

# POLICY AND COMMUNICATIONS BULLETIN THE CLINICAL CENTER

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Medical Administrative Series

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MANUAL TRANSMITTAL SHEET

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SUBJECT: Clinical Center Medical Staff Bylaws

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1. Explanation of Material Transmitted: This bulletin transmits for inclusion in the Medical Administrative Series Manual the revised Bylaws of the Medical Staff of the Warren Grant Magnuson Clinical Center.
2. Material Superseded: MAS No. M02-3, dated 17 May 2002
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DISTRIBUTION:

Physicians, Dentists and Other Practitioners Participating in  
Patient Care

**BYLAWS**  
**of the Medical Staff of the**  
**Warren Grant Magnuson Clinical Center**  
**National Institutes of Health**

**November 2003**

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## INTRODUCTION

The Warren Grant Magnuson Clinical Center (CC) was established January 16, 1952, by the Surgeon General, U.S. Public Health Service (PHS), under the authority of Section 202 of the Public Health Service Act. The CC is a Center of the National Institutes of Health (NIH). The primary mission of the CC is to provide the specialized hospital care necessary for the clinical research studies of the several NIH Institutes and Centers.

The Medical Staff are members of an Institute, Center or CC Department: collectively, they function as a staff organization. The goal of the Medical Staff is to strive for the highest quality of clinical research and patient care. The Staff work with the Director of the CC, who is also the Associate Director for Clinical Research, NIH, and who maintains ultimate authority in matters relating to patient care. Cooperative efforts of the Medical Staff, the Medical Executive Committee, and the Director, CC, are required to provide the excellent medical care that is a necessary component of clinical research.

## GOVERNING AUTHORITY

The ultimate governing authority for all PHS facilities is the Secretary of the Department of Health and Human Services, (HHS). The Associate Director for Clinical Research, NIH, serves as the governing authority *in situ* for the CC. In this capacity, the incumbent has overall responsibility for directing the hospital consonant with the objective of delivering high-quality patient care.

ARTICLE I. NAME

The name of this organization shall be the Medical Staff of the CC, NIH.

## ARTICLE II. PURPOSES AND RESPONSIBILITIES

### 2.1 PURPOSES

The purposes of this organization shall be to:

- a. Serve as the primary means for accountability to the Director, CC, in matters regarding the professional performance and ethical conduct of CC staff members and allied health professionals, and to strive toward the improvement of patient care delivery in the hospital.
- b. Support and encourage excellence in medical research while promoting the advancement of medical knowledge.
- c. Provide a means through which the Medical Staff may participate in the hospital's policymaking and planning processes.
- d. Assure compliance with rules and regulations governing the Medical Staff.

### 2.2 RESPONSIBILITIES OF THE ORGANIZED MEDICAL STAFF

The responsibilities of the Medical Staff are to:

- a. Recommend to the Director, CC, action with respect to clinical privileges, the specified services of allied health professionals, and corrective action (see Article IX).
- b. Recommend to the Director, CC, programs to establish, maintain, improve, and enforce professional standards in the delivery of health care in the hospital.
- c. Apprise the Director, CC, of the quality and efficiency of patient care through regular reports and recommendations concerning the implementation, operation, and results of quality review, evaluation, and monitoring activities.
- d. Initiate and pursue, when warranted, corrective action with respect to practitioners.

- e. Develop amendments to and seek compliance with these Bylaws, the rules of the Medical Staff, and other hospital policies.
- f. Exercise the authority granted by these Bylaws as necessary to fulfill the foregoing responsibilities.

## ARTICLE III. MEDICAL STAFF MEMBERSHIP

### 3.1 NATURE OF MEDICAL STAFF MEMBERSHIP

Medical Staff membership shall be extended only to practitioners who continue to meet the requirements set forth in these Bylaws. Each member of the Medical Staff shall agree in writing to abide by these Bylaws. Appointment to the Medical Staff shall confer on members only such clinical privileges and prerogatives as have been recommended by the IC Clinical Director or CC Department Chief and approved by the Director, CC, with additional stipulations stated in Article VIII. No practitioner shall admit patients to the hospital or its outpatient clinics unless he/she is a designated member of the Senior Medical Staff. (See Article VIII, Section 8.6.2, for exception.)

### 3.2 BASIC QUALIFICATIONS FOR MEMBERSHIP

Membership shall not be denied on the basis of race, sex, color, creed, national origin, age, or physical handicap.

It is desirable for Senior Staff practicing in recognized specialties and subspecialties to be board certified in those areas.

To be eligible for Medical Staff membership, the applicant must:

- a. For the Senior, Junior, Consultant, or Research Staff, be a graduate of an approved school of medicine, dentistry, osteopathy, or podiatry and have had a minimum of one year of postgraduate clinical training (or its equivalent); for the Adjunct Staff, possess educational credentials appropriate for the health care position to be occupied.
- b. For other than the Research Staff, have ECFMG certification if the applicant is a foreign medical graduate (i.e., a graduate of a school elsewhere than in the United States, a territory of the United States, Puerto Rico, or Canada, that is listed in the *World Directory of Medical Schools*).
- c. Meet applicable requirements of the Office of Personnel Management (OPM) and/or the PHS (viz., Commissioned

Corps) relative to training and experience, evidence of clinical competence, and health status.

- d. Maintain the highest ethical standards in professional activities.
- e. Be duly appointed to an Institute or Center Branch with a clinical service or to a CC Department.
- f. Be currently licensed to practice his/her profession in a U.S. State or Territory unless granted a waiver.

Waivers of licensure requirements may be made in accordance with regulations established by HHS and PHS. In addition, exemptions to requirements established by the Medical Executive Committee may be made at the discretion of the Medical Executive Committee and with the approval of the Director, CC, upon the recommendation of both an IC Clinical Director (or CC Department Chief) and the Chair, Credentials Committee.

### 3.3 BASIC RESPONSIBILITIES OF MEMBERSHIP

Members of the Medical Staff shall:

- a. Provide their patients with care at the generally recognized professional level of quality.
- b. Abide by the Medical Staff Bylaws and by all other applicable policies and rules of the hospital, including, but not limited to, the Medical Administrative Series and the Medical Staff and Medical Record Handbooks.
- c. Effectively discharge the clinical, research, educational, and other hospital functions for which they have responsibility.
- d. Complete in accordance with established CC policy the medical and other required records for all patients admitted to the hospital and its clinics or cared for in any way.
- e. Maintain current professional licensure unless granted a waiver or exemption.

- f. Provide evidence of retraining in CPR within 90 days of appointment and at each reappointment. Members of the Consultant Staff shall be exempt from this requirement.
- g. Appear before the Medical Executive Committee or any of its standing committees upon request.
- h. Provide evidence of annual training in Universal Precautions.

#### 3.4 EFFECT OF CURRENT AND/OR PAST AFFILIATIONS WITH THE CC OR OTHER INSTITUTIONS

A physician, dentist, podiatrist, or other health care professional is not automatically entitled to Medical Staff membership, to appointment to a particular Staff category, to affiliation with a particular Institute or Center clinical service or CC Department, or to particular privileges, because of prior, current, or pending status or privileges at the CC or other health care institutions.

## ARTICLE IV. CATEGORIES OF THE MEDICAL STAFF

### 4.1 CATEGORIES

The Medical Staff comprises five categories: Senior, Junior, Research, Consultant, and Adjunct.

### 4.2 SENIOR STAFF

#### 4.2.1 Specific Qualifications

Senior Staff are physicians (defined as doctors of medicine or osteopathy), dentists, and podiatrists qualified by education, training and experience, and current clinical competence to assume independent responsibility for the care of patients and the conduct of clinical research.

Senior Staff will usually be board certified (in the clinical specialty or subspecialty in which privileges are sought) or, at least, eligible to take the examination(s) required for such certification.

#### 4.2.2 Prerogatives

Senior Staff can:

- a. Exercise clinical privileges granted under Article VIII.
- b. Vote on matters presented at meetings of the Medical Staff and committees of which they are members, unless otherwise provided by resolution of the Medical Staff or a committee and approved by the Medical Executive Committee and the Director, CC.

### 4.3 JUNIOR STAFF

#### 4.3.1 Specific Qualifications

- a. Junior Staff are physicians, dentists, and podiatrists qualified by education, training and experience, and current clinical competence to provide patient care

and/or participate in clinical research under supervision of Senior Staff.

- b. Junior Staff who are foreign medical graduates (i.e., graduates of schools elsewhere than in the U.S., Canada, or Puerto Rico that are listed in the *World Directory of Medical Schools*) and who are exempt from licensure requirements because of their status in the Visiting Program must hold a valid certificate from the ECFMG.

#### 4.3.2 Prerogatives

Junior Staff can:

- a. Exercise clinical privileges granted under Article VIII.
- b. Vote on matters presented at meetings of the Medical Staff and committees of which they are members, unless otherwise provided by resolution of the Staff or a committee and approved by the Medical Executive Committee and the Director, CC.

#### 4.3.3 Supervision

Each ACGME-accredited training program is required to maintain a level of supervision of residents by faculty that complies with all ACGME requirements. Resident supervision should reflect graduated levels of responsibility based on individual skill and level of training.

Other IC clinical training programs shall have a policy regarding appropriate supervision of residents and other trainees who participate in patient care in their programs.

### 4.4 RESEARCH STAFF

#### 4.4.1 Specific Qualifications

Research Staff are physicians, dentists, and podiatrists qualified by education, training and experience, and current clinical competence to participate in research and patient

care incidental to that research. They do so under supervision of Senior Staff, who are government employees, and they do not have final responsibility for the diagnosis or treatment of any patient.

#### 4.4.2 Prerogatives

- a. Research Staff exercise clinical privileges granted under Article VIII and are permitted to have only "patient contact incidental to research"; i.e., their clinical privileges are limited to the program of research that is their primary purpose in coming to the NIH. Their privileges are thus limited to those required by their specific research responsibilities. The incidental patient care activities they perform are to be conducted under the supervision of a member of the Senior Staff. Members of the Research Staff may not deliver primary patient care, which remains the responsibility of the Junior and Senior Staff. Primary patient care includes on-call duties, performing definitive admission histories and physical examinations, as defined by JCAHO, authorizing general medical orders, serving as a medically responsible investigator, and having final responsibility for the diagnosis and treatment of patients.

Members of the Research staff may practice within their area of expertise, may serve as a Principal Investigator on protocols that specify a Medical Advisor, may enter orders from a predetermined order set, called a "Per Protocol Order Set," pertaining to their specific research protocol(s), may have retrieval access to the medical information system (MIS) and may dictate medical reports, subject to the supervision of a member of the Senior Staff.

- b. Research Staff with "incidental patient contact" privileges receive no experience creditable toward any board certification.

#### 4.5 CONSULTANT STAFF

#### 4.5.1 Qualifications

- a. Consultant Staff are physicians, dentists, podiatrists, and other health care professionals not primarily employed at the NIH, who are of recognized professional ability and who may be called upon for advice and assistance on patient care problems.
- b. Consultant Staff will usually be board certified in their particular clinical specialty or subspecialty.

#### 4.5.2 Prerogatives

Consultant Staff shall exercise clinical privileges granted under Article VIII.

### 4.6 ADDITIONAL DESIGNATIONS

- 4.6.1 Primary Physician - A member of the Staff who is most intimately involved in the day-to-day treatment of a particular patient. Members of the Junior or Senior Staff may be primary physicians.
- 4.6.2 Attending Physician - A member of the Staff who is ultimately responsible for a patient's overall treatment and management during a particular episode of care such as an inpatient admission or series of outpatient visits. Members of the Senior Staff may be designated by their IC Clinical Director or CC Department Head as attending physicians.
- 4.6.3 Accountable Investigator - A member of the staff who is a tenure or tenure-track investigator who is responsible and accountable for the scientific quality and the expenditure of resources for the conduct of a clinical research protocol.
- 4.6.4 Medical Advisor - A member of the CC Junior or Senior Medical Staff responsible for assisting a Principal Investigator who is not a Junior or Senior Medical Staff member in the development of the clinical aspects of the protocol and for advising the PI on clinical matters.

