
The Deane F. Johnson Center for Neurotherapeutics at UCLA



Policies and Procedures Manual
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POLICY AND PROCEDURE MANUAL

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VISION, MISSION, AND VALUES

Vision Statement

- ❑ The Deane F. Johnson Center (JCNT) at UCLA will advance neurotherapeutics and drug development for new treatments of neurological diseases.

Mission Statement

- ❑ JCNT will provide an infrastructure that facilitates the efficient and timely accomplishment of the clinical trials.
- ❑ JCNT will advance the science of clinical trials, including design, analysis and implementation of biomarkers.
- ❑ JCNT will provide high quality preceptorships and other forms of training to physicians in training, community practitioners, and pharmaceutical personnel.

Values

- ❑ Committed to capturing quality data in clinical trials for clinical trial sponsors.
- ❑ Committed to optimizing the experience of patients and their caregivers participating in clinical trials.
- ❑ Committed to integrating advances in basic science, imaging, genetics and other fields onto clinical trials methodology.
- ❑ Committed to providing optimal educational experiences for all educational program participants including, students, physicians in training, community practitioners and pharmaceutical personnel.
- ❑ Committed to enhancing information exchange among trialists to assist in advancement of clinical trial methodology, use of biomarkers, and understanding of mechanisms across diseases and among pharmaceutical agents.

HISTORY

The Deane F. Johnson Center for Neurotherapeutics (JCNT) opened its doors on October 12, 2004, as a clinical trial center devoted to advancing treatment of neurological diseases. JCNT provides advanced academic expertise and resources, clinical trials support, and educational programs. JCNT represents a unique national resource and an innovative collaboration of UCLA Neurology faculty members, philanthropists, and pharmaceutical companies dedicated to advancing treatments for brain diseases.

Kate Edelman Johnson is the principal philanthropic supporter through The Deane F. Johnson Alzheimer's Research Foundation. Deane F. Johnson was a very successful entertainment attorney in Los Angeles and became President of Time Warner, Inc. He succumbed to Alzheimer's disease in 1999 and his widow, Kate Edelman Johnson, created the Deane F. Johnson Alzheimer's Research Foundation to combat this tragic illness. Ms. Edelman Johnson is a producer and entrepreneur in the entertainment industry who sustains several major philanthropic commitments.

The JCNT is directed by Jeffrey L. Cummings, M.D., The Augustus S. Rose Professor of Neurology and Professor of Psychiatry and Biobehavioral Sciences at UCLA. Dr. Cummings has fifteen years of experience in clinical trials, is a member of the NIH-sponsored Alzheimer's Disease Cooperative Study, and is a frequent consultant to industry.

The JCNT is coordinated by Christine Tam. Ms. Tam's background is in nursing and research administration. She received her Certified IRB Professional diploma (CIP) from the Council for Certification of IRB Professionals (CCIP) of the Applied Research Ethics National Association (ARENA).

GOVERNANCE OF JCNT

JCNT's organizational structure is designed to give optimal support for its mission of facilitating clinical trials and accelerating the development of new treatments for patients with neurological disorders. JCNT's governing members consist of the JCNT Director, Coordinator, and Executive Committee. JCNT's governance aims to achieve the following goals:

- Align the actions of the Center toward aggregate mutual benefit
- Provide the means by which each individual part of the Center can trust that the other parts each make their contribution to the mutual benefit of the Center and that none gain unfairly at the expense of others
- Provide a means by which information can quickly flow between the various stakeholders to ensure that the changing nature of both the stakeholder needs and desires and the environment in which the Center operates get effectively factored into decision processes

JCNT DIRECTOR

The JCNT Director is responsible for maintaining an active and productive clinical trials program in neurotherapeutics. Duties include the following:

- Articulating a vision of the future for the JCNT that will identify JCNT's existing strengths
- Developing the strategic thrusts and interacting with key stakeholders to build on these strengths to achieve scientific advances and economic growth for the Center
- Developing a plan to implement a growth strategy
- Recruiting employees who can contribute to the strategic thrusts of the Center
- Selecting a Research Advisory Committee of experts to assist in articulating the vision, developing the strategy, defining the goals, devising a plan of action, selecting members, advising on research themes and projects, and monitoring the progress of the JCNT
- Collaborating with other public or private organizations that share the goal of developing clinical trials research

JCNT COORDINATOR

The JCNT Director is responsible for implementing the strategic plan to advance JCNT's clinical research programs. Duties include the following:

- Administration over JCNT's daily operational activities
- Developing educational activities for the health care community
- Developing relationships with public or private organizations that share the goal of supporting clinical trials research
- Assisting in achieving the strategic thrusts of the Center

EXECUTIVE COMMITTEE

The JCNT Executive Committee is responsible for supervising, controlling, and directing the affairs of the Center, its programs, and publications. It also implements the policies and supervises the disbursement of its funds.

PHYSICAL FACILITIES

The design of the JCNT facilitates the proper conduct of patient-oriented investigations. The space was designed for ideal interactions with trial monitors and others involved in trial oversight. The JCNT is housed at UCLA's 300 Medical Plaza and is conveniently located next to the Neurology Clinic and offers state-of-the-art facilities.

FACILITIES

A. EXAM ROOMS

1. We offer exam rooms that are to be used for patient examinations and invasive procedures such as blood draws and lumbar punctures.

