CENTERS FOR AIDS RESEARCH (CFAR) AND DEVELOPMENTAL CFAR (D-CFAR)

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PURPOSE


Participating Institutes of the National Institutes of Health (NIH) invite applications for center core grants (P30) to support Centers for AIDS Research (CFAR) and Developmental CFARs (D-CFAR). CFAR cores provide infrastructure and promote basic, clinical, behavioral and translational AIDS research activities at institutions that receive significant AIDS funding from multiple NIH Institutes or Centers. CFARs foster synergy and improve coordination of research, support emerging research opportunities, and promote economy of scale through resources shared by multiple independent laboratories. CFARs are not intended to be "Centers of Excellence" in specific areas of AIDS research, but instead are intended to promote all AIDS research efforts at CFAR institutions. D-CFARs provide modest support for a limited period to assist investigators in the development of a competitive CFAR. Before preparing an application to support a CFAR or D-CFAR, investigators are urged to consult with the program staff listed under "Inquiries."

DEFINITIONS

Throughout this program announcement P30 applications to support CFARs are abbreviated as “CFAR applications” and the corresponding P30 awards to support CFARs are abbreviated as “CFAR awards.” “Core” or “core facilities” are defined as entities providing services or expertise to be shared by multiple independent laboratories. NIH CFAR awards support administrative, developmental, basic science and clinical science cores for AIDS research. AIDS research and AIDS-related research are abbreviated as “AIDS research.”

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS led national activity for setting priority areas. This Program Announcement (PA), Centers for AIDS Research (CFAR) and Developmental CFAR (D-CFAR), is related to priority areas 4 (Substance Abuse: Alcohol and Other Drugs), 6 (Mental Health and Mental Disorders), 14 (Maternal and Infant Health), 15 (Heart Disease and Stroke), 16 (Cancer), 18 (HIV Infection), 19 (Sexually Transmitted Diseases), 20 (Immunization and Infectious Diseases), and 21 (Clinical Preventive Services). Potential applicants may obtain a copy of "Healthy People 2000" at http://odphp.osophs.dhhs.gov/pubs/hp2000.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and 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.

A. NIH AIDS Funded Research Base

The purpose of CFARs is to support the AIDS research activities of investigators at applicant institution(s) that have significant NIH funding for AIDS research. Significant NIH AIDS funds are defined as an NIH AIDS Funded Research Base in excess of $6 million in annual total cost for the NIH fiscal year (October 1 to September 30) preceding receipt of CFAR applications. (FRB). The FRB includes the total cost of research awards and the number of these awards to investigators participating in the CFAR. The research base includes peer-reviewed AIDS grants, cooperative agreements, and research contracts utilizing only the following mechanisms: P01, R01, R03, R21, R29, R35, R37, U01, U10, U19, and K series awards, R18, and N01
(excluding contracts that primarily fund the production of materials or services for support of research). Excluded from the NIH AIDS Funded Research Base are all funds from any source other than NIH.

Multi-institutional CFAR applications may combine the NIH AIDS funded research of all the investigators at the institutions participating in the proposed CFAR to meet the NIH AIDS Funded Research Base requirement. CFARs that use a distant institution for a core facility, but are not including all of the NIH AIDS investigators at that institution as part of the CFAR may not use the Funded Research Base of any single investigators at that institution.

B. One CFAR award per institution

No institution will receive more than one CFAR award. Institutions that have significant overlap in faculty, resources or administration should submit only one application. Independent campuses that are part of a large, multiple city university are considered to be separate institutions. Applicants are encouraged to contact program staff listed under “Inquiries” for additional guidance.

C. Two types of CFAR awards

This program announcement describes two types of CFAR awards. The first is for a standard CFAR, and does not differ significantly from currently funded CFARs. The second is a Developmental CFAR (D-CFAR) for AIDS investigators at an institution, which while eligible, does not yet have a CFAR. The D-CFAR will provide the support necessary to develop a collaborative network that may permit the institution to be more competitive for a standard CFAR award. The D-CFAR award is described in more detail below.

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D. Guidelines for multi-institutional CFARs

In some cases, two or more institutions that can demonstrate a credible plan for collaborative research networks using CFAR cores may wish to submit an application for a single CFAR award. Reviewers will look critically at the request for multi-institutional applications for the following indicators: a demonstration of exceptional need to establish a collaboration between investigators at separate institutions; evidence of unique plans, such as the development of organized communications systems, to overcome the scientific and management challenges that are naturally a part of multi-institutional collaborations; specific plans to address anticipated budgetary problems in the transfer of funds and resources from one institution to another; and evidence for centralized authority of the CFAR Director for the purpose of management of the CFAR facilities at other sites.

A multi-institutional CFAR application must designate a prime institution that will receive the award and provide details of agreements regarding coordination and support of cores and activities at other participating institutions.