#### 4.7 ADJUNCT MEDICAL STAFF

- 4.7.1 Definition - Individuals ineligible for active Medical Staff membership but who require formal credentialing by the Credentials Committee and approval by the Medical Executive Committee and Director, CC, because they independently perform certain identifiable clinical duties that do not fit into the Staff Affiliate (see Article V) credentialing process.
- 4.7.2 Composition - This category comprises (but is not limited to) physician assistants, clinical scientists (such as clinical psychologists or audiologists) who require direct patient contact, and nurse anesthetists or nurse practitioners who have been credentialed by the Nursing Department and require subsequent approval of those unique patient care privileges that they are qualified to perform by virtue of their licensure and certification.
- 4.7.3 Prerogatives - Members of the Adjunct Staff exercise privileges granted under Article VIII.

The Medical Executive Committee may apply constraints to the practice of Adjunct Staff members.

#### 4.8 WAIVER OF QUALIFICATIONS

Any qualifications, unless required by OPM or PHS rules, may be waived by the Director, CC, in conjunction with the Medical Executive Committee, where such a waiver is deemed in the best interest of patient care.

#### 4.9 STATEMENT OF EQUIVALENCY

Unless otherwise specified or obvious from the context, references to *physicians* in these Bylaws or in other publications or policies of the Clinical Center shall be construed to include *dentists*.

## ARTICLE V. STAFF AFFILIATES

Health professionals in Institutes, Centers and CC Departments who are not physicians, dentists, or podiatrists and who practice direct, independent patient care activities are eligible for designation as Staff Affiliates. This category shall include, but not be limited to, respiratory therapists, physical therapists, occupational therapists, recreational therapists, speech pathologists, social workers, clinical pharmacists, dietitians, ophthalmic technicians, dental hygienists, genetic counselors, phlebotomists, perfusionists, diagnostic radiologic technicians and clinical scientists in other disciplines. In their area of competence, Staff Affiliates may participate directly in research, manage patients, record notes in patient records, and write orders to the extent established by the appropriate Clinical Director or CC Department Head, when under the supervision of a Medical Staff member.

Staff Affiliates may be NIH employees, contract employees, NIH Special Volunteers, Visiting (Research) Affiliates, or Consultant Affiliates.

Staff Affiliates are not members of the Medical Staff and may not serve on the Medical Executive Committee, but they may serve on Medical Staff committees.

## ARTICLE VI. STUDENTS AND OBSERVERS

Both undergraduate students in medicine, dentistry, and other clinical care disciplines, and postgraduate/postdoctoral clinical care practitioners come to the CC for experience in a clinical research setting. These individuals function under the preceptorship and direct supervision of a Senior Staff member, who is responsible for their behavior and performance. Their clinical contacts are restricted to a degree consonant with their training and experience, and they shall not have any responsibility for the direct care and management of patients. Since these individuals are neither members of the Medical Staff nor of the Affiliate Staff, they are ineligible to vote, hold office, or serve on any Medical Staff committee, nor are they credentialed as members of the Medical Staff.

## ARTICLE VII. PROCEDURES FOR APPOINTMENT AND REAPPOINTMENT

### 7.1 SENIOR, JUNIOR, RESEARCH, CONSULTANT, AND ADJUNCT STAFF

#### 7.1.1 Initial Appointment

- a. Applications for appointment to the Senior, Junior, Research, Consultant, and Adjunct Medical Staff shall be submitted on the prescribed forms and shall include detailed information on the applicant's education, training, and professional qualifications. The applicant is responsible for producing adequate documentation for a proper evaluation of his/her credentials, current clinical competence, and physical and mental health status, and for the resolution of any questions about these or other basic qualification requirements specified in Article IV. The application form for appointment to the Medical Staff will contain a series of questions that the applicant must answer regarding adverse occurrences involving licensure, malpractice coverage, hospital appointment or reduction/revoking of privileges. Each "yes" response to an adverse event must be explained in writing.
- b. IC Clinical Directors, Chiefs of CC Departments, and the Director, CC, as appropriate, shall be responsible for reviewing and approving completed applications and related documentation. They shall assess the qualifications of applicants, verify their credentials, and determine whether any of the applicants' previous professional memberships, clinical privileges, or licenses have been revoked or in any way restricted, in which case the applicant shall provide a written, signed explanation. In the case of candidates for the Consultant Staff, the application shall also be reviewed and approved by the Chief of the appropriate Consultant Panel, if applicable.
- c. Upon review and approval of applications, IC Clinical Directors, Chiefs of CC Departments, and the Director, CC, as appropriate, shall forward all materials to

Credentialing Services, CC for processing and review. The Credentials Committee shall review the qualifications, character, professional competence, and ethical standing of the applicants, and certify that all necessary qualifications for Staff membership and the requested clinical privileges have been documented. It may conduct further investigation, as necessary. Within 30 days, the Credentials Committee's Chair shall indicate in writing to the Medical Executive Committee the Committee's recommendation for acceptance, rejection, or deferment. The Committee should specify any conditions attached to the privileges recommended.

- d. By applying for membership, an applicant agrees to appear before the Credentials Committee and/or Medical Executive Committee, as necessary, and authorizes members of those committees and the CC Administration to consult with Medical Staff members of other hospitals with which the applicant has been associated, as well as with other appropriate parties who may have information bearing on his/her competence and ethical qualifications.

#### 7.1.2 Appointment Process

- a. At its next regular meeting after receipt of the Credentials Committee's recommendation, the Medical Executive Committee shall act on the application and, if approved, recommend the clinical privileges to be granted and which privileges may be qualified by probationary or other conditions.
- b. Any deferred applications shall be reconsidered within 60 days with a recommendation for appointment or non-appointment.
- c. When, following review by the Credentials Committee, the Medical Executive Committee recommends non-appointment, the Chair shall promptly notify the applicant of the reasons and the procedures for requesting a hearing. No such adverse

recommendation shall be forwarded to the Director, CC, until after the applicant has exercised or waived the right to a hearing, as provided in Article X of these Bylaws.

- d. Applications on which the Medical Executive Committee has recommended approval shall be forwarded to the Director, CC, for review and approval. The Director, CC, is the ultimate authority for making appointments to the Medical Staff and for granting clinical privileges.

### 7.1.3 Terms of Appointment

- a. The term of appointment to NIH and assignment to clinical responsibility of Senior Staff; Junior Staff, including Clinical Fellows and Resident physicians, dentists, and podiatrists; Research Staff; and Adjunct Staff are subject to applicable OPM and PHS regulations. Appointments to the CC Medical Staff and clinical privileges of these practitioners shall be reviewed at least every two years.
- b. Consultant Staff are appointed as needed. The continued need for retaining the services of each consultant and redelineation of clinical privileges shall be assessed at least every two years by the respective IC Clinical Director or CC Department Head, in collaboration with the appropriate Consultant Chief, if applicable. Necessary changes shall be reported to Credentialing Services, CC.
- c. The appointment and clinical privileges of any Medical Staff member (or Staff Affiliate) who has a contractual relationship with the NIH, or who works for an entity that provides services to Clinical Center patients under contract, terminate immediately when the contract ends.

The termination of Staff appointment and clinical privileges of contract Medical Staff is not subject to the terms of Article X of these Bylaws.

#### 7.1.4 Reappointment Process

- a. When a Medical Staff member's term of appointment expires, and not exceeding two years in any case, he/she shall apply for reappointment and for redelineation of clinical privileges.
- b. IC Clinical Directors, Chiefs of CC Departments, the Deputy Director for Clinical Care, CC, and the Director, CC, as appropriate, shall review the status and clinical privileges of their Medical Staff members and submit to the Medical Executive Committee, through the Credentials Committee, a list of all recommended changes for each Staff member. These recommendations shall be based on professional competence, judged from quality improvement activities, health status, professional conduct, evidence of current licensure, evidence of Continuing Medical Education (CME), 50% of which is specialty specific, participation in Medical Staff and CC affairs, and compliance with the Medical Staff Bylaws and rules. The reapplication form for appointment to the Medical Staff will contain a series of questions that the applicant must answer regarding adverse occurrences involving licensure, malpractice coverage, hospital appointment or reduction/revoking of privileges. Each “yes” response to an adverse event must be explained in writing.

#### 7.1.5 The National Practitioner Data Bank

As required by current law or regulation, Credentialing Services will query the National Practitioner Data Bank as a part of the initial credentialing procedure and at the time of recredentialing and redelineation of privileges, to determine whether any information is on file regarding the applicant. Information provided by the National Practitioner Data Bank shall be processed in accordance with published CC policy.

### 7.1.6 Staff Clinician/Staff Scientist Designations

- a. Senior and Junior Medical Staff who fill clinical service roles shall be considered for Staff Clinician designation upon the recommendation of their Branch Chief or Clinical Director (or CC Department Head), and concurrence of their Scientific Director, to their IC Director, in accordance with procedures and criteria approved by the Medical Executive Committee. Staff Clinician status is not associated with oversight of independent resources. Permanent appointments are allowed by exception, after additional reviews (e.g., General Schedule).
- b. Senior and Junior Medical Staff who fill predominantly basic research service roles shall be considered for Staff Scientist designation upon the recommendation of their Scientific Director to their IC Director in accordance with OIR policy.

## 7.2 STAFF AFFILIATES

- 7.2.1 As provided in Article V, qualified health professionals who practice direct, independent patient care activities and who are not physicians, dentists, or podiatrists may be designated as Staff Affiliates upon recommendation of the appropriate IC Clinical Director or CC Department Head and subsequent approval by the specific credentialing group authorized by the Director, CC, to approve such privileges. Each Institute, Center or CC Department that wishes to appoint as Staff Affiliates and grant clinical privileges to individuals within a particular professional health care discipline or category shall formulate a process and develop appropriate instruments (e.g., privilege delineation forms). A description of the credentialing process, together with the instruments that will be used, will be submitted to the Credentials Committee, Medical Executive Committee, and Director, CC, for approval. The process shall define the method by which the qualifications of candidates for appointment will be reviewed; the criteria for the initial granting and biennial redelineation of clinical privileges (as specified in Section 7.1 of these Bylaws); the type(s) of

information that Staff Affiliate candidates must submit to document their training, experience, professional ability, clinical competence, etc. (and which the Institute, Center or CC Department will maintain on the appointee, consistent with PHS and OPM policy, e.g., evidence of current licensure/registration); and the mechanisms for granting, when necessary, temporary clinical privileges. After their credentialing process has been approved, each credentialing group shall keep the names of their Staff Affiliates available for review.

Each CC affiliate credentialing program director must submit a semi-annual report to the Credentials Committee, including a list of individuals appointed, reappointed, departed, or whose privileges have lapsed without renewal, along with a brief summary of problems encountered (if any), and recommendations for improvement. Reports shall be addressed to the Chair, Credentials Committee, through the Chief, Credentialing Services, CC. The Credentials Committee shall review and discuss reports submitted, ask for additional information where appropriate and report follow-up, problems or subsequent recommendations to the Medical Executive Committee.

- 7.2.2 If there are candidate Staff Affiliates who cannot be credentialed under a given Institute's, Center's or CC Department's approved process, credentialing instruments prescribed by the CC will be used, and the channels for approval of their appointment and clinical privileges shall be the Credentials Committee, Medical Executive Committee, and Director, CC. The Credentials Committee's Chair may recommend to the Medical Executive Committee the formation of a new credentialing group to handle subsequent actions, if appropriate.
- 7.2.3 All Staff Affiliates who will be paid CC consultants must have their credentials reviewed and approved by the Credentials Committee, Medical Executive Committee, and Director, CC.

7.2.4 The provisions of subsection 7.1.3.d., pertaining to the termination of appointments and clinical privileges of contract Medical Staff, also apply to contract Staff Affiliates.

### 7.3 RECIPROCAL ACCEPTANCE OF CONSULTANTS FROM OTHER INSTITUTIONS

7.3.1 When service or training programs are formally established with local healthcare institutions, the Medical Executive Committee and the Director, CC, may accept consultant services from medical staff members as verified by that institution, provided that the credentialing mechanism of that institution has been examined and approved by the Credentials Committee and the Medical Executive Committee, and provided further that the institution has been accredited by the Joint Commission on Accreditation of Healthcare Organizations and that the institution's credentialing process met the JCAHO standards at the time of its last survey. Such individuals are not credentialed as members of the CC medical staff.