2. Equipment Provided:

- Exam table
- Diagnostic equipment such as ophthalmoscope, blood pressure machines, and pulse oximeters
- Patient supplies such as gowns, tongue depressors, bandages, etc.
- Personal computer with internet access

B. CONSULTATION ROOMS

1. We offer consultation rooms that are to be used for neuropsychological testing and clinical assessments.

2. Equipment Provided:

- Table and chairs
- Personal computer with internet access

C. LABORATORY

1. We offer a laboratory to store and centrifuge specimens samples.

2. Equipment Provided:

- Centrifuge
- Refrigerators (-70, -30, 4 Celsius)
- Storage area

D. CONFERENCE ROOM

1. We offer a conference room for meetings and study monitor interactions.

2. Equipment Provided:

- Conference style table with chairs which seats twelve persons
- Projector screen

ROOM POLICIES

Room policies were designed to facilitate patient flow and to respect and preserve the appearance and utility of JCNT rooms.

1. Priority: The JCNT is available for UCLA medical faculty and staff. Use will be allocated by priority with highest priority given to Principal Investigators of Neurology clinical trials and second priority to groups with collaborative and cooperative associations with the Center faculty. Federally sponsored studies will be given priority over industry-sponsored trials. JCNT reserves the right to reschedule your appointment for a higher priority study.

2. Fee Schedule: A fee schedule for JCNT is included in the Policy and Procedures Manual. Payment for use of the facility is required.

3. General Policies: All users must treat the facility with respect and care. The rooms are to be left in a neat, orderly condition with equipment and chairs replaced, and all items not belonging to the room removed.

- a. Prior to scheduling, the JCNT must have a copy on file of the current IRB approved protocol and consents to ensure that studies conducted at the JCNT is compliant with institutional and government regulations.
- b. Effective August 1, 2006, the Principal Investigator will submit JCNT Application for all new studies to the fund manager to indicate his or her intention to use the JCNT facility and/or services.
- c. Individuals or groups seeking to use a JCNT room shall request the day and time that the room is needed via email to JCNT Coordinator at ctam@mednet.ucla.edu.
- d. It is advised to request a room at least one week in advance because space is limited at the JCNT and rooms tend to fill up quickly on clinic days.
- e. During the time of booking, it is important to indicate the study title/IRB number, Principal Investigator name, and whether invasive procedures such as blood draws and/or other invasive procedures will be performed. These procedures are limited to Rooms B207, B209, and B213 only.
- f. The names of the subjects must be emailed to JCNT Coordinator at ctam@mednet.ucla.edu at least 48 hours prior to the study date to ensure that the Neurology Clinic Front Desk is properly notified and that subjects are sent to their correct rooms.
- g. It is the responsibility of the PI to ensure that any patients seen at JCNT for standard procedures check in with the appropriate desk to ensure that billing for standard procedures is captured. It is also the responsibility of the PI to ensure that research documents are copied into the medical records for subjects who are patients.
- h. To ensure proper subject flow, coordinators/clinicians must be present at the time of appointment to receive their subjects.
- i. Standing appointments will be held only if PI/Coordinators can document room occupancy by emailing the names of the subjects at least 48 hours prior to the treatment date. Otherwise, the rooms will be released for others to use.
- j. Any adverse events must be reported immediately to the JCNT staff and other appropriate agencies (Institutional Review Board, UCLA Hospital Compliance, Sponsor, etc.).
- k. JCNT has the right to refuse studies and revoke Center privileges at will.
- l. Failure to abide by the above policies may result in loss of privileges for use of JCNT facilities.

4. Information: To inquire about our facility, please contact JCNT Coordinator, Christine Tam (ctam@mednet.ucla.edu), (310) 206-9485, 300 Medical Plaza, Suite B204, Los Angeles, CA 90095.

IRB POLICIES

All research studies conducted at the JCNT must be reviewed and approved by the Institutional Review Board (IRB) to ensure protection of the rights and welfare of research subjects. At UCLA, the IRB is called The Office for Protection of Research Subjects (OPRS). 45 Code Federal Regulations 46.110 (45 CFR 46.110) allows for expedited review for certain kinds of research.

The OPRS is responsible for the oversight and implementation of 45 CFR 46. The IRB application and all supportive documentation are examined when the JCNT application is reviewed. The OPRS is also responsible for the implementation for the National Institutes of Health (NIH) policies of inclusion of women, minorities, and children in all protocols, as appropriate.

The activities of the Data Safety and Monitoring Boards also need to be coordinated through the OPRS. If the OPRS becomes aware of information that would bear on the safe of a protocol conducted at the JCNT, it is incumbent upon the OPRS to re-review that protocol. Likewise, it is the investigator's duty to notify the OPRS of any new information considered relevant to the safety and/or efficacy of a protocol for which he or she is responsible.

Documentation of the IRB approval of protocols, as well as copies of currently approved consent forms, must be maintained in the JCNT administrative files. "IRB approval" means full, final IRB approval including investigational new drug (IND) assignment from Food and Drug Administration (FDA) if an IND or investigational device exemption (IDE) is required. Failure to do so may result in loss of privileges for use of JCNT facilities.

The JCNT also offers assistance in IRB applications and submissions.

FACILITY FEE POLICIES AND PROCEDURES

Individuals or groups seeking to submit a proposal for funding using JCNT resources should refer to the fee schedule regarding facility fee application. Specific questions may be directed to the JCNT phone number at (310) 206-9485 or email: ctam@mednet.ucla.edu.