E. Cores outside of the CFAR institution

With appropriate justification, CFAR awards may support a core at a distant site, including a foreign site that provides a unique resource such as a primate facility or a high-resolution NMR facility. To achieve administrative efficiency and foster collaboration, each unique resource should serve as a core for only a single CFAR, and that all cores within any single “outside” institution should be part of the same CFAR award. NIH AIDS funding of the investigators at this core facility is not included as part of the Funded Research Base of the CFAR (see Funded Research Base, below).
F. Funding for CFARs from multiple NIH Institutes

CFARs will be awarded and administered by NIAID. However, a CFAR award will consist of funds from multiple NIH Institutes. Management over site of the CFAR grants will be provided through an NIH CFAR Steering Committee composed of representatives from the co-funding NIH Institutes and from the Office of AIDS Research (OAR). It is therefore suggested that the applicant first contact the NIAID program representatives listed under ‘Inquires’ to discuss general CFAR issues and then to contact other program representatives listed under “Inquires” to discuss how CFARs can enhance the AIDS research already being funded by each NIH Institute.

G. CFAR support for all NIH AIDS investigators

NIH will provide applicants with a spreadsheet (Excel) indicating all investigators receiving NIH AIDS funding at an applicant(s) institution, arranged by NIH funding Institute. Applicants should indicate, in the spreadsheet, those investigators who have formally agreed to participate in the CFAR, and include this spreadsheet in their application.

It is important that the CFAR be inclusive of the full range of AIDS science funded at a given institution. Therefore, review committees will be interested in why some investigators listed in the spreadsheet chose not to be part of the CFAR. Applicants may also delineate investigators at their institution(s) who will become part of the CFAR but who were not included in the spreadsheet. The reason for inclusion, or exclusion, of a given investigator should be addressed.

H. Funds available

A CFAR award (total cost) will be limited to 10% of the amount of funds received by the applicant institution(s) for AIDS research as reported by OAR for the NIH fiscal year preceding receipt of the application. New CFAR awards will not exceed $1.5 million annually. Recompeting CFARs will be limited to an inflationary increase beyond the funding level of the current grant, or $1.5 M, whichever is greater. If the Funded Research Base of a recompeting CFAR should go below $15M, the applicant is limited to requesting 10% of the new Funded Research Base.

MECHANISM AND LENGTH OF SUPPORT

This PA will use the National Institutes of Health (NIH) Center Core Grant (P30) award mechanism. Responsibility for the planning, direction and execution of the proposed project will be solely that of the applicant. The total requested project period may not exceed five years for a standard CFAR and applicants are encouraged to apply for five years. For D-CFARs, the total requested project period may not exceed three years.

BACKGROUND

The CFAR program was established in 1988 and was renewed in 1993 and 1997. In May 1999, an ad hoc external review committee convened by the Office of AIDS Research reviewed the CFAR program. Suggestions of the review committee have been incorporated into this program announcement. The mission of the CFAR program and mechanisms for achieving this mission were developed by the CFAR directors in 1995 and revised in 1996 and 1998.

The mission of the CFARs is to support a multi-disciplinary environment that promotes basic, clinical, behavioral, and translational research in the prevention, detection, and treatment of HIV infection and AIDS. The CFARs accomplish this mission by:

A. Providing scientific leadership dedicated to AIDS research
B. Providing institutional infrastructure dedicated to AIDS research
C. Stimulating scientific collaboration and translational research
D. Fostering scientific communication
E. Sponsoring training and education
F. Promoting knowledge of CFAR research findings and the importance of AIDS research through community outreach
G. Facilitating development of AIDS therapeutics, vaccines and diagnostics through promotion of scientific interactions between CFARs and industry.
RESEARCH OBJECTIVES FOR CFARS AND D-CFARS

A. CFAR added value

CFARs should provide added value to the institution’s AIDS research efforts through support of activities that cannot easily be provided by standard research grants. For example, CFARs promote and encourage activities that enhance collaboration and coordination of AIDS research. CFARs promote translational research activities, i.e., studies bringing findings of the laboratory to the clinic, and vice versa.

Measures of added value include, but are not limited to: interdisciplinary publications; evidence of CFAR enhancement of existing programs at the institution; the number of protocols started within the institution; patent applications filed or issued; institutional support for activities previously supported by the CFAR. For recompeting CFARs, Tables 1 and 2 are provided on the CFAR web site (http://www.niaid.nih.gov/research/cfar/cfarpa.htm), which should be used by the applicant to show various translational research activities. The activities shown are not meant to be all-inclusive.

B. CFAR should serve the requirements of all NIH-funded AIDS investigators at the applicant institutions

Cores should address the needs of AIDS investigators at the applicant institution(s). Successful CFARs have been responsive to all AIDS investigators at their institution. Applicants should describe in detail the operation of each core (quality control, procedures, safety, training, etc.) and how the proposed policies and procedures protect and incorporate the divergent needs of CFAR investigators. Please see additional details concerning policies and procedures under “Administrative Core”. Applicants are encouraged to contact program staff listed under “Inquiries” to discuss strategies being planned for how the CFAR will foster collaboration among AIDS investigators from divergent disciplines.

C. CFARs have scientific and fiscal flexibility and responsibility

A CFAR has the responsibility to use its resources in the best manner to meet the needs of its investigators. A CFAR has the authority to change allocation of resources according to the guidelines of the CFAR operating policies and procedures. Applicants should describe how proposed policies and procedures provide structure for decision-making on several levels and how each of the following individuals or groups would participate in the decision process: core director, CFAR director, internal advisory board, CFAR investigators, and external advisory board. Applicants should also state the process for informing NIH of major changes in the CFAR.

