INSTRUCTIONS

FELLOWSHIP TRAINING PROGRAMS IN CLINICAL PHARMACOLOGY

I. Introduction

Qualified fellowship training programs in clinical pharmacology must provide the intellectual environment, formal instruction, peer interaction, and clinical experience necessary for fellows to acquire knowledge, skills, and attitudes essential to the practice of clinical pharmacology. An accredited fellowship program in clinical pharmacology will provide at least two years of well-supervised educational experience.

II. Institutional Resources and Responsibilities

A. Administration

1. In order to meet the special requirements of the clinical pharmacology fellowship, sponsoring institutions must have a meaningful affiliation with an LCME-accredited medical school unless the institution can demonstrate equivalent commitment to education and research.
2. To qualify as a sponsor of a clinical pharmacology training program, an institution must promote meaningful interaction of clinical pharmacology fellows with residents and fellows from other clinical services by serving as a significant training site for a minimum of at least two accredited general residency programs (e.g., internal medicine, family medicine, pediatrics). The institution must serve as the sponsor of these two programs, and a sufficient number of residents in these programs should regularly participate in training in the institution.
3. The institution must have demonstrated a commitment to clinical pharmacology as evidenced by divisional, departmental, center, or sectional status of the unit responsible for the training program with reporting responsibility directly to the Department Chairperson, Dean, or Center Director.
4. Adequate financial support must be evidenced by appropriate compensation for faculty and fellows, suitable facilities for educational programs, appropriate support services, and opportunities for research.
5. Fellows must have no more than 20% of their time committed to clinical responsibility unrelated to education, research, or consultation in clinical pharmacology.
6. The Program director must have the authority to organize, implement, and provide leadership for the activities of the educational program at all sites. The program director should be director of the clinical pharmacology unit or have a reporting relationship that ensures appropriate authority.

When special activities are part of the training programs (e.g., geriatric clinic, pediatric clinic) a clear line of authority must be established between the clinical pharmacology program director and those responsible for the special activity.

7. Major changes in leadership, governance, institutional support, and goals which affect the educational programs must be communicated promptly to the Accreditation Committee for Fellowship Training in Clinical Pharmacology either by the institutional administration or by the program director. Major changes in the structure of the educational program (e.g., addition of a new educational track, addition of fellows beyond the approved complement) must be approved by the Accreditation Committee for Fellowship Training in Clinical Pharmacology prior to implementation. An expedited review process will be provided.

B. Participating Institutions

When the resources of two or more institutions are utilized in the program, letters of affiliation must be approved by the institutional governance. Affiliated institutions should not be so geographically distant as to make it difficult for fellows to attend their continuity clinics, clinical rounds or required classes and conferences. Assignments at affiliated institutions must not be made primarily to meet service needs.

C. Faculty

The program director and teaching faculty must be selected for their professional ability and commitment to teaching, medical education, patient care and the scientific and humanistic basis of clinical pharmacology. All faculty members must ordinarily have received certification by the American Board of Clinical Pharmacology, or present equivalent credentials or experience acceptable to the Accreditation Committee for Fellowship Training in Clinical Pharmacology. Faculty members must participate in structured faculty development programs including evaluation of teaching effectiveness. They must actively participate in one or more national clinical pharmacology or pharmacology societies, in continuing medical education and scholarly activities and in preparing scientific publications and conducting research. While not all faculty members must be investigators, the faculty as a whole must demonstrate involvement in research, defined broadly to include biomedical, clinical educational and health services research.

