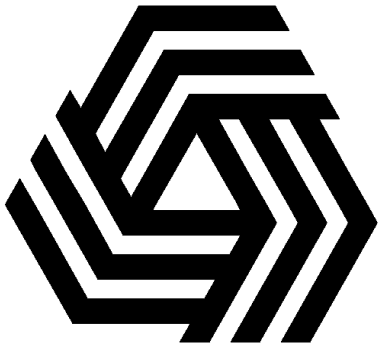

**National Center for Research Resources**
**National Institutes of Health**
**Department of Health and Human Services**

# Clinical Research

## Guidelines for the General Clinical Research Centers (GCRC) Program

### Supplement II: Clinical Associate Physician (CAP) Award

**January 1999**

An Administrative Document Issued by the
National Center for Research Resources

## Contact Information:

*Clinical Research*
*National Center for Research Resources*
*National Institutes of Health*
*One Rockledge Centre, Suite 6030*
*6705 Rockledge Drive*
*Bethesda, MD 20892*

*phone: (301) 435-0790*
*fax: (301) 480-3661*
*e-mail: CRADir@ncrr.nih.gov*

*Clinical Research area Web site:*
*http://www.ncrr.nih.gov/clinical.htm*

# GUIDELINES FOR THE CLINICAL ASSOCIATE PHYSICIAN AWARD
**(Application Receipt Dates: February 1, June 1, and October 1)**

## I. PURPOSE

The purpose of these guidelines is to consolidate and modify the current General Clinical Research Centers' (GCRC) supplemental programs to support more effectively the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. These changes to the Clinical Associate Physician (CAP) award will provide increased support for a period of mentored study and research to clinically trained professionals who have the potential to develop into productive, clinical investigators focussing on patient-oriented research.

For the purposes of this competitive supplemental award, patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: (1) mechanisms of human disease; (2) therapeutic interventions; (3) clinical trials; and (4) the development of new technologies.

The National Center for Research Resources (NCRR) intends to increase the number of scientists trained to conduct high-quality clinical research. Accordingly, changes to these guidelines form an important part of this National Institute of Health (NIH) initiative to attract talented individuals to the challenges of clinical research, and are intended to increase the availability of high-quality, multi-disciplinary didactic training of such candidates. Upon completion of an award, candidates should have acquired the knowledge and the skills necessary to compete for independent research support.

The objectives of the CAP award guidelines are as follows:

- to increase both the monetary support and duration of the CAP awards to levels comparable to those of other biomedical career development awards;

- to encourage research-oriented clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches that will allow them to conduct patient-oriented research;

- to increase the pool of clinical researchers who can conduct patient-oriented studies using advanced technologies to address disease problems; and

- to provide support starting at an earlier stage of career development for patient-oriented research.

The CAP award facilitates development of clinicians who have participated in research at various levels and are committed to developing into independent clinical investigators. This award will enable candidates who hold clinical degrees to undertake up to five years of special study and supervised research with the goal of developing into independent investigators who are capable of conducting patient-oriented research. (See under ELIGIBILITY REQUIREMENTS below.) While the focus of the development program is on the conduct of patient-oriented research, complementary, appropriate laboratory experiences may be included as part of the development program.

Because of the intent to progress to research independence, the prospective candidate for the CAP award should propose a period of study and career development consistent with her or his previous research and clinical experience. For example, a candidate with limited experience in a given field of research may find a program lasting for five years which includes a designated period of didactic training phased with a closely supervised research experience to be the most efficient means of attaining independence. A candidate with previous research experience, however, may require a program with appropriate patient-oriented research and appropriate, complementary laboratory research sufficient to allow a transition to independence which may require less than five years. All programs should be carefully tailored to meet the individual needs of the candidate, including the length of the proposed program, and must include a mentor(s) who is competent to provide the appropriate research guidance.

