NIMH
National Institute of Mental Health

Division of Intramural Research Programs

Clinical Care in a Research Setting

Produced by the DIRP Office of the Clinical Director

March 14, 2008

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ADMISSION DOCUMENTATION

EVERY patient and normal (healthy) volunteer seen in person at the Clinical Center (CC) (or in an approved satellite location such as Cedar Lane) must be REGISTERED AS A CC PATIENT. For screening as well as other admissions, patients and normal (healthy) volunteers (NV) should be assigned to an ACTIVE protocol.

The physician's admission note should include documentation of diagnosis, history and physical examination. The history and physical examination must be completed within 24 hours of admission to the inpatient unit. The history and physical includes:

1. Chief complaint/purpose of visit
2. Present illness
3. Assessment of dangerousness to self or others
4. Past medical history
5. Medication/allergy history
6. Review of systems
7. Relevant past social and family history.

It is advisable that you keep your own copy of the history and physical for up to one year.

ADMISSION PROCESS

All new inpatient and outpatient admissions require entry of subject data into the CC Administrative Travel and Voucher (ATV) Request system. Information is available at: **https://atv.cc.nih.gov/adt/index.jsp**. Additionally, for inpatients, please complete the OCD preadmission form found at: **http://intramural.nimh.nih.gov/ocd/ocd_docs.html**. These forms may be completed by social workers or research assistants.

ADVANCE DIRECTIVES (See also DPA)

An advance directive is a legal document that allows a patient to indicate in writing his or her wishes about future health care and medical research decisions. Further information may be found through the unit nurses and social workers and at:
http://www.bioethics.nih.gov/clinical/advance.pdf.

AMA (AGAINST MEDICAL ADVICE) DISCHARGE

Participation in clinical research is voluntary. If a psychiatric patient decides he or she no longer wants to participate in research, the principle investigator and the medically responsible clinician must be notified. The patient must be assessed for safety to self/others by a credentialed medical staff member. If the evaluating clinician determines that continued hospitalization is indicated, but the patient does not meet criteria for involuntary commitment, then an AMA discharge should be arranged. If involuntary hospitalization is deemed necessary, transfer must be arranged to a community hospital that accepts involuntary patients. **See Involuntary Commitment**. The patient must be asked to complete form 1829 (9/87)

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AMA (AGAINST MEDICAL ADVICE) DISCHARGE - cont.

"release from responsibility for discharge" **http://intranet.cc.nih.gov/medicalrecords/forms/pdf/NIH-1829.pdf** to document their request to leave against medical advice. This form must be witnessed by a staff member and the form placed in the medical record, along with a corresponding progress note describing the patient's status upon discharge.

BIOETHICS DEPARTMENT

The CC Bioethics Department provides a bioethics consultation service to assist with the identification and resolution of ethical issues that arise in the conduct of clinical research. Any staff member, research subject or interested party may request a bioethics consultation. Information can be found at: **http://www.bioethics.nih.gov** or by calling 301-496-2429.

CAPACITY ASSESSMENT FOR DECISION MAKING

Capacity assessments for decision making are provided by the staff of the Human Subjects Protection Unit as mandated by the Institutional Review Board (IRB) for specific protocols that enroll potentially vulnerable subjects (**http://intramural.nimh.nih.gov/ocd/ocd_hsp.html**). Capacity assessments are semi-structured interviews performed to assess understanding, appreciation, reasoning, and the voluntary-nature of the informed consent process. To schedule a capacity assessment, contact Cherri Stanmore (301-402-6846).

CHART AUDITS

A physician representative of each clinical section will be responsible for performing monthly inpatient and outpatient chart audits under the supervision of the OCD staff. Audits are critical to ACGME and JCAHO accreditation. Review forms are found at **http://intramural.nimh.nih.gov/ocd/performance-improvement-program-audit-tool-inpatient.doc** and **http://intramural.nimh.nih.gov/ocd/performance-improvement-program-audit-tool-outpatient.doc.** They may also be submitted electronically. First and second year fellows from each Branch are assigned to audit the charts of another Branch. Lisa Horowitz will contact you in September with your assignment. Please contact the Branch you are auditing and the Branch auditing you (it is not always reciprocal) to set up arrangements for obtaining the charts.

CHILD ABUSE/NEGLECT

Evidence of current or past abuse or neglect of a pediatric subject must be reported immediately to Montgomery County Department of Social Services (240-777-4417) and in writing to the Clinical Director who reviews the report and then forwards a copy to the Clinical

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CHILD ABUSE/NEGLECT - cont.

Director. If the reported abuse occurs on the NIH campus, the NIH police should also be notified (301-496-5685).

If an adult subject reports a history of being abused as a child and there is reason to believe the alleged perpetrator could still be putting children at risk, this should also be reported to Montgomery County Department of Social Services (240-777-4417) and in writing to the Clinical Director who then forwards a copy to the Clinical Center Director. Further information is found in the Clinical Center (CC) Medical Administrative policy (MAS) M94-05 (11/03) at: **http://intranet.cc.nih.gov/mec/mas/**.

CLINICAL CARE IN A RESEARCH SETTING

All medical and psychiatric care provided at the Clinical Center (**http://www.cc.nih.gov/about/welcome.shtml**) is done so within the context of an IRB approved research protocol. Each protocol prescribes the scope of clinical evaluations and procedures conducted with research subjects. See "Protomechanics" (**http://www.cc.nih.gov/ccc/protomechanics**) and "Standards for Clinical Research" (**http://www.cc.nih.gov/ccc/clinicalresearch/index.html**). All research subjects (both normal (healthy) volunteers and patients) are voluntary participants in research protocols.