A CFAR has considerable flexibility and authority to alter funding of a basic or clinical core, to delete a core, or to initiate a new core. Applicants should state what policies and procedures will be used as the basis for reallocation of initial core funding that will permit the establishment of new cores, as needed, without additional funding.

The extent to which FAR funding may leverage other resources in support of AIDS research is an important measure of a CFAR’s value to AIDS investigators. Basic and clinical cores may be supported totally by CFAR funds, or only in part by CFAR funds. Applicants are encouraged to develop creative collaborations to improve utilization of existing resources. Convincing justification will be necessary for duplication of any basic or clinical core that exists in a similar form elsewhere in the applicant institution(s). Applicants should describe how cores with partial CFAR funding will be used to enhance the research of CFAR investigators. For example, a CFAR core supported by other funding (e.g., a NIAID AIDS Clinical Trial Unit or an NCI Cancer Center core facility) may become more accessible to AIDS investigators through CFAR association and coordination. Commitments for continued funding in the non-competitive continuation years of all NIH grants are dependent upon the availability of funds. Applicants should describe policies and procedures for CFAR “down-sizing” decisions if there is decreased funding for continuation years.

D. Additional CFAR supported activities

CFARs traditionally use a variety of strategies to achieve the research objectives of the award. Examples include industry collaborations, development of minority scientists in AIDS research, AIDS research communications to non-scientists, addressing problems in enrollment and retention of women and minority groups in AIDS clinical trials, international collaborations, and other activities that meet the AIDS research needs of applicant institutions.
Applicants are encouraged to explore collaborative, multi-institutional linkages with international sites and minority institutions. Such linkages foster international training and collaborative studies and are able to meet needs that cannot be easily addressed by other types of funding mechanisms. Coordination with international programs funded by the Fogarty Center are strongly encouraged. Contact information for Fogarty programs is provided under “Inquiries”.

Examples of ways in which current CFARs are able to assist in the development of new investigators, including junior faculty, and minority investigators, both domestic and international, are as follows. These examples are not meant to be all-inclusive.

1. Specific mentoring programs for junior faculty that may include support for the preparation of developmental award applications;

2. Establishing a collaboration between investigators at institutions in the developing world that could include mini-sabbaticals to the CFAR for use of core facilities by the investigator at the distant site and mentoring of investigators in the developing world by CFAR investigators at the distant site, or via computer linkages;

3. Developing specific collaborations with other NIH programs such as the AIDS International Training and Research Program (AITRP) with the Fogarty Center or the Research Centers in Minority Institutions (RCMI) program with the National Center for Research Resources (NCRR).

E. CFAR awards support four different types of cores: administrative, developmental, basic science, and clinical studies:

Each CFAR must have a single administrative and a single developmental core, and a minimum of one basic and one clinical science cores selected to optimally support the AIDS research at the applicant institution(s). The smallest CFAR would consist of one of each type of core (administrative, developmental, basic, and clinical). The terms basic and clinical cores are generic names, and the definition of what constitutes a basic or clinical core is sufficiently broad to meet the needs of the applicant institution(s), and may vary among CFAR applicants. For example, epidemiology, biostatistics, ethnography, and behavioral cores could be classified as either basic or clinical cores.

An applicant’s initial choice of basic and clinical cores is an important measure of the science management process. Applicants should describe the basic and clinical cores to be supported at the time that the CFAR is awarded, how this choice of cores was selected, other potential cores that were evaluated but not selected, mechanisms for evaluating utilization of proposed cores, and criteria for increasing or decreasing funding of these cores during the course of award.

1. Administrative Core

The administrative core is responsible for the management of all CFAR activities. The administrative core is led by a CFAR director (P30 grant’s principal investigator) who should be a recognized leader in the field of AIDS research. The administrative core also may require a senior administrator, a CFAR office that is a clearly separate entity, and a modest staff for support of CFAR activities. The responsibilities and time allocation of each staff person and the proposed operation procedures for the administrative core should be described in detail.

The administrative core section of the CFAR application should contain separate sections describing the strategic plan and policies and procedures. Both of these sections will be incorporated by reference into the Terms and Conditions of Award. Successful applicants are required to go through an annual strategic planning process to assess current and expected scientific and fiscal needs and planned adjustments, according to the stated policies and procedures.

a) Strategic plan

The purpose of the strategic plan is to identify the most significant opportunities and gaps in science at the applicant institution that will be addressed by the CFAR in the short and long term, and to identify objective milestones to measure success or failure. The following process and organization is suggested for the strategic plan:
i. Strengths - Describe the strengths of the CFAR including a summary of research of CFAR participants and the current facilities and resources available. Outline the major AIDS studies to be assisted by CFAR funding and organize them by relevancy to the mission of co-funding Institutes (one page or less is suggested per funding Institute). Cite grant numbers listed in the Excel table showing the NIH AIDS Funded Research Base of the institution(s).

ii. Opportunities - Identify and evaluate all potential opportunities for use of CFAR funds. This analysis will probably require outreach for suggestions from all potential CFAR participants. Conduct a cost/benefit analysis to determine which opportunities both utilize the applicant’s unique strengths and address the missions of NIH funding Institutes.

