

The National Institute of Environmental Health Sciences

GUIDELINES
FOR
MARINE AND FRESHWATER BIOMEDICAL CENTERS

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I. INTRODUCTION

The mission of the National Institute of Environmental Health Sciences is to support research and research training relating to the etiology, mechanisms, diagnosis, treatment and prevention of human diseases and disorders caused by environmental chemicals and other factors. To achieve this mission, NIEHS, through the Division of Extramural Research and Training (DERT) employs a number of support mechanisms which are available to investigators. Among these are various types of research grants, including traditional Research Project Grants and Research Program Project Grants, Core Center Grants, and individual and institutional National Research Service Awards (training grants). Research and training areas of interest to the Institute are outlined in our information package, available from the NIEHS Information Office or from the Division of Extramural Research and Training, NIEHS.

The Marine and Freshwater Biomedical Sciences (MFBS) Center Grant (P30) is an institutional award, made in the name of a principal investigator, to support centralized resources and facilities shared by investigators with existing research projects and to stimulate a multidisciplinary approach to a joint research effort. It is awarded competitively, initially for five years, and may be renewed for periods of up to five years. Two types of MFBS Centers are appropriate for this program, those which function throughout the year and those whose activities are primarily during the summer months. Although no funds are provided for the direct support of research projects in the MFBS Centers, except for pilot projects in the year-round Centers and short-term projects in the Centers active primarily during the summer, the MFBS Center grant helps to integrate and promote research in existing projects and to establish an administrative framework within a common theme. By providing a Center structure, Core resources, and community outreach, this support is intended to enhance the productivity of traditional research grants at the institution and improve the health of the community and nation.

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This document provides information on NIH-NIEHS policies and procedures for NIEHS MFBS Center Grants (P30), including a general description, outline of essential characteristics, administrative requirements, scientific core requirements, allowable budget items, application process, review procedures, and review factors. It is important to realize that these guidelines are intended to provide meaningful direction and instruction about the MFBS center grant concept and as such, they are fairly comprehensive and structured. This is not intended to preclude the consideration of deviations on a case-by-case basis after discussions with and concurrence by appropriate DERT staff.

I. GENERAL DESCRIPTION

The NIEHS Center grant is designed to provide core support and to foster the coordination of interdisciplinary interaction and cooperation among a group of established investigators conducting high-quality research clearly related to the effects of environmental factors on human health. The intent of the NIEHS in employing this mechanism is to integrate and build upon existing programs and institutional resources that are already developed, peer reviewed, and supported on an individual project basis.

The MFBS Center grant provides core support to promote the greater utilization of marine and freshwater organisms as models for elucidating mechanisms of toxicity of environmental agents that will ultimately address problems of human health. It is not the purpose of the program to support research in marine and freshwater sciences, physiology of aquatic species, ecology, pollution monitoring, food safety, chemical transformation in the aquatic environment, food chain biomagnification, etc. These types of studies are best supported by other agencies.

The MFBS Center grant should provide an administrative structure and an environment which will strengthen and increase productivity, and generate new ideas through organized interdisciplinary collaborative efforts. As such, the MFBS Center grant provides an added dimension that includes capability and potential for a net accomplishment which will be greater than that possible by the support of individual projects alone. The MFBS Center grant provides support for core resources and facilities to be used by Center investigators in order to coordinate their activities. This support may include administrative and facilities personnel, equipment, supplies, and services. In addition, it may provide funds

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for program enrichment and for pilot studies. For Centers which function throughout the year, the NIEHS MFBS Center grant does not provide direct funding for ongoing research projects. These are expected to be funded through other sources and support mechanisms, mainly individual research grants and program projects awarded by the NIH. For Centers which function primarily during the summer months, the MFBS Center grant does provide support for ongoing short-term research projects. Stipends and tuition for trainees are not available through the MFBS Center grant funding; such funding must be sought through other mechanisms.

III. ESSENTIAL CHARACTERISTICS OF AN MFBS CENTER

The MFBS Centers are a national resource for multidisciplinary approaches to problems in human environmental health. As a group they form a network that fosters communication, innovation, and high-quality research. They are expected to provide a stimulating, multidisciplinary environment that attracts both established investigators and promising young investigators. They are also a key source of expertise to the NIEHS when dealing with emerging issues in environmental health and a means for communicating environmental health issues to the public and to elected representatives. Therefore, community outreach and education programs (COEP) are encouraged.

At the time of submission of an initial application, any institution or consortium wishing to qualify for the MFBS Center grant must have an active, established program in biomedical research in environmental health sciences. The existence of an ongoing, extramurally supported biomedical research base is the prerequisite for the establishment and continued support of a MFBS Center. A minimum of \$250,000 (direct costs) of peer reviewed extramural support for Center related research is required of applicant investigators at the time of application. The quality of this research base will be evaluated by considering the competitiveness of the funding sources and the breadth of support in the proposed center (see part E). Primary consideration in the peer review process will be given to how the proposed Center will extend and stimulate this research. Focus, relevance, interrelationships, quality, (and to some extent) quantity, productivity, and demonstrated or potential interdisciplinary coordination are all important considerations.

Over and above the base of high quality research programs, a number of other factors are essential for an effective MFBS Center, and these characteristics must

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be demonstrated to the reviewers of the application. The degree to which each of the following characteristics can be documented will be a major determining factor in the peer reviewers' evaluation and ranking of the application.

A. Interdisciplinary Coordination

There must be evidence of interdisciplinary research that is or will be facilitated by a high degree of interdisciplinary coordination, interaction, and cooperation among Center members. A Center's support should facilitate creative interactive research activities and should increase efficiency by providing support for shared equipment and centralized multi-user facilities. Examples of interdisciplinary coordination and cooperation resulting from the structure provided by a Center include, but are not limited to:

1. Collaborative, interdisciplinary research efforts,
2. Collaboration among laboratory investigators,
3. Publications resulting from such collaborative efforts,
4. Significant sharing of facilities and equipment, and
5. Seminars involving all Center members.