COLLABORATIONS

There are specific policies for collaborations with outside institutions. See **http://irb.ninds.nih.gov**. Consult with the IRB staff and the NIMH Office of Technology Transfer (**winfiels@mail.nih.gov**) to determine the need for a CRADA, MTA or Simple Letter Agreement. More information can be found at the Office of Human Subjects Research website: **http://ohsr.od.nih.gov**

COMMITTEE FOR THE SCIENTIFIC REVIEW OF PROTOCOLS (CSRP)

All protocols are submitted to this Committee prior to review by the IRB. The CSRP assesses scientific quality and appropriateness of the study to the goals and mission of the NIMH IRP.

CONFIDENTIALITY

Staff members are reminded not to discuss patient information in "public" areas of the outpatient clinic or nursing units. In addition, medical charts and research records should also be secured out of public view. All electronic communications containing patient information should be transmitted via "secure e-mail." To have secure e-mail set up, e-mail **securemail@cc.nih.gov.**

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CONFLICT OF INTEREST

Avoiding financial and other conflicts of interest is important for NIH, where the trust and protection of research subjects is vital to our mission to improve the public health. All NIH study investigators must review the "guide to preventing financial and non-financial conflicts of interest in human subjects research at NIH" which can be found on the CNS IRB website: **http://irb.ninds.nih.gov/.**

It is the responsibility of the PI to assure that all investigators on his/her protocol have received and reviewed the conflict of interest guidelines, and any potential conflicts of interest have been disclosed. The PI must submit a protocol conflict of interest statement (**http://irb.ninds.nih.gov/IRBForms.asp?cat=8**) to the Institute Ethics Office for review by the Deputy Ethics Counselor (DEC). This review must occur at the initiation of a protocol, at the time of the continuing review, and for any substantive amendments.

Investigators must also complete form 716/717 (Initial Report of Financial Interests in Substantially Affected Organizations for Employees of the National Institutes of Health) disclosing their financial withholdings to comply with the conflict of interest guidelines. The form can be found at **http://ethics.od.nih.gov/forms/hhs-717-1.pdf**. The Institute Ethics Office reviews the 716 or 717 forms for each principal and associate investigator on any given protocol to determine whether a conflict of interest exists.

CONGRESSIONAL INQUIRIES

Any telephone or written inquiries received from a congressional staff member regarding enrollment of someone in a study, or for any other reason, must be reported to the Office of the Clinical Director (OCD).

CREDENTIALING AND CLINICAL PRIVILEGES

The Clinical Director of NIMH is responsible for reviewing and approving the completed applications and related documentation for the credentialing of medical staff. The CC Credentialing Committee then reviews and indicates final approval for review by the Medical Executive Committee and clinical privileges are then granted by the Director of the CC. Ms. Donna Howard (301-496-4588) is the Credentialing Coordinator for NIMH.

CRIS (CLINICAL RESEARCH INFORMATION SYSTEM)

The Clinical Research Information System was implemented on July 31, 2004. It ties together and supports patient care, research and management in the Clinical Center and the Mark O. Hatfield Clinical Research Center. The website for training information is: **http://training.cit.nih.gov/courselst.asp?lname=cris**

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CRIS CODES

Computer information system codes are not to be shared (think of them as electronic signatures). Such a violation is a serious breech of conduct and will result in disciplinary action.

DANGEROUSNESS TO SELF AND/OR OTHERS - ASSESSMENT

The following information should be included in the Medical Record by the physician as a routine part of data gathering and continuing evaluation. **The Progress Note sheets on every psychiatric patient should contain the following:**

1. Explicit information about past history of suicidal or homicidal thoughts, feelings, and behavior as described by the patient and members of his/her family, or as noted in the other sources of information (medical records from physicians, clinics, hospitals).
2. An ongoing estimate of the current potential for dangerousness (gleaned from verbal and behavioral cues).
3. Suggested medical and nursing care approaches (observation, staff support, limit setting, etc.) designed to cope with the patient's suicidal behavior. **State which of these measures are presently in effect in explicit, clear terms.**
4. Specific commentary on how these issues have been discussed with the patient, his/her family, and the responses to this discussion.
5. State for the record what assurance you have that the observational and other protective measures are being carried out. Have you determined this from explicit statements in the nursing notes and/or verbal checking with patient care personnel?

DOCUMENTATION

Documentation of patient care in the charts is required. Physician orders are entered into CRIS. Physician documentation is handwritten on medical progress notes or printed onto templates approved by the Medical Records Department. Notes printed onto blank paper will not be placed in the patient's chart. Specific documentation is required for the following: an assessment of dangerousness, informed consent, outpatient visits, physical exams, procedures, change in status, and screenings.

New guidelines for psychiatric inpatients, established by the NIMH Clinical Director in May 2006, require that the physician document at least three times per week in the medical record (i.e., three weekly inpatient notes). Suicidality should be addressed specifically. If interdisciplinary notes are written in a staff conference, the physician must sign them. (This can substitute for one of the weekly physician notes.) When a patient's privileges are increased or decreased, a brief note must be written justifying the change in frequency of observation.

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DURABLE POWER OF ATTORNEY (DPA)

(See Advance Directive)

A durable power of attorney for NIH research participation is a mechanism that allows for the designation of a surrogate decision maker for research. A DPA may be required by specific protocols. Subjects may also wish to appoint a DPA if they are facing the possibility of difficulty with future decision making. For further information you can contact the CC Bioethics Department or CORE (Carol Kinslow is the CORE representative for DPA consultation: **carolkinslow@mail.nih.gov**).