iii. Action Plan - Choose the highest priority opportunities and develop a detailed plan for the first year of funding. Examples of an action plan include determining which cores will be established; determining how existing cohorts will be utilized; identifying the categories of support for developmental projects, communication and outreach, and identifying the lectures and meetings the CFAR will sponsor. Some CFARs may find that specific thematic areas emerge from this strategic planning process. Development of an action plan that capitalizes on such programmatic themes is encouraged, but not required.

iv. Outcome Measurements - Determine how progress on action plans will be measured. Include anecdotal and objective measurements of how CFAR provides “added value” or the unique contributions of CFARs that cannot be provided by research awards. Select long-term goals for the funding period, and annual milestones for the first year.

In addition to other items, place information about any advisory committees under the administrative core. Describe membership of all committees, how participants were selected, and terms of appointment, authority and responsibility of members.

The ability to manage the CFAR award will be judged by the clarity and thoughtfulness of the scientific management strategies proposed for the administrative and developmental core sections of the proposal, and evidence of the selection and organization of additional cores through acquisition of information, support, and participation of the AIDS investigators at the applicant institution(s).

b) Policies and Procedures

Policies should be considered to be “a set of guiding principles of operation”. There are no "correct" policies and different CFARs may adopt different policies. Below are several examples of justifiable but not necessarily compatible policies that might be used to address funding issues. Funding issues are an example of only one area that the CFAR will consider in the development of policies and procedures.

- CFAR funding will be allocated by discipline in proportion to research performed in those disciplines.
- CFAR funding will be allocated for projects based on a majority vote of all CFAR members.
- CFAR funding will be allocated for projects based on majority vote of an internal advisory board.

Procedures should be considered to be a set of specific actions used to conduct the affairs of the CFAR. Procedures should specify how various tasks will be accomplished within the policy guidelines of the CFAR. The policies and procedures should describe:

- the proposed roles of the CFAR director, core directors, CFAR investigators, advisory boards, institutional officials, and NIH program staff in the decision-making process.

- the annual strategic planning process. Examples of issues CFAR members should consider: how funds will be allocated to all types of cores and activities; procedures for changes in support of any cores; how CFAR-sponsored conferences, seminars, workshops, and other activities will be identified; how priorities for communication, outreach and additional CFAR activities will be established; how cores, core directors, leaders of additional CFAR activities, internal and external advisory committees will be selected and evaluated; the authority and responsibility of internal and external advisory committees; how developmental projects are selected and evaluated; how cores are selected and reports are developed, including the annual strategic plan and the noncompetitive renewal.
other mechanisms used to determine AIDS research basic and clinical core needs at the applicant institution(s), assign priorities to potential cores, and select the basic and clinical cores that are included in the application.

2. Developmental Core

The intent of a CFAR developmental core is to support scientific studies for short periods of time to develop preliminary data for peer-reviewed research applications. Four general areas are eligible for support through the developmental core: investigators new to AIDS research who have not previously received R01-type awards in AIDS research, feasibility studies, emerging research opportunities and AIDS research activities of newly recruited faculty. Applicants are encouraged to explore using the developmental core to fund a collaborative study that encompasses two scientific disciplines, especially two that may not have traditionally collaborated (q.v., basic scientists and scientists studying complementary and alternative medicine, such as chiropractic or acupuncture; or behavioral scientists and population geneticists). Examples provided are not meant to be all-inclusive. Applicants may wish to consult with the program staff listed under “Inquiries” to discuss how developmental cores are used at current CFARs.

The CFAR administrative core should establish the mechanisms for allocation of developmental funds and for annual evaluation of supported activities. CFAR applicants should describe the mechanism to be used for identification, peer-review selection, and outcome evaluation of projects supported by the developmental core. Applicants who have current CFARs should describe outcome evaluation of previously funded developmental projects. The applicant should use the table provided for this purpose and include with the application (Table 3).

The developmental core section should include a plan for the use of the first year developmental funds.

3. Basic Science Cores

Basic science cores support shared research activities that cannot easily be funded through standard research granting mechanisms. Basic science cores should provide economy of scale through use by multiple laboratories and should foster collaboration between basic and clinical investigators. Basic science cores do not substitute for resources that are obtainable commercially, or replace existing resources normally supported by individual research grants. Cores should have a clear focus, and contribute to translational research. Reviewers will look for an emphasis on well managed and efficient core functions above the overall number and breadth of cores in a given application. Please use Table 4 to indicate all core facilities at your institution and whether or not CFAR members will be utilizing them.

CFAR applications should describe the basic science cores to be supported at the time of the award and any changes anticipated during the course of the award. A basic science core should be designed to support multiple AIDS investigators and applicants should indicate the anticipated users and the percent time of use by each. Mechanisms should be described to prioritize usage, evaluate annual use, and justify level of continued CFAR support in comparison with other AIDS research needs at the applicant institution(s).

4. Clinical Cores

Clinical cores should have a clear focus and provide the resources for AIDS translational research collaboration between clinical and basic scientists. Activities that will not be supported by a CFAR clinical core are normal patient care including screening of clinical specimens, diagnosis, treatment or rehabilitation. Reviewers will look for an emphasis on well managed and efficient core functions above the overall number and breadth of cores in a given application.

