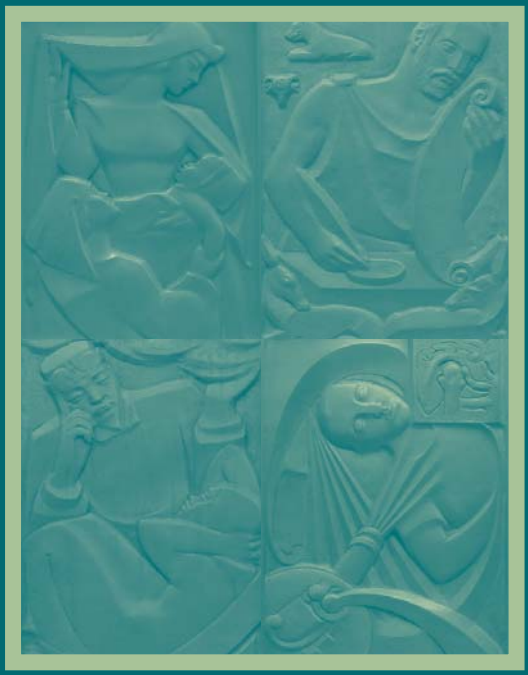
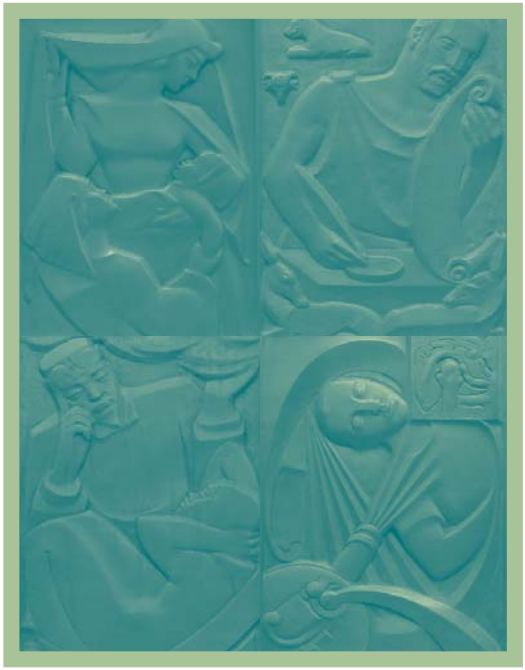
U. S. Department of Health and Human Services
National Institutes of Health
December 2006

NATIONAL INSTITUTES OF HEALTH



STANDARDS FOR
Patient Care at the NIH Clinical Center

NATIONAL INSTITUTES OF HEALTH



STANDARDS FOR
Patient Care at the NIH Clinical Center

PREFACE

The *Standards for Patient Care* address essential principles and processes for the clinical care of the volunteers who come to the National Institutes of Health Clinical Center to participate in clinical research. Excellent patient care is the overarching goal. These standards offer guidance on such components as the objective measurement of medical staff competence, preadmission planning, and multidisciplinary patient care, and the importance of clear and timely communication with referring physicians.

The Clinical Center Medical Executive Committee developed and approved these standards, which complement the *Standards for Clinical Research* (http://www.cc.nih.gov/ccc/clinicalresearch/index.html) set forth in 2000.

The Medical Executive Committee acknowledges and appreciates the efforts of Dr. Richard Cannon, clinical director, National Heart, Lung, and Blood Institute and former MEC chair, who initiated and coordinated the preparation of these standards by the MEC. The NIH institutes and centers are represented on the MEC by their clinical directors.

Other NIH standards for training, ethics, and conduct for scientists include the following: *Guidelines for the Conduct of Research in the Intramural Research Program* at NIH (http://www.nih.gov/news/irnews/guidelines.htm) and *A Guide to Training and Mentoring in the Intramural Research Program at NIH* (http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/mentor-guide.htm).

John I. Gallin, M.D.
Director
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2006 Chair
Clinical Center Medical Executive Committee

December 2006

INTRODUCTION

Patients come to the National Institutes of Health Clinical Center as partners in clinical research. This clinical research is designed to clarify mechanisms of disease, test techniques for diagnosing disease, and evaluate new treatments. The clinical staff make considerable efforts to ensure that protocol participants understand the nature and scope of research and the risks and possible benefits of participation.