The DPA for research form is included in the CC Advance Directive Form.
http://intranet.cc.nih.gov/mec/mas/

ELDER/VULNERABLE ABUSE

Evidence of abuse of vulnerable adults requires reporting to the Maryland Adult Protective Services (1-800-917-7383) and to the Clinical Director who will report it to the Clinical Center Director. **http://intranet.cc.nih.gov/mec/mas/**

ELOPEMENT/AWOL

In the event of an inpatient elopement (subject leaves without permission/discharge or fails to return from pass), contact the primary physician, the Unit Administrator, the Nurse Manager, the Branch Chief, the Clinical Director, and the subject's family.
http://intranet.cc.nih.gov/mec/mas/

EMERGENCIES

Emergencies in the CRC - See CC Emergency Handbook -
http://intranet.cc.nih.gov/od/emergencyplan/
Fire Department (Code Red) and Rescue Squad - Call 911
CPR Team (Code Blue) - Call 111
Police - Call 911
Engineering - Call 108
STAT Page Operator - Call 112

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Clinical Care Information

EMPLOYEE PARTICIPATION IN NIMH RESEARCH STUDIES

The OCD has established a policy that NIMH employees and contractors (both Intramural and Extramural) and CC employees who work in the 7SE, 1SW or OP4 patient care areas are not allowed to participate in NIMH protocols either as patients or normal (healthy) controls. This restriction also applies to first degree relatives. This policy was established several years ago to protect the confidentiality of employees and their immediate families (most NIMH studies require a diagnostic interview and psychiatric history) and to protect the professional relationship between employees and their supervisors and between employees and their colleagues.

EVALUATIONS OF CLINICAL FELLOWS

All clinical fellows will be evaluated by their primary supervisor annually and will have the opportunity to evaluate their supervisor. ACGME (American College of Graduate Medical Education) requires an evaluation of PGY-4 residents twice yearly. Evaluations are completed using E-value, an electronic evaluation system available at: **www.e-value.net**.

HIV TESTING

See **http://internal.cc.nih.gov/policies/PDF/M89-1.pdf** for the CC Administrative Policy on HIV Testing.

HOME VISITS

In order for NIMH staff to be authorized to make home visits, the IRB must have approved home visits as part of the protocol and the staff members making the visits must have a description of the home visit related duties in their Position Description. If a physician's involvement with subjects at a non-NIH site has been approved by his/her supervisor as part of his/her official duties, then any activities within the scope of those duties, while performed at that site, are covered by the Federal Tort Claims Act and Section 224 of the PHS Act. CC employees need approval from their immediate supervisor before they can make home visits.

Documentation of home visits:
If the subject has a CC ID number, document the home visits on a progress note and send to the medical record department.

If the subject does not have a CC ID number, keep a record of the home visit on a progress note with the patient's name on it and place it in the research file.

If the subject enrolls in a study and obtains a CC ID number, the note may be transferred to the CC medical record.

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HUMAN SUBJECTS PROTECTION (HSP) Unit and Marketing and Community Relations (MCR) UNIT (formerly the Central Office for Recruitment and Evaluation (C.O.R.E.))

The Human Subjects Protection Unit is under the direct supervision of the Office of the Clinical Director. Staff members (consisting of social workers and nurses, called Clinical Research Advocates) monitor the informed consent process performed by Intramural staff, perform capacity assessment for studies involving potentially impaired subjects, consult on human subject protection issues, and monitor the research participation of all NIMH inpatients. Information can be found at: **http://intramural.nimh.nih.gov/ocd/clin-dir/ocd_hsp.html**.

IMAGING STUDIES (see Radiation Safety)

MRI

For subjects who undergo research MRIs, a structural MRI must be submitted to the CC Department of Radiology for a clinical diagnostic reading at least once a year. These findings must be reviewed in a timely manner by the study physician.
http://intranet.nmrf.nih.gov

PET

The CC PET Department tracks individual radiation exposure on an annual basis. Exposure limits are defined by the Radiation Safety Committee. Research subjects may be ineligible for PET studies if they have multiple exposures in the same year. See the website for further details: **http://www.cc.nih.gov/pet/pet_facilities.html**

Radiation Safety

The radiation safety course is required for all staff working with or around radioactive sources. The training provides instruction about radiation hazards and appropriate precautions.
http://drs.ors.od.nih.gov

INFORMED CONSENT

Medical and nursing staff members are responsible for assuring that the appropriate Informed Consent Document has been signed before a study begins and that a signed and witnessed copy is placed in the chart. The patient should also be given a copy of the consent form. Medical staff should also keep a copy in the research file. Make sure the date on the consent form is current (not expired). Consent forms are valid for one year. Multiple different consent forms should not be administered at the same time. Informed consent to participate in a research protocol may be obtained only by the principal or associate investigator(s) unless otherwise

INFORMED CONSENT - cont.

specified in the protocol. Some protocols require monitoring of informed consent by a member of the CORE staff.

Protocol consent forms are available on the "web" at **http://www.cc.nih.gov/protocolconsents/**. It is the responsibility of every investigator to read the consent before administering it to a patient. Incorrect copies have been found on the web. All consents should be printed directly from the website on the day the consents are administered to avoid use of an expired document.

INPATIENT UNITS

The NIMH patients in the CRC are admitted to: 1SW, 1NW, 7SE and 5SW Day Hospital. Operation of the inpatient units varies. The unit nurse manager will orient new Fellows to the specific policies of each unit.

1SW admits pediatric patients from the Child Psychiatry Branch (CHP) and the Emotion and Development Branch (EDB).

7SE admits adult patients from the Mood & Anxiety Disorder Program (MAP) and the Genes, Cognition and Psychosis Program (GCAP).

1SW and 7SE as locked units. You may gain access via the "buzzer" on the main doors or if you need regular access, your identification badge can be authorized (through your Administrative Officer) to allow entrance onto these units.