Mechanisms should be described to prioritize usage, to evaluate annual use, and to justify the level of continued CFAR support in comparison with other AIDS research needs at the applicant institution(s).

F. Institutional Commitment

Institutional commitment is particularly important for the coordination of resources across the broad areas and potential boundaries of research supported by the co-funding Institutes. Examples of the types of institutional commitment that are demonstrated by current CFARs are: the level of institutional funding, space allocations, co-funding, endowments, designating the status of a center program in the institutional bylaws, and providing a waiver or partial waiver for indirect costs for certain components of the grant, such as funding through the developmental core. These are examples, and are not exclusive of other possible ways in which an institution may
demonstrate support for the CFAR. Provide a letter(s) from the appropriate institutional official(s) (e.g., Dean, President, or Provost) defining:

1. Position, authority, and reporting responsibility (on institution's organizational chart) for the CFAR director.

2. Financial and other resource support for the CFAR that will be provided by the applicant institution(s).

3. Authority or influence that the CFAR director has and will have over other AIDS projects, facilities and space, as well as decision-making authority for new faculty and support personnel.

**CFAR BUDGET ITEMS**

**A. Percent Effort**

The percent effort requested should be limited to time devoted specifically to managing CFAR activities and not to research activities. The effort devoted to CFAR activities should not be that which would normally be supported by research grants. Information documenting the level of effort on CFAR activities must be included in the application. All requested personnel costs should be carefully justified.

The percent effort of the CFAR director should be justified in the context of the director’s other responsibilities. Administrative support (a secretary or an administrative assistant) should be requested for the CFAR office only for matters directly pertaining to the CFAR.

Core directors are CFAR members who are responsible for the overall technical excellence of a core facility. The CFAR supported percent effort of core directors involved in research activities should only include core management time. The CFAR may support technical staff to provide CFAR services in core facilities.

The use of developmental core funds for junior faculty salary support is allowed. Established investigators with R01-type grants are expected to have salary support from other sources.

**B. Core Budgets**

Core budgets may include equipment, supplies, support contracts, and other necessary expenses. All items should be fully justified for allocation of CFAR funds.

**C. Other Administrative Costs**

This category includes the costs necessary for the central administration and fiscal management of the CFAR, including relevant and reasonable costs for reprints, graphics, and publications for developmental core users.

**D. Travel**

CFAR directors’ meeting(s) — The CFAR director, the CFAR administrator, and one senior scientist per center will meet at least once, and possibly, two times per year, at the NIH, at a CFAR site, or at the site of a scientific conference that most of the directors plan to attend. Applicants should include travel funds specifically for these meetings in the CFAR administrative core budget request. For budget purposes, applicants may assume a total annual direct cost of $6,500 for the CFAR director’s meeting(s).

Other Travel — Applicants may request and justify travel funds in addition to the funds required for the two directors’ meetings. These funds should not be used for travel to scientific meetings. They may be used for travel to meet with collaborators at foreign sites. For example, this travel could be used to promote collaboration among CFAR investigators and AIDS investigators not in a CFAR program, or at distant cores. These additional travel funds should not exceed $20,000 annual direct costs.

**DEVELOPMENTAL CFARs (D-CFAR)**

The NIH recognizes the need to provide funding to potential CFAR awardees who need to expand or enhance a particular CFAR component in order to facilitate collaborative interactions. For example, applicants may wish to expand AIDS complementary or alternative medicine, behavioral science, or basic science at an institution that has
traditionally had a more narrow scientific focus in AIDS and AIDS-related research. Other examples include expansion of communications technology among investigators who have begun, or are planning, collaborative studies, using the developmental core to fund a collaborative study that encompasses two scientific disciplines, especially two that may not have traditionally collaborated (q.v., basic scientists and scientists studying complementary and alternative medicine, such as chiropractic or acupuncture; or behavioral scientists and population geneticists), or developing an outreach program that could not be started through institutional or research grant funding. The D-CFAR mechanism may not be used to obtain a supplement to an existing CFAR award.

All eligibility requirements and specific descriptions provided in this PA for the CFAR awards are also required for and relevant to, the D-CFAR awards. The minimum number and type of cores for a D-CFAR is the same as for a standard CFAR: one administrative, one developmental, one basic and one clinical. There are several differences between a D-CFAR and a CFAR. The maximum funding level for the D-CFAR award is $750,000 and it is a one-time award for 3 years. We encourage independent AIDS investigators interested in expanding collaborative efforts at their institution to consider applying for this award.

Applicants who have never received a CFAR award are eligible to apply, as are previous CFAR applicants who have not been successful in recompeting for the CFAR award. Applicants who have not received a CFAR award may choose to apply for either a standard or developmental CFAR award. Because the D-CFAR is designed to assist the applicant in the organization and development of a competitive CFAR application, reviewers will look very carefully at applications from previous CFARs regarding the feasibility of overcoming obstacles previously identified by review committees. Applicants should clearly indicate in the title of the application and in the abstract that this is for the D-CFAR award. If no indication is provided it will be assumed that the application is for a standard CFAR.