Following review for scientific quality and the protection of research subjects, clinical investigators design and implement their research efforts with the goal of generalizable knowledge that may benefit future patients with disease, if not the research subjects themselves.

In 2000, the Medical Executive Committee developed *Standards for Clinical Research* (see http://www.cc.nih.gov/ccc/clinicalresearch/index.html) to assure high-quality intramural clinical research programs. In 2006, the Medical Executive Committee approved and adopted the following *Standards for Patient Care* (http://www.cc.nih.gov/ccc/patientcare/index.html) to foster commitment across the NIH institutes and centers to excellence in the care of patients while they are serving as research subjects at the NIH Clinical Center.

SUMMARY OF STANDARDS

1 CREDENTIALING AND PRIVILEGING

Each institute and center will conduct assessments of practitioner competency at initial credentialing and during recredentialing cycles, using quantitative measures.

2 PREADMISSION PREPARATION

Physicians, dentists, other licensed independent practitioners, and nurses will conduct preadmission planning for each scheduled patient admission.

3 MULTIDISCIPLINARY PATIENT CARE ROUNDS

All relevant staff constituting a multidisciplinary team will conduct clinical rounds with each primary care team at least weekly.

4 PATIENT MANAGEMENT AND TREATMENT GUIDELINES

When appropriate for patient care, NIH clinical staff will use treatment guidelines that are endorsed by national organizations and/or developed by specialists in the NIH institutes and centers.

5 PATIENT DISCHARGE AND REFERRING PHYSICIAN INTERFACE

The NIH clinical staff will prepare for referring physicians a concise summary of each patient's evaluation, treatment, and management recommendations and will provide this within a week of patient discharge—or earlier if necessary for appropriate continuity of care. At discharge, we will provide to patients written documentation that includes their discharge instructions, medications list, and a contact phone number at the Clinical Center.

6 QUALITY ASSURANCE/QUALITY IMPROVEMENT

The NIH institutes and centers will conduct Quality Assurance/Quality Improvement Rounds at least once monthly to review occurrences and complications of procedures that caused—or had the potential to cause—patient harm.

7 MORBIDITY/MORTALITY ROUNDS

The Clinical Center will conduct Morbidity and Mortality Rounds at regular intervals, drawing upon patients chosen because their cases are appropriate for instructing a large audience of medical staff.

8 GREAT TEACHERS LECTURES AND MEDICAL AND ETHICS GRAND ROUNDS

Great Teachers Lectures and Medical and Ethics Grand Rounds should continue and offer CME credit to those attending.

1 CREDENTIALING AND PRIVILEGING

Rationale

The institutes and centers appoint medical staff members (1) to further their medical or surgical specialty/subspecialty training in a research setting or (2) to conduct clinical research after having completed training. For the candidate's initial appointment, following nomination for medical staff membership by senior faculty of the NIH institute or center, the Clinical Center follows established procedures for verifying completion of medical education, postgraduate training, and licensure, and for identification of possible adverse occurrences at other institutions.

The nomination process for initial credentialing generally requests clinical privileges commensurate with the potential medical staff member's training and anticipated Clinical Center activities. Factors to support credentialing decision-making include verification of competence from the applicant's prior program director, letters of recommendation, and a search, using national databases, for adverse occurrences during previous medical staff appointments.

Following initial credentialing and awarding of privileges to a medical staff member, the supervisory senior medical staff should be vigilant to assure the medical staff member's sustained cognitive and technical competence.

Standard

The branch chiefs or section heads of the NIH institutes and centers will use a Clinical Competency Assessment form to document continued competence at the time of recredentialing. The practitioner's clinical director must review this form before its submission to the Credentials Committee.

Objective data to be considered may include inpatient and outpatient activity, numbers of procedures performed, complications associated with procedures, participation in

quality assurance meetings, professional education (including attendance at IC or Clinical Center grand rounds presentations), and adherence to clinical administrative requirements (e.g., completion and timeliness of procedure notes, consult notes, and admission/transfer of service/discharge notes).

If senior staff determine that a medical staff member under consideration for recredentialing needs monitoring or specialized training elsewhere, this indication must accompany the request for new privileges. We encourage supervisory medical staff to review the Professional Practice Evaluation form with practitioners at intervals between credentialing cycles because these reviews can be a valuable mentoring and performance improvement tool.