Scientists conducting independent research with limited or non-existent interdisciplinary interactions cannot be considered to be functioning collectively within a Center. Such individuals are supported independently by more suitable mechanisms, such as individual research grants (R01).

B. Organization and Facilities

The Center must have appropriate and adequate organization and facilities for the conduct and evaluation of Center activities. The facilities and organizational arrangements should stimulate collaboration among constituent programs. This factor is discussed in greater detail under (V.B) Facilities and Services Cores.

C. Center Director

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Each applicant institution will specify a Center Director with adequate authority to be responsible for the organization and operation of the Center. The Director should be an experienced and respected individual who can provide scientific and administrative leadership for the total program. He/she must be able to coordinate, integrate, and provide guidance in the establishment of new programs and direct Center resources to existing programs to maximize productivity. The authority of the Center Director should include the control of appointments to the Center (and by extension, the ability and means to delete individuals from the Center). A Deputy Center Director must also be designated to serve in the absence of the Director, with other responsibilities described.

D. Institutional Commitment

There must be an adequate commitment of the parent institution(s) to the MFBS Center. The Center should be recognized as an important element within the organizational structure. Institutional commitment may be manifested by various combinations of personnel, facilities, and financial obligations and commitments.

E. Research Grant Base

Because the purpose of the Center grant is to accelerate progress in research and application of research results in human populations, a minimum base of research grant support by proposed Center investigators is required. At the time of submission of a competing application, the proposed Center structure must have at least \$250,000 direct cost of peer-reviewed research grants on environmental health-related topics awarded during the fiscal year in which the Center grant application is submitted. These grants should have a minimum of two years of funding remaining in the project period, not including any administrative extensions, either with or without additional funds. Qualifying research grant support should be distributed among the proposed participating Center investigators and be representative of the type of research that the proposed cores can be expected to enhance. Research grant support from sources other than PHS will be considered on a case-by-case basis if it can be demonstrated to NIEHS staff and to reviewers of the center grant application: (1) that the research is sufficiently related to human health and to the elucidation of adverse effects of environmental agents on human health; (2) that the grant award is the result of an openly announced and appropriately competitive process; and (3) that the grant application was

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subject to a peer review of comparable rigor of that of PHS. If the qualifying grant base includes other than PHS research grant support, the scientific merit of that research and the degree to which it satisfies the three criteria above may be subject to review by the Environmental Health Sciences Review Committee.

Prior to submission of an application, the proposed Center Director must consult with Institute Staff regarding the adequacy of the research base.

IV. ADMINISTRATIVE CORE COMPONENT

The administrative structure of the Center will, for the most part, be left to the applicant institution (subject to review by NIH peer review mechanisms). NIH's experience has demonstrated that the effective development of a Center program requires close interaction between the Center Director, the Center investigators, appropriate institutional administrative personnel, the staff of the NIEHS and other members of the institution in which the Center is located. It is expected that the organization of the administrative core will provide a supportive structure sufficient to ensure accomplishment of the following:

- A. Coordination and integration of the Center components and activities,
- B. Advice to the Center Director about the productivity, effectiveness, and appropriateness of the activities and staff of the Center,
- C. Interaction with other Centers, the NIEHS, and other appropriate individuals, groups, or organizations,
- D. Administration of the Center's pilot project program including selection of projects and evaluation of the success of the program.

This administrative structure should include the establishment of an internal advisory committee, selected from the principal investigators and core leaders of the Center to assist the Center Director in making scientific and administrative decisions. The role of this committee in evaluating relationships of all projects to overall objectives of the Center, assessment of progress of ongoing research programs and continual reevaluation of the use of Center resources should be made clear in the application. This committee may also function in the identification and selection of key personnel for recruitment to the Center.

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In the case of an extended absence of the Center Director, the appointed Deputy Director will administer the Center during the unavailability of the Director. If the position of Director becomes vacant, a new permanent Director acceptable to the NIEHS and the National Advisory Environmental Health Sciences Council must be appointed as soon as possible by the institution. Deliberations regarding the appointment should involve the NIEHS staff. In general, the NIEHS will require that the new Director have scientific and administrative qualifications comparable to those of the original Director.

In addition to the internal advisory committee, an external advisory committee to the Center Director must be established. The External Advisory Committee should consist of two (2) to three (3) scientists, including a chairman, who are from outside the grantee institution. It is inappropriate for any individual associated with the Center or with administrative responsibility for any aspect of the Center to serve on the External Advisory Committee. The function of this committee is to assist in evaluating the merit of the research programs of the Center, the relevance and importance of the individual components to the objectives of the Center, the effectiveness of communications within the Center, the effectiveness of the pilot project program, and the value and anticipated contributions of proposed new Center initiatives. Likewise, the External Advisory Committee is expected to make recommendations concerning the removal of core support from projects no longer considered fruitful or relevant.

The External Advisory Committee should meet at least once annually, and the committee may be supplemented by the use of ad hoc members knowledgeable in particular areas or segments of the Program being reviewed. In competing continuation applications, documentation concerning the functioning and effectiveness of the external and internal advisory committees must be included.

The Administrative Core should also identify one individual with appropriate fiscal expertise who will function as the business manager for the Center. This individual may be located at the Center level, the Department level or be an institution business official, but it is important that this one person be responsible for the fiscal aspects of the Center grant and be directly involved in its non-scientific management. This person will also serve as the point of contact with the Grants Management Staff of NIEHS. The business manager should also be a participant at the meetings of the internal advisory committee to assure that institutional concerns are recognized in the melding of interest of the MFBS Center and the individual projects. While budget formulation and planning undoubtedly will begin with the Center Director in collaboration with the

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scientific staff, the business manager must be involved deeply in the process and must give final approval. The diversity of support requires that the institution evaluate such things as equipment on hand versus that requested for core facilities, the usage of core facilities by individual research projects and documentation on equipment maintenance costs borne by individual grants and core center grants. This information should be available to the NIEHS prior to the initial scientific review.