1. During the study proposal submission process, the Principal Investigator will submit JCNT Application to the fund manager to indicate his or her intention to use the JCNT facility and/or services. Failure to comply may result in loss of JCNT privileges.
2. The fund manager will submit the JCNT Application (see page 11) along with a copy of the budget and study protocol to the JCNT coordinator. The JCNT coordinator will assess utilization to determine the charges. The charges will be incorporated into the budget for final approval by the fund manager, Principal Investigator, and Department Chair.
3. The funds will be transferred and collected as milestone payments accrue. Start up fees will be collected from the initial payment (e.g. when JCNT staff have prepared IRB documents, etc.). JCNT use will be tracked electronically via the software system, Velos, and charged against the fund.
4. No-show appointments and late fees will not be counted against the account. However, the PI or Coordinator must notify JCNT via email at ctam@mednet.ucla.edu within 24 hours of no-show or cancellation in order to not incur room charges. Excessive cancellations/no-shows are discouraged and will be dealt with on a case-to-case basis.
5. Any media coverage will be first directed to JCNT coordinator for approval.
6. Beginning December 1, 2007, all industry-sponsored trials regardless of initiation date will incur room charges.
7. Beginning January 1, 2009, all studies (including federally funded) at JCNT regardless of funding will incur room charges.

SUBJECT REGISTRATION

I. Introduction

Effective December 1, 2008, The Deane F. Johnson Center for Neurotherapeutics at UCLA (JCNT) will have a new subject registration process.

Standard Operating Procedures (SOP) are provided below to allow more efficient intake of subjects into JCNT.

II. UCLA Staff, Faculty, or Student Procedures

A. PI or Coordinators will email names and medical identification numbers to the JCNT Coordinator (ctam@mednet.ucla.edu) at least 48 hours prior to the study date.

B. If medical identification number is not available for the subject (for example, normal subject), the following information must be emailed to the JCNT Coordinator in lieu of the medical record number*:

1. Name
2. Date of Birth
3. Mother's Maiden Name
4. Last 4 digits of their social security number

*Please note that the above personal identifying information will be submitted to Neurology Clinic where a medical identification number will be generated for them. Neurology Clinic will then email PI/coordinators the medical identification numbers of their subjects for future submission requests.

C. JCNT subject lists will be submitted to Neurology Clinic (cminott@mednet.ucla.edu) at least 48 hours prior to the study date.

D. When the subject arrives at Neurology Front Desk, the receptionist will immediately direct the subject to the JCNT Office at B216.

FEE SCHEDULE

ITEM	COST
Room Charge* Non-Federal	\$50/hr
Federal	No Charge
Institutional Review Board (IRB) Preparation (Includes Application, Consent Forms and all supportive documents to IRB until initial approval)	\$600
Submission of Amendments to IRB	\$320
Submission to Office of Contracts and Grants	\$300
Trial Identification	\$500
Preparation of General Clinical Research Center (GCRC) Application	\$200
Submission to Investigational Pharmacy	\$300
Submission to Pathology and Laboratory Medicine	\$300
Application for Certificate of Confidentiality	\$200
Study Coordinator Fees*	\$30/hr
Nursing Services Fees*	\$50/hr

* Minimum charge 1 hour, additional in 15-minute increments



THE DEANE F. JOHNSON CENTER FOR NEUROTHERAPEUTICS

JCNT APPLICATION

INSTRUCTIONS: Please complete form, attach the budget, approved IRB protocol and consents, and turn in to your fund manager. Thank you.

PRINCIPAL INVESTIGATOR: Address Phone	
STUDY COORDINATOR/CONTACT PERSON: Address Phone	
SPONSOR: Address Phone	
STUDY NAME/IRB NUMBER/APPROVAL DATE:	
IS THIS AN INVESTIGATOR OR SPONSOR INITIATED STUDY?	
FUND MANAGER: Address Phone	
RECHARGE NUMBER	
ROOMS REQUESTED: <i>Please specify types of rooms needed (e.g. exam rooms, conference rooms, consultation rooms, etc.)</i>	
NUMBER OF SUBJECTS AT UCLA:	
SERVICES REQUESTED: <i>Please specify types of services needed (e.g. IRB application assistance, etc.)</i>	
TOTAL CHARGES:	

VELOS ERESEARCH POLICIES AND PROCEDURES

The JCNT uses the computer software and database system called Velos eResearch for its clinical research management. Velos eResearch is a web-based application that is password protected to limit access and SSL encrypted to protect information. JCNT users will be required to apply to the JCNT and schedule appointments using Velos eResearch. The program also offers other research management functions that the Principal Investigator and his or her research team can elect to utilize. Software training will be made available by the JCNT Coordinator.

Application to the JCNT using the Velos eResearch program is mandatory. Prospective applicants will go to the website: _____ and follow the instructions to apply. The process includes uploading the following documents to the program:

- JCNT Application
- IRB approved protocols and consents
- Study Budget

Scheduling rooms and/or services at JCNT will require the use the Velos eResearch program.

Velos eResearch can also offer other research management functions for the Principal Investigator and his or her research team. These functions such as financial tracking and patient data monitoring are elective and may assist the research team in managing their clinical research. Training will be made available by the JCNT Coordinator.