2 PREADMISSION PREPARATION

Rationale

The patients admitted to the Clinical Center often require specialized testing or procedures conducted by institute and Clinical Center staff that are necessary for their protocol participation or their appropriate medical care. Further, specialists and consultants from other institutes may participate in the patients' evaluation and care.

To ensure (1) optimal patient care in a timely manner and (2) efficient use of Clinical Center and institute resources, preadmission scheduling of tests and procedures and coordination of activities are necessary. Such planning will promote patients' confidence that their unique needs have been considered and accommodated—to the extent that is possible—during their stays at the Clinical Center.

Standard

The clinical staff will conduct preadmission planning for each scheduled admission of patients. These discussions should address patient schedules and special needs (e.g., language or mobility). Physicians, dentists, and other

licensed independent practitioners, nursing staff (including the nurse manager), research nurses, and protocol coordinators may participate in these meetings, which also may involve social workers, nutritionists, pharmacists, and other members of the multidisciplinary care team.

To maximize efficient use of patient-care unit resources and anticipate the possible need to "board" patients on other units, meeting participants may discuss bed utilization.

Patients will receive information about their scheduled admissions in writing, by phone call, or via informational Web sites created by institutes and centers. This may include practical information about the Clinical Center and the patient-care unit to which the patient will be admitted as well as specific information about the protocol.

3 MULTIDISCIPLINARY PATIENT CARE ROUNDS

Rationale

Patients often encounter a large number of staff and pecialists during their hospitalizations. The primary care team must be responsible for distilling all recommendations in a coherent manner that achieves optimal treatment decisions, patient education, and recommendations to referring physicians.

Standard

All the relevant staff constituting a multidisciplinary team should hold and document clinical rounds at least weekly during patients' hospitalizations and prior to discharge.

The purpose of these multidisciplinary clinical rounds is to discuss patient data, progress in the protocol, problems relating to the patient's care, evaluations by specialists, and recommendations for management.

The primary care team can then use this information to devise treatment plans, prepare patient education, and formulate recommendations for referring physicians.

4 PATIENT MANAGEMENT AND TREATMENT GUIDELINES

Rationale

To optimize treatment of many common diseases and promote more uniform approaches to specific aspects of patient care, experts in medical specialties increasingly generate treatment guidelines that they base on data from randomized clinical trials.

Even when the primary treatment is determined by a clinical research protocol, supportive care for seriously ill patients may benefit from guidelines developed by institute and center specialists.

Standard

The medical staff will have access to treatment guidelines endorsed by national organizations.

We encourage investigators and consultants, when appropriate, to consider practice guidelines in developing their recommendations for patient management.

In addition, we encourage multi-specialty teams to develop patient management and treatment guidelines for supportive care of patients in clinical research protocols that are based on clinical trial data and expert opinions.

5 PATIENT DISCHARGE AND REFERRING PHYSICIAN INTERFACE

Rationale

When patients come to the Clinical Center to participate in clinical research, they expect the clinical staff to explain the results of testing, procedures performed, and management recommendations to them and, upon their discharge, also to provide these explanations to their physicians to ensure appropriate continuity of care.

Standard

Care teams that may include the attending physician or dentist, fellows, other licensed independent health-care practitioners, research nurses, and patient-care unit nursing staff will meet with patients (with a translator, if necessary, and with family or others, if requested) at the time of their discharge to explain their evaluation, treatment, and management recommendations as well as the follow-up that may be required at the Clinical Center. The care teams will provide patients with a form containing (at a minimum) discharge instructions, their medication list, and a contact phone number at the Clinical Center.

Referring physicians will receive a concise summary of evaluation, treatment, and management recommendations from the responsible attending physician or other designated licensed independent practitioner within a week of discharge, or earlier if necessary for appropriate continuity of care. In addition, they will receive a more detailed admission and discharge summary from a staff practitioner or fellow.

The attending physician's letter should provide a phone or pager number in case the patient or referring physician has questions or concerns. The attending physician or a staff practitioner or fellow should convey more urgent issues to the referring physician by phone conversation prior to, or at the time of, discharge.