In addition to its responsibilities for fostering communication and cooperation within the Center and developing program goals which will optimally exploit its resources, interests and expertise, the Administrative Core must provide a framework through which the Center can work with the NIEHS and with other EHS Centers to meet national environmental health research needs. In order to facilitate communication and dissemination of information and review of problems and national needs in the environmental health sciences, meetings of all Center Directors and appropriate NIEHS staff are held semiannually. Each Center institution and the NIEHS act as host institution on a rotating basis. These meetings are scheduled well in advance, and provide a forum for discussion of program accomplishments, needs, etc. by each Center Director and the Director, NIEHS, and his/her staff.

V. SCIENTIFIC CORE COMPONENTS

The funding for a MFBS Center is intended to provide an administrative framework and a resource infrastructure for the support of the research activities of the Center. The Center itself is generally structured to consist of an administrative core, research cores, facilities cores, service cores, a pilot projects program, a community outreach and education program (COEP) and, optionally, an enrichment program. In all cases, the emphasis should be on the development and support of shared resources, facilities or programs which will benefit and strengthen the Center. The justification for the establishment of a Core component should be based on ongoing and competitively funded research programs.

A. Research Cores

A MFBS Center may consist of one or more Research Cores depending on the size of the Center (number of investigators and research base, research disciplines, etc.) Research Cores are designed to consolidate and focus environmental health science research efforts into a series of administrative

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and programmatic units. These units, each under the leadership of a Core Director or Coordinator, may be organized along disciplinary lines (such as Biochemistry, Neurotoxicology), other identifiable research areas selected by the applicant, or some combination of these. Whatever organization is chosen, however, each core should be characterized by an essential element of internal cohesion and synergy among its members. In addition, in order to justify a research based core, the application should address two important review criteria.

- The unit should provide an intellectual resource to the rest of the Center and enhance the activities of the other units.
- The unit's research activities should provide a program of sufficient scientific merit to be able to provide such a resource.

In describing each of these program areas it is important to relate how the program will benefit from inclusion in the Center, and particularly from any funds requested from the Center grant. It is also important to describe what impact each core will have on the Center activities as a whole.

The description and plan for each of the individual program areas should include statements of the goals and aims of the Core, as well as brief descriptions of the research base for the Core. Center investigators should be productive, established, independent researchers. Each Center is required to develop guidelines for Center participation by investigators. Since the MFBS Center Grant does not provide direct funding for research projects other than pilot studies, the application should contain summaries of research activities being conducted by Center staff rather than protocols. Important aspects to include in this narrative are:

1. Interactions and interrelationships of the research efforts;
2. Uses and benefits of Core services;
3. Plans to develop productive collaboration among Center investigators; and
4. In the case of renewal applications, the effect that the presence of the Center has had in regard to the foregoing during the funded grant period.

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The application should also emphasize new directions in which the core intends to move, how existing staff intends to follow up on new opportunities within their scientific competence and areas where new staff are likely to be recruited. It is from this discussion that reviewers are likely to infer the sense of innovation and vision among the Center investigators which would establish the Core group as a component of a national resource in environmental health research.

Active research grants funded by NIH, and other federal agencies supporting biomedical research which have undergone peer review, will be presumed to be scientifically meritorious and will be reviewed primarily for appropriateness of core use and for integration in Center programs rather than for scientific merit. Research projects funded from other sources and research contracts from all sources may be reviewed for scientific merit as well as for appropriateness for inclusion in the core and the research base. Projects and investigators may be deleted from the core based on either review criterion. The assessed scientific merit and overall impact of core activities on environmental health science research in the Center will determine the relative merit assessment of the core.

B. Facilities and Services Cores

A major function of a MFBS Center grant is for the support of research core facilities and services which have multiple users. These cores should be designed to furnish groups of Center investigators with some technique, service, or instrumentation in a manner that will enhance the research in progress, consolidate manpower effort, and contribute to cost effectiveness in terms of providing a service at less cost and possibly higher quality than if each investigator were to attempt the same thing individually. Examples of such facilities and services are: an animal core, an electron microscopy core, a tissue culture core, a pathology support core, a statistical support core, an oligonucleotide synthesis core, an analytical chemistry core, etc. The establishment and continued support for facilities and research services cores by a Center grant must be justified on the basis of use by independently funded Center investigators. Although the use of these cores by pilot projects cannot be used to demonstrate the need for a core, their utilization by pilot projects is encouraged. Use of core facilities by projects funded by research and development contracts will be evaluated on an individual basis. In general, use of Core facilities by contracts must be paid for in full from the contract funds, not from the NIEHS Center grant funds.

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Documentation of the use of the Facilities and Services Cores by the research programs of the Center should be done by a descriptive narrative of environmental health-related research activities at the institution and any collaborating institutions which rely upon the use of each facility or service core. This narrative may be included within the description of a research core or may appear as a separate section of the application, depending upon the nature of the service support being requested.

The application should provide a total operational budget for each facility or service together with the percentage of support requested from the Core Center Grant. At the time of the site visit, user logs should be available to validate the extent of use and degree of sharing, should the reviewers request it. In the case of new proposed Centers or new facilities and Service Cores within an existing Center, similar information regarding anticipated use of the Cores should be provided.