Applicants applying for a D-CFAR award should plan on providing as much detail for the administrative and developmental cores as is required for the standard CFAR application. Please see the instructions for the administrative and developmental core for CFARs, above. The strategic plan should provide sufficient detail for the procedures used to identify challenges at the institution and proposed solutions that would lead to development of a competitive CFAR application within the three-year funding period. Proposed outcome measurements for the strategies and core facilities selected for year 1 should be clearly explained, as well as procedures for adjusting the plan for years 2 and 3, should changes be needed.

Like the standard CFAR award, the D-CFAR does not support research activities, except through the developmental core, for limited funding, and for limited periods of time. It does provide funding to foster synergy and improve coordination of research, support emerging research opportunities, and promote economy of scale through resources shared by multiple independent laboratories. D-CFARs also encourages other activities that serve the requirements of AIDS research. See ‘Additional CFAR supported activities’. Any of these activities may be fostered through a D-CFAR award.

Because both the funding period and level are less than that for a CFAR award, the D-CFAR is not expected to propose all core facilities that would be proposed for a standard CFAR. The emphasis with D-CFAR is on the identification of gaps or deficiencies that would hinder development of a competitive CFAR application, and core facilities that will reduce or eliminate these gaps.

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 subpopulations 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 492B 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, Vol. 23, No. 11, March 18, 1994 available on the web at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not94-100.html
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 and 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.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this program announcement. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information allows staff to estimate the potential review workload and to help avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Dianne Tingley at the address listed under INQUIRIES by the letter of intent receipt date listed in the heading of the program announcement.

APPLICATION PROCEDURES

Applicants are strongly encouraged to contact program staff early in application development with any questions regarding the responsiveness of their proposal to the goals of this PA.

A. Application form

Applications are to be submitted on the grant application form PHS 398 (rev. 4/98) and will be accepted at the application deadlines indicated on page one of this program announcement. Application 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.

Applicants planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended/revised version of the preceding grant application types requesting $500,000 or more in direct costs for any year are advised that he or she must contact the Institute or Center (IC) program staff before submitting the application, i.e., as plans for the study are being developed. Furthermore, the application must obtain agreement from the IC staff that the IC will accept the application for consideration for award. Finally, the applicant must identify, in a cover letter sent with the application, the staff member and Institute or Center who agreed to accept assignment of the application.

This policy requires an applicant to obtain agreement for acceptance of both new and amended application and any such subsequent amendment. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 at http://grants.nih.gov/grants/guide/notice-files/not98-030.html

The title and number of the program announcement must be typed on line 2 of the face page of the application form and the YES box must be marked. Applicants should clearly indicate in the title of the application and in the abstract that this is for the D-CFAR award. If no indication is provided it will be assumed that the application is for a standard CFAR.

B. Limitation on Submission of Amended/Revised Applications

In June 1996, NIH announced a policy limiting the number of amended versions of an application that will be accepted to two. This policy applies to all grant mechanisms. If an applicant is not successful after three attempts at funding (the initial submission and two revisions), she/he is expected to make a significant change in the direction and approach for subsequent research applications. Additional information can be found at the
following sites: http://grants.nih.gov/grants/policy/amendedapps.htm and http://grants.nih.gov/grants/guide/notice-files/not99-146.html (Item 2). Prior to preparation of a new application after three submissions, applicants are strongly encouraged to discuss plans with the program contacts listed under “Inquiries”.

C. Page limitations

For applications in response to this program announcement, the page limitation is 300 pages for the entire CFAR or D-CFAR application, excluding only appendices. Please note that appendices are provided only to the reviewers assigned to the application, and not to all reviewers. Appendices should not contain information required for review by other committee members. The 300-page limit is a maximum and applicants are encouraged to be concise. Applicant submitting a revised application may include an additional 30 pages to discuss the response to the reviewer’s comments. It is helpful to the review committee if these are placed at the beginning of the research plan, with reference to locations in the application where changes can be found.

D. Spreadsheets and Tables

NIH will provide applicants with a spreadsheet (Excel) indicating all investigators receiving NIH AIDS funding at an applicant’s institution (or institutions if a multi-institution application), arranged by NIH Institute. Applicants should indicate in the field provided, those investigators who have formally agreed to participate in the CFAR. Please contact Dr. Janet Young (Contact information will be found under “Inquiries”).

The NIH will provide tables in Word 2000 for additional information required of both new and recompeting applications. These may be found at the CFAR program announcement website: http://www.niaid.nih.gov/research/cfar/cfarpa.htm

In the future the NIH may provide these tables in the form of an Access database.

E. Organization of Application

In order to facilitate the review process, applicants should follow the instructions described in “Special Instructions for Preparation of the CFAR Application.” The Special Instructions provides information on how to organize and present information in the CFAR application to facilitate review and award. The CFAR web site includes the Special Instructions and the CFAR Program Announcement: http://www.niaid.nih.gov/research/cfar/cfarpa.htm

Printed copies of both documents may be obtained from the Program Staff listed below.