7.3.2 If a local health care institution's credentialing mechanisms have been approved, members of that medical staff may dispense consultant services at the CC. Such actions require a memorandum signed by a member of the CC Senior Medical Staff and approved by the member's Branch Chief or Clinical Director, which identifies the consultant and the services to be provided, as well as a letter from the consultant's home institution certifying that the applicant is a member in good standing of their medical staff. The memorandum should be forwarded to Credentialing Services, CC for processing.

7.3.3 Reciprocal services, as provided for in section 7.3.2, are to be used for low volume, non-recurring, consultative patient care. If an individual provides consultative services seven or more times in a twelve-month period, he/she must apply for a permanent appointment to the Clinical Center's Medical Staff as a consultant.

ARTICLE VIII. DELINEATION  
AND APPROVAL OF CLINICAL PRIVILEGES

8.1 GENERAL

- 8.1.1 Medical Staff and Staff Affiliates shall exercise only those clinical privileges granted by the Director, CC, upon the recommendation of the IC Clinical Director or Chief, CC Department, the Credentials Committee, and the Medical Executive Committee.
- 8.1.2 Applications for Medical Staff and Staff Affiliate appointment and reappointment must specify the clinical privileges requested.
- 8.1.3 Individuals in administrative positions achieve and maintain their clinical privileges through the same procedures followed by all other individuals with delineated clinical privileges.
- 8.1.4 Each practitioner's clinical privileges shall be reviewed and redelineated at least every two years as described in 8.1.1.
- 8.1.5 Sex, race, creed, national origin, physical handicap, or age are not factors in granting or denying clinical privileges.

8.2 BASES FOR DELINEATION AND APPROVAL OF CLINICAL PRIVILEGES

- 8.2.1 Applications for delineation of clinical privileges shall be evaluated on the quality of the practitioner's education and training, experience, current clinical competence and professional ability, health status, and evidence of current licensure (unless waived by the Director, NIH or designee, as documented and verified in the practitioner's credentials file.
- 8.2.2 Quality improvement files and peer recommendations from Institutes, Centers or CC Departments are part of the basis for recommending clinical privileges.

- 8.2.3 Recommendations for addition, renewal, nonrenewal, curtailment, or denial of clinical privileges shall be based on direct observation and documentation of care provided, the results of treatment, the review of medical records, conclusions drawn from quality improvement activities, and other evidence pertinent to an evaluation of the quality of care provided by the practitioner concerned.
- 8.2.4 Requests for additional clinical privileges or change of Staff Category may be submitted, when necessary, in the interim between reappointments. Such requests shall be processed in the same fashion as appointments, consistent with Sections 8.1.1, 8.1.2, 8.1.3, 8.1.5, 8.2.1, 8.2.2, and 8.2.3.

### 8.3 INTERIM PRIVILEGES

- 8.3.1 Interim privileges may be granted to Medical Staff and Staff Affiliates by the Director, CC, upon the recommendation of the Chair, Credentials Committee, in situations where time or other circumstances do not permit completion of the normal credentialing process. Before granting interim privileges, the Director, CC, shall review all documentation and information necessary to establish the clinical competence and ethical standing of the practitioner.
- 8.3.2 The approval of interim privileges shall remain effective only until completion of processing, through established channels, of the practitioner's formal application for Medical Staff or Staff Affiliate appointment and/or clinical privileges, and in no case for more than 45 days. Interim privileges are not renewable.
- 8.3.3 Practitioners granted interim privileges must abide by the CC Medical Staff Bylaws and rules, and shall be under the supervision of the appropriate IC Clinical Director or CC Department Chief, as applicable, or another Senior Staff member whom the latter may designate. Specific supervision and reporting may be required of practitioners granted interim privileges.

8.3.4 The Director, CC, may terminate a practitioner's interim privileges at any time, subject to subsequent review by the Medical Executive Committee.

#### 8.4 TEMPORARY PRIVILEGES

8.4.1 Temporary privileges may be granted by the Director, CC, to a practitioner when the forms and documents normally required for credentialing cannot be submitted. In such cases, the Institute or Center Branch Chief or CC Department Head shall submit a memorandum through the Chair, Credentials Committee, to the Director, CC, listing the qualifications of the practitioner, the specific duties to be performed, and the reason why a request for permanent privileges has not been submitted.

8.4.2 Temporary privileges shall be granted for a period not to exceed five days and may not routinely be renewed. Under extraordinary circumstances it may be necessary to grant temporary privileges on more than one occasion.

8.4.3 Practitioners granted temporary privileges must abide by the CC Medical Staff Bylaws and rules, and shall be under the supervision of the appropriate IC Clinical Director or CC Department Head, as applicable, or other Senior Staff member whom the latter may designate. Specific supervision and reporting may be required of practitioners granted temporary privileges.

8.4.4 The Director, CC, may terminate a practitioner's temporary privileges at any time, subject to subsequent review by the Medical Executive Committee.

#### 8.5 EMERGENCY PRIVILEGES

8.5.1 In an emergency, any member of the Medical or Affiliate Staff shall be permitted to do everything possible, within the scope of his/her license, using every facility of the hospital, including any necessary consultations, to save a patient's life or to save a patient from serious harm, regardless of the practitioner's staff status or clinical privileges.

- 8.5.2 In an emergency, Senior Staff may request assistance from a practitioner who is not already an approved consultant, provided that he/she notifies the Director, CC, or, if after regular working hours, the senior CC administrative official on call.
- 8.5.3 An "emergency" is defined as a condition in which serious permanent harm would result to a patient, or one in which the life of a patient is in immediate danger and any delay in initiating treatment would add to that danger.

## 8.6 ADMITTING PRIVILEGES

- 8.6.1 Only Senior Staff designated by their Clinical Director or CC Department Chief can admit patients to the hospital's inpatient and outpatient services, subject to limitations imposed by the Institute or Center Service/CC Department and availability of beds. (See Section 4.6.3).
- 8.6.2 Under special circumstances, individuals not on the Senior Staff may be granted limited and carefully delineated admitting privileges, on a case-by-case basis, by the Director, CC, upon the recommendation of an IC Clinical Director or CC Department Chief and the Medical Executive Committee (e.g., Adjunct Staff with first registration outpatient admitting privileges).
- 8.6.3 A member of the Senior Staff is responsible for the overall medical care of the patient. (See Section 4.6.2)

## 8.7 STAFF AFFILIATE PRIVILEGES

- 8.7.1 Based on their qualifications and to the degree permitted by applicable law, Staff Affiliates may be granted clinical privileges to the extent recommended and/or approved by the IC Clinical Director or CC Department Chief, the Credentials Committee, Medical Executive Committee, and Director, CC, as applicable.

8.7.2 The bases for delineating and approving clinical privileges of Staff Affiliates shall be consistent with those specified in Sections 7.2 and 8.2, above.

**8.8 PRIVILEGE TO SERVE AS PRINCIPAL INVESTIGATOR ON A CLINICAL RESEARCH PROTOCOL**

8.8.1 The principal investigator (PI) is responsible and accountable for the design, conduct, and monitoring of a clinical research protocol.

8.8.2 There may be only one PI on a clinical research protocol.

8.8.3 The PI must be a health professional qualified, in the judgment of the Institutional Review Board (IRB) and Clinical Director, on the basis of education, training, experience, and demonstrated professional competence, to assume responsibility for the particular clinical research study at the CC. PIs must take and pass the required Clinical Research Training course.

8.8.4 A suitably qualified member of the Senior Staff, Junior Staff, Research Staff, or Adjunct Staff, or a registered nurse, pharmacologist, psychologist or other health professional, may serve as a PI.

8.8.5 When the PI is not a member of the Junior or Senior Staff, or when the Clinical Director, IRB, or Director, CC, consider it warranted, a Medical Advisor must be identified in the protocol. The Medical Advisor must be a member of the CC Junior or Senior Medical Staff. It shall be the responsibility of the Medical Advisor to assist in the development of the clinical aspects of the protocol and advise the PI on clinical matters.

8.8.6 Consultants and students may not serve as PI or as Medical Advisor on a clinical research protocol.

## ARTICLE IX. CORRECTIVE ACTION

### 9.1 CRITERIA FOR INITIATION

Corrective action may be initiated towards any Medical Staff member or any Staff Affiliate for:

- a. Violations of the Medical Staff Bylaws, rules, or standards of professional clinical practice of the CC.
- b. Conduct, either inside or outside the hospital, that is deemed inadequate or substandard clinical or professional performance, detrimental to patient safety or to the delivery of quality patient care, or disruptive to the operation of the hospital.

### 9.2 PROCEDURES

#### 9.2.1 Requests and Notices

- a. Requests for corrective action towards a Medical Staff member or Staff Affiliate may be made by members of the Medical Executive Committee, by the Chiefs of CC Departments, by any member of the Medical Staff, by the Director, CC, or other CC administrative staff, by the Chair of any standing committee of the Medical Executive Committee, or by patients and their families.
- b. All requests for corrective action shall be submitted in writing to the Clinical Director of the Institute or Center, or to the Director, CC. Such requests shall reference the specific behavior that constitutes the grounds for the request.
- c. The IC Clinical Director shall promptly notify the Director, CC, and Chair, Medical Executive Committee, of requests for corrective action that are received and shall continue to keep them informed of action taken. If the complainees works for the CC, the Director, CC, shall keep the Chair, Medical Executive Committee, similarly informed.

## 9.2.2 Investigation

- a. At their discretion, the IC Clinical Director or the Director, CC, may appoint an individual or an *ad hoc* committee to investigate the complaint. Any such individual or committee must be drawn from practitioners in Institutes, Centers or CC Departments other than that of the complaine, who have no direct involvement with the case. The practitioner (complaine) will be given prompt written notice of the investigation. If necessary, non-NIH clinicians may serve as consultants to the committee and be provided with technical information consistent with requirements of the Privacy Act and other Federal laws and regulations.
- b. The individual or committee appointed to investigate the case may interview the complaine. Prior to the interview, the complaine shall be given a written explanation of the nature of the complaints. At such interview, the complaine shall be told the nature of the complaints and shall be invited to explain or rebut them.

This interview shall not constitute a hearing as provided for in Article X of these Bylaws.

- c. The individual or committee appointed to investigate the complaint shall, within 60 days, report the findings and recommendations of the investigation in writing to the IC Clinical Director or Director, CC, as applicable. At their discretion, the IC Clinical Director or Director, CC, may forward the report and any additional recommendations they deem appropriate to the Chair, Medical Executive Committee, for consideration by the Medical Executive Committee, or, if necessary, return it to the investigating individual or committee for clarification or further development.

### 9.3 TYPES OF CORRECTIVE ACTION

If the case is referred for consideration, the Medical Executive Committee, after studying the complaint, the recommendations of the investigating individual or committee, and any recommendations made by the IC Clinical Director or Director, CC, shall determine the type of action, if any, to be recommended and shall inform both the complaine and complainant. If discipline is required, the corrective action shall be based on the seriousness of the infraction(s) and its (their) implications. The types of corrective action that may be recommended, either singly or in combination, are:

- a. Oral or written admonishment.
- b. Written reprimand.
- c. Denial of initial staff appointment.
- d. Probation.
- e. Suspension or revocation of Staff membership.
- f. Requirement for professional treatment.
- g. Suspension of privileged parking for 30 days or more.
- h. Denial of reappointment.
- I. Denial of requested clinical privileges.
- j. Reduction, suspension, or revocation of clinical privileges for a time period determined by the Medical Executive Committee.
- k. Denial of requested advancement in Staff category.
- l. Demotion.
- m. Reassignment.
- n. Termination of employment.

### 9.4 PROCEDURAL LIMITATIONS

Corrective actions other than summary suspensions described in Section 9.5 below shall be subject to PHS and OPM rules. Corrective actions by the Medical Executive Committee shall not preclude other administrative actions by the Institutes, Centers, NIH, PHS, or the Commissioned Corps, subject to applicable PHS and OPM rules.