All core support derived from the MFBS Center grant must be acknowledged on RO1 and PO1 applications. Therefore, prior to the initial scientific review for competing renewal applications, the Grants Management staff of NIEHS will verify that all grant applications have included the appropriate budgetary information. When a Center is first established, individual investigator-initiated research project grants may include funds for a part of the services that will ultimately be available from the Cores. At the time of renewal (competitive and noncompetitive) individual investigators must remove from the budgets of individual research project grants those costs associated with the services that are received from the Cores. The elapsed time before this adjustment is made generally constitutes a very minor overlap, since it is usually several months before a core is fully functional. It is acceptable for a Center to have nominal charges to individual grantees for Core services. In this case, these are allowable budgetary items in the investigators' individual grants. A mechanism should be proposed in the Center application to monitor these budgetary adjustments and to ensure that Center investigators using cores can provide a satisfactory explanation of their relation to the Center in their individual grants.

Information in Center renewal applications should generally cover the same points as initial applications. In addition, past performance and accomplishments should be described. The effect of the service provided by a Core on investigator productivity, in meeting stated goals and objectives, and the cost effectiveness of the core should be addressed.

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Each core must have a designated leader who will be responsible for core activities. The application should explain the organization and proposed mode of operation of each core. It should include a plan for prioritizing investigator use of the core as well as a definition of qualified proposed and potential users. This definition need not be too narrow, since some limited use of a core might be an enticement to established investigators in other fields to lend their expertise to the field of environmental health. If the core also is used to train investigators in special techniques, the extent of and approach to this training should be included. The use of the core for training purposes is encouraged.

C. Pilot Projects

Inclusion of a pilot projects program in MFBS Centers is strongly recommended. Because they encourage new and creative research approaches they are considered an important, integral part of the support provided by the Centers Program. Therefore, funds should be designated to provide support of short-term research projects to explore the feasibility of new areas of study and new research leads, and to enable investigators to collect sufficient data to pursue support through other funding mechanisms. MFBS Centers are encouraged to commit whatever portion of the budget to this activity that will stimulate the vitality of the Center. Pilot projects are primarily intended to:

1. Provide initial support for new investigators to establish new lines of research,
2. Allow exploration of possible innovative new directions representing a significant departure from ongoing funded research for established investigators in environmental health sciences, and
3. Stimulate investigators from other areas of endeavor to apply their expertise to environmental health research.

While the administrative framework for management of the Center's pilot projects program is left to the Center Director's discretion, certain minimal requirements must be met. The management of the program must include provision for:

1. A mechanism that ensures preparation and appropriate announcement

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of the availability of pilot funding.

2. A mechanism for the scientific merit review of pilot project proposals. Copies of all of the proposals with documentation of their reviews, relative ranking, and final action must be retained by the Center. The records must be available to reviewers in the event of a site visit.
3. A mechanism to maintain a record of subsequent results of each pilot study (abstract, R01 submission, etc.) recipient. This record must be available to reviewers at the time of the initial scientific review. Input by both the Internal Advisory Committee and the External Advisory Committee in the management of the Pilot Studies Program is strongly encouraged.

In competing continuation applications, the review of this program will be based on the record of accomplishments, the management of the program, and an assessment of overall potential needs and opportunities. Therefore, in general, a competing continuation application should include:

1. A historical overview of the Pilot Project program,
2. A description of Center management of the program,
3. A listing of all pilot projects which were supported during the last project period, giving the title, amount awarded, investigator, a brief description of the project and, if known, the results and outcome in terms of eventual grant submissions, awards and publications.

D. Program Enrichment Activities

Limited funds for Center enrichment purposes (e.g., special lectures, visiting professors, symposia, etc.) may be allowed when specifically described and the cost itemized. Justification should be provided for the relationship to the Center as a whole and not to a single, separately funded project.

E. Community Outreach and Education

All MFBS Centers must develop and sustain community outreach and education activities and are encouraged to collaborate with NIEHS Staff in

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developing printed and audiovisual educational materials. These outreach activities should be identified as programs supported by the NIEHS MFBS Center. The objective of the community outreach and education program (COEP) is the translation of research information into knowledge applied to public health. Therefore, each center is encouraged to develop a COEP consistent with the research strengths of the center. This may consist of continuing professional education; public awareness; occupational group education; disease prevention programs; primary, secondary and college general education; telephone inquiry and information programs; community issue programs; etc. The COEP might be contained within the administrative core or comprise an independent core unit. Activities should be coordinated with the NIEHS Office of Communication to assure consistent policy and avoid duplication of efforts. The program should not go beyond public and community education about reducing environmental disease risk and/or hazard exposure recognition as the COEP is not intended to give medical or legal advice. A level of support of \$30,000 should be allocated for COEP.

F. Other Center Activities

These are Center facilities that provide highly unique or specialized services or resources to related research programs outside of the Center. These are intended to enable a Center that has highly sophisticated technology available to provide usually expensive services at significantly lower cost or to make available some unique and valuable resource. Requests for these individualized types of core support should be discussed with the NIEHS staff prior to their inclusion in requests for Center funding and are subject to merit review by the EHS Review Committee and to review for relevance to environmental health research by the NAEHS Council.

VI. ALLOWABLE BUDGET ITEMS

The appropriate OMB cost principles as modified by the Federal Regulations applicable to these grants and the PHS Grants Administration Manual and Grants Policy Statement govern the general rules of allowability, allocability and reasonableness of costs. These guidelines will be a part of the terms and conditions under which these awards are made. Requested core funds must be in support of the research programs of the Center. It is important to recognize that, even though a cost may be allowable, it is the responsibility of the applicant to adequately justify the inclusion and amounts of all items for which funding is requested. Should an award be made, it is NIH practice to limit escalation;

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accordingly, an adjusted escalation factor will be utilized in computing future year costs, unless the Center is already at the cap. (Currently, the standard escalation factor is limited to no more than 4%.)