5SW Day Hospital is a multi-Institute unit that admits short-term procedure NIMH adult patients.

1NW is a multi-Institute pediatric unit that admits patients of the Pediatric Neuropsychiatry Branch (PDN).

The nursing staff of these units is:

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INPATIENT UNITS - cont.

1SW Child and Adolescent Behavioral Health 301-451-1515
Bruce Steakly, R.N.--Nurse Manager
Tim Houston, R.N.--Clinical Manager
Diane Lawrence, R.N. --Nurse Educator
Kim Cox R.N., M.S.N.-Clinical Nurse Specialist

7SE Adult Behavioral Health 301-451-0846
Sandra Bowles, R.N., C.N.A., M.A.--Nurse Manager
Sybil Barnaby, R.N., M.S.N.--Clinical Manager/GCAP
Kim Cox, R.N., M.S.N.--Clinical Nurse Specialist/GCAP
Deloris Elliot, R.N., M.S.N. --Clinical Nurse Specialist/MAP
Vicky Liberty, R.N., B.S.N.--Clinical Manager/MAP
Valerie Green, R.N.--Team Leader (MAP patients)
Toni Santucci, R.N.--Team Leader (GCAP patients)

5SW Day Hospital 301-451-0671
Lomar Yap, R.N. - Nurse Manager

1NW Pediatric Unit 301-451-0345
Felicia Andrews, R.N. - Nurse Manager

INSTITUTIONAL REVIEW BOARD (IRB)

The Combined Neuroscience (CNS) (NEI, NIAAA, NINDS, NICDC, NIMH) IRB reviews all protocols to ensure human subjects protection and ethical conduct of research. Your Branch Chief and the senior staff of your Branch are important resources for protocol submission. The Chair of the IRB is Dr. Barbara Karp (301-496-0150). Dr. Maryland Pao (301-435-5770) is the Deputy Chair and is available to NIMH Principal Investigators for questions. The NIMH Associate Director for Protocol Management is Ms. Jeanne Radcliffe (301-594-7732). The Protocol and Credentialing Coordinator is Ms. Donna Howard (301-496-4588). To schedule a visit to an IRB meeting, please call Ms. Howard. All required IRB forms are on the website (**http://irb.ninds.nih.gov/**). All protocol actions must be submitted through the Protocol Tracking Management System (PTMS) found at this website.

The Office of Human Subjects Research (OHSR) guidelines for writing research protocols and

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INSTITUTIONAL REVIEW BOARD (IRB) - cont.

informed consent documents are at: http://ohsr.od.nih.gov/. A guide to preparing and conducting a clinical research study called Protomechanics is available at: **http://www.cc.nih.gov/ccc/protomechanics/**.

INTRAMURAL RESEARCH PROGRAM

The Division of Intramural Research Program (DIRP) at the NIMH is the internal research division at the NIMH. NIMH scientists conduct research ranging from studies of mechanisms of normal brain function, conducted at the behavioral, systems, cellular and molecular levels, to clinical investigations into the diagnosis, treatment, and prevention of mental illness. See the DIRP website for more details: **http://intramural.nimh.nih.gov/about/index.html**

INTRAMURAL RESEARCH PROGRAM STAFF

Information about NIMH DIRP programs, branches, sections and labs can be found at: **http://intramural.nimh.nih.gov/research/labs.html**

INVOLUNTARY COMMITMENT

We cannot commit patients involuntarily to the NIH since this is a voluntary research hospital. For detailed information on transferring patients to community facilities see Guidelines for Emergency Transfer at: **http://intramural.nimh.nih.gov/ocd/guidelines-for-emergency-transfer.pdf**.

IT RESOURCES

NIMH IRP Chiefs/Managers are responsible for ensuring that they and their staff are aware of NIH Policy Manual 2806 - Limited Authorized Personal Use of NIH Information Technology (IT). For guidance, see the NIH Manual: **http://www3.od.nih.gov/oma/manualchapters/management/2806/**.

LEGAL LIABILITY

The Federal Tort Claims Act (FTCA), 28 U.S.C.A (2671) generally provides that the United States Government should be liable for property, injury or loss and personal injury or death caused by negligence, wrongful act or omission of any employee of the government while the employee is acting within the scope of his/her office of employment.

Section 224 of the Public Health Service Act, 42 U.S.C.A. (233) generally provides that the FTCA is the exclusive remedy available to an individual injured as a result of negligence of an officer or employee of the PHS while providing health care within the scope of his/her employment.

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MANUSCRIPT CLEARANCE

All manuscripts must be cleared before publication by Ms. Dawn Johnson in the NIMH Office of the Scientific Director by sending a copy of the manuscript clearance form (available at **http://intramural.nimh.nih.gov/admin-svc/adsvc_forms.html**) along with a copy of your manuscript to nimhirpmsclearance@mail.nih.gov. Your Lab/Branch Chief should be cc'd on the e-mail. Contact Ms. Johnson with any questions at **dawnjohnson@mail.nih.gov**.

MARKETING AND COMMUNITY RELATIONS UNIT (formerly part of the Central Office for Recruitment and Evaluation (C.O.R.E.))

The Marketing and Community Relations (MCR) Unit is supervised by Susanna Sung, M.S.W., L.C.S.W., who reports to Jean Murphy, R.N., M.S.N., Associate Clinical Director. The mission of this unit is to facilitate the process of subject recruitment into NIMH clinical trials. Consultation is available to Branch recruitment staff on the design and implementation of marketing plans. Community outreach activities are provided. All ads for patient and healthy volunteer subjects must be reviewed by the Unit before submission to the CNS IRB as a protocol amendment.

