meet the needs of the Pre- NPEBC?

The initial review group will also examine: the appropriateness of proposed project budget and duration; the adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research and plans for the recruitment and retention of subjects; the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion; the provisions for the protection of human and animal subjects; and the safety of the research environment.

AWARD CRITERIA

Pre-NPEBC awards will be based on the quality of the proposed project as determined by peer review, availability of funds, and program priority.

INQUIRIES

Inquiries concerning this PA are encouraged. The opportunity to clarify anyissues or questions from potential applicants is welcome.

Inquiries or contacts concerning institute-specific technical or financial issues should be directed to the NIH BISTI technical or financial contacts listed at the following Web site: http://grants.nih.gov/grants/bistic/bistic_contacts.cfm .

Inquiries regarding general programmatic issues or notices of intent should be directed to:

Dr. James Cassatt
NIGMS
45 Center Drive
Bethesda, MD 20892-6200
TEL: 301-594-0828
FAX: 301-480-2004
Email: jc12b@nih.gov

Inquiries concerning review issues should be directed to:

Dr. Elliot Postow
Center for Scientific Review
6701 Rockledge Drive – Room 4160
Bethesda, MD 20892

TEL: (301) 435-0911
FAX: (301) 480-2241
Email: postowe@csr.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.394. Awards are made under authorization of sections 301 and 405 of the Public Health Service Act as amended by 42 USC 241 and 284 and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-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.

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