A. Professional Personnel Salaries

Due to the \$300,000 cap on MFBS Centers, request for salary support should be limited in order to have funds to adequately support the service cores, pilot study program and other essential activities of the Center. For all of the categories of personnel listed below, the requested percentage of an individual's salary may not exceed the percentage of effort devoted specifically to meeting actual center responsibilities. However, the total percentage time devoted to Center related activities, paid or unpaid by the Center including time on Center related research projects paid by other grants should be stated. This will result in a total time commitment of over 100% due to "double counting", but the inclusion of this level of time effort on both the Center and research grants is a more accurate indication of involvement in Center activities. Documentation substantiating this level of effort must be included in the application and levels of effort should be described in each appropriate part (core) of the application.

1. Senior Leadership Personnel

This category includes individuals who have responsibility for overall direction of the entire Center. Examples of senior leadership personnel that qualify include: Center director, deputy director, associate directors, and similar positions.

2. Major Program Leaders and Core Leaders

For MFBS Centers which are active throughout the year, this category includes the designated leaders, directors or coordinators of the identified research cores of the application. Program directors or leaders are eligible for salary support under this category for the time and effort they devote to carrying out functions such as research planning, supervision, coordination activities, core administration, and staff training. In addition to these leadership activities, program directors should be active participants in high-quality research such as being a principal investigator on a funded research grant. A description of activities and time estimates for all core directors' functions must be included in the proposal.

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Program directors will not be funded unless they direct bona fide programs and are judged by peer reviewers of the core grant to be appropriate leaders of such programs. Program Leaders may receive additional salary support as supervisors of shared resources. Individuals identified as Core Leaders or other senior leadership personnel must be designated as key personnel on the application.

For MFBS Centers which function primarily during the summer, the program leaders are those investigators who agree to participate in the Center and conduct high quality research related to environmental health sciences using aquatic models. Some of these participants may be eligible for salary support if their research is important to the success of the Center or they carry out duties which are essential to the operation of the Center.

3. Center Investigators

Appointment as a Center investigator is an indication of active participation in the Center's interdisciplinary and coordinated approach to research on problems in environmental health. The Center investigator benefits from the appointment by being able to use core facilities, etc., at no charge to his/her research project and by participating in the interactive framework of the Center. The Center benefits from the scientific and intellectual input of these investigators. The anticipated result will be a synergistic effect on the research programs in the Center due to the existence of the Center grant. Therefore, no salary support for research activities is allowed. However, time commitments to Center-related activities should be indicated.

4. Administrative and Support Personnel

- a. Salaries and support for Center administrative and clerical personnel, such as the business manager, secretaries, and clerical support staff, may be provided. These costs should not duplicate or replace costs included in the institution's indirect cost rate. The justification for clerical support should describe fully the duties to be performed for each requested position and include information on how many other clerical positions are in the Department or Center, how many are employed by Center investigators, and explain the source of funding for each.

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b. Technical and Support Personnel

Salary support for technical personnel or positions to be filled in core units may be included. However, the time and salary of all technical and support personnel must be related to a Core laboratory facility or a core function. If the individual functions primarily in providing a core service or function, the justification for the position should be made on the basis of the use record of the core. Appropriate acknowledgement will be verified by the Grants Management staff of NIEHS prior to Center application review. As a general rule, funds for the support of shop personnel and mechanical maintenance should be included as a part of the institutional base for indirect cost calculations and are unallowable as direct costs to the Center. However, in highly unusual circumstances, costs for specialized research core facilities which would not otherwise be available at the Institution without the existence of the Environmental Health Sciences Center may be allowable with proper justification and documentation. Prior to including such costs in the application the Center Director is strongly encouraged to discuss the proposed costs with program and grants management staff of the NIEHS.

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B. Equipment/Facilities

This category includes items for generalized use in the Center to provide service for several projects or a Core function. Center grant funding is particularly useful for purchases and operation of large items of equipment which are difficult to justify in individual grant applications. When items of equipment are requested, similar items already available must be reported and a clear justification for the new ones in terms of function must be provided. The application should provide a list of potential users and projects, giving grant numbers if possible. The applicant must also provide, on the budget justification page, any duplicate requests which have been made for funding the equipment requested. Co-funding of expensive items of equipment is encouraged. The requested budget for the equipment should be in the core providing this service and not in the administrative core budget.

C. Supplies

Consumable supplies, such as office materials, glassware, animals, chemicals, etc. may be requested, provided they are items used in common by Center personnel and serve to reduce the cost requirements for individual projects.

D. Travel

Travel of the Center Director, one other Center scientist, and an administrator to meetings with other NIEHS Center Directors or to other center facilities pursuant to the administration of the center; and travel of scientific, technical or administrative staff for training that would enhance the quality of a core unit operation or travel required to maintain the operation of a core unit is allowed. However, this must be focussed, active, intensive training such as a specific course or workshop as opposed to a session at a national meeting or the equivalent. All travel should be budgeted within the appropriate core unit. Travel of the Center Director to relevant scientific meetings is also permitted, but travel of other scientific staff to scientific meetings or for the purpose of dissemination of research results is not allowed; these costs being more appropriately borne by individual research grants.

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E. Consultants

Named consultants and members of the External Advisory Committee and their associated costs may be included. Support of consultants must be fully justified in terms of program needs. Cost of visiting scientists and seminar speakers in conjunction with the enrichment activities are allowable but all items must be fully itemized and justified.

F. Pilot Projects

As described previously in Section (V.C.) pilot projects are strongly encouraged. Renewal applications should clearly delineate and report the specific allocations of grant funds to the pilot projects program for each year of funding, providing details as described earlier.

G. Other Expenses

Maintenance contracts on general use equipment, duplication costs for annual reports, computer rentals, etc. may be included if fully justified by the application. Requests for funds for equipment maintenance must specify what items are to be maintained, the total yearly cost for maintaining each item, the main users of the item, any other source requesting funding for maintenance of these items, and the amount being contributed from other sources. Publication costs and page charges related to research results of pilot projects are allowed; however, publication costs and page charges for dissemination of other research results by staff investigators are not allowable. The latter should be paid by individual research grants. Costs of developing, printing, and distributing educational materials are permissible to the extent authorized by PHS policy. Inclusion of a statement recognizing that the document was created in whole or in part with PHS funds should be included on publications.