## II. ELIGIBILITY REQUIREMENTS

Candidates must have a clinical degree: M.D., D.D.S., or an equivalent degree. Candidates must have also completed their clinical training, including specialty and, if applicable, subspecialty (non-research) training prior to receiving an award. However, candidates may submit an application prior the completion of clinical training. Candidates must identify a mentor with extensive clinical research experience, and must be willing to spend a minimum of 75 percent of full-time professional effort conducting research career development and clinical research.

Applications should be submitted, on behalf of candidates, by the Principal Investigator (PI) of the NCRR-funded GCRC at the parent institution. Minorities, women, and individuals with disabilities are encouraged to apply. At the time of award, candidates must be citizens or non-citizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence (i.e., in possession of a currently valid Alien Registration Receipt Card I-551, or other legal verification of such status). Non-citizen nationals are usually those persons born in possessions of the United States (i.e., American Samoa and Swains Island). Individuals in the United States on temporary or student visas are not eligible.

Former PIs on NIH research project grants (R01), FIRST Awards (R29), sub-projects of program project (P01) or center grants (P50), or the equivalent, are not eligible. Former PIs of an NIH small grants (R03) or exploratory/developmental grants (R21) remain eligible. A candidate for the CAP may not concurrently apply for any other NIH award that duplicates the provisions of this award nor have another submitted application pending. CAP award recipients are strongly

encouraged to apply for independent research grant support, either federal or private, during the latter period of this award.

## III. MECHANISM OF SUPPORT

Each CAP award will be made as a competitive supplement to a currently funded GCRC. Planning, direction, and execution of the program will be the responsibility of the candidate and her/his mentor on behalf of the applicant institution. The requested project period may not exceed five years and the award is not renewable.

## IV. RESEARCH OBJECTIVES

### A. Environment:

The GCRC must have a well-established research and clinical career development program. It must also have qualified investigators who focus on patient-oriented research to serve as mentors. The PI of the GCRC must be able to demonstrate a commitment to the development of the candidate as a productive, independent investigator. The candidate, mentor(s), and the PI of the GCRC must be able to describe an in-depth, multi-disciplinary career development program that will utilize the relevant research and educational resources available within the parent institution and the GCRC.

### B. Program:

The CAP award provides up to five years of support. At least 75 percent of the recipient's full-time professional effort must be devoted to the goals of this award. The remainder may be devoted to other clinical, teaching, or research pursuits consonant with the objectives of the award. Both the didactic and the research phases of an award period must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the career goals of the candidate. Candidates must demonstrate they have adequate training in or will participate in courses such as hypothesis development, data management, epidemiology, study design, and statistics, as well as the legal and ethical issues associated with research on human subjects. The program must be designed and presented to fit the needs of the applicant within the time frame proposed.

### C. Mentor(s):

The recipient must receive appropriate mentoring throughout the duration of the program. Where feasible, women, minority individuals and individuals with disabilities should be involved as mentors and serve as role models. Candidates must name a primary mentor, who together with the applicant, is responsible for the planning, direction, and execution of the program. Candidates may also nominate additional mentors as appropriate to meet the goals of the program.

## D. Allowable Costs:

**1. Salary:** NCRR will provide a salary for the award recipient of up to $75,000 per year plus commensurate fringe benefits for a minimum of 75 percent effort. Although a greater effort may be proposed, the maximum allowable salary is $75,000. The institution may supplement the NCRR contribution with other funds up to a level that is consistent with the institution's salary scale. Institutional supplementation of salary must not require duties or responsibilities that would interfere with the purpose of the award. Direct salary is exclusive of fringe benefits and facilities and administrative costs.

The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the same department. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

CAP recipients are encouraged to submit other grant applications during the latter period of this award as long as doing so does not have an impact on the 75 percent of full-time effort devoted to the CAP award. If successful, the non-CAP award can be used to supplement the salary for the remaining 25 percent non-CAP effort as well as supplies and equipment.