1. The Program Director

   a. The strength of the fellowship program is directly related to the professional competence and leadership qualities of the program director, whose

term of appointment must be sufficient to ensure continuity of the program. Irrespective of the source of compensation, the program director must be an institutionally based appointee whose primary responsibility is the organization, implementation and supervision of the training program. Regardless of the organizational arrangement of the institution, the program director must be authorized to evaluate the quality of performance by fellows, and have the authority to ensure effective teaching. The program director must obtain teaching commitments from other teachers involved in the education of the clinical pharmacology fellows.

b. The program director must be a licensed physician with broad knowledge of, experience with, and commitment to clinical pharmacology. He/she must have sufficient academic and administrative experience to ensure effective implementation of these Special Requirements and should have had at least five years experience in the field of clinical pharmacology as an active faculty member. The program director must ordinarily be certified by the American Board of Clinical Pharmacology, Inc. or possess equivalent qualifications in clinical pharmacology. The program director must meet professional standards of ethical behavior.

c. If the program director is replaced, the Accreditation Committee for Fellowship Training in Clinical Pharmacology must be notified by the institution promptly, with an explanation for the change. The qualifications of the new program director must be presented in detail, and a curriculum vitae must be submitted. The Accreditation Committee for Fellowship Training in Clinical Pharmacology may schedule a site visit when a new program director is appointed.

2. Other Faculty

a. Irrespective of the source of compensation there must be at least two additional institutionally based faculty members affiliated with the clinical pharmacology training program.

b. Each fellow must have a minimum of 10 hours per week of direct faculty supervision (fellow-faculty ratio of 6:1 or less). Faculty must not have other obligations during this teaching time. Such supervision would occur in structured classroom

lectures, patient-oriented small group educational activities, such as inpatient teaching attending rounds and preceptorships in ambulatory care, such as outpatient medical clinics, outpatient subspecialty clinics, office practices, and in research facilities.

c. Qualified individuals (institutionally based) must be designated to be responsible for teaching activities in general clinical pharmacology and in each of the designated special topics. Other members of the teaching staff may be voluntary, part-time or full-time. The teaching staff must share with the program director a commitment to the goals and objectives of the teaching program including development in the fellows of clinical pharmacology knowledge, clinical, technical and management skills, and clinical judgement. The faculty must be able to nurture the attributes of the scholar, scientist, teacher and humanist. Faculty members must be available to fellows for advice and counseling.

D. Fellows

1. Appointment of Fellows

Programs must demonstrate the ability to matriculate and retain qualified fellows. Fellows should be appointed only when their documented prior experience and attitudes demonstrate the presence of the abilities necessary to master successfully the knowledge and skill required of clinical pharmacologists. All fellows must have demonstrated understanding and facility in using the English language. In addition fellows should be continued in the training program only when their clinical judgement, knowledge of clinical pharmacology, history-taking, physical-examination and procedural skills, humanistic qualities, professional attitudes, moral and ethical behavior, and clinical performance are documented to be entirely satisfactory for a given level of training. Before accepting a fellow in transfer from another accredited training program, a written evaluation of past performance must be received in a timely fashion from the fellow's current and/or previous program director.

2. Number of Fellows

The total number of fellows enrolled in the program must not exceed the number of faculty or the patient and facility resources available to support an appropriate educational program. In accrediting the program, the Accreditation Committee for Fellowship Training in Clinical Pharmacology will stipulate the maximum number of clinical fellows that can

be enrolled at any given time. Program directors must obtain approval from the Accreditation Committee for Fellowship Training in Clinical Pharmacology prior to increasing the number of approved fellowship positions.

E. The Patient Population

Patients must be available in sufficient numbers for training purposes and must exhibit an adequate variety of therapeutic problems to provide broad experience in general clinical pharmacology in inpatient and ambulatory or other settings. There must be an adequate number of patients of both genders and a broad range of age, including both pediatric and geriatric groups if possible.

F. Facilities

1. General

Modern facilities to accomplish the overall educational program must be available and functioning. There must be adequate space and equipment for the educational program, including meeting rooms, classrooms, computers, visual and other educational aids, office space for teaching staff and laboratory facilities. Clinical and research services must be provided in an adequate fashion.

2. Ambulatory Care Facilities

Adequate facilities, support services and space for outpatient teaching and patient care must be available. Fellows must be provided with clinical experience in efficient, effective ambulatory care settings. Medical records, X-rays films and results of diagnostic studies must be readily available.

3. Clinical Facilities for Drug Trials

Every fellow must obtain experience in conducting clinical drug research studies. These clinical research studies may be sponsored by the pharmaceutical industry, N.I.H., foundations, medical school funding or other funding. A balance of funding for peer-reviewed projects is desirable.