MEDICAL ADMINISTRATIVE SERIES (MAS)

The Medical Administrative Series (MAS) manual contains all the CC policies related to health care and the Medical Staff Bylaws. It is available at: **http://intranet.cc.nih.gov/mec/mas/**.

These policies are approved by the Medical Executive Committee.

Here is a sampling of policies that may be relevant to medical staff: Clinical Center Medical Staff Bylaws; Identification and Management of Sentinel Events; Impaired Practitioner Program; Medical Orders in the Clinical Center; Informed Consent; Intramural Consultative Services; Suspected Adverse Drug Reaction Reporting; Patient Room Searches; Guidelines For The Dispensing Of Drugs To Outpatients And Discharged Patients; Consent Process In Research Involving Impaired Subjects; Licensure Of The Medical Staff; Administration Of Sedation; Inpatient Pass Policy; Policy and Procedure for Patient Medications Brought Into the Clinical Center Upon Admission; Participation of Clinical Research Volunteers in NIH Clinical Center Biomedical Research Protocols, Restraint and Seclusion.

MEDICAL EMERGENCIES

Life-threatening emergencies of patients and employees are the responsibility of the Code Team (dial 111). Routine medical consultation for patients is obtained through the Clinical

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MEDICAL EMERGENCIES - cont.

Center Internal Medicine Consult Service at beeper 102-12663 during regular working hours.

For non-life-threatening medical emergencies of mental health inpatient or outpatients, contact Critical Care Medicine at 301-496-2352 to obtain immediate evaluation and care.

Non-life threatening emergencies of staff members and families are treated in the 6th Floor Occupation Medical Services Clinic (301-496-4411).

MEDICAL STUDENTS AND RESIDENTS

Medical students and residents will be permitted to do only those things consonant with their level of training under the direct supervision of a credentialed staff member. Countersignatures will be required on all medical record entries.

MEDICALLY-RESPONSIBLE INVESTIGATOR

Non-credentialed physicians and all other non-physician Principal Investigators must designate a "medically responsible investigator" for their protocols. In the NIMH, this individual is responsible for the medical and psychiatric oversight of all subjects while actively enrolled in the protocol and is identified on the last page of the protocol consent form including contact information. The IRB reviews each protocol for the designation of a medically responsible investigator with appropriate CC credentials.

MRI/PET GUIDELINES

See **Imaging Studies** Section.

NIMH DIRP NEW EMPLOYEE GUIDE

This guide contains useful information for new employees.
http://intramural.nimh.nih.gov/newguide/new-emp-guide.pdf

NON-ENGLISH SPEAKING RESEARCH SUBJECTS

Procedures depend upon whether the enrollment of said subject is planned or unplanned. If the investigator plans to enroll non-English speaking subjects, the protocol must be translated into the specific language of the subjects. The CC policy MAS 77-2 should be reviewed: **http://internal.cc.nih.gov/policies/PDF/M77-2.pdf**.

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NON-ENGLISH SPEAKING RESEARCH SUBJECTS - cont.

For the unplanned or occasional participation of a non-English speaking subject, the basic elements of Informed Consent are available in translations of the 10 most commonly used languages in the Clinical Center. These summaries can prove helpful whether or not the IRB requires that the entire protocol be translated or that a summary of the protocol be given. See this website: **http://www.cc.nih.gov/protocolconsents/**.

Clinical Center interpreting services for patients are coordinated through the Director of Volunteers and Language Interpreters at 301-496-1807 or e-mail **InterpretingServices@ors.od.nih.gov**. For written and recorded translations, submit one copy of text to be translated to Translation Unit, NIH Library, Building 10. On non-Behavioral Health units, one can access a language line using a designated telephone in the patient's room.

NORMAL (HEALTHY) VOLUNTEER PAYMENT

Policy at the Clinical Center requires that research volunteers provide a social security number or federal tax identification number and demographic information in order to be reimbursed for research participation at: **http://www.cc.nih.gov/participate.shtml**.

NURSING ASSESSMENT

As per CC Nursing Department policy, a nursing assessment of study subjects must be completed for all protocols that receive nursing support.

OCCUPATIONAL MEDICAL SERVICE (OMS)

OMS provides a variety of health care services to NIH employees. Non-employees may be seen for emergency medical care. OMS is located on the 6th floor of the Ambulatory Care Facility (ACRF). It is open Monday through Friday, 7:30 a.m. to 5:30 p.m. The telephone number is 301-496-4411.

OCCURRENCE REPORTS AND SERIOUS ADVERSE EVENTS REPORT

In addition to creating an occurrence report for any adverse event, report any serious adverse event (suicide attempt, prolonged hospitalization, death, AWOL, negative clinical outcome, medication errors, patient injuries) to the Office of the Clinical Director and the IRB. An ongoing record of adverse events associated with each protocol must be maintained so that they can be summarized for the annual review of your protocols. A full description of adverse event reporting requirements and forms may be found at: **http://irb.ninds.nih.gov**. (The Code of Federal Regulations can be found at this site.)

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OFFICE OF HUMAN SUBJECTS RESEARCH (OHSR)

The OHSR was established to help IRP investigators understand and comply with the ethical guidelines and regulatory requirements for research involving human subjects. OHSR's overall goal is to promote and support the IRP's efforts to conduct innovative research while protecting the rights and promoting the welfare of human subjects.
http://www.hhs.gov/ohrp/

OFFICE OF THE CLINICAL DIRECTOR (OCD)

The mission of the Office of the Clinical Director (OCD) is to ensure that subjects participating in NIMH protocols receive the highest quality of clinical care. This is accomplished by the activities of the Human Subjects Protection (HSP) Unit, the NIMH Intramural Research Program Protocol Office, the CNS Institutional Review Board (IRB), clinical fellowship training activities, and the Psychiatry Consultation-Liaison Service. The overall responsibilities of the Office include the following: oversight of the clinical care provided to our research subjects, the protection of human subjects (including the protocol review process), administration of the quality assurance program, authorization of medical staff credentials, and allocation of CC resources.