I. Velos eResearch Overview of Functionality

A. Velos eResearch Console

1. IRB protocol designer
2. Schedule generator
3. Research network
4. My eResearch Portal

B. Budgeting/Milestones

1. Patient budgets
2. Study budgets
3. Milestone tracking
4. Achievement reporting

C. Patient Tracking

1. Alerts/reminders
2. Enhanced scheduling
3. CRF Status Tracking
4. Adverse Event Tracking

D. Patient Profile

1. Patient records
2. EMR integration
3. Eligibility criteria
4. Patient recruitment

E. Application Generator

1. On-line forms
2. Study specific forms
3. Application extensions
4. Site specific Apps

PRIVACY AND CONFIDENTIALITY AND HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) POLICIES

The JCNT is committed to protecting the confidentiality of subjects' health information. JCNT users and staff are responsible for upholding privacy and confidentiality standards for the research subjects, to whom we owe a great deal for altruistically volunteering themselves for the advancement of society and for the benefit of mankind.

PRIVACY AND CONFIDENTIALITY

Principal Investigators and research staff must do their best not to discuss subject health information in open, public areas. Consultations with the subjects should be performed in a private setting, such as an exam room with doors closed. Appropriate security measures such as maintaining subject identifiers in locked cabinets and not sharing computer user names and passwords must be observed.

Disclosures to subjects such as consent forms should state that any information obtained in connection with the research and that could identify the subject will remain confidential and will be disclosed only with the subject's permission or as required by law. It should detail the extent to which confidentiality will be adhered to and how specific records identifying the subject will be maintained [45 CFR 46.116(a)(5)].

Suggested text for this section is as follows:

* The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- o if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- o if required by law

Limits to Confidentiality

Depending on the subject matter of the research, there may be limits to the investigator's promise of confidentiality to the subject. An example would be if a subject reveals information about possible child or elder abuse or if the investigator and/or the research staff discover the possibility of abuse. (Please see Chapter 7 of OPRS Guidelines, Responsibilities of Principal Investigators: Confidentiality" and Chapter 10 of OPRS Guidelines, "Special State of California Requirements: Reporting Suspected Abuse of Children, Elderly Individuals, and Others" for more information.) For example, the following text is recommended for research consent forms:

Under California law, the privilege of confidentiality does not extend to information about sexual or physical abuse of children or the elderly. If any member of the program staff has or is given such information, he or she is required to report it to authorities. The obligation to report includes alleged or probable abuse as well known abuse.

Confidentiality of Audio/Video-Tapes and Photographs

Investigators are required to protect and/or disguise an individual subject's identity when using photographs, videos, or audio-tape recordings. Statements regarding the use of photographs, videos, or audio-tape recordings should be consistent in both parental permission forms and children assent forms. For example, if the child's assent form indicates that the photographs, videos, or audio-tape recordings are confidential and only the investigators will have access to the material, then the parental permission form should not indicate that the parent/guardian will have access to the tapes or photographs.

The investigator should clearly outline in the consent form whether the tapes will be used for classroom presentations, conventions, presentations, or possibly released to news or advertising media. The consent form should also indicate when the tapes/photographs will be destroyed. In addition, the consent form should indicate the provisions for masking the subjects' identity. It is recommended that the following statement be used in consent forms for research that includes photographs, videos, or audio-tape recordings:

In the process of the research you will be videotaped (and/or photographed, and/or audio-taped). The tapes or photographs will be used for teaching and/or research purposes [indicate the types of purposes] only and your identity will not be disclosed. [The statement should also include an indication of when the tapes will be destroyed.]

If the subject is identifiable from the photographs, videos, or audio-tape recordings, the following disclosure is suggested:

You have the right to review the tapes/photographs made as a part of the study to determine whether they should be edited or erased in whole or in part.

Releasing Information

If the investigator intends to release any information, the standard statement of confidentiality should be modified to state the person(s) or agency to whom information will be furnished, the nature of the information, the purpose of the disclosure and whether the subject's name will be used. When the research records may be subject to inspection by the FDA, a funding agency, or an industrial sponsor, the following information must be included in the consent form:

Authorized representatives of the Food and Drug Administration (FDA) [or a funding agency such as the National Institutes of Health] and the manufacturer of a drug [or device] being tested [insert name of company] may need to review records of individual subjects. As a result, they may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

When the results of the research are to be published or presented at conferences, it is the investigator's responsibility to make sure that no personal information will be included that would reveal a subject's identity.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Background

In April 2003, the University of California completed a major effort to become compliant with the federal Privacy Rule that was created as a result of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The focus of the Privacy Rule was the management of protected health information ("PHI").

By April 20, 2005 all HIPAA covered entities, including UCLA Healthcare, must be compliant with the Security Rule. The Security Rule, also promulgated as part of HIPAA, establishes comprehensive security requirements relating to the electronic creation, transfer, storage and receipt of PHI (which is known as "ePHI"). Each such security "standard" is comprised of a number of implementation specifications. If an implementation standard is required, the covered entity must implement policies and/or procedures to meet the implementation specification requirements. If the standard is addressable, the covered entity must assess whether the specification is reasonable and appropriate for its environment, and as applicable to the covered entity, implement the specification. If the standard cannot

be implemented, the covered entity must document why it would not be reasonable and appropriate to implement the standard, and implement an equivalent alternative measure if reasonable and appropriate.

The Privacy Rule and Security Rule Compared

Although the Privacy Rule applies to all forms of patients' PHI, the Security Rule covers only PHI that is in electronic form.