## 9.5 SUMMARY SUSPENSION

### 9.5.1 General

- a. The Chair, Medical Executive Committee, the Director or Deputy Director for Clinical Care, CC, an IC Clinical Director, a CC Department Chief, or, in unusual circumstances affecting fitness for duty and posing immediate danger to patients, a Senior Staff member, shall each individually have the right, upon determining that an action must be taken immediately in the best interest of patient care in the CC, to suspend all or any portion of the clinical privileges of a Medical Staff member or of a Staff Affiliate. Whenever possible, the appropriate IC Clinical Director or CC Department Chief shall be consulted before such summary suspension. Under extraordinary circumstances, a Junior Staff member may summarily suspend privileges. This Junior Staff member should immediately notify the appropriate Clinical Director or CC Department Head and Director, CC, who will decide, as soon as possible, whether this suspension should be continued. The Clinical Director shall immediately notify the Chair, Medical Executive Committee, of a suspension action against any physician.
- b. Summary suspension shall become effective immediately upon imposition, and the respective IC Clinical Director or the Director, CC, shall promptly give notice of the suspension to the practitioner. The appropriate Clinical Director or CC Department Chief shall designate alternative coverage for patients of the suspended practitioner.

### 9.5.2 Investigation

Summary suspension is not considered a formal disciplinary action, because the practitioner is not protected by substantive procedural safeguards. Within a reasonable time after a summary suspension has been imposed, an investigation shall be initiated to review that action. This investigation shall be carried out as described in Section 9.2.

### 9.5.3 Procedural Limitations

Any action beyond the summary suspension shall be taken subject to applicable PHS and OPM rules.

## 9.6 AUTOMATIC SUSPENSION

### 9.6.1 Delinquent Medical Records

- a. For repeated failure to complete medical records in a timely fashion, a practitioner's clinical and research privileges may be automatically suspended by his/her IC Clinical Director or CC Department Chief or by the Director, CC. The definition of delinquency shall be determined by the Medical Executive Committee in concert with the Medical Record Committee and shall be made known to all members of the Medical Staff.
- b. Upon the recommendation of the Medical Record Committee, its Chair shall report to the Chair, Medical Executive Committee, individuals who are seriously delinquent in completing their medical records. Individuals who fail to complete these records within 15 days after written notification shall be required to appear before the Medical Executive Committee with their Branch Chief or IC Clinical Director, or CC Department Chief, to explain the reasons for non-compliance. If a satisfactory explanation is not provided, the practitioner's Medical Staff/clinical privileges shall be suspended immediately. This suspension prohibits the individual from patient care and research activities at the CC until all delinquent medical records are completed.

### 9.6.2 Licensure and Controlled Substances Registration

- a. Action by a Federal, state, or local licensing body or law enforcement agency, revoking, suspending, or in any way restricting a practitioner's license or registration or placing the individual on probation

shall result in automatic review of the individual's clinical privileges in the CC.

- b. This review shall be carried out as described in Section 9.2 above. Should the official agency subsequently reverse its earlier action, this does not guarantee restoration of the practitioner's clinical privileges in the CC.
- c. Any action taken other than summary suspension of clinical privileges shall be subject to applicable PHS and OPM rules.

### 9.6.3 Failure to Provide Evidence of Licensure

- a. As a part of the Medical Staff credentialing or recredentialing process, each candidate must provide evidence of current, active licensure, which is confirmed by staff of Credentialing Services through primary verification with the State of licensure whenever there is no fee for the verification. If a State assesses a fee for such verification (e.g., Arkansas, Delaware, District of Columbia, Mississippi), the applicant must submit an original license or renewal certificate, or true copy thereof. A temporary waiver of this requirement may be granted to a civil servant by the Director, NIH, or designee, on a case by case basis. The avoidance of licensure fees is not considered sufficient reason for granting such a waiver. Alternatively, IC Clinical Directors or CC Department Chiefs may certify, on the application for staff appointment, that they have personally verified active licensure for a candidate. Consultants may substitute an original letter from the credentials authority of their home institution that identifies state of licensure, license number and expiration date.
- b. Candidates may be given a grace period of up to one year, from the date of initial appointment, to obtain a license, and clinical privileges may be granted pending receipt of such licensure. Candidates in an approved

NIH residency program must obtain a license within one year of eligibility to do so, based on the unique training requirements of the specialty. In such cases, the application for Medical Staff membership must be accompanied by a memorandum from the Residency Program Director, identifying the date the individual resident will be eligible to apply for licensure. If evidence of licensure is not provided by the end of the grace period, all clinical privileges shall be suspended for a period of 29 days, during which time the individual shall be required to appear before the Medical Executive Committee to explain why his/her privileges should not be revoked.

#### 9.6.4 Failure to Provide Evidence of Cardiopulmonary Resuscitation Training

- a. Unless a waiver has been granted, all members of the medical staff (excluding consultants) credentialed to practice shall hold evidence of recent Cardiopulmonary Resuscitation (CPR) training.
- b. Failure to provide evidence of CPR training as a part of the recertification process will result in the practitioner's credentials and clinical privileges being suspended for a period not to exceed 29 days, during which time the practitioner will be required to appear before the Medical Executive Committee to show cause why his/her privileges should not be revoked.

#### 9.7 Notification of Authorities

As required, the names of practitioners who have been subjected to adverse actions on clinical grounds or who have had payments made on malpractice claims against them will be reported to the appropriate state licensing authority, the National Practitioner Data Bank, and/or other credentialing organization by the Deputy Director for Clinical Care, CC.

## ARTICLE X. HEARING PROCEDURES

### 10.1 GENERAL

A hearing shall be available to practitioners subjected to the following recommended adverse actions, except to the extent that PHS and OPM rules apply.

- a. Oral or written admonishment.
- b. Written reprimand.
- c. Denial of initial staff appointment.
- d. Probation.
- e. Suspension or revocation of Staff membership.
- f. Requirement for professional treatment.
- g. Suspension of privileged parking for 30 days or more.
- h. Denial of reappointment.
- i. Denial of requested clinical privileges.
- j. Reduction, suspension, or revocation of clinical privileges for a time period determined by the Medical Executive Committee.
- k. Denial of requested advancement in Staff category.
- l. Demotion.
- m. Reassignment.
- n. Termination of employment.

### 10.2 NOTICE AND REQUEST

A practitioner against whom an adverse action described in Section 10.1 has been recommended shall be given written notice of such action either by personal service or by certified mail with return receipt requested. This notice shall specify the precise reasons for the recommended adverse action and inform the practitioner that he/she may make a written request to the Director, CC, or Chair, Medical Executive Committee, for a hearing before an *ad hoc* Hearing Committee of the Medical Executive Committee. A request for a hearing must be delivered to either of the above individuals either in person or by certified mail within 30 calendar days after the date of the notice. Failure of a practitioner to request a hearing within the time and manner here provided shall be deemed a waiver of the right to such a hearing and voluntary acceptance of the recommended action. In that

event, the recommended action made by the Medical Executive Committee shall be forwarded to the Director, CC for final action.

### 10.3 HEARING ARRANGEMENTS

Upon notification of a request for a hearing, the Director, CC, or Chair, Medical Executive Committee, shall arrange a time for a hearing. The affected practitioner shall be promptly notified of the scheduled time, place, and date of the hearing, the list of witnesses who are expected to testify, so far as is known or anticipated, and a copy of any investigation report and recommendations developed under Section 9.2.2. Notification will be by personal service or certified mail with return receipt requested. The hearing date shall be not less than 30 days from the date of receipt of the request, unless an earlier date is agreed to mutually.

### 10.4 *AD HOC* HEARING COMMITTEE

The Director, CC, or Chair, Medical Executive Committee, shall appoint an *ad hoc* Hearing Committee of not less than five members. No individual involved in the initial adverse action shall be a member of the Hearing Committee. At least three shall be voting members of the Medical Executive Committee. One member shall be designated as Chair.

### 10.5 CONDUCT OF HEARING

- a. These Bylaws provide professional review hearings to resolve matters bearing on professional competency and conduct. Accordingly, unless the affected practitioner chooses to be represented by legal counsel at the hearing, an attorney from the Office of General Counsel (OGC) will not be present. The choice of an affected practitioner not to be represented by counsel at the hearing will not affect the practitioner's or the *ad hoc* Hearing Committee's right to legal counsel in preparation for the hearing. If the practitioner chooses to be represented by legal counsel at the hearing, an OGC attorney may be present to advise and represent the *ad hoc* Hearing Committee.

- b. The Chair of the *ad hoc* Hearing Committee shall be responsible for the conduct of the hearing, the calling of witnesses and assuring that all participants have a reasonable opportunity to be heard, to present and to examine relevant oral and documentary evidence in an efficient, expeditious, and civil manner. The Hearing Committee may request and the affected practitioner may elect to file a written statement at the close of the hearing, or if the Chair permits, promptly thereafter.

Minutes or a transcript shall be kept of the hearing. The record of the proceeding is not subject to public review or discovery and shall be filed in the Office of the Deputy Director for Clinical Care, CC.

- c. The Hearing Committee may, without special notice, postpone, recess, or reconvene the hearing for the convenience of the participants or to obtain additional evidence or consultation. Upon conclusion of the presentation of oral and written evidence, the hearing record shall be closed. The Hearing Committee may then, at a convenient time, deliberate outside the presence of the practitioner for whom the hearing was convened. As soon as possible following conclusion of deliberations, the *ad hoc* Hearing Committee shall forward its written report and recommendations, together with the hearing record and all other documentation, to the Chair, Medical Executive Committee, the Director, CC, and the practitioner. The report may recommend confirmation, modification, or rejection of the proposed adverse action. No practitioner shall be entitled to more than one hearing and one full Medical Executive Committee review on any single matter.
- d. Failure of the practitioner to appear at the hearing without good cause shall constitute a waiver of the right to a hearing and deemed acceptance of the recommended action.

## 10.6 MEDICAL EXECUTIVE COMMITTEE REVIEW

- a. Within 10 calendar days after notice of an adverse decision by the Hearing Committee, the affected practitioner may deliver to the Chair, Medical Executive Committee, in person or by certified mail, a written request for review of the case by the full Medical Executive Committee. A written request for review shall include a clear and concise statement of the grounds for review and the facts in support of the request for review. Failure of a practitioner to request such review within the time and in the manner herein provided shall be deemed a waiver of the right to review and deemed voluntary acceptance of the *ad hoc* Hearing Committee's action.
- b. The Medical Executive Committee shall review a case on the record of the *ad hoc* Hearing Committee unless the Medical Executive Committee decides that the circumstances require a hearing *de novo*. The decision of the Medical Executive Committee on whether to hold a *de novo* hearing shall be final. The Medical Executive Committee shall act to review the practitioner's case in a closed executive session and either affirm, modify, reverse, or remand for further proceedings, the *ad hoc* Hearing Committee's decision.

## 10.7 FINAL DECISION

The Chair, Medical Executive Committee, shall inform the practitioner in writing within 5 calendar days of the Medical Executive Committee's recommendation, which shall be forwarded to the Director, CC, whose decision shall be final.

## ARTICLE XI. ORGANIZATION FOR CLINICAL SERVICES

### 11.1 GENERAL

CC inpatient and outpatient clinical services are provided by practitioners who are members of Institutes or Centers with intramural clinical research programs, by practitioners who are members of CC Departments, and by contract practitioners who are members of the CC Medical Staff or Affiliate Staff.

For advice and assistance in problems of medical care, Senior Staff may request the services of any member of the CC Senior, Junior, Adjunct, or Consultant Staff. ICs and CC Departments having expertise in particular clinical specialties and subspecialties are responsible for supplying consultative services in those areas.