H. Alterations and Renovations

Funds for alteration and renovation of existing facilities may be requested so long as required for operation of the Center programs. However, NIEHS Staff should be consulted as early as possible in the planning of these facilities for special instructions, limitations, etc. Funds for alterations and renovation will not be allowed unless there will be at least two years remaining on the grant at completion of the proposed alterations and

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renovations.

I. Contracts and Consortium Arrangements

These are, in general, allowed but require special budgetary and reporting format. The NIEHS Staff should be consulted prior to submission for special instructions.

J. Program Income

Applicants for center grants must include in their applications a reasonable estimate of the amount and source of any program income expected to be generated as a result of any center activity for which support is being sought. Program income generated, whether anticipated in the application or realized subsequent to award, shall be treated as follows:

The first \$25,000 shall be utilized in accordance with the additional costs alternative, the remainder shall be utilized in accordance with the deduction alternative. Questions related to the generation and/or appropriate disposition of program income should be directed to Division staff.

K. Items not fundable under a P30 MFBS Center grant include:

1. Direct support of individual research projects;
2. Salary and support for central institutional administrative personnel usually paid from institutional overhead charges, such as budget officers, grant assistants, and maintenance personnel;
3. Salary and support for administrative activities such as public relations;
4. Travel of investigators, other than the Center Director, to scientific meetings;
5. Page and publication charges for staff investigators other than for pilot studies; and
6. Stipends and/or tuition for trainees.

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L. Budget Limitations

Applications for MFBS Center grants are limited to \$300,000 direct costs per year. Exceptions to this limit may be made in consultation with NIEHS officials for special emphasis programs.

VII. APPLICATION PROCESS

A. Pre-application

Interested investigators are strongly urged to consult with NIEHS program staff prior to the preparation of an application. It is recognized that the preparation of applications for multi-investigator grants requires a substantial investment of time, effort, and resources by the Center Director and the applicant institution. During initial conversations the NIEHS staff can discuss the potential applicant's plans for a Center and whether or not they are consistent with the guidelines for Centers and mission responsibilities for NIEHS. The base of peer-reviewed research support to proposed Center investigators must be approved by NIEHS staff prior to acceptance of an application. If appropriate, alternate support mechanisms may be suggested.

The potential applicant is strongly advised to submit a Letter of Intent which should include a concise description of the proposed Center. The description should indicate the unifying theme and research goals and give an estimate of the anticipated requested level of support. It is helpful if the potential applicant can, in anticipation of informal discussions with NIEHS staff, identify individually-supported projects with names of responsible investigators proposed as part of the Center along with curriculum vitae for core Center staff and provide a statement of existing research resources and proposed additions to be requested in the application. With this information, NIEHS staff will be better prepared to advise and assist the applicant in structuring and completing a formal application. Advice given by the staff should not be misconstrued as authorization for award. Staff will not evaluate or discuss merit of scientific aspects of the proposal.

B. Preparation of Applications

This section supplements the Information and Instructions for Application for Research Grant (Form PHS 398 rev 5/95) which is included in NIH grant application kits. Because these application forms are designed primarily for individual research grants, additional information is required when used for Center Grants. Except as modified in the following sections, the general instructions should be followed.

1. New Applications

The following information should precede the main text of the application.

- a. The face page and page 2. Item 2 of the face page should be "Marine and Freshwater Biomedical Sciences Center Grant." A title should be chosen to correspond to the major theme of the Center.
- b. Complete Table of Contents, page 3. (Remember to number all pages consecutively, renumbering the printed application kit page numbers, if necessary).
- c. The complete consolidated budget for the entire Core Center (page 4). Continuation pages may be used if needed to list all personnel.
- d. The consolidated, or total, budget for the proposed project period (using page 5 of the application kit).
- e. A summary table showing the budget summary for all core units, subunits, and pilot projects for the next budget period (use Exhibit II).
- f. Distribution of Professional Effort on this application (Exhibit III).
- g. A separate budget for each core unit or activity must be included using duplicates of application kit pages 4 and 5. ("First 12-month

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period" and "All Years of Support Requested".) All proposed costs must be fully justified for both the 12-month and future years budgets as indicated in Form 398 instruction sheet. In addition the budget justification should specify the proportion of each investigator salary that is being requested under each of the investigator categories, i.e., Core leader. Similar justifications should accompany requests for technical personnel.

- h. A listing, by Principal Investigator, of all grant support currently active by Center investigators. Each grant should be listed only once. Information to be included is: Principal Investigator, complete grant, number, title, total project period, total amount, current annual amount. NIEHS-supported grants should be listed first, followed by other NIH grants, other federal contracts and cooperative agreements, and other sources. Individual postdoctoral fellowships should not be listed.

These data should be consolidated into a table which reflects the following:

- (1) Number and amount of all other NIEHS support.
- (2) Number and amount of other NIH (excluding NIEHS) support.
- (3) Number and amount of other Federal (excluding NIH) support.
- (4) Number and amount of all non-Federal support.

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- i. The page entitled "Other Support" should be filled out for each investigator for whom support is requested. Information to be included is shown in Exhibit IV.

Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel.

- j. Biographical Sketches. The Principal Investigator should be first, followed by the other investigators, in alphabetical order. Research support for the last three years should not be included as part of the biographical sketch. Bio sketches are limited to two pages.
- k. The Main Body of the Application. The introduction should concisely present the proposed research strategy, including background information leading to the request for MFBS Center support-, a description of the aims and objectives of the Center, benefits to be achieved by funding as a Center grant, special program resources, and overview descriptions of activities and functions of each core unit and subunit, emphasizing areas of coordination. This should be followed by more detailed presentations of the Administrative Core and the other Core Units, providing the information elaborated in the preceding sections of this Guide.