OCD STAFF

Staff members and contact information may be found at:
http://intramural.nimh.nih.gov/ocd/ocd_staff.html

OFFSITE PROTOCOLS

All protocols must specify the location where research activities will occur - on site (NIH) or offsite (outside of NIH). All offsite research activities require the approval of the IRB.

- Research activities in a subject's home (See also Home Visits)
- Research Activities in another medical setting
- Collaboration with other investigators/institutions with indirect research activities only (nonpatient contact) (See also Collaborations)

OFFSITE RESEARCH ACTIVITIES

Patients and normal (healthy) volunteers participating in NIMH protocols may not be seen outside the Clinical Center without explicit permission of the Clinical Director. The protocol must include a description of the activities that will occur offsite and must be approved by the IRB.

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ON CALL/OFFICER OF THE DAY (OD)

The OD provides coverage of NIMH inpatients and outpatients when a member of the responsible treatment team is not readily available. In addition, the OD provides coverage throughout the CC for the Psychiatry Consultation-Liaison Service as assigned. A complete description may be found at: **http://intramural.nimh.nih.gov/ocd/officer-of-the-day.pdf**.

OUTPATIENT MEDICAL RECORD DOCUMENTATION

The current policy for Outpatient Medical Record Documentation is found at **http://intranet.cc.nih.gov/medicalrecords/**. [The Clinical Center requires that the First Visit Registration Form be completed for all outpatients on their first visit.]

OUTPATIENT PROCEDURES

Most NIMH outpatients are seen in the outpatient 4 (OP4) clinic. Guidelines for clinic procedures may be found at **http://intramural.nimh.nih.gov/ocd/outpatient-clinical-guidelines.pdf**

OUTSIDE ACTIVITIES (see also Private Practice)

There are several forms used to request approval to engage in an outside activity (personal, outside work).**http://ethics.od.nih.gov/forms.htm**

Form 520 is required to be submitted before initiation of activities outside regular official duties and with outside organizations.

Official Duty Approval Requests - Official duty approval is no longer required for an employee who wants to simply attend an event. Travel documents and Video Attended Gatherings (VAG) [Form 2803] approvals are still required, if applicable. However, if an employee will be speaking, presenting a poster, taking part in a panel or manning a booth (or otherwise presenting information officially), advance official duty approval must be obtained.

Official duty approval is required for consulting for industry (complete Part B), legal consulting/testimony (Part C), and Professional Practice for physicians, nurses, and allied health care professionals (complete Part D).

If the outside activity falls into the above areas, complete Form 2657 and attach it to your packet.

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OUTSIDE ACTIVITIES (see also Private Practice) - cont.

For approval to give a CME lecture as an outside activity, include a letter from the institution (where you are giving the lecture) that states it is a CME lecture. Attach this to the Form 520 when submitted.

Contact your Administrative Officer with any questions.

PASS AND PRIVILEGE POLICIES BY UNIT

A pass order must be written for an inpatient requesting to leave the NIH grounds. A new pass order must be written by the physician for each pass request.

Patients who request a pass will be assessed by both nursing and medical staff before leaving the unit. This assessment must be documented in the medical record.

A change in privilege status must be documented and should include a note describing the rationale for this change. Program specific practices for passes and privilege status may be obtained on 1SW and 7SE.

PATIENT CARE MEETING

This meeting is held (unless otherwise indicated) at 12:30 p.m. on the first Monday of each month in the 7SE conference room. The purpose of the meeting is to discuss patient care problems, quality assurance issues, and general matters related to the "State of the Institute." A medical staff representative from each Branch is required to attend. If you cannot attend, please designate a substitute.

PHYSICAL EXAMINATIONS

Physical examinations are required on all inpatient admissions. Individual protocols will specify whether or not a physical examination is required for study participation. An outpatient physical examination is valid for one year from the date performed providing a medical history indicates no changes since the last examination and this is documented as such. Generally the physical examination is performed to determine study eligibility and/or medical clearance for study enrollment. Subjects should be counseled that this examination should not be substituted for a routine annual physical examination by his/her primary medical doctor.

A chaperone for physicals on members of opposite sex is required.

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PHYSICIAN ORDERS

CRIS is the computerized system that allows a licensed independent practitioner to write patient orders and to access lab results. To obtain a CRIS code: **http://cris.cc.nih.gov/accounts/index.html**.

Verbal orders may be entered by a nurse in a medical emergency or when the physician does not have access to CRIS. Verbal orders must be electronically countersigned within 72 hours. Verbal orders may not be issued to discharge a patient; transfer a patient outside the Clinical Center; order schedule II controlled substances for outpatients; order discharge or pass medications to be used outside CC facilities; initiate oncology chemotherapy agents; or order investigational agents being studied under an IND. The MAS policy on physician orders may be found at **http://internal.cc.nih.gov/policies/PDF/M04-1.pdf**

PRIVATE PRACTICE (see also Outside Activities)

In order to avoid the appearance of or actual conflict of interest, the following general guidelines shall apply to NIMH staff who have an outside private practice:

You should not receive a fee for either consultation or on-going treatment of a patient if:

a) the patient appears to be eligible and interested in participation in an NIMH intramural research protocol (unless you have informed the patient that private consultation with an NIMH staff member usually makes the patient ineligible for referral to all NIMH research programs for the following twelve months); or,
b) the patient has previously been a participant in an NIMH study, or
c) you were originally contacted in your official capacity about the patient's eligibility for NIMH programs.