### 11.2 INSTITUTE AND CENTER CLINICAL SERVICES

- a. Every Institute and Center that conducts clinical research in the CC shall have an organized Clinical Care Service headed by an IC Clinical Director. The Clinical Director is the IC's Chief Clinician and exercises overall medical direction and supervision of the clinical services, both inpatient and outpatient, rendered by the practitioners of his/her Institute or Center. He/She is accountable to the Medical Executive Committee and the Director, CC, for the quality of patient care rendered by practitioners in his/her Institute or Center.
- b. Currently, the Institutes and Centers with intramural clinical research programs are:

National Cancer Institute  
National Center for Complementary and Alternative  
Medicine  
National Eye Institute  
National Heart, Lung, and Blood Institute  
National Institute of Allergy and Infectious Diseases  
National Institute of Arthritis and Musculoskeletal and Skin  
Diseases  
National Institute of Child Health and Human Development

National Institute of Deafness and Other Communication Disorders

National Institute of Dental and Craniofacial Research

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute of Environmental Health Sciences

National Institute of Neurological Disorders and Stroke

National Institute of Mental Health

National Institute on Aging

National Institute on Alcohol Abuse and Alcoholism

National Institute on Drug Abuse

National Institute of Nursing Research

National Human Genome Research Institute

- c. Policies of IC Clinical Services shall not conflict with these Bylaws.

### 11.3 DUTIES OF IC CLINICAL DIRECTORS

Each Clinical Director shall:

- a. Implement a systematic process for monitoring and evaluating the quality of the care of all patients served by the Institute or Center, and the professional performance of all practitioners with clinical privileges in that Institute or Center. Such monitoring and evaluation is performed through the routine collection of information about important aspects of patient care provided in the Institute or Center and about the clinical performance of its practitioners. If problems are identified, the necessary corrective actions will be taken.
- b. Assure that IC personnel with delineated clinical privileges participate in continuing education activities that relate to the privileges granted.
- c. Develop and implement continuing education programs for IC clinical care practitioners in cooperation with the Office of Education, NIH.

- d. Serve as a voting member of the Medical Executive Committee and assist in the formulation of CC medical and medical-administrative policies and rules.
- e. Transmit to the Medical Executive Committee his/her IC's recommendations concerning the appointment of, delineation of clinical privileges for, and corrective action towards practitioners in that IC.
- f. Enforce within his/her IC the CC Medical Staff Bylaws and rules, and all other applicable policies and rules established by the CC, NIH, PHS, and HHS.
- g. Implement within his/her IC actions recommended by the Medical Executive Committee and ratified by the Director, CC.
- h. Perform such other duties commensurate with Medical Executive Committee membership as may on occasion be reasonably requested by the Chair, Medical Executive Committee.
- i. Oversee his/her IC's clinical research programs and provide advisory assistance to the IC's Scientific Director and Director on matters pertaining to the IC's clinical research effort.
- j. Participate in CC- and NIH-wide planning processes, particularly as they involve intramural clinical research program needs, changes, and resources.
- k. Provide clinical/scientific consultation to his/her Institute or Center through participation in contract and grant review and in other *ad hoc* activities.
- l. Interact as Institute or Center Chief Clinician with other IC Clinical Directors or appropriate personnel in programs requiring inter-Institute collaboration and shared patient care responsibilities.
- m. Function, at the request of the Institute or Center Director, as Chief Clinician in representing intramural clinical research

to the public and appropriate funding and supervisory offices within the NIH and government, with the concurrence of the IC Scientific Director.

- n. Provide oversight of the consultative services provided by the Institute or Center.

#### 11.4 CC CLINICAL DEPARTMENTS

- a. CC Clinical Departments provide essential clinical services in areas not provided by the IC consultation services. Each Clinical Department is headed by a physician or biomedical scientist who is a Senior Staff member appointed by the Director, CC, and approved by the Director, NIH. Department Chiefs are accountable to the Director, CC, for the conduct of their departments and for the quality of clinical services and patient care rendered by their staffs. When problems are identified, the necessary corrective actions will be taken.
- b. The Deputy Director for Clinical Care, CC, shall serve as the Clinical Director of the CC and, in this role, shall execute duties and responsibilities essentially equivalent to those performed by IC Clinical Directors.
- c. Currently, the CC Clinical Departments are:

Department of Anesthesia and Surgical Services  
Clinical Bioethics Department  
Department of Laboratory Medicine  
Critical Care Medicine Department  
Diagnostic Radiology Department  
Nuclear Medicine Department  
Nursing Department  
Pharmacy Department  
Positron Emission Tomography Department  
Rehabilitation Medicine Department  
Transfusion Medicine Department

The Outpatient Department is under the direction of a member of the CC's administrative staff who is accountable to the Director, CC, for the administrative aspects of the Department's operations.

- d. Policies and procedures of CC Departments shall not be in conflict with these Bylaws.

#### 11.5 DUTIES OF CC CLINICAL DEPARTMENT CHIEFS

Each CC Clinical Department Chief shall:

- a. Assure the implementation of a systematic process for monitoring and evaluating:
  - (1) the quality and appropriateness of clinical services provided, and of the care and treatment of patients served by the Department, and
  - (2) the professional performance of all practitioners with clinical privileges in that Department. Such monitoring and evaluation is performed through the routine collection of information about important aspects of services delivered and about the clinical performance of its practitioners.
- b. Assure that Department personnel with delineated clinical privileges participate in continuing education activities that relate to the privileges granted.
- c. Develop and implement continuing education programs for Department clinical personnel in cooperation with the Office of Education, NIH.
- d. Transmit to the Director, CC, his/her Department's recommendations concerning the appointment of, delineation of clinical privileges for, and corrective action towards practitioners in that Department.
- e. Enforce within his/her Department the CC Medical Staff Bylaws and rules, and all other applicable policies and rules established by the CC, NIH, PHS, and HHS.
- f. Oversee his/her Department's clinical research programs and advise the Director, CC, on matters pertaining to the Department's clinical research effort.

- g. Participate in CC- and, where appropriate, NIH-wide planning processes, particularly as they involve intramural clinical research program needs, changes and resources.

## 11.6 CONSULTANT SERVICES

- a. General

Consultative services in the various clinical specialties may be obtained from both intramural NIH and approved outside personnel. The names of available in-house consultants and of approved outside consultants, and information about how they can be reached, may be obtained from the MIS.

Junior or Senior Staff members may request the services of an approved (i.e., credentialed) CC consultant. Prior to calling outside consultants, the staff member should contact the appropriate in-house consult service to evaluate the clinical issue. If the in-house consultant concurs that additional services are appropriate, the staff member may proceed to contact the outside consultant as directed in the MIS.

If the services needed are from an unapproved (i.e., not previously credentialed) consultant, the Staff member shall obtain approval from the Director, CC, through the appropriate IC Clinical Director or CC Department Head, the Credentials Committee, and the Medical Executive Committee. In an emergency, a Senior Staff member may call any outside consultant, approved or not, whose expertise is needed. In such instances, the Senior Staff member shall inform the CC Director (or designee), or, if after regular working hours, the senior CC administrative official on call.

In those cases where in-house and outside consultants are not members of an established CC Consult Service, the responsible IC Clinical Director or CC Department Head shall monitor annually the services rendered and continuing need for consultants, and report necessary changes to the

Director, CC through the Consultation Review Committee and Medical Executive Committee.

b. Consult Service Chiefs

- (1) Consult Service Chiefs are Senior Staff who organize and oversee activities of in-house consultants rendering specialized services to patients in the CC.
- (2) Consult Service Chiefs submit an annual report to the Consultation Review Committee, detailing the volume of consults, service structure, personnel, internal quality improvement processes, response to survey data on user satisfaction and quality of consults, service delivery problems, support needs, and any other relevant issues.

c. Fees

Salaried Staff members receive no fees for patient care. Clinical care consultants who are not federal employees and who seek reimbursement for services provided must first enter into a written agreement with the CC/NIH. Consultants cannot be paid retroactively for services rendered before the establishment of such agreement.

Consultants receive the remuneration established by the Director, NIH.

No member of the Medical or Affiliate Staff shall receive from, or pay to, another practitioner, either directly or indirectly, any part of a CC fee received for professional services.

## ARTICLE XII. COMMITTEES AND FUNCTIONS

### 12.1 GENERAL

The Medical Executive Committee advises the Director, CC, and develops policies governing standards of medical care in the CC. The Medical Executive Committee represents and acts for the Medical Staff and other clinical professionals in the CC.

Upon approval by the Director, CC, the Medical Executive Committee may establish standing and other committees to perform the functions listed in Section 12.3 and elsewhere in these Bylaws. Such committees include representation from the Medical Staff. Individuals who are not Medical Staff members may be appointed to serve on these committees.

### 12.2 MEDICAL EXECUTIVE COMMITTEE

#### 12.2.1 Members

Voting members of the Medical Executive Committee are the Clinical Directors of Institutes and Centers with intramural clinical research programs, or their designees; the Deputy Director for Clinical Care and Chief, Nursing and Patient Care Services, CC; the Chief of The NCI Surgical Service; the Chief of the Intensive Care Unit; and an Institute, Center or CC pediatrician, whose term of appointment to the Committee shall be two years. For the latter, a list of recommended individuals shall be proposed to the Director, CC, by the Pediatric Care Committee.

Upon the recommendation of the Medical Executive Committee, the Director, CC, may appoint a Junior Staff member to serve on the Committee, with vote.

The Director, CC; a Clinical Center administrative representative designated by the Director, CC; the Director, NIH, or his/her designee; a representative of the Office of General Counsel, NIH; and the Executive Secretary of the Medical Executive Committee serve as ex officio, non-voting members of the Committee.

### 12.2.2 Chair

The Chair, Medical Executive Committee, is appointed annually by the Director, CC, from a list of three members nominated by the Committee. The incumbent Chair is eligible for renomination and reappointment but shall not serve more than two terms consecutively. Only IC Clinical Directors are eligible for nomination.

The Chair votes only in case of a tie.

### 12.2.3 Vice-Chair

The immediate past Chair serves as Vice-Chair and directs meetings of the Committee in the absence of the Chair. When the Chair succeeds himself/herself in this office, the Director, CC, selects and appoints, from the panel nominated by the Committee, an IC Clinical Director to serve as Vice-Chair.

### 12.2.4 Qualifications and Mechanisms for Removal

Members of the Medical Executive Committee who are members of the CC's Medical or Nursing Staff must remain in good standing throughout their terms of office. Any such member failing to remain in good standing is subject to removal by the Director, NIH, on advice of the Director, CC. Removal of Medical Executive Committee officers from their positions is made upon recommendation from the Director, CC, to the Director, NIH, after a majority vote by the Medical Executive Committee.

### 12.2.5 Vacancies

If the Chair becomes vacant, the Vice-Chair becomes the Chair and the Director, CC, with the advice of the Medical Executive Committee, selects and appoints a new Vice-Chair to complete the remaining term of office.

### 12.2.6 Functions

The Medical Executive Committee:

- a. Develops policies concerning medical practice and patient safety at the CC, receives and acts upon reports of various committees, and coordinates the general policies of the various clinical Departments and Services. Findings and actions are transmitted to the Director, CC, for approval. When approved, policies recommended by the Committee become operating policies of the CC.
- b. Makes recommendations to the Director, CC, on all matters relating to Medical Staff appointment, clinical privileges, and corrective action.
- c. Continually assesses the overall quality of patient care in the hospital.
- d. Recommends the resources needed to provide quality clinical care to CC patients, assigns IC responsibilities for providing clinical services, and implements decisions regarding allocation of resources to the Institutes and Centers providing clinical services.
- e. Recommends to the Director, CC, any allocation or reallocation of resources needed to maintain or improve medical care in the hospital.
- f. Serves as a hearing body for adverse actions.
- g. Provides oversight of the consultative services provided at the CC.

### 12.2.7 Meetings

- a. Participation in regular business meetings is limited to voting and *ex officio* members, and to others who may attend by arrangement with the Chair.

- b. Regular business meetings are held the first and third Tuesday of each month. In the absence of urgent business, the Chair may postpone or cancel a regular meeting, provided at least one meeting is held during the month. Both meetings in August may be canceled at the discretion of the Chair.
- c. Special executive sessions and colloquia may be called by the Chair or the Director, CC, or at the request of at least three voting members. Participants at such meetings are determined by the Chair in consultation with the Director, CC.
- d. A majority of the voting members constitutes a quorum. In the absence of a voting member, a substitute is designated to attend and may vote.
- e. Majority and minority views and a record of the vote in numbers are presented to the Director, CC, if the vote is not unanimous.
- f. The Director, CC, provides for the staffing resources of the Medical Executive Committee.