The HIPAA Security Rule defines ePHI as any **electronic** information that is created or received by a health care provider that relates to the past, present, or future physical or mental health of an individual, and identifies the individual. This includes ePHI that is created, received, maintained or transmitted. For example, ePHI may be transmitted over the Internet, or stored on a computer, a CD, a disk, magnetic tape or other related means. The Security Rule does not cover PHI that is transmitted or stored on paper or provided orally.

Security Standards

The security standards are divided into the categories of administrative, physical, and technical safeguards. (Regulatory definitions of the safeguards can be found in the Security Rule at 45 C.F.R. section 164.304).

1. Administrative Safeguards

In general, these are the administrative functions that should be implemented to meet the security standards. These include assignment or delegation of security responsibility to an individual and security training requirements.

2. Physical Safeguards

In general, these are the mechanisms required to protect electronic systems, equipment and the data they hold, from threats, environmental hazards and unauthorized intrusion. They include restricting access to ePHI and retaining off-site computer backups.

3. Technical Safeguards.

In general, these are primarily the automated processes used to protect data and control access to data. They include using authentication controls to verify that the person signing onto a computer is authorized to access ePHI, or encrypting and decrypting data as it is being stored and/or transmitted.

(Taken From UCLA Healthcare Corporate Compliance Policies and Procedures Policy No 9450 and <http://www.oprs.ucla.edu/human/manual/hspcmanual/4C#Ch4CI> on June 20, 2006)

SAFETY POLICIES AND PROCEDURES

The JCNT is concerned about the health and wellbeing of patients and research staff and aims to ensure that all precautions are in place to prevent the transmission of blood-borne pathogens. The prevention of transmission of blood-borne pathogens is supported through educating staff and students, and assisting those who may be infected with these pathogens. For detailed policy and procedures, please refer to the Westwood - UCLA Healthcare Policy website at <http://www.mednet.ucla.edu/Policies/?facility=ww>. Definitions are provided in the Appendix.

The purpose of this policy is to ensure that the transmission of blood-borne pathogens is controlled, such that the personal and social impact of infection is minimized. It is also the purpose of this policy to encourage research staff to modify "at risk" behaviors.

In performing the following procedures/tasks, occupational exposures can occur:

- * Handling contaminated sharp instruments, needles, and other laboratory devices
- * Surgical procedures
- * Handling of patients (and all associated equipment, bedding, etc.) infected with human bloodborne pathogens
- * Pathology procedures involving contact with tissue and other body substances
- * Procedures involving the containment and management of "regulated waste" disposal
- * All procedures involving contact with cerebral spinal fluid, mucous membranes, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, blood and all other body substances

PROCEDURES

Hand Washing

1. Hand washing is required, and is accomplished at hand washing facilities that are readily accessible to employees.
2. Hands are washed immediately or as soon as feasible after removal of gloves or other personal protective equipment.
3. Antiseptic towelettes are supplied when hand washing facilities are not readily available. When towelettes are used, hands are washed with soap and running water as soon as possible.

Sharps Disposal

1. Efforts to eliminate or minimize the risk of occupational exposure to sharp devices, e.g., scalpels, needles, etc., are reviewed and evaluated on an ongoing basis by the UCLA Office of Environmental Health and Safety.
2. Needles are not recapped by hand. If needles must be recapped, the procedure is accomplished using a one-handed technique.
3. Contaminated needles are not bent, sheared or broken before disposal.
4. All contaminated sharps are disposed of in puncture-resistant, leak-proof containers, and are labeled with the biohazard symbol, or are color-coded red.
5. Sharps containers are easily accessible to personnel and are located in areas convenient to where sharps are used.
6. Sharps containers are routinely inspected and replaced as indicated when contents are found to be inadequately contained.
7. Sharps containers are discarded with the infectious waste stream when 3/4 full or less.
8. Safe practices are used when handling or reprocessing reusable sharps.
9. Mechanical pipettes are required where appropriate and are available for use where necessary. Mouth pipetting is prohibited.

General Precautions

1. Eating, drinking, applying cosmetics and handling contact lenses is prohibited in work areas where there is potential of occupational exposure.
2. Storage of food and drink is prohibited in places where potentially infectious materials are kept.
3. All specimens of blood or other potentially infectious materials are contained in leak-proof containers during handling, processing, storage, transport or shipping. Specimens are not left uncovered on counter tops. All specimens are handled using standard precautions.
4. Equipment that may become contaminated is inspected for blood or other potentially infectious materials regularly and decontaminated as necessary.
5. All activities involving other potentially infectious materials are conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.
6. Respiratory etiquette should be used in all intake areas. Instruct patients to cover nose and mouth if coughing. If they have flu symptoms, use tissues or a surgical mask. Instruct patients to clean hands (wash with soap and water or alcohol-based hand rub). If possible, give them a separate area to sit. Facilitate moving them to a private room ASAP.
7. If a staff member is exposed to TB, they should report the incident to Hospital Epidemiology according to the TB Exposure Plan (policy IC 005 on the web). All clinical staff are mandated to have a TB test annually. Clinical staff must be fit tested to care for patients who have TB. LA County must be notified when a TB patient is discharged into the community.
8. To meet CDC hand hygiene guidelines, we need use an alcohol-base hand rub and rub it in until dry or, if hands are visibly soiled, wash our hands for 15 seconds with soap and water. We are required to do this before and after each patient contact and before and after using gloves.
9. A healthcare-associated infection will be managed as a sentinel event when it is associated with permanent loss of function or unanticipated death.
10. If an employee has a sharps or body fluids exposure, they should follow the Exposure Control Plan for Bloodborne Pathogens (policy IC 006) on the web.
11. Patient refrigerator temperatures must be checked daily. Patient food stored in the refrigerator must be dated and discarded after 72 hours. Milk cartons are for single patient use only. Do not return opened milk to the refrigerator.
12. When using Sani Wipes and hospital-approved disinfectants to clean environmental surfaces or equipment, the solution must be left to dry for 10 minutes to be fully effective.