2. Continuation Applications

A continuation grant application must be submitted annually on Form PHS 2590 at least two months prior to the end of each annual budget period. A central office of the grantee institution has the responsibility for notifying the Center Director of the time for submission of the application and for providing the necessary application kit and

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computerized face page. Timely submission of continuation applications is essential to avoid possible discontinuity of support. The application should include the following:

- a. A Table of Contents following the face page;
- b. A composite budget for the entire Center for the next budget period (any change in recommended level of support must be fully explained and justified);
- c. A summary table showing the budget summary for all core units, subunits, and pilot projects for the next budget (use Exhibit II format);
- d. A listing of all sources of current and pending support for each core investigator including, in an explanatory note, changes in effort and salaries of core personnel;
- e. An itemized budget for each core unit and subunit (use duplicated budget sheets from the application form and fully explain and justify all changes in personnel and other budget items that are different from those reported in the previous year's budget);
- f. A biographical sketch of any new professional personnel and an explanation and justification of additions to the Center;
- g. Fiscal data for the current budget period (follow the Form PHS 2590 instruction sheet). Explain fully and justify expenditures which differ significantly from the awarded budget;
- h. A summary progress report (follow the Form PHS 2590 instruction sheet, except, at the beginning, give a concise list of new findings with an assessment of each new finding in terms of basic science, application to environmental health and national health policies and decisions);
- i. Summary progress reports for ongoing or completed pilot studies;
- j. Proposed feasibility studies (new starts), including descriptions as indicated in the section on "New Applications."

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Regarding publications, list only those published or in press since the last continuation progress report.

Note: Public Health Service Grants Policy requires that three reprints of publications resulting from work supported in whole or in part by the PHS grant must be submitted to the awarding component.

Comprehensive Annual Center Report. In addition to the summary progress report required for continuation applications, the Center Director prepares and submits separately, following the conclusion of each budget period, a comprehensive annual report of all activities relating to the Center. Typically, this report includes (a) an "Introduction and Summary" of research, training and other programs; (b) director's report on major research accomplishments (highlights); (c) detailed progress reports on each research project conducted by core scientists, grouped according to research core unit or subunit, with appropriate references and a list of publications since the last annual report (d) a progress report on feasibility or pilot projects; (e) a report on the outreach program including the purpose, communities affected, and evaluation of success of the outreach program in meeting its objectives and (f) an administrative report, discussing relevant personnel and other matters. These reports are distributed to other Center Directors, NIEHS staff, and may be distributed elsewhere as the Center Director deems appropriate.

3. Competing Renewals

Instructions for new applications pertain also to competing renewal applications. In addition, however, competing renewal applications must contain a progress report covering the entire project period of the Center since the initial application or the most recent competing renewal application. This progress report should contain an overall executive summary of the most significant advancements of the Center as well as the complete progress of each of the cores. In addition to information provided in new applications, give:

- a. A list showing changes, if any, in responsible investigators since the most recent competitive review,
- b. The rationale for changes, if any, in percent effort and salaries charged to the core for each investigator, including technicians and other support personnel,

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- c. A list of discontinued or modified Core Units, with an explanation for discontinuation or modification, and
- d. A list of all publications and completed manuscripts which have acknowledged Center support and resulted from the Center staff research during the period covered by the progress report. Do not list publications from prior project periods.

4. Competing Supplemental Applications

Generally, Supplemental Applications are not allowed that exceed the \$250,000 limitation on MFBS Centers. However, there may be certain circumstances where supplemental applications will be allowed. Consultation with and approval of NIEHS staff is required if the total budget of the Center with supplemental funds exceeds \$250,000. Note that agreement to accept the application for review does not imply a commitment to fund.

Applications for supplemental funds should be made on Form NIH 398, with the words "Supplemental Application" typed on the face page above the words "Grant Application." Complete the face page for supplemental funds requested and all other items as indicated, then give sufficient detail about the requested addition for adequate evaluation of the proposal. Since the original application may not be available during the review, it is essential that the Center be described to set the stage for the supplemental request. In the overview, all information requested in the "New Applications" section should be included but adjusted to the requirements of the supplement. Give (a) table of contents; (b) composite core units and subunits budget for the first 12-month budget period and for future years for each core unit and subunit for which supplemental funds are being requested; (c) Summary Tables for each year of requested supplemental support in terms of the entire Center and new efforts or expansion for which the supplement is being requested (Exhibits I- II). In addition, describe events leading to the need for supplemental support. Give a summary progress report for the Center, indicating clearly the research directions leading to the need for supplemental funds and the rationale for the new or expanded activity.

5. Use of Human Subjects and Animal Welfare

Current NIH policy requires approval indicated on items 4 and 5 of the face page of the PHS 398 form for all projects involving the use of human subjects

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and vertebrate animals whether new, competing renewal, or supplemental. Additional information is required for EHS Center grants, however. Please provide, as an attachment, a separate list of each individual project involving human subjects and a list of each project involving vertebrate animals, regardless of source of support, in which core personnel are involved. As a minimum, this list should include the investigator's name, grant or contract number, title of project, and date of the most recent institutional review and certification. Letters from the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) should be included that state that any research (pilot studies or other non-NIH reviewed research) performed under this grant will obtain IRB and IACUC approval.

C. Application Submission

Applications for all types of Center grants--new, competing renewal, and supplemental--competing for funds in a given fiscal year are submitted on a single receipt date announced through a solicitation in the NIH Guide to Grants and Contracts. In general, the schedule shown below will apply:

<u>Guide</u> Announcement	July - August
Receipt Date	February 1
Initial (Scientific) Review	July
Council Review	September
Start Date	April 1

This schedule and single receipt date allows new applicants sufficient lead time to prepare an application and to plan for implementation if funded. Applicants for competing continuations will have approximately seven months between Council review and the start date. It also permits responsible financial management by the Institute of its Centers Program.