F. Mailing Instructions

Applications must be mailed to both the NIH Center for Scientific Review and to the NIAID Division of Extramural activities. For purposes of identification and processing, Item 2 on the face page of the application must be marked “yes”. Also, the title and number of this program announcement must be typed in Item 2 (i.e., “CENTERS FOR AIDS RESEARCH (CFAR),” or DEVELOPMENTAL CENTERS FOR AIDS RESEARCH – (D-CFAR),” PAR-00-054). The completed signed original application (text + appendices) and three single-sided copies of the application (text) must be sent or delivered 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)

Two single-sided copies of the application (text) and five copies of appendices must be sent or delivered to: Dianne Tingley, listed under “Inquiries”.

Upon receipt, applications will be reviewed for completeness by the NIH Center for Scientific Review and for responsiveness to the goals of this PA by NIAID staff in consultation with the other co-funding Institutes. Incomplete or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive will be evaluated for scientific and technical merit by an Initial Review Group (IRG) of NIAID. As part of the initial merit review, all applications will receive a written critique, be assigned a priority score, and receive a second level review by an appropriate national advisory council(s) or board(s).

**REVIEW CRITERIA**

Review criteria are based on the mission of the CFAR Program and mechanisms for achieving this mission. The initial review group (IRG) will evaluate CFAR and D-CFAR applications for significance, approach, innovation, investigator, and environment. In these evaluations, the IRG will also look for evidence of successful performance from applicants that have had CFAR awards or similar programs at their institutions.

The organizational structure of sections of a CFAR application resembles that of an R01 application:

<table>
<thead>
<tr>
<th>CFAR Application</th>
<th>R01 Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Strengths</td>
<td>-Background</td>
</tr>
<tr>
<td>-Opportunities</td>
<td>-Significance</td>
</tr>
<tr>
<td>-Action Plan and Outcome Measurements</td>
<td>-Specific Aims</td>
</tr>
<tr>
<td>-Policies and Procedures</td>
<td>-Materials &amp; Methods</td>
</tr>
<tr>
<td>-Choice of Cores and their</td>
<td>-Preliminary Results</td>
</tr>
<tr>
<td>Operating Structures for new applications</td>
<td>-Progress Report for renewal applications</td>
</tr>
</tbody>
</table>

The NIH review criteria have been adapted to ensure that the major components of a CFAR application are evaluated appropriately. The score should reflect the overall impact that the project could have on the field based on consideration of the five criteria, with the emphasis on each criterion varying from one application to another, depending on the nature of the application and its relative strengths. Note that an application need not be strong in all categories to be judged likely to have major scientific impact and thus deserve an outstanding priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward. Review criteria are listed separately for the standard CFAR and the developmental CFAR (D-CFAR) awards.

**REVIEW CRITERIA FOR STANDARD CFARS**

**Significance** – The effect that a CFAR award would have on an applicant’s AIDS research efforts

1. The ability of cores to support the research base, foster synergy, enhance AIDS research collaborations and produce an economy of scale
2. Evidence that CFAR will enhance proposed scientific communication, outreach, training efforts, international collaborations, and collaborations with industry.
3. Developmental core procedures for selection of projects and outcomes evaluation

**Approach** – The quality of the CFAR scientific planning and management process

4. Annual strategic planning process.
5. Policy and procedures to judge value of cores and reassign funding priorities; outcome measurements
6. Methods for selection of basic and clinical core users and for prioritization of use

**Innovation** – The utilization of CFAR resources in unique ways to achieve the scientific goals of all AIDS investigators at the participating institution(s)

7. The degree of variety in AIDS research projects and disciplines that commit to participation in and coordination through the CFAR structure
8. The incorporation into the CFAR of resources (cores, projects, cohorts, trials, etc.) that are supported in part or not at all by CFAR funds
Investigator – The choice of appropriate leaders to carry out the CFAR mission

9. Choice of CFAR director, e.g., managerial experience, commitment, leadership in AIDS research and at the applicant institution
10. Choice of core directors and key personnel, e.g., qualifications, competence and commitment
11. Proposed advisory groups: their responsibility and methods for their selection

Environment – The likelihood that a CFAR will achieve its objectives

12. Evidence for CFAR providing value added to the AIDS research at the institution
13. Institutional commitment including space, institutional financial support and other institutional resources and oversight provided for CFAR activities
14. Previous history of support for developmental projects and outcomes
15. Previous history of translational research efforts
16. Appropriateness of budget of the overall CFAR and of the individual cores

Review Criteria for D-CFARs

Significance – The effect that a D-CFAR award would have on an applicant’s AIDS research efforts

1. Evidence that the proposal will lead to development of a CFAR application that would be competitive for a standard CFAR award
2. The ability of cores to support the research base, foster synergy, enhance AIDS research collaborations and produce an economy of scale
3. The ability of proposed scientific communication, outreach, training efforts, international collaborations, and collaborations with industry to assist AIDS investigators and lead to development of a competitive CFAR application
4. Developmental core procedures for selection of projects and outcomes evaluation

Approach – The quality of the CFAR scientific planning and management process

5. Annual strategic planning process
6. Policy and procedures to judge value of cores and reassign funding priorities; outcome measurements
7. Methods for selection of basic and clinical core users and for prioritization of use
8. Policies and procedures to identify gaps and mechanisms for filling them