#### 12.2.8 Duties of the Chair

The Chair, Medical Executive Committee:

- a. Cooperates with the CC Administration in all matters of mutual concern within the hospital. Works with the Director, CC, to ensure implementation of Medical Executive Committee initiatives.
- b. Calls, presides at, and is responsible for the agenda of all Medical Executive Committee meetings and of all general meetings of the Medical Staff.
- c. Is responsible for the enforcement of the Medical Staff Bylaws and rules, and other applicable CC policies and rules.

- d. The Chair, Medical Executive Committee, appoints the Chairs and members of *ad hoc* committees and recommends for appointment the Chairs and members of standing committees and subcommittees.
- e. May serve as an *ex officio* member without vote on all Medical Staff committees.
- f. Serves as an *ex officio* member of the Board of Governors.
- g. Represents the views of the Medical Staff to the Director, CC.
- h. In consultation with the Deputy Director for Clinical Care, CC, oversees the practice of the Medical Staff to ensure consistency with CC goals and with applicable requirements of NIH, PHS, HHS, and outside accrediting and approval bodies.
- i. Speaks for the Medical Staff in its external professional and public relations.

## 12.3 COMMITTEES OF THE MEDICAL EXECUTIVE COMMITTEE

### 12.3.1 Members and Appointment

- a. The Chair, Medical Executive Committee, designates those standing or *ad hoc* committees required to fulfill the responsibilities of the Committee and Medical Staff. The Director, CC, approves the functions of these committees whose rosters may include persons not on the Committee.
- b. The Chair, Medical Executive Committee, appoints the Chairs and members of *ad hoc* committees and recommends for appointment the Chairs and members of standing committees and subcommittees. When an individual is appointed to represent an Institute, Center, or a CC Department on a committee, the appointment shall be cleared by the IC Clinical Director or CC Department Head.

- c. The Director, CC, approves the functions of all committees and appoints the Chairs and members of all standing committees and subcommittees. Except as noted below, the Chairs and members of all standing committees and subcommittees are appointed for two-year terms, commencing on 1 January. Appointments may be renewed by the Director, CC, upon the recommendation of the IC Clinical Director, the Committee's Chair, and/or the Chair, Medical Executive Committee.

#### 12.3.2 Procedures

- a. Committees of the Medical Executive Committee meet at the call of their Chairs. Individual standing committees shall meet as specified in Section 12.3.3. Minutes are kept of all meetings, and information copies are filed with the Office of Medical Executive Committee Services, CC.
- b. Half the voting members of a committee constitute a quorum. In the absence of a committee member, an alternate may attend and vote, subject to approval by the Committee's Chair.
- c. Consultants and other personnel with special expertise may participate as *ad hoc* committee members as needed if approved by the Committee's Chair. *Ad hoc* members are not permitted to vote.
- d. Each committee submits written reports to the Medical Executive Committee, as specified in Section 12.3.3. Committees are advisory to the Medical Executive Committee. The Committee may accept a committee's report without being bound to recommend to the Director, CC, the action(s) proposed by the committee. The Committee makes its own recommendations to the Director, CC.
- e. The Chair of each committee annually submits to the Office of the Medical Executive Committee, CC, a

current list of the committee's members, which includes their name, title, and organizational affiliation.

### 12.3.3 Standing Committees of the Medical Executive Committee

#### a. Ambulatory Care Committee

##### (1) Members

The Committee is composed of representatives of IC and CC Services that deliver ambulatory care. It includes representation from each of the following:

- (a) Senior Staff with admitting privileges from each of the Institutes and Centers.
- (b) CC Ambulatory Care Head Nurses.
- (c) Office of the Director, CC.
- (d) The Chief, Outpatient Department, CC.
- (e) Medical Record Department, CC.

##### (2) Functions

The Committee:

- (a) Proposes policy for outpatient care for approval by the Medical Executive Committee and/or Director, CC.
- (b) Evaluates reports from the CC Administration regarding long- and short-range planning.
- (c) Evaluates the following areas of operations and activities: 1) the quality of patient care, by ensuring compliance with applicable Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) standards and by requesting audits to be completed by committees responsible for monitoring

both administrative and medical compliance; 2) the interaction of patient care delivery systems, and the development and practice of clinical research programs; and 3) the evaluation of administrative systems.

(3) Reports

The Committee's Chair submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activities and recommendations. These should include the major issues addressed, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

b. Cardiopulmonary Resuscitation (CPR) Committee

(1) Members

The Committee is chaired by a senior member of the Critical Care Medicine Department, and has permanent members representing the CC's Anesthesiology Service, Respiratory Therapy Section (Critical Care Medicine Department), Nursing and Pharmacy Departments, and Administration.

*Ad hoc* representatives may be added.

(2) Functions

The Committee recommends policy and reviews procedures related to all aspects of CPR in the CC. Actions taken in response to a cardiac arrest page are reviewed by the Committee to ensure compliance with established procedures.

(3) Reports

The Committee's Chair submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activities and recommendations. These should include the major issues addressed, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

c. Clinical Quality Committee

(1) Purpose

The Committee is the principal focus of the CC's clinical quality improvement program. It provides direction to and liaison among the Medical Executive Committee, CC clinical and service Departments, the ICs, and the hospital's Administration in matters pertaining to the quality and appropriateness of patient care. The Committee is advisory to the Medical Executive Committee and Director, CC.

(2) Members

The Committee's membership includes the Chairs of standing committees of the Medical Executive Committee, representatives of CC Administration and Departments, representatives of IC clinical Services, and other *ad hoc* individuals as indicated:

(a) CC Representatives:

The Deputy Director for Clinical Care (*ex officio*); the Special Assistant to the Deputy Director for Clinical Care; the Safety Officer; the Patient Representative; and representatives from the Anesthesiology Service and Laboratory Medicine, Clinical Center Communications, Critical Care Medicine, Diagnostic Radiology, Information

Systems, Human Resources, Medical Record, Nuclear Medicine, Nursing, Nutrition, Outpatient, Pathological Anatomy, Pharmacy, Rehabilitation Medicine, Social Work, Surgical Services, and Transfusion Medicine Departments, and from the CC's Standardization Committee.

(b) IC Representatives:

IC representatives participate at the invitation of the Chair.

(c) The Chairs of (or representatives from) the following Medical Executive Committee Standing Committees:

Ambulatory Care, CPR, Credentials, Ethics, Infections, Medical Record, Pediatric Care, Pharmacy and Therapeutics, Physician-Nurse, Safety, Surgical Case Review, and Transfusion Committees.

(d) Other Representatives:

A representative from the Human Subjects Research Advisory Committee (HSRAC), designated by the Chair, HSRAC, and a representative (*ex officio*) from the NIH Branch, Office of the General Counsel, Office of the Secretary, HHS.

(3) Functions

The Committee:

- (a) Discusses reports on quality and appropriateness of care issues identified by Medical Executive Committee committees, CC Departments, and individuals with quality improvement responsibilities, and makes

recommendations to the Medical Executive Committee.

- (b) Informs the Medical Executive Committee, CC Administration and Departments, and ICs of pertinent actions taken or contemplated by one or the other.
- (c) Advises the Medical Executive Committee and Director, CC, on all matters related to clinical quality improvement.
- (d) Coordinates clinical quality improvement activities and tracks identified problems to ensure appropriate resolutions.
- (e) Serves as the focus of the hospital-wide patient safety and clinical quality improvement activities.
- (f) Collates the reports submitted by its membership and, upon Committee approval, transmits them to the Medical Executive Committee.
- (g) Evaluates the CC's Clinical Quality Program annually.

(4) Chair

- (a) The Deputy Director for Clinical Care, CC, is the Chair, Clinical Quality Committee.
- (b) The Chair votes only in case of a tie.

(5) Meetings

The Committee meets monthly unless a decision is made by the Chair to cancel a meeting. The Chair may call special meetings as necessary or cancel scheduled meetings when appropriate.

(6) Reports

The Committee Chair reports to the Medical Executive Committee as circumstances warrant.

The Committee Chair annually provides to the Director, CC, through the Medical Executive Committee, a comprehensive report on the quality of care rendered at the CC and on efforts to monitor and improve such care.

d. Consultation Review Committee

(1) Members

The committee is composed of two Clinical Directors, one of whom is the Chair; three senior clinicians from diverse specialties who are actively engaged in clinical practice in the Clinical Center; the Chair of the Clinical Quality Committee; and supplemental ad hoc members as needed in the judgment of the Chair for review of specific services. Administrative support will be provided by the Clinical Center through the Office of the Deputy Director for Clinical Care.

(2) Functions

The committee meets at least quarterly, or at the call of the Chair, and

- (a) Coordinates annual routine review of each consult service; as part of this review process, receives results of survey questionnaires, and a report from each consult service chief.
- (b) Works directly with the Clinical Quality Committee and the Clinical Directors to review urgent matters identified by the consult service survey questionnaires,

incident report system, health care personnel, or patients.

- (c) Recommends to the MEC additional services needed in the Clinical Center.
- (d) Recommends to the MEC any special recognition for excellence in consultation services, as well as remedial action for Consult Services deemed inadequate.

(3) Reports

The Committee's Chair submits reports to the Chair, Medical Executive Committee, at least quarterly, summarizing Committee activities and recommendations. These should include a summary of reviews of consult services, and other recommendations related to the quality of consultative services delivered in the Clinical Center.

e. Credentials Committee

(1) Members

The number of committee members may be determined by the Chair, Credentials Committee. However, the membership must be comprised of, at a minimum, two IC Clinical Directors, a surgeon, dentist, and a CC staff physician who are members of the Senior Staff, as well as a member from the Adjunct Staff and the Chief, Credentialing Services, CC.

The Chief, Credentialing Services, CC, shall serve as a permanent member of the Committee. The IC Clinical Directors shall serve for four years. The other members shall serve for three years and may be reappointed.

The IC Clinical Directors shall serve consecutive

two-year terms: first as Deputy Chair and, subsequently, as Chair. The Chair, in consultation with the Deputy Chair, the Credentialing Services Chief, and the Clinical Center Director, shall recommend to the Medical Executive Committee a replacement for the Clinical Director leaving the Committee. When the Chair completes his/her term, or otherwise no longer continues to serve, that individual is not eligible to serve on the Credentials Committee until each Institute's or Center's Clinical Director has served in rotation. Exceptions to this may be granted by the Medical Executive Committee.

(2) Functions

The Committee investigates the credentials of all practitioners seeking Medical Staff appointments and clinical privileges in the CC and makes recommendations to the Medical Executive Committee regarding their appointment, Staff category, and delineation of privileges. It also reviews all information available on the clinical competence and performance of individual practitioners seeking reappointment and redelineation, and makes recommendations to the Medical Executive Committee.

(3) Reports

The Committee's Chair submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee actions and recommendations. These should include the major issues addressed, such as problems in the credentialing process, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

The Chair also periodically addresses the Medical

Executive Committee directly on matters within the Committee's purview.

f. Ethics Committee

(1) Members

The Clinical Center Ethics Committee is a multidisciplinary body composed of individuals from the CC staff and the local community. As much as possible, the Committee should be broadly representative of each Institute and Center that has a clinical program. At the same time, Committee membership includes representatives from specific categories of CC staff: administrators, physicians, nurses, chaplains, social workers, and Department of Clinical Bioethics staff, CC Patient Representative, and Office of General Counsel. Ethicists, attorneys, health care professionals and others from institutions outside NIH may also serve as members. Moreover, representation is sought from members of the community at large and the NIH Patient Advisory Committee.

(2) Functions

(a) Education

- (i) To work cooperatively with the DCBE to promote awareness of, and provide guidance on, cases in which ethical problems may arise.
- (ii) To encourage and assist the DCBE in the development and implementation of educational programs in bioethics for the CC staff, the NIH community, and the community at large.

(iii) To provide initial and ongoing educational activities for CCEC members.

(b) Policy Development

(i) To serve as an advisory body to the CC Medical Executive Committee, DCBE and others upon request in the review and/or formulation of policies and guidelines concerning ethical issues in research subject care.