If you have seen a patient in private practice, you may not refer that patient for participation in an NIH intramural research program for one year after termination of your private practice relationship.

The central purpose of the guidelines is to prevent the occurrence of a genuine conflict of interest which might interfere with appropriate clinical care or might damage the reputation of the employee of the Institute.

Private clinical practice must be requested on Form HHS-520, "Request for Approval of Outside Activity," and is generally permitted, if on one's own time, subject to administrative restrictions. The average number of hours per week devoted to private practice should be limited so that it does not interfere with official duties. General experience suggests an approximate limit of 10 hours for a full-time employee. You must conduct outside activities outside of "normal working hours" (Monday through Friday, 9:00 a.m. to 5:00 p.m., for a full-time employee). There are no provisions for adjusting tour of duty hours to allow for outside activities during these hours.

Clinical Care in a Research Setting

PRIVATE PRACTICE (see also Outside Activities) - cont.

an NIH intramural research program for one year after termination of your private practice relationship.

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Private clinical practice must be requested on Form HHS-520, "Request for Approval of Outside Activity," and is generally permitted, if on one's own time, subject to administrative restrictions. The average number of hours per week devoted to private practice should be limited so that it does not interfere with official duties. General experience suggests an approximate limit of 10 hours for a full-time employee. You must conduct outside activities outside of "normal working hours" (Monday through Friday, 9:00 a.m. to 5:00 p.m., for a full-time employee). There are no provisions for adjusting tour of duty hours to allow for outside activities during these hours.

Annual leave should be taken if an emergency requires the staff member to conduct outside activities during working hours.

Government facilities and resources may not be used for outside activities.

If your outside clinical practice is closely connected with an institution, the institutional affiliation should be carefully reviewed to assure the absence of conflict of interest. Your NIMH affiliation should not be used in any promotional or informational material prepared by or for the outside institution, or in any press coverage of the institution's programs.

PROTOCOL ORDER SETS

You may wish to establish a fixed set of orders used routinely for specific studies or types of patients. To do so complete the form available at: **http://cris.cc.nih.gov/changes/orderset.html**

PSYCHIATRY CONSULTATION-LIAISON SERVICE

Psychiatry Consultation-Liaison service responsibilities for first and second year fellows are found at: **http://intramural.nimh.nih.gov/ocd/psych-consult-service.pdf**

RADIATION SAFETY

Information on radiation safety may be found in the **Imaging Studies** Section.

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Clinical Care in a Research Setting

RECRUITMENT

See section on Marketing and Community Relations Unit

REFERRAL GUIDELINES (see also Private Practice)

Questions and Answers:

Q: Is it a conflict of interest for someone in the Extramural Program to mark a referral to the Intramural Program of the same Institute?

A: Presuming that the employee of the Extramural Program is not using public office for private gain or making a commitment or promise of any kind purporting to bind the acceptance of the individual, this does not appear to create a conflict of interest as long as the standards for referral and acceptance of the individual into a protocol are applied the same as they would be to any other prospective subject. There is one additional exception: an Extramural Program employee, who is engaged in an outside professional practice, may not refer a patient with whom he or she has a continuing professional relationship. See NIH Manual 2300-735-4, Outside Work, Financial Interest and Related Activities, § H.3.e(1).

Q: Is it a policy violation for an Intramural doctor to refer a patient that he or she sees privately to a study in NIMH or a different Intramural Institute?

A: Yes. Section H.3.e.(1) of NIH Manual 2300-735-4, Outside Work, Financial Interest and Related Activities requires that employees engaged in private professional practice must agree that no patient, with whom a continuing health professional-patient relationship is established in outside professional practice, will be referred to the NIH either as inpatient or an outpatient as a consequence of that relationship. Section H.3.e.(2) further provides that the employee will never knowingly establish a physician [health professional]-patient relationship in outside private practice with any current or recently discharged NIH patient.

REFERRALS

Information on studies currently recruiting subjects is found at **http://patientinfo.nimh.nih.gov**. Assistance with inquiries regarding protocol participation is available from the HSP Unit staff at 301-496-5645 or to the appropriate research group for consideration.

RESEARCH ASSISTANTS - INTRAMURAL RESEARCH TRAINING AWARDEES (IRTAs

Research Assistants - IRTAs can perform duties involving clinical contact only under the supervision of credentialed staff. They may not administer informed consents unless previously approved by the IRB. In order to perform single blood draws they must take the Clinical Center phlebotomy training. They are not permitted to start IVs or draw blood through an intravenous or arterial line.

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RESTRAINT AND SECLUSION POLICY (MAS 94-10)

Please review carefully at **http://intranet.cc.nih.gov/mec/mas/**

ROOM SEARCHES

The Clinical Center has a policy related to conducting patient room searches. In general, on the behavioral health units, patients are informed prior to executing a room search. See the NIH CC MAS for further details: **http://internal.cc.nih.gov/policies/PDF/M81-3.pdf**

SAMPLE GUIDELINES

The IRB must approve the exchange of clinical samples (including human tissue, data, and scans) with non-NIH collaborators. Relevant protocols and consent forms must be explicit about the intention to send tissue samples and brain imaging data to outside collaborators. If this research activity was not anticipated when the protocol was first written or last reviewed, then the protocol and consents should be amended as necessary. The protocol should detail the nature of the collaboration an d how tissue samples will be stored and exchanged. Even human subjects samples that have been coded (but still linked to personal identifiers) require IRB approval. See the OHSR website at: **http://ohsr.od.nih.gov/info/sheet14.html** and **http://ohsr.od.nih.gov/info/sheet15.html**. Samples that have been stripped of all personal identifiers and therefore have no link to their source (i.e., "anonymized") may be shared with outside collaborations without IRB approval if OHSR grants an exemption (contact OHSR at 301 402-3444 for more information). When a protocol is terminated, the termination memo should state whether samples exist, how they are stored and tracked and what the intended future use will be. Subsequent new research use of those samples requires IRB approval as outlined above. If new subject accrual will cease but you plan to continue analysis of stored samples, you should keep the protocol open for "analysis of existing data" which will provide the required mechanism for ongoing IRB review of human subjects' research.