4. Drug Analysis Laboratory

Adequate facilities must be provided to provide experience in doing common analytical methods of drug analysis. Every fellow must spend time learning modern drug analysis techniques on instruments such as HPLC, gas chromatograph, etc.

5. Medical Records

a. A medical records department which facilitates both quality patient care and education must be available.

b. Clinical records documenting both inpatient and ambulatory encounters must be maintained so that easy and prompt accessibility is assured at all times. Fellows must gain experience in documenting

consultation encounters and therapeutic audits. The record system must be organized to permit the collection and evaluation of selected material from clinical records for clinical investigation.

6. The Medical Library

A medical library under the direction of a qualified librarian must be readily accessible. There must be a means of access to appropriate reference material during those times when the library is not open and staffed. The library must contain a representative selection of books and journals on clinical pharmacology. An Index Medicus and an interlibrary loan system must be present. The sponsoring institution must provide fellows with access to an on-site computerized search system.

III. The Curriculum and the Teaching Program

A. Organization and Structure

1. The clinical pharmacology unit must be organized to provide a coherent, integrated and progressive educational program in the broad field of clinical pharmacology. The training program must be structured to ensure that each fellow acquires the knowledge, the clinical management and interpersonal skills, the professional attitudes and behaviors, and the experience required to become a proficient clinical pharmacologist.
2. The program description for each fellow must be set down in a concise current written document (i.e., a curriculum).
3. The written program description should include a listing of the fellow's required experiences. For each category, the written description should include: its educational purpose; the teaching methods; the educational content; and the methods used in evaluating performance. The document should identify the strengths and limitations specific to the resources of the sponsoring institution.

B. Required Experience

1. Obtain a research experience relevant to Clinical Pharmacology.
2. Clinical experience in the domain of Clinical Pharmacology is encouraged but not required, with the specifics determined by the individual program.
3. Participation in the activities of a Pharmacy & Therapeutics Committee if possible.
4. Institutional Review Board participation or observation if possible.
5. Participate in and pass a medical pharmacology course with a substantial component of the course devoted to therapeutics unless exempted by way of prior experience

(including having taken and passed a course in medical school) as determined by the director of the training program.

6. Formal education in a prospectively defined manner in the following topics:
    a. Biostatistics, unless exempted by prior experience as determined by the director of the training program
    b. Drug regulation and development
    c. Drug analytic methods
    d. Pharmacogenetics
    e. Pharmacokinetics / Pharmacodynamics
    f. Post-marketing drug surveillance
    g. Adverse drug reactions
    h. Toxicology / Poisoning
    i. Drug effects & disposition in special subjects / settings:
        1. Elderly
        2. Pediatrics
        3. Organ dysfunction
        4. Drug interactions
        5. Pregnancy and Lactation
    j. Substance abuse
7. Experience in teaching: this may be gained by presenting at scientific meetings, local seminars, conferences, and courses for students or house staff.

IV. Professional and Ethical Behavior

A. Professionalism

Fellows are expected to demonstrate the values of professionalism. These values include placing the patient's needs ahead of self-interest, being responsive to the needs of society, maintaining a commitment to scholarship and enhancing the ability of all colleagues in the health profession to discharge their responsibilities optimally. Training programs must provide an environment in which high standards of professionalism and a commitment to continual improvement are evident.

B. Humanistic Qualities

Fellows must exhibit the humanistic qualities of integrity, respect, compassion, professional responsibility, courtesy, and sensitivity to the patients' needs. These attributes should be emphasized throughout the curriculum, and evaluated by faculty, peers and others during clinical encounters.

C. Clinical Ethics

Fellows must be taught the principles of bioethics as applied to drug therapy decisions and decisions involved in ethical issues in clinical trials. Fellows must also be taught the basic legal principles inherent in the practice of clinical pharmacology, including informed

consent, patient advocacy, and related state laws concerning patient's rights.