Personal Protective Equipment (PPE)

1. All departments where occupational exposures occur have previously identified and defined barriers to be worn for tasks involving blood and body fluid (including sharps) contact.
2. PPE is considered "appropriate" by OSHA only if it does not permit "blood or other potentially infectious materials to pass through or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used."
3. PPE is supplied and is readily available, or issued to the employee, in all areas where occupational exposure can occur.
4. PPE includes, but is not limited to, gloves, gowns, laboratory coats, face shields and/or masks, eye protection, and others.
5. Gloves are worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures and/or when handling or touching contaminated items or surfaces. Disposable (single-use) gloves are removed as soon as is practical when contaminated, or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Disposable gloves are not washed or reused. Hypo-allergenic gloves, glove liners, powderless gloves, or other similar alternatives are readily accessible to those employees who are allergic to the gloves normally provided.

6. Masks in combination with eye protection devices such as goggles or glasses with solid side shields, or chin-length face shields are worn whenever splashes, spray or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
7. Gowns and other protective clothing such as aprons or lab coats, or similar outer garments are worn in occupational exposure situations. Type and characteristics of protective clothing will depend upon the task and the degree of anticipated exposure.
8. Surgical caps or hoods, or shoe covers or boots, are worn in instances when gross contamination can reasonably be anticipated, e.g., animal surgeries, etc.
9. When a protective garment(s) is penetrated by blood, or other potentially infectious materials and the substance has reached the employee's own work clothes, street clothes, or undergarments, the clothing is removed immediately, or as soon as is possible prior to the employee leaving the work area.

Spills and Waste

1. Remediation of spilled potentially infectious materials is the responsibility of the person/lab causing the spill. Only trained personnel will remediate spilled biohazardous material. Upon spilling a potentially infectious agent, human blood or body parts, etc., the area must be isolated and others warned to stay away until further notice. University Security can assist in isolating an area (controlling pedestrian traffic) if necessary, but may not assist in the actual remediation. Whenever possible, a 10:1 water to bleach solution will be used to decontaminate surfaces or equipment. Liquids may be decontaminated with a 10:1 solution of liquid to bleach. All potentially contaminated materials that may not be decontaminated with bleach, or are used in the decontamination process, must be autoclaved or discarded in a red, biohazardous waste bag.
2. Broken glassware that may be contaminated is not picked up directly with the hands. It is cleaned up using mechanical means, such as a brush and dustpan, tongs, or forceps, according to established procedures.
3. All bins, pails, cans, and similar receptacles intended for reuse that have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials are inspected and decontaminated on a regularly scheduled basis, according to established procedure.
4. OSHA-defined regulated waste is handled and managed in accordance with the Hospital Policy, "Guidelines for Infectious Waste Management." Disposal of all regulated waste is done according to applicable regulations and other jurisdictions.

EVACUATION - PATIENT CARE AREA PURPOSE: To provide the strategy for the possible evacuation of all or part of any building or facility within the Hospital System. Also, to identify the four different types of evacuations and situations in which each should be implemented.

POLICY: Evacuations are coordinated efforts that involve many people. All directions and activities must be clearly communicated and understood by participants. Employees must be familiar with the different types of evacuations, when each is appropriate, and how to perform the duties necessary to ensure an effective and efficient evacuation. Patient care and safety must always be maintained. At the discretion of the Chief Operating Officer, Incident Commander, Administrator-on-Call or Nurse Supervisor-on-Duty, an evacuation of a patient care area may necessitate the declaration of a Code Triage – Internal.

Evacuation Types: There are four types of evacuations, the implementation of which depends on the present and anticipated risk to persons and property posed by the event.

A. Defend in Place

Defend-in-Place ("non-evacuation") is utilized when an area is not at risk from the event as indicated by the event, associated observations or alarms.

1. Maintain awareness of situation.
2. Listen for, and seek, updates/cancellations.

B. Horizontal Evacuations

Horizontal evacuations from a threatened area to a non-threatened area should assure life safety in most situations.

1. Remain calm.
2. Follow directions of area supervisor.
3. Move patients and personnel first. Then move necessary patient care equipment and supplies to the other side of fire doors in corridor.
4. Account for all patients and staff. Check off the names of patients as they are evacuated.
5. Continue care for all patients during transport and relocation.
6. Follow post evacuation instructions provided at the new location.
7. Keep patient files and records with the patient.
8. Notify Administration regarding status of evacuation, when evacuation is complete, the impact to patients and that all patients are accounted for, as soon as possible.

C. Vertical Evacuations

Vertical evacuations from a threatened area to a non-threatened area on another floor may be necessary when it is undesirable or unsafe to remain in place. Relocate to a lower floor, if possible. Remain calm.