Consult with the IRB Chair and the NIMH Office of Technology Transfer to determine the need for a CRADA, MTA or Simple Letter Agreement. In general, samples that are part of a scientific collaboration with potential intellectual property issues (e.g., collaboration with industry) should be sent or received within the context of a CRADA. Samples shared but not part of a formal collaboration should be sent or received with an MTA. Intellectual property rights can not be granted with this mechanism. Samples shared with an academic colleague should be done through a Simple Letter Agreement. Final NIH policy in this circumstance is pending.

Clinical Care in a Research Setting

SEDATION

ACLS training is required for physicians who order sedation prior to procedures. A one time oral dose for anxiety prior to procedures (PET/MRI) is permitted without this training.

The policy and sample of the conscious sedation worksheet can be found at the website: **http://internal.cc.nih.gov/policies/PDF/M92-9.pdf**

SMOKING IN AND AROUND THE CLINICAL CENTER

Smoking by patients, staff, or visitors is not permitted in the CC or within 100 feet of any entrances. A special area for patients who smoke, and who for clinical reasons are restricted to the patient care unit, has been provided. An order permitting access to this area must be written by the patient's physician. At the time of the initial request for access to the smoking area the patient will be offered information on smoking cessation. Further information on the smoking policy may be found at **http://www.cc.nih.gov/ccsmokefree/M92-18.pdf**.

SOCIAL WORKERS

Social workers facilitate the research objectives of the NIMH by providing a wide range of clinical, research, recruitment and screening support to patients and families participating in clinical trials. OCD social workers support the Psychiatry Consultation-Liaison Service, the C.O.R.E. and offer administrative support. Branch social workers support the recruitment and education of new patients to particular clinical trials and other activities as directed by their Branch supervisors. Clinical Center social workers function as integral members of the interdisciplinary team whose duties includes clinical work (individual and group) with adults and children diagnosed with psychiatric illnesses; education; community referral and discharge planning.

Most of the social workers hired through the NIMH as well as through the NIH Clinical Center are Masters level trained. All social workers are credentialed as per Clinical Center Social Work Department policy. In addition, NIH serves as a training facility offering clinical supervision and placement to graduate-level social workers pursuing Masters and Doctoral degrees.

SUICIDALITY

Information is found at the **Dangerousness to Self and/or Others** Section.

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Clinical Care in a Research Setting

TRAINING/COURSES

NIH offers a wide array of training opportunities to its scientific staff. Regulations and policies require that all scientific staff take certain training courses, as well as others determined by your areas of research. Please discuss training and course requirements with your supervisor. All staff are required to take the Introduction to the Responsible Conduct of Research which is found at: **http://ResearchEthics.od.nih.gov.**

Other courses can be found at: **http://intramural.nimh.nih.gov/mandatory-tng.html**.

TRANSFER OR DISCHARGE OF INPATIENTS TO OTHER HOSPITAL FACILITIES

When transferring NIMH patients from the Clinical Center to another hospital, in or out of Maryland, it is vital that detailed planning precede the transfer to insure that it can be accomplished safely and effectively. Guidelines for Emergency Transfer are available at: **http://intramural.nimh.nih.gov/ocd/guidelines-for-emergency-transfer.pdf**.

TREATMENT OPTIMIZATION

The length of stay for treatment optimization must be specified in the protocol and consent form. Those with extensive lengths of stay beyond that defined in the protocol require approval by the Office of the Clinical Director.

UNIVERSAL PRECAUTIONS

Universal Precautions Training can be found at the website: **http://intranet.cc.nih.gov/hospitalepidemiology/training/universalprecautions.shtml** or call 301-496-2209.

The Clinical Center Universal Precautions Pamphlet can also be found at the above website.

Gloves are to be worn only while handling specimens within a CC or Institute lab and are not to be worn when transporting specimens outside of laboratory areas (e.g. in hallways or common areas). Specimens should be transported in closed containers. Clinicians should complete universal precautions training (301-402-2209) and laboratory personnel should complete a laboratory safety course (301-496-3353).

Clinical Care in a Research Setting

UNIVERSAL PRECAUTIONS - cont.

Gloves are required at all times when working with blood or body fluids. Gloves must not be worn in restrooms, conference rooms, common laboratory storage areas, office areas or any area outside of the laboratory (clean gloves may be worn for medical reasons with prior approval). Gloves must be removed prior to use of telephones in the nurses' station. Once the specimen has been transferred to the plastic bag for transport to the laboratory, gloves are discarded. Discard contaminated gloves as soon as possible. Glove must be discarded in the contaminated trash boxes whether used or clean. Wash hands after discarding gloves. Persons with glove reactions should report to OMS for evaluation.

VIDEOTAPING OF PATIENTS/NORMAL (HEALTHY) VOLUNTEERS

For filming by external media, the subject must sign NIH Form 549 which is placed in his/her medical record. For clinical care or research purposes the subject's licensed independent practitioner must write an order in CRIS for photographs, videos, and for recordings. If the videotape is to be used for research purposes the protocol and informed consent should include a description of the procedure and its purpose.