Innovation – The utilization of D-CFAR resources in unique ways to achieve the scientific goals of all AIDS investigators at the participating institution(s)

9. The degree of variety in AIDS research projects and disciplines that commit to participation in and coordination through the D-CFAR structure
10. The incorporation into the D-CFAR of resources (cores, projects, cohorts, trials, etc.) that are supported in part or not at all by D-CFAR funds
11. Resources available to enhance a particular D-CFAR focus in order to facilitate future collaborative interactions

Investigator – The choice of appropriate leaders to carry out the D-CFAR mission

12. Choice of D-CFAR director, e.g., managerial experience, commitment, leadership in AIDS research and at the applicant institution
13. Choice of core directors and key personnel, e.g., qualifications, competence and commitment
14. Proposed advisory groups: responsibility, methods for their selection, and contribution to the overall D-CFAR goals

Environment – The likelihood that a D-CFAR will achieve its objectives

15. Evidence for D-CFAR providing value added to the AIDS research at the institution
16. Institutional commitment including space, institutional financial support and other institutional resources and oversight provided for D-CFAR activities
17. Appropriateness of budget of the overall D-CFAR and of the individual cores
18. Proposed strategy for expanding the D-CFAR focus

In addition, applicants for either the CFAR or D-CFAR award must demonstrate adequate provisions for the protection of human and animal subjects, the safety of the research environment, and conformance with the NIH “Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research” and “Guidelines for the Inclusion of Children as Research Subjects”.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

A. Quality of the proposed project as determined by peer review
B. Availability of funds
C. Institute's priority for area of proposed research

CONDITIONS OF AWARD

The Conditions of Award will incorporate the following items proposed by the applicant with potential modifications based on recommendations of the Initial Review Committee:

A. CFAR Strategic Plan
B. CFAR Policies and Procedures
C. CFAR Advisory Committee(s) authority and responsibility

Any changes in these items from the Notice of Award will require concurrence of NIH.

INQUIRIES

A. Electronic communication

The opportunity to clarify any issues or questions regarding CFARs or CFAR applications is welcome. Especially encouraged are inquiries through the CFAR web site:
http://www.niaid.nih.gov/research/cfar/cfarpa.htm

In addition to submitting inquiries at this web site, applicants may view inquiries by others, read the official NIH responses, and obtain suggestions for application organization.

B. NIAID Review Staff

Questions on review issues may be directed to:

Dianne Tingley, Ph.D.
Scientific Review Program
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Room 2148
6700-B Rockledge Drive MSC 7616
Bethesda, MD 20892-7616
Telephone: (301) 496-2550
FAX: (301) 402-2638
Email: dt15g@nih.gov
For express/courier service: Bethesda, MD 20817
C. NIAID Grants Management Staff

Questions on fiscal issues may be directed to:

Ms. Victoria Putprush
Grants Management Branch
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Room 2124
6700-B Rockledge Drive - MSC 7614
Bethesda, MD 20892-7614
Telephone: (301) 402-6580
FAX: (301) 480-3780
Email: vp8g@nih.gov

D. NIH CFAR and D-CFAR Steering Committee for programmatic issues

Questions regarding CFAR or D-CFAR management issues, scientific issues, or program interests of NIAID may be directed to:

Janet M. Young, Ph.D.
Basic Science Program
Division of AIDS
National Institute of Allergy and Infectious Diseases
Room 4137
6700-B Rockledge Drive MSC 7626
Bethesda, MD 20892-7626
Telephone: (301) 496-6714
FAX: (301) 402-3211
Email: jy6r@nih.gov

Questions related to CFAR and D-CFAR scientific and program interests of other Institutes and Centers may be directed to:

FIC

Kenneth Bridbord, M.D.
Director
Division of International Training and Research
Fogarty International Center
National Institutes of Health
Building 31, Room B2C39
31 Center Drive MSC 2220
Bethesda, MD 20892-2220
Telephone: (301) 496-2516
FAX: (301) 402-2056
Email: bridbord@nih.gov

NCCAM

Richard Nahin, Ph.D., MPH
Division of Extramural Research
National Center for Complementary and Alternative Medicine
Bldg. 31, Room 5B-58
31 Center Drive MSC 2182
Bethesda, MD 20892-2182
Telephone: (301) 496-4792
FAX: (301) 402-4741
Email: NahinR@od.nih.gov

NCI

Jaswant Bhorjee, Ph.D.
Program Officer
Cancer Centers Program
OCTR, OD
National Cancer Institute
6130 Executive Boulevard, Room 502
Rockville, MD 20852
Telephone: (301) 496-8531
FAX: (301) 402-0181
Email: jb118r@nih.gov

NHLBI

Elaine Sloand, M.D.
AIDS Coordinator
Office of the Director
National Heart, Lung and Blood Institute
Bldg. 31 Room 4A11
31 Center Drive MSC 2490
Bethesda, MD 20892-2490
Telephone: (301) 496-3245
FAX: (301) 594-1290
Email: es38n@nih.gov
AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, 93.856 - Microbiology and Infectious Diseases Research and 93.855 - Immunology, Allergy and Transplantation Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under NIH grant policies and Federal Regulations 42 CFR Part 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, and 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.