1. Follow directions of area supervisor.
2. Move patients and personnel and then necessary patient care equipment and supplies to the other side of fire doors in corridor. Maintain patient records/files with the patient.
3. Transport patients and staff down a safe stairwell (for fire and/or smoke) to a safe patient care location within the Medical Center. Keep to the right in the stairwells and keep going down until safe to re-enter the building or to exit.
4. Account for all patients and staff. Check off the names of patients as they are evacuated.
5. Continue care for all patients during transport and relocation.
6. Follow post evacuation instructions provided at the new location.
7. Notify Administration regarding status of evacuation, when evacuation is complete, the impact to patients and that all patients are accounted for, as soon as possible.

D. Building Evacuations

Only the Director, Incident Commander, Administrator On-Call, or the Nurse Supervisor On-Duty can order general building-wide evacuations. The local Fire Department may also order an evacuation, in consultation with an appropriate administrator. A building-wide evacuation will necessitate utilization of the Alternate Care Site Plan. Building-wide evacuations are ordered when it is unsafe or undesirable to remain in the building.

1. Remain calm.
2. Listen carefully to the orders to evacuate and to the supervisor.
3. Identify patients most easily moved and begin with them.
4. Transport patients and personnel down a safe stairwell or elevator, and if safe, out of the building following posted evacuation routes or other safe routes, as directed by Supervisor or comparable authority.
5. Check off the names of patients as they are evacuated.
6. Transport essential patient care equipment and supplies.
7. Bring patient records with patient.
8. Account for all patients and staff.
9. Continue care for all patients during transport and relocation.
10. Assemble at the building-specific Evacuation Assembly Area: In front of 300 Medical Plaza on Westwood Blvd.
11. Follow post-evacuation instructions provided at the new location.

Evacuation Procedures

A. Ambulatory

1. Form a line along the designated route to lead patients out.
2. Account for patients by checking off their names as they leave the area and arrive at final destination.

3. Transport appropriate patient records such as Kardex and medication books with the patient, if possible.
4. Check all rooms to ensure they are empty and identify that the room has been checked.
5. Use stairwells, not elevators.
6. Use stairwell landings as areas of safe refuge if it is not possible to transport patients down the stairs. Immediately notify emergency responder of location of patients.

B. Non-Ambulatory

1. Use gurneys, stretchers, wheelchairs, blankets, or sheets to transport patients to the designated exit.
2. Account for patients by checking off their names as they leave the area and arrive at final destination.
3. Transport appropriate patient records with the patient, if possible.
4. Check all rooms to ensure they are empty and identify that the room has been checked.
5. Use stairwells, not elevators.
6. Use stairwell landings as areas of safe refuge if it is not possible to transport patients down the stairs. Immediately notify emergency responder of location of patients

Note: If immediate evacuation of non-ambulatory patients or other incapacitated persons is necessary, carries may be used to transport persons to a safe place. All carries should be demonstrated and practiced prior to use in emergencies.

(Taken from UCLA Healthcare Policy and Georgetown University Medical Center guidelines)

USE OF WESTERN IRB POLICIES AND PROCEDURES

Certain Phase III and IV clinical trial studies are eligible for use of Western Institutional Review Board (WIRB) for clinical trials IRB approval. The following policies and procedures govern the identification and processing of such studies.

I. Application process for review by Western IRB (WIRB)

The principal investigator (PI) for the study or his/her designee will fill out the Application for Western IRB (WIRB) Review. The Application can be found on-line at JCNT.org (click on JCNT Resources, For Professionals). All sections must be filled out completely before the Application can be processed. The PI will upload necessary study documents for review. The Application will be reviewed by the JCNT director, who will in turn notify the PI via email whether the study has been approved, deferred for further clarification, or rejected.

II. The process and specific criteria for determining which studies qualify for review by WIRB

The Department Chair has designated the JCNT director to act as primary reviewer for clinical trials that may meet eligibility criteria for submission to the WIRB. The functions of the JCNT coordinator shall be overseen by the JCNT director.

A. The JCNT director shall use the following criteria for determining which studies qualify for review by WIRB.

1. Inclusion criteria

- a. Phase III and IV studies that meet the UCLA definition of a “clinical trial” (i.e. *The controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes*)
- b. The protocol must be designed and written by an external sponsoring company
- c. The sponsor of the research must be a for-profit entity or company
- d. The sponsor will pay the entire cost associated with the use of WIRB

2. Exclusion criteria

- a. Studies which involve gene transfer or gene medicine
- b. Embryonic stem cell research
- c. Research study funded by a federal agency
- d. Investigator-initiated or cooperative group research

B. The JCNT coordinator shall be responsible for the following:

- a. Providing verification to the Office of Clinical Trials that the chair or designated faculty reviewer has approved a protocol for submission to the WIRB, that the PI is eligible to conduct research submitted to the WIRB, and the PI and research staff have completed the required human subjects training prior to submission to the WIRB.
- b. Facilitating gathering of required information and communication between the PI/research team and the WIRB and the Office of Clinical Trials, particularly for the submission of a protocol according to processes established by the WIRB and the Office of Clinical Trials.
- c. Performing such tracking and record-keeping as deemed necessary by the department or by the Office of Clinical Trials.
- d. Alerting the WIRB and the Office of Clinical Trials of all communications to/from the Food and

Drug Administration, the federal Office for Human Research Protections, or any other federal or state agency regarding studies referred to the WIRB.

e. Helping to assure compliance with applicable UCLA policies and procedures, WIRB decisions and requirements, as well as with all applicable federal, State, and local laws regarding the protection of human subjects in research.

f. Ensuring prompt payment of WIRB fees billed to PIs.

g. Conducting random quality assurance audits of documentation throughout the year.

i. Internal tracking systems for ensuring continuity of approvals, including the initial approval, annual renewals, and addenda

The JCNT director will be responsible for the oversight of continuity of approvals, including the initial approval, annual renewals, and addenda.