The original and six copies of the completed application should be mailed to the Division of Research Grants. Addressed labels are included in the Form PHS 398 application kits. In addition to those copies submitted to the Division of Research Grants, please send four informational copies, under separate cover, to the Program Administrator (see item X below). These copies are useful to the staff for planning purposes.

In addition, any appendix material should be mailed directly to the Chief, Scientific Review Branch (see item 10 below). This should be done following

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acknowledgement of receipt and assignment of the application. Approximately 15-17 collated copies of appendix material are requested.

The Division of Research Grants has the responsibility of assigning an application to the appropriate NIH Institute. The Institute assignment is based on the scientific goals of the entire program and the Division of Research Grants, in consultation with the Institute, makes the decision as to whether or not a given application fits established criteria for a Center grant. All applications for NIEHS Center grants will be reviewed by staff upon receipt for completeness and for responsiveness to the requirements set forth in this document. Applications found to be incomplete or non-responsive will be returned to the applicant organization without scientific review.

VIII. REVIEW PROCEDURES

A Center grant application assigned to the National Institute of Environmental Health Sciences will be reviewed for scientific merit by the Environmental Health Sciences Review Committee (EHSRC).

A site visit to the applicant institution is usually made to evaluate the overall merit of the application. The site visit team includes consultants who have expertise in the major research areas of the proposed Center, the EHSRC Scientific Review Administrator, and NIEHS staff observer(s).

A site visit is not a prerequisite, however, for consideration of an application by the EHSRC. Therefore, the application is considered a complete document for review purposes. Furthermore, the applicant should not use the site visit as an occasion for adding core units, research projects, or investigators, for making major changes, or for delivering another exposition of the application. Rather, it should be used by the principal investigator and associates to elaborate on the research program and core units, cost effectiveness and quality-control features of the core units, and on other center activities for which funding is requested, as well as to answer reviewers' questions. The site visit team will not consider any component core unit that is presented for evaluation at the site visit which has not been included in the application. The findings of the site visit team are reported and discussed by the members of the Environmental Health Sciences Review Committee, which makes the final peer review recommendations and assigns the priority score.

The final review and recommendation on all applications assigned to NIEHS is made by the National Advisory Environmental Health Sciences Council. A chartered

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subcommittee of the Council, the Centers Subcommittee, is charged with an oversight function of the Environmental Health Sciences Centers Program. The NAEHS Council is the primary body for determining the significance of the application to the program goals and mission of the NIEHS.

IX. REVIEW FACTORS

The primary consideration for a Center grant application is the ability of the Center structure and personnel to bring together quality research activities into an interactive, multi-disciplinary operation. Quality scientific research is a pre-requisite for the application, and without it the application will fail. Hence, the review criteria for the overall program are:

- A. The anticipated and/or documented impact of the Center grant on the existing scientific programs at the grantee institution. This includes the anticipated and/or documented contribution of the Center to the use of aquatic organisms in environmental health science research.
- B. The qualifications of core scientists and the physical and intellectual environment of the group as a national resource for environmental health research and training. The existence of a base of ongoing, supported biomedical research of high quality is a prerequisite for the establishment and continuation of a MFBS Center and is an important component of the review.
- C. The multidisciplinary scope of the program, the degree of interrelationship, and synergism of research that might be expected to derive from Center support.
- D. The leadership ability and scientific stature of the Center Director and his/her ability to meet the program's demands of time and effort.
- E. Provisions for coordinating the research and research support cores.
- F. The Institutional Commitments to the Center.
- G. The plans for the administration and conduct of the pilot project program and, in the case of competing renewal applicants, the success of the pilot project program.

The review criteria for the Core Units are:

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- A. The scientific merit and justification of the core unit in relation to the overall research activities of the Center and the appropriateness of the requested budget for the unit.
- B. Accomplishments of the overall organization and the proposed core unit to date.
- C. Plans for future directions and the importance of planned research in each core unit in accomplishing the mission of the Center and the NIEHS.
- D. The qualifications, scientific acuity and imagination, experience, and commitment of investigators responsible for core units and subunits.
- E. The integration of the core unit into the center activities and its contribution to the Center as a whole.
- F. The academic and physical environment in which research is being conducted, including adequacy of space, equipment, and individual and departmental interaction, both real and potential.
- G. Arrangements for: (a) internal quality control of ongoing research; (b) allocation of funds; (c) day-to-day management; and (d) internal and external communication and cooperation between investigators.
- H. Evidence of cost effectiveness and quality control of research support cores.
- I. Institutional commitments to the requirements of the Core.
- J. Appropriateness of personnel assignments in terms of functions they will perform.
- K. Appropriateness of equipment, supply, and other requests relative to the activities of each core unit.
- L. The advantages, or synergism of research, that might be expected to derive from core support.

X. NIEHS CONTACT PERSON

Programmatic inquires about MFBS Center Grants should be addressed to:

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Dr. Allen Dearry
Program Administrator, Centers Program
Chief, Chemical Exposures and Molecular Biology Branch
Division of Extramural Research and Training
Office of Program Development
National Institute of Environmental Health Sciences
P. O. Box 12233
111 T. W. Alexander Drive
Research Triangle Park, North Carolina 27709
Telephone: (919) 541-4943 Fax: (919) 541-4937
E-mail: dearry@niehs.nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Laura Williams
Grants Management Specialist, Centers Program
Grants Management Branch
Office of Program Operations
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
111 T. W. Alexander Drive
Research Triangle Park, North Carolina 27709
Telephone: (919) 541-7629 Fax: (919) 541-1373
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