**2. Research Development Support:** NCRR will provide generally up to $25,000 per year for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; (d) statistical services including personnel support and computer time not routinely available at the GCRC site.

**3. Ancillary Personnel Support:** Salary for mentors, secretarial, and administrative assistance can not be drawn from the CAP award.

**4. Facilities and Administrative Costs:** These costs will be reimbursed as part of the funded GCRC grant. The Facilities and Administrative (F&A) costs for the CAP portion of the GCRC grant are limited to a maximum of 8 percent.

## E. Evaluation:

In carrying out its stewardship of human resource related programs, the NCRR may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of the award period for updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

**F. Other Income:**

Fees resulting from clinical practice, professional consultation, or other comparable activities required by the research and research-related activities of this award may not be retained by the CAP award recipient. Such fees must be assigned to the parent institution for disposition by any of the following methods:

The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefits payments must be within the established policies of the grantee institution.

The funds may be used for health-related research purposes.

The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services, NIH, and should be forwarded to the Director, Division of Financial Management, NIH, Bethesda, MD 20892. Checks must identify the relevant award account and the reason for payment.

Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, or honoraria from other institutions for lectures or seminars, provided these activities remain incidental and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

Usually, funds budgeted in an NIH-supported research or research training grant for the salaries or fringe benefits of individuals, but freed as a result of such a career award, may not be rebudgeted. The awarding component will give consideration to approval for the use of released funds only under unusual circumstances. Any proposed retention of funds released as a result of a CAP award must receive prior written approval of NCRR.

**G. Special Leave:**

Temporary transfer to another institution, including a foreign laboratory, may be permitted if the reason for the transfer is directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed 3 months. For longer periods, prior written approval of NCRR is required. To obtain such approval, the award recipient must submit a letter to NCRR describing the plan, countersigned by the PI of the parent GCRC grant and the appropriate institutional official. This must be accompanied by a copy of a letter or other evidence from the institution where the leave is to be taken to assure that satisfactory arrangements have been made. The CAP award will continue to provide support during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of NCRR and will be granted only in unusual situations. Support from other sources is

permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible. Parental leave will be granted consistent with the policies of the NIH and the grantee institution.

**H. Termination or Change of Institution:**

When a grantee institution plans to terminate a CAP award, NCRR must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. If the individual is moving to an institution that has an eligible GCRC, the CAP award may be continued, provided the following:

- A new CAP award application is submitted by the PI of the second GCRC;
- All conditions of the original award are met at the new GCRC including the presence of a qualified mentor;
- The period of support requested is no more than the time remaining within the original award period; and
- The new application is submitted far enough in advance of the requested effective date such that it can be reviewed by an initial review group and/or NCRR's National Advisory Research Resources Council (NARRC). Alternatively, if appropriate, the review may be carried out by NCRR staff depending upon the circumstances.

A final progress report is required when the award is either terminated or relinquished to another institution.

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 new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous polices (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which has been in effect since 1990. The new policy contains new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," published in the Federal Register of March 28,1994 (FR 59 14508-14513), and reprinted in the NIH Guide For Grants And Contracts of March 18,1994, Volume 23, Number 11. It is also available at http://www.nih.gov/grants/guide/1994/94.03.18/.

Investigators may obtain copies from these sources or from NCRR program staff. Program staff may also provide additional relevant information concerning the policy.

NIH Policy and Guidelines on the 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 NIH, unless there are scientific and ethical reasons not to include them. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the *NIH Guide for Grants and Contracts*, March 6, 1998 and is available electronically at:
http://www.nih.gov/grants/guide/notice-files/not98-024.html.

As part of the scientific and technical merit evaluation of the research plan, reviewers will be instructed to address the adequacy of plans for including women, minorities, and children as appropriate for the scientific goals of the research, or justification for exclusion.