Each study will be tracked using a user name and password protected web-based system. The PI will upload study documents (IRB, radiation safety, etc.) onto the web-based system. The system will track addenda and expiration dates and post study status. At months 3, 2, and 1 prior to the expiration date, the system will notify the PI via email. If the PI does not renew the study, the study will close.

ii. The process for reporting, reviewing, and making determinations regarding adverse events

A. The JCNT director will oversee the process of reporting adverse events to the appropriate entities and implement compliance with the recommendations made by the WIRB. The WIRB will review and determine any actions required regarding adverse events.

B. All participating program investigators will be required to report the following types of adverse events and other occurrences:

a. Any adverse event that is both serious and unexpected that occurs during the conduct of a study.

b. All deaths of subjects (while on study or within 30 days of completion).

c. Problems involving the conduct of the study, including Protocol Deviations.

d. Study sponsored-generated reports that the sponsor requires for review and acknowledgement by the WIRB.

This report must be typed and submitted to the WIRB, the JCNT director, the Study Sponsor, and/or FDA within 5 working days of knowledge of the adverse event. Serious adverse events (SAEs) are to be reported within 48 hours as stated by University policy.

C. DSMB

Data Safety Monitoring Board (DSMB) reports should be submitted to the WIRB and the JCNT director as soon as available.

D. Closed Studies

1. Closed to Enrollment

If a study is no longer enrolling subjects, adverse events will be reported until the study is closed, meaning that each subject is done receiving treatment and data collection has been completed.

2. Closed at UCLA

If a study has been closed at UCLA for more than 30 days, but the study is still ongoing at other centers, the Adverse Event reports do not need to be submitted to the WIRB and the JCNT director unless:

a. If the Sponsor requests that the reports be submitted, but the study has been closed at UCLA, the events may be attached together with a memo indicating that the study has been closed at UCLA for

more than 30 days, and the information does not impact the previously enrolled subjects.

b. If the adverse event occurs off-site and may impact the previously enrolled subjects, the event must be forwarded to the WIRB and the JCNT director even if the study is closed.

c. If an event should be reviewed because it may impact the previously enrolled subjects, the report must indicate that the study is closed but the information is relevant to the subjects that had been enrolled. The principal investigator will be responsible for informing the WIRB and the JCNT director of pertinent information that was communicated to him or her by the Sponsor.

V. Procedures for tracking necessary approvals from other institutional compliance committees such as the Medical Radiation Safety Committee, and the Institutional Biosafety Committee

A. The JCNT director will be responsible for overseeing that all necessary approvals have been obtained from other institutional compliance committees by the clinical trial coordinators.

B. Each study will be tracked using a user name and password protected web-based system. The PI will upload study documents (IRB, radiation safety, etc.) onto the web-based system. If the study lacks the appropriate institutional compliance approval, the system will not allow the PI to continue the study entry process until all approvals have been submitted. The JCNT director will use the web-based system as a tool to monitor study compliance.

C. When all approvals and eligibility requirements have been met, the JCNT coordinator will give the JCNT director a summary document recommending (or not) that the site PI receive approval for use of the WIRB. After review by the JCNT director, the document will be forwarded to the Chair of Neurology. The form will include the following:

1. Check-off boxes to indicate that eligibility requirements have been met.
2. Indication of financial interest of the PI and sub-investigators and adherence to UCLA's policy regarding disclosure of financial interest.
3. Signature lines for Program Chiefs, PIs, or their designees to indicate that approval notices have been received from the committees and reviewed for completeness.
4. Signature line for the JCNT director to indicate that a complete submission package has been received and the study is approved (or not) to be submitted to the WIRB. This completed form will be sent to the WIRB with the approval notices from the institutional compliance committees.
5. Once the JCNT director has accepted the document, it will be forwarded to the Chair of Neurology. When the Chair has reviewed and accepted the document, the JCNT director will be notified and he/she then will in turn notify the PI that the trial can be submitted to the WIRB.

VI. A policy to ensure that sponsors cover the costs of review by the Western IRB and the JCNT coordinator

Policy will be implemented within the 1) department, 2) The Office of Clinical Trials, 3) Central Accounting stating that there are mandatory, non-refundable IRB and JCNT fees to be covered by the Sponsor that include, but are not restricted to, application, amendments, renewals, and protocol review. This policy is to be reflected in the budget and clinical research agreement (contract) signed with the Sponsor. JCNT review will be included in the facility fee to be collected from all trials using JCNT facilities.

APPENDIX

Bloodborne pathogens - pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV).

Clinical trial/study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. Taken from Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (April 1996)

Occupational exposure - reasonably anticipated skin, eye, mucous membrane, non-intact skin, or parenteral contact with blood and other potentially infectious materials that may result from the performance of an employee's duties.

Other potentially infectious materials - semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva, any body fluid that is visibly contaminated with blood, all body fluids in situations where it is difficult or impossible to differentiate between the fluids, and any unfixed tissue or organ (other than intact skin) from a human (living or dead).

Universal precautions - All human blood or body fluid is to be considered potentially infectious. Appropriate personal protective equipment and engineering controls will be utilized for any procedure in which direct contact with human blood or body fluid is possible.