V. Evaluation

A. Fellows

1. Formative Evaluation

a. It is essential that the program director evaluate fellows on a regular basis. The evaluation should include intellectual abilities, manual skills, attitudes and interpersonal relationships. It is recommended that such evaluation be conducted at least every six months.

b. Records must be maintained by documentation in a log book or by an equivalent method to demonstrate that fellows have had an adequate experience with clinical consultations or therapeutic audits. Such records should be of sufficient detail to permit use in future credentialing.

2. Summative Evaluation

The program director must prepare a detailed, written evaluation of the progress of each fellow annually and at the conclusion of the fellow's period of training in the program. Such evaluations must stipulate the degree to which the fellow has mastered each component of the program. A record of the evaluation must be maintained in the progress files to substantiate future judgments provided to hospital credentials committee certifying boards, licensing agencies, and other appropriate bodies. In the event of an adverse annual evaluation, fellows must be offered the opportunity to address judgments of academic deficiencies or misconduct before an appropriate constituted competence committee. Academic due process provides fundamental fairness to the fellow and protects the institution by assuring accurate, proper and definitive resolution of disputed evaluations.

B. Faculty and Program

1. Fellows Evaluation of Faculty and Program

Provision must be made for fellows to evaluate the faculty and program annually. The results of such evaluations should be used for faculty counseling, and for selecting faculty members for remedial instruction in teaching.

2. Certifying Examination

One measure of a program is the performance of the graduates on the certifying examination of the American Board of Clinical Pharmacology. This certifying examination will ordinarily be taken in May of the year following the year of completion of the fellowship.

VI. Application Procedure

A. Formal Application

The formal application for *accreditation of a fellowship program* in clinical pharmacology and the *registration of a fellowship program* in clinical pharmacology are found on this web site. Fill out all of the requested material in detail, answering all questions. Submit the completed application (one original set of all documents and one electronic document set via e-mail or on CD) with the required fees to the American Board of Clinical Pharmacology, Inc.

Accreditation

The fee for accreditation of a program is $3000, which covers the required site visit, and is valid for a five-year period, after which the application for accreditation must be repeated. An annual report to the Board indicating any areas of substantial change which might affect your accreditation status is to be submitted on the anniversary of your approval and should be in summary form.

Registration

There will be an initial $600 fee for registration of a program with a renewal fee of $200 per year. Registered programs will have three years from the date their registration is accepted to apply for accreditation.

Should you have any questions regarding these instructions or the two application forms, contact Yolanda Colunga at the Administrative Office.

B. Site Visit

If the review of original application for accreditation of a fellowship program by the Accreditation Committee of the ABCP is favorable, a site visit of the prospective program by a member of the ABCP is required.

C. Final Approval

Final approval for accreditation of a fellowship program in clinical pharmacology will be made by a vote of the members of the ABCP after a recommendation has been made to the Board by the Accreditation Committee for Fellowship Training in Clinical Pharmacology. The decision of the Board will be final. A negative decision does not preclude a subsequent application by the same institution.

D. Appeal Process

An appeal process may be initiated after notification by the ABCP of the outcome of the decision on an application for accreditation of a program.

1. The appeal must be initiated in writing by the program director within two weeks of notification.

2. Application materials submitted after the Accreditation Committee deadlines will not be considered in an appeal.
3. The Chairman of the ABCP will appoint two members of the Executive Committee to review the application, the appeal petition, and findings of the Accreditation Committee; and a report of findings will be submitted to the Accreditation Committee.
4. The Accreditation Committee will review the application and the report from the Executive Committee members.
5. Outcome
    a. If the Accreditation Committee and Executive Committee members concur with the decision the program director will be notified of the decision.
    b. If the Accreditation Committee and Executive Committee members do not agree, each will write a report to Chairman of the ABCP, who will review it with the Executive Committee or, at Chairman's discretion, with the ABCP at large. A final vote will be taken and the basis for opinions rendered will be provided in a report written by the chairman of the ABCP. The Program Director will be notified of results of the appeal.

E. Review approval of programs will occur at intervals of not more than 5 years.