6 QUALITY ASSURANCE/QUALITY IMPROVEMENT

Rationale

The clinical staff must be vigilant to ensure high-quality patient care that includes identification of adverse events and occurrences that may be preventable. Untoward events may occur as a result of practitioner or staff errors, unfamiliarity with protocol requirements, or inadequate policies related to patient care. The Clinical Center has established an electronic Occurrence Reporting System (ORS) for use by staff to report, review, and respond to patient-related occurrences. The purpose of the ORS is to inform senior leadership of these events and offer the opportunity for further study to determine which of these events might be preventable. The system also affords CC leadership and clinical staff the opportunity to see whether interventions designed to reduce risks for untoward occurrences are effective.

Standard

To review the occurrences and complications of procedures that caused—or had the potential to cause—patient harm, the institutes and centers should conduct Quality Assurance/Performance Improvement Rounds on a regular basis. These rounds also provide an appropriate opportunity to discuss especially serious outcomes of protocol participation—even when unassociated with an occurrence or procedural complication.

These conferences, which should be attended by all levels of patient-care staff, will regularly include the unit nurse manager and other representatives from the nursing staff. When appropriate, other key staff (e.g., from the Pharmacy or Social Work Department) may be included.

The goals of these meetings are to identify policies or practices that may have contributed to the occurrence and to formulate measures to prevent recurrence of these events. Occurrences that are particularly serious or complex should be brought to the attention of appropriate Clinical Center

leadership. The Clinical Center leadership will (1) initiate a root-cause analysis for determining the cause(s) of the event and (2) formulate preventive actions. The Medical Executive Committee will be informed about the results of root-cause analyses that have broader implications for patient care and will advise the CC Director about the implementation of strategies designed to address identified deficiencies in patient-care processes.

The leadership of the institutes and centers should encourage their staffs to use the Occurrence Reporting System because of the opportunity it provides to improve the quality of patient care at the Clinical Center.

Confidential documentation of these rounds should be maintained, and changes in policy or practice disseminated to all patient-care staff.

The institute and center leadership should keep records of rocedural complications and actions taken to prevent future occurrences, where appropriate. These actions may include supervision, additional training (here or elsewhere), or termination of privileges to perform specific procedures.

7 MORBIDITY/MORTALITY ROUNDS

Rationale

Death and disability—whether from natural history of disease or due to adverse occurrences during protocol participation—provide important learning opportunities for medical staff. Many NIH institutes hold these conferences, but attendance may be restricted to staff directly involved in that patient's care or to institute staff only.

Standard

The Clinical Center shall hold Morbidity and Mortality Rounds. The cases for these rounds will be chosen for their broad teaching importance when presented to a larger audience of institute and Clinical Center medical

staff. These rounds will include a presentation by a member of the patient's care team as well as comments by selected specialists when appropriate.

8 GREAT TEACHERS LECTURES AND MEDICAL AND ETHICS GRAND ROUNDS

Rationale

Experts from within and outside the Clinical Center can share wisdom and experience in the management of complex patient-care issues.

Standard

The Clinical Center will continue to invite outstanding clinicians and ethicists to conduct the Wednesday noon Grand Rounds presentations—with CME credits available to the staff attending.

The leadership of the institutes and centers will encourage staff attendance.

COVER ILLUSTRATIONS:

Images depict designs on the elevator doors outside Masur Auditorium. Russian-American Artist Vincent Glinsky designed the images, which symbolically show important advances in medical history. Cast in metal, the doors were installed in 1953 when the original hospital building opened.

(Left side, top to bottom)

DOROTHEA LYNDE DIX
(1802–1887)
an American crusader, pioneered in providing humane treatment for the mentally ill.

SIGMUND FREUD (1856–1939)
born in Moravia, founded the psychoanalytical school of psychology, based on his theory that unconscious motives determine behavior.

(Right side, top to bottom)

HIPPOCRATES
(c. 460–c. 375 B.C.E.)
a Greek who is often called the "father of medicine," rejected the superstitious magic of primitive medicine and laid the foundations for medicine as a branch of science.

WILHELM CONRAD ROENTGEN
(1845–1923)
a German physicist, in 1895 produced the electromagnetic radiation known today as x-rays (Roentgen rays)