## V. APPLICATION PROCEDURES

Applications are to be submitted on the current version of form PHS 398 and will be accepted on or before the receipt deadlines indicated in the application kit (February 1, June 1, and October 1). Applications filed by those dates have the corresponding earliest beginning dates of December 1, April 1, and July 1. Application forms are available at most institutional offices of sponsored research and from the Office of Extramural Outreach and Information Resources, Office of Extramural Research, National Institutes of Health, 6701 Rockledge Drive, Room 6095, Bethesda, Maryland 20892-7910, phone (301) 435-0714, fAX: (301) 480-0525, e-mail: asknih.od.nih.gov. Forms are also available on the NIH Website at http://www.nih.gov/grants/funding/phs398/phs398.html.

Submit a signed, original typewritten application with the Checklist, and three signed photocopies, in one package to:

Center for Scientific Review (CSR), National Institutes of Health, 6701 Rockledge Drive, Room 1040, Bethesda, MD 20892-7710 or for express/courier service use Bethesda, MD 20817-7710. (CSR was formerly the Division of Research Grants.)

In addition, send two copies to:

Clinical Research, National Center for Research Resources, 6705 Rockledge Drive, Room 6070, Bethesda, MD 20892-7965
or for express/courier service use Bethesda, MD 20817-7965
(Enclose three sealed letters of reference in this mailing.)

The application must contain the following:

**Face Page**

Item 1. TITLE OF PROJECT: The CAP applicant's name should be inserted in the title. For example, "GCRC-CAP-Kelly Smith, M.D." Do not include the title of the applicant's research project here.

Item 2a. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT: "Yes"

Number: Leave Blank
Title: "GCRC CAP Supplement"

Item 3. Principal Investigator/Program Director: Name of Principal Investigator of the parent GCRC grant. Do not indicate the Program Director's name here.

**Candidate**

* A description of the candidate's commitment to a career in patient-oriented research.
* Evidence of the candidate's potential to develop into an independent investigator.
* A description of immediate and long-term career objectives, explaining how the award will contribute to their attainment.
* A commitment of at least 75 percent effort to the proposed clinical research program.
* Three sealed letters of recommendation addressing the candidate's potential for a patient-oriented research career. The mentor's statement in letter form (see below) should not be included as one of the letters of recommendation, although the mentor(s) may submit a separate letter(s) of recommendation. These letters must be included with the copies of the applications submitted to the GCRC Program Director, Clinical Research, NCRR.

**Career Development Plan**

* A description of the career development plan, incorporating consideration of the candidate's goals and prior experience. It must describe a systematic plan to obtain the necessary theoretical and conceptual background, in addition to the research experience, necessary to launch an independent research career. Candidates must describe the availability of courses such as research design, biostatistics, epidemiology, ethics, and regulatory issues at their institution and the integration of these studies into their career development plan.

  Less experienced candidates may require an initial period of one or two years during which subjects are studied in a didactic environment. This would be followed by a period

of intense, supervised research experience. Candidates with more research experience at the time of application may need a shorter developmental period. In both cases, the career development plan must be tailored to the needs of the individual candidate and the ultimate goal of achieving independence as a clinical researcher.

* Candidates must describe plans to receive instruction in the responsible conduct of research. These plans must detail the proposed subject matter, format, frequency, and duration of instruction. No award will be made if an application lacks these components.

**Research Plan**

* A description of the clinical research plan (not to exceed 25 pages) must be described as outlined in form PHS 398 and include sections on Specific Aims, Background and Significance, Progress Report/ Preliminary Studies, Research Design and Methods. The candidate should consult with the mentor regarding the development of this section.

**Mentor's Statement**

* The application must include information on the mentor(s) including information on research qualifications in the area proposed by the candidate and previous experience as a research supervisor. The application must also describe the nature and extent of supervision that will occur during the proposed award period.

**Environment and Institutional Commitment**

* The PI of the GCRC must document a strong, well-established research and training program related to the candidate's area of interest. This should reflect a high-quality research environment having staff capable and willing to collaborate productively with the candidate. The PI of the GCRC must also provide a statement of commitment to facilitating the candidate's development into a productive, independent investigator.