(ii) To identify federal and state legislation, regulation, and policy guidelines relevant to bioethical issues and to evaluate the applicability to the CC.

(c) Case Consultation/Case Review

To provide on-call CCEC members to serve on the consultation team for the CC Bioethics Consultation Service (CCBCS).

(ii) To provide a forum for the discussion of ethical questions and concerns that arise in the CC relative to care of research subjects that are not addressed by other committees.

(iii) To review retrospectively selected cases that have been considered by the CCBCS.

(iv) To consider prospectively cases that have been triaged by the CCBCS and deemed appropriate for Committee consultation.

(3) Reports

The Committee's Chair submits to the Medical Executive Committee quarterly reports summarizing Committee activities and recommendations. These reports are due two weeks after the end of each calendar quarter.

g. Infections Committee

(1) Members

The Committee includes members of the Hospital Epidemiology Service, representatives of the medical and surgical specialties, the NIH Occupational Medical Service, and the CC's Administration and Laboratory Medicine, Pharmacy, Material Handling, Nutrition, Transfusion Medicine, and Nursing Departments. For the latter, both clinical nursing and nursing administration are represented.

The Committee's Chair is a physician with a background in epidemiology and expertise in preventing and managing nosocomial infections.

(2) Functions

The Committee recommends policies and procedures for the prevention, surveillance, and control of nosocomial infections, and monitors the use of antibiotics. It regularly reviews CC infection and antibiotic usage reports and recommends to the Medical Executive Committee any actions deemed necessary.

The committee, as represented by its Chair, can place a patient in isolation and, in consultation with the Director, CC, can institute emergency measures to prevent the spread of infection in the hospital.

(3) Reports

The Committee's Chair submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activities and recommendations. These should include the major issues addressed, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

h. Information Systems Committee

(1) Members

The committee is composed of: the Associate Director for Information Systems and the Head of the Information Systems Department; the Head of the Medical Record Department; Legal Counsel; a Representative for the Deputy Director of the NIH; a representative from the Office of Clinical Center Communications; the Head of the Outpatient Department; the Chief of the Pharmacy Service; users, including three Clinical Directors, a minimum of two clinical investigators, a minimum of one research nurse, and a minimum of one representative from the Nursing Department skilled in informatics; and supplemental ad hoc members as needed in the judgment of the Chairs. The Chair will be selected by the Director, CC, from the Medical Executive Committee membership.

(2) Functions

The committee meets at least bi-monthly and

- (a) coordinates all information systems activity in the Clinical Center
- (b) responds to MEC initiatives and requests for information

- (c) Recommends to the MEC additional services needed in the Clinical Center
- (d) Develops standards for an idealized, seamless environment for information exchange
- (e) Conducts an annual customer survey to assess the efficacy of existing systems and the need for additions, enhancements, and altered priorities
- (f) addresses issues of confidentiality and integrity of patient records

(3) Reports

The Committee's Chair submits reports to the Chair, Medical Executive Committee, at least quarterly, summarizing Committee activities and recommendations.

Reports the findings from the annual customer survey to the MEC.

i. Medical Record Committee

(1) Members

The Committee is representative of all CC Services whose activities involve medical records. Representation includes, but is not limited to, the following: the Clinical Care Staff of each Institute and Center, the CC Nursing and Medical Record Departments, and Office of the Director, and one member who represents all other CC clinical departments. For the latter, an alphabetical rotation following the order of presentation of CC Departments in the NIH telephone directory shall be used.

(2) Functions

The Committee meets at least quarterly and:

- (a) Formulates and reviews the minimum requirements of the medical record. Recommends changes in medical record requirements to the Medical Executive Committee.
- (b) Is responsible for the format of the medical record. This includes form design, control, sequence, and arrangement.
- (c) Proposes policies and procedures to ensure the appropriate availability and the confidentiality of the medical record.
- (d) Assures compliance with the minimum medical record requirements of the CC and of the Joint Commission on Accreditation of Healthcare Organizations.
- (e) Upon recommendation by the Chief, Medical Record Department, the Chair, Medical Record Committee reports to the Chair, Medical Executive Committee, individuals who are seriously deficient in completing their medical records. Individuals failing to complete deficient medical records within 15 working days after notification from the Chair, Medical Record Committee, are required to appear before the Medical Executive Committee, with their Branch Chief or Clinical Director, to explain the non-compliance. If this explanation is unsatisfactory, the Medical Committee may immediately suspend the individual's Medical Staff privileges until the deficiencies are corrected. This suspension prohibits the individual from performing either research or patient care at the CC.

(3) Reports

The Committee's Chair submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activities and recommendations. These should include any findings or recommendations pertaining to overall compliance with established minimum medical record requirements, the major issues addressed, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

j. Pediatric Care Committee

(1) Members

The membership of the Committee includes:

- (a) Clinical Directors, or their designees, and Senior Investigators from three primary-user ICs (e.g., NCI, NIAID, and NICHD); at least one representative of the smaller-user ICs (e.g., NEI, NHLBI, or NINDS);
- (b) Physician and/or non-physician representatives from CC Departments involved in pediatric care (Administration, Anesthesiology, Critical Care, Diagnostic Radiology, Nutrition, Pharmacy, Rehabilitation Medicine, Social Work, and Spiritual Ministry);
- (c) Pediatric Nursing Service Chief;
- (d) Principal Investigators;
- (e) Other appropriate personnel recommended by the Committee's Chair and/or the Chair, Medical Executive Committee, and appointed by the Director, CC.

The Committee's Chair may add *ad hoc* representatives as needed.

(2) Functions

The Committee advises the Medical Executive Committee and Director, CC. It provides governance for CC pediatric programs and recommends policies and procedures related to all aspects of pediatric care in the CC; serves to improve coordination among the Institutes, Centers and CC Departments involved in the delivery of pediatric care in the hospital and shares information on pediatric issues; and reviews the quality of pediatric services provided in the CC.

The Committee meets at least quarterly.

(3) Reports

The Committee's Chair submits, to the Chair, Medical Executive Committee, quarterly reports summarizing Committee activities and recommendations. These should include the major issues addressed, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

k. Pharmacy and Therapeutics Committee

(1) Members

The Committee is composed of physicians and dentists, designated by the Clinical Directors of Institutes and Centers active in the use of Pharmacy services, who are knowledgeable about drug, biologic, and other pharmaceutical therapies; a CC nurse knowledgeable about practices on the nursing units regarding oral and parenteral administration of medications; the

Chief, Pharmacy Department, CC; and a representative of the CC Administration.

(2) Functions

The Committee meets at least quarterly and:

- (a) Develops and monitors policies and procedures pertaining to the use of drugs and other pharmaceuticals.
- (b) Maintains the hospital's drug formulary.
- (c) Educates physicians, dentists, nurses, and students on matters pertaining to drugs and other pharmaceuticals and their use.
- (d) Establishes standards, consistent with Federal and other regulations, regarding the use of investigational drugs and/or research in the use of recognized drugs.
- (e) Reviews adverse reactions to drugs and other pharmaceuticals.
- (f) Reviews drug utilization.

(3) Reports

The Committee's Chair submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activities and recommendations. These should include the review of adverse drug reactions and medication errors, major issues addressed, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

## I. Safety Committee

### (1) Membership

Members of the Safety Committee act as a management board that monitors hospital-wide surveillance activities for the governing board. The committee is composed of the Chair (who is the Safety Officer, CC) and members representing clinical, administrative, and support services. These include:

- Nursing Department, CC
- Building Services Manager's Office, CC
- Security Section, CPB, DPS
- Office of the Director, CC
- Clinical Care Instrumentation Section, BEIP, NCRR
- Fire Prevention Section, EMB, DS
- Occupational Safety & Health Branch, DS
- Maintenance Engineering Section, PWB, DES
- Occupational Medical Service, DS

Additional members, such as those from organizations listed below, may be appointed by the Director, CC, in consultation with the Safety Officer.

- Materials Management Department, CC
- Respiratory Therapy Service, CCMD, CC
- Anesthesia and Surgical Services, CC
- Nutrition Department, CC
- Housekeeping and Fabric Care Department, CC
- Department of Laboratory Medicine, CC
- Department of Transfusion Medicine, CC
- Office of the Deputy Director for Clinical Care, CC

### (2) Responsibilities

The members are responsible for:

- monitoring hazard surveillance data provided by the various organizations (e.g., security, biomedical engineering, fire prevention) that provide safety support services for the hospital.
- working with the Safety Officer to intervene whenever conditions exist that pose an immediate threat to life or health or pose a threat of damage to equipment or buildings.
- reviewing and approving procedures that outline measures to reduce occupational risks and deal with facility emergencies, such reviews taking place as frequently as necessary but at least every three years.
- participating in the safety surveys completed in the hospital departments and clinical service areas.
- annually evaluating the objectives, scope, performance, and effectiveness of the documented safety plans.

### (3) Meetings

The Safety Committee is scheduled to meet on the third Wednesday of every month, or at the call of the Chair. Schedule changes that vary from the above must be approved by the members.

Written minutes are kept on file in the Safety Office as a permanent record of the committee's proceedings.

A quorum of 50% of the members must be present to vote. The Chair votes only in case of a tie.

(4) Reports

The Safety Committee is directly responsible to the Medical Executive Committee. A quarterly report of the activities of the Safety Committee is submitted to the Medical Executive Committee. An annual report of safety activities is submitted to the Office of the Director, CC, and to the CC's Department Heads.

m. Surgical-Administrative Committee

(1) Members

The Committee's membership includes:

- (a) a surgeon from the NCI, NINDS, NEI, NICHD, and NIDCD.
- (b) the Chief, Anesthesia and Surgical Services, CC.
- (c) the Chief, Surgical Services, CC.
- (d) the Chief, Heart Catheterization Laboratory, NHLBI.
- (e) a Senior Staff oral and maxillofacial surgeon, NIDR.
- (f) a member of the Office of the Deputy Director for Clinical Care's staff, CC.

(2) Functions

The Committee makes recommendations to the Medical Executive Committee and the Director, CC, on:

- (a) Coordination of procedures and affairs in the operating room area and of services ancillary to surgery.

- (b) Coordination of the following functions in Institutes and Centers lacking a general surgical staff:
  - (i) Provision for emergency surgery.
  - (ii) Provision, when requested, for surgery needed in the research projects of Institutes and Centers not employing any surgical staff.
  - (iii) Coverage of surgical consultations.

(3) Reports

The Committee's Chair reports to the Medical Executive Committee directly, as necessary, on matters within the Committee's purview.

n. Surgical Case Review Committee

(1) Members

The Committee is composed of representatives from the surgical services of NCI, NINDS, NEI, NICHD, and NIDCD; Laboratory of Pathology, NCI; the Chief, Anesthesia and Surgical Services, CC, and Chief of Surgical Services, CC; a Senior Staff Oral Surgeon, NIDCR; and a member of the Office of the Deputy Director for Clinical Care's staff, CC.

(2) Functions

The Committee meets as necessary to review discrepancies among preoperative, post-operative, and tissue diagnoses, and the justification for surgical procedures, whether or not tissue was removed.

The technical quality of surgical procedures is reviewed at least monthly by the respective

Institute Surgical Branch. Reports are submitted to the Chair, Clinical Quality Committee, through the Institute's or Center's Clinical Director, for transmittal to the Chair, Medical Executive Committee.

The Committee reviews use of pathological anatomy services to insure appropriate allocation of resources and appropriate interaction and communication between clinical services and the Laboratory of Pathology.

The Committee reviews the quality of pathological anatomy services to ensure delivery of optimal patient care.

(3) Reports

The Committee's Chair reports to the Medical Executive Committee as necessary, and submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activities and recommendations. These should include the major issues addressed, decisions, and pending actions. These reports are due two weeks after the end of each calendar quarter.

o. Transfusion Committee

(1) Members

The Committee is composed of nine members selected from the following areas: the CC Departments of Transfusion Medicine, Laboratory Medicine (Hematology Service), Nursing, Anesthesiology, Outpatient Services, and Administration; Hematology Service, NHLBI; Medicine Branch, NCI; Pediatric Oncology Branch, NCI; and Surgery Branch, NCI. Additional members may include representatives from the Critical Care Medicine Department, CC, and

hematologists from NIDDK and other Institutes and Centers.