**Budget Instructions**

The total direct costs must be requested in accordance with these guidelines, following the budget instructions described below.

* Face page - As a reminder, Item 7 should be completed to indicate direct costs requested and Item 8 should reflect Total Costs (Direct plus Facilities and Administrative).

* Detailed Budget. The only items listed should be the CAP salary, fringe benefits and the items described above under ALLOWABLE COSTS.

* List the name, role on project and percent effort for all project personnel (salaried or unsalaried) and provide a narrative justification for each person based on his/her role on

the project and proposed level of effort. Identify all consultants by name and organizational affiliation and describe the services to be performed.

* Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research.

* If consortium/contractual costs are requested, provide the percentage of the subcontract Total Costs (Direct plus Facilities and Administrative) relative to the total direct costs of the overall project. The subcontract budget justification should be prepared following the instructions provided above.

**Biographical Sketch**

A biographical sketch is required for all key personnel, following the modified instructions below. Do not exceed the two-page limit for each person.

* Complete the education block at the top of the page.

* List current position(s) and those held previously that are directly relevant to the application.

* List selected peer-reviewed publications that are directly relevant to the proposed project, with full citation.

* Provide information on research projects completed and/or research grants participated in during the last five years that are relevant to the proposed project. Title, principal investigator, funding source, and role on project must be provided.

**Other Support**

Complete the other support pages for the CAP, mentors, and consultants.

## VI. REVIEW CONSIDERATIONS

Applications will be reviewed for completeness by the CSR and for responsiveness to this program announcement by NCRR staff. 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 a peer review group convened by the NCRR in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the NARRC.

The following review criteria will be applied:

**Candidate**

* Quality of the candidate's academic and clinical record;

* Potential to develop into an independent clinical researcher focussed on patient-oriented research; and

* Commitment to a career in patient-oriented research.

**Career Development Plan**

* Likelihood that the career development plan will contribute substantially to the scientific development of the candidate;

* Appropriateness of the content and duration of the proposed didactic and research phases of the award;

* Consistency of the career development plan with the candidate's career goals and prior research experience; and

* Quality of the proposed training in the responsible conduct of research.

**Research Plan**

Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. Although it is understood that these applications do not require the level of detail necessary in regular research grant proposals, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

* Appropriateness of the research plan to the stage of research development and as a vehicle for developing the research skills as described in the career development plan;

* Scientific and technical merit of the research question, design and methodology;

* Relevance of the proposed research to the candidate's career objectives;

* Relevance of the proposed research to the resources of the GCRC;

* Adequacy of plans for gender and minority inclusion as appropriate for the scientific goals of the research, or justification for exclusion; and

* Adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion.

**Mentor**

* Appropriateness of mentor's research qualifications in the area of this application;

* Quality and extent of mentor's proposed role in providing guidance and advice to the candidate;

* Previous experience in fostering the development of researchers;

* History of research productivity and support. Environment and GCRC/Institution's commitment;

* The GCRC/Institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program;

* Adequacy of research facilities and the availability of appropriate educational opportunities;

* Quality and relevance of the environment for scientific and professional development of the candidate; and

* GCRC/Institution's commitment to an appropriate balance of research and clinical responsibilities.

**Budget**

* Justification of the requested budget in relation to career development goals and research aims.

## VII. AWARD CRITERIA

NCRR will notify the PI of the GCRC of the NARRC’s recommendation shortly after its meeting. Funding decisions will be made based on the recommendations of the initial review group and the Council, and the availability of funds.

## INQUIRIES

Written and telephone inquiries concerning this program announcement are strongly encouraged especially during the planning phase of the application. Inquiries should be addressed to the following:

Clinical Research
National Center for Research Resources
6705 Rockledge Drive, Room 6070
Bethesda, MD 20892-7965
phone: (301) 435-0790.