(2) Functions

The Committee meets at least quarterly and:

- (a) Assures safety, quality, and adequacy of blood and blood components for patient use.
- (b) Reviews summaries of all transfusions and, where necessary, records of specific cases, and makes recommendations regarding transfusion policies.
- (c) Reviews transfusion reactions and makes recommendations to improve practice.
- (d) Develops and maintains a program for continuing education.
- (e) Supports the improvements of methodology and the continuing education of professional and technical personnel.
- (f) Through the Department of Transfusion Medicine, CC, maintains a cooperative relationship with other blood-collecting agencies and assists in the recruitment of volunteer blood donors.
- (g) Reviews and assesses priorities for the most appropriate use of blood and blood products.
- (h) Assures compliance with JCAHO requirements.

(3) Reports

The Committee's Chair submits to the Chair,

Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activities and recommendations. These should include the major issues addressed, such as those involving the utilization of blood and blood components, and investigations of incidents related to the administration of blood and blood products; decisions; and pending actions. These reports are due two weeks after the end of each calendar quarter.

#### 12.3.4 Committee Membership Lists

The Chair of each of the above committees submits annually to the Office of Medical Executive Committee Services, CC, a list of the committee's current members, which includes their names, titles, and organizational affiliations.

### 12.4 OTHER COMMITTEES

#### 12.4.1 Education Committee

##### a. Members

The Committee consists of a Chair, the Director, Office of Education, and representatives from the Institutes and Centers (Scientific Directors, Clinical Directors, and/or Branch Chiefs) as appointed by the Deputy Director for Intramural Research, NIH.

##### b. Functions

The Committee is advisory to the Director, Office of Education, NIH, who reports to the NIH Deputy Director for Intramural Research. It advises on policy matters relating to intramural postdoctoral programs that emphasize biomedical research training. This includes the following categories: Clinical Fellows, Staff Fellows, Senior Staff Fellows, IRTAs, and NRSAs. The Committee is responsible for advising on educational issues and salary/stipend levels for all programs. The

Committee also reviews issues regarding the NIH Visiting Program as they relate to balance and equity between foreign and domestic scientists. The Committee also advises the Director, Office of Education, on educational programs that target medical, dental, graduate, and undergraduate students as well as students and teachers at the secondary level and below.

#### 12.4.2 NIH Graduate Medical Education Committee

##### a. Members

The committee is co-chaired by the Director, Graduate Medical Education, in the Office of Education, and by a program director in one of the NIH ACGME-accredited programs. The Director of the Office of Education sits on the committee in an ex officio capacity. Its membership includes the director of each accredited residency program, two residents, and three members of the Senior Staff appointed by the Chair.

##### b. Functions

The Accreditation Council for Graduate Medical Education (ACGME) requires that all institutions offering approved residency training programs establish a Graduate Medical Education Committee. The NIH committee conducts periodic internal reviews of all ACGME approved programs to ensure that they adhere to the educational standards that apply to all programs regardless of medical specialty.

##### c. Reports

The Committee's Chairs report to the Medical Executive Committee twice annually, and submit to the Chair, Medical Executive Committee, reports summarizing Committee activities. These include the major issues addressed, decisions, and pending actions. The reports are generally submitted in July and January of each year.

### 12.4.3 NIH Radiation Safety Committee and Radioactive Drug Research Committee

#### a. General

Under the authority of a U.S. Nuclear Regulatory Commission Type A Specific License of Broad Scope, the NIH Radiation Safety Committee (RSC) authorizes the use of radioactive materials and radiation sources in biomedical research and medical diagnosis and treatment. The RSC also oversees the NIH Radiation Safety Program (RSP) to ensure the safe use of all radioactive materials and radiation sources throughout NIH and certain off-campus NIH facilities.

The NIH Radioactive Drug Research Committee (RDRC) functions as a subcommittee of the RSC as mandated by FDA Regulation 21 CFR 361.1, "Radioactive Drugs for Certain Research Uses," to approve the research use in humans of radioactive drugs for which an approved New Drug Application (NDA) or an approved Investigational New Drug Application (IND) does not exist or is not required.

#### b. Membership

##### (1) The RSC:

The RSC is composed of at least eleven members, including the NIH Radiation Safety Officer (RSO) *ex officio*, and ten members appointed by the Director, NIH. Six of these represent clinical users of radioactive materials and radiation sources, including representatives of the CC's Nuclear Medicine and Diagnostic Radiology Departments; the Radiation Oncology Branch, NCI; the Radiopharmacists, CC; the Nursing Staff, CC; and one other clinical Authorized Investigator. These six clinical-use related members are nominated by the CC Medical Executive Committee and approved by the Director, CC.

Two other members of the RSC represent laboratory (non-clinical) users and must be Authorized Investigators, trained and experienced in the safe use of radioactive materials. These members are nominated by the NIH Board of Scientific Directors.

The remaining two members of the RSC are the Chair of the RDSC, *ex officio*, and a representative of NIH management who is not a radiation user. Additional qualified members may be appointed to the RSC as necessary.

The RSO, or a designee from the RSO's office, serves as Executive Secretary of the RSC and maintains the official Committee files.

(2) The RDRC:

The RDRC is composed of at least five members, including a nuclear medicine physician, a person qualified to formulate radioactive drugs, and a person with competence in radiation dosimetry and safety. The Chair, RDRC, is appointed by the Chair, RSC. The other members are selected by the Chair, RDRC, with approval by the Chair, RSC.

c. Functions

(1) The RSC:

- (a) Delegates to the RSO authority to implement the NIH RSP and enforce applicable Federal regulations and NIH radiation safety policies and procedures, to ensure the safety of persons and protection of the environment.
- (b) Provides technical advice, assistance, and management-level support to the RSO in implementing the RSP and the NIH program for keeping radiation exposures to

employees, patients, and research subjects as low as reasonably achievable (ALARA).

- (c) Reviews the qualifications of licensed physicians and grants approval as Authorized Investigators for Human Use of radioactive materials and radiation sources.
- (d) Reviews all proposed clinical research projects (protocols) involving the use of radioactive materials or radiation sources for research purposes, and not for the medical benefit of the subject. Grants approval (Radiation Authorization) to qualified physicians (Authorized Investigators) for specific research uses of radioactive materials or radiation sources pursuant to a protocol. Grants approval to qualified physicians for routine, clinically indicated uses of radioactive drugs or radiologic procedures.
- (e) Reviews the NIH RSP at least annually, to ensure that all its activities are in compliance with Federal regulatory requirements, NIH radiation safety policies, and with the NIH ALARA Program.

(2) The RDRC:

The NIH RDRC grants approval to proposed protocols that use radioactive drugs for research purposes in humans, for which an approved NDA or approved IND does not exist or is not required. There are many restrictions inherent in using this regulatory provision, including absence of pharmacologic effect, maximum radiation dose limits, intent of the research, and others. If a proposed study does not meet the regulatory criteria, it cannot be approved under this special regulatory provision, and an IND approval must be obtained from the FDA. A protocol approved by the RDRC must also receive the approval of the RSC

before it is submitted to the Director, CC, for final approval.

#### 12.4.4 CC Standardization Committee

##### a. Members

(1) The Committee is composed of one representative from each of the following:

- Physician, Anesthesia and Surgical Services, CC
- Physician, Pediatric Program
- Biomedical Engineering and Instrumentation Program, DRS
- Critical Care Medicine, CC
- Pharmacy Department, CC
- Nursing Department, CC, as follows:
  - Nursing Education (1)
  - Critical Care (1)
  - Mental Health (1)
  - Oncology (1)
  - Allergy and Infectious Diseases (1)
  - Pediatrics (1)
  - Staff Nurses (2)
- Chief, Materials Management Department (MMD), CC
- Chief, Central Hospital Supply, MMD, CC
- RN, Surgical Services, CC
- Safety Officer, CC
- Hospital Administrative Officer, CC
- Department of Laboratory Medicine, CC
- Assistant Hospital Administrator, CC

(2) Members are nominated by appropriate CC Department Heads or IC Clinical Directors and serve for two years, renewable at the discretion of the member's Program/Department Head.

##### b. Chair

The Chair is appointed by the Director, CC, from among

the members of the Committee, and serves for two years. The Chair votes only in case of a tie.

c. Meetings

- (1) Meetings will be held monthly, with two-thirds of the membership constituting a quorum. A quorum must be present during any vote. If a vote is not unanimous, a record of the vote in numbers and minority views will be recorded.
- (2) Members unable to attend should appoint someone to attend and vote for them.

d. Functions

- (1) The Committee reviews requests for new supplies, equipment, and services to be used in the Clinical Center.
- (2) The Committee reviews all patient-related product recalls and incident reports involving supplies, products, equipment, and services, and proposes action.

e. Reports

- (1) Minutes of each meeting will be prepared by the Committee secretary and distributed to all members, Department Chiefs, Head Nurses, and Nursing Service Chiefs.
- (2) The Committee reports to the Medical Executive Committee as necessary and submits to the Chair, Medical Executive Committee, through the Chair, Clinical Quality Committee, quarterly reports summarizing Committee activity and recommendations.
- (3) The Committee will consult and communicate with the Hospital Infections Committee, the Pharmacy and Therapeutics Committee, the Safety Committee, the Nursing Procedures Committee, and other appropriate committees regarding areas of mutual concern.

## ARTICLE XIII. MEETINGS

### 13.1 MEETINGS OF THE CC MEDICAL STAFF

#### 13.1.1 Annual Meeting

Meetings of the full Medical Staff may be convened annually or more frequently, if indicated, as determined by the Chair, Medical Executive Committee, in collaboration with the Director, CC. An agenda is issued at least one month in advance of a meeting.

#### 13.1.2 Clinical Staff Conferences

The several IC Clinical Services, together with appropriate CC clinical services, hold monthly Combined Medical Staff Conferences, except during the months of June, July, and August. The conferences focus on clinical matters of interest to the majority of the Medical Staff. Participation in such conferences is not limited to members of the Medical Staff.

The Director and Deputy Director for Clinical Care, CC, in collaboration with IC Clinical Directors and CC Department Heads, determine the subjects to be discussed, the format for conducting conferences, and the method used to rotate assignments among the various clinical Services and Departments.

### 13.2 MEETINGS OF THE CC PROFESSIONAL STAFF

Meetings of the CC professional staff may be convened at the discretion of the Director, CC, and upon recommendation by the Chair, Medical Executive Committee, or others, when information bearing on the delivery and quality of patient care in the hospital needs to be communicated to the CC professional staff collectively.

### 13.3 MEETINGS WITHIN IC AND CC CLINICAL SERVICES

IC and CC Clinical Services hold staff meetings monthly or more frequently, at the direction of the respective IC Clinical Director or CC Department Head. The quality and appropriateness of patient care services and progress toward quality improvement objectives

are reviewed at these meetings. The minutes (or reports) of meetings are submitted to the Director, CC, through the Chair, Clinical Quality Committee, and cover major issues discussed, decisions, and pending actions.

#### ARTICLE XIV. MEDICAL STAFF RULES

The Medical Executive Committee adopts rules governing the work of the Medical Staff. These rules take effect when approved by the Director, CC, and are codified in Policy and Communication Bulletins under the CC's Medical Administrative Series. Rules may be amended at any regular business meeting of the Medical Executive Committee.

## ARTICLE XV. AMENDMENTS TO BYLAWS

These Bylaws are reviewed annually by an *ad hoc* subcommittee appointed by the Chair, Medical Executive Committee. The Bylaws may be amended at any regular business meeting of the Medical Executive Committee. Proposed amendments are written and circulated to all Committee members, and there is one reading before final discussion and passage. Affirmation by a majority of voting members is required for adoption. Amendments adopted by the Committee take effect when approved by the Director, CC, and are made available to all persons subject to the Bylaws.

## ARTICLE XVI. ADOPTION OF BYLAWS

These Bylaws shall be adopted at a regular business meeting of the Medical Executive Committee, shall replace any previous Bylaws of the CC Medical Staff, and shall become effective when approved by the Director, CC.