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<b>Infection Control Manual</b>		
	Policy Name	<b>Creutzfeldt-Jakob Disease (CJD)</b>
	Policy Number	<b>IC 0011</b>
	Date this Version Effective	<b>April 2015</b>
	Responsible for Content	<b>Hospital Epidemiology</b>

## I. Description

Describes the recommendations to prevent the transmission of CJD within the healthcare setting.

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## II. Rationale

CJD is transmitted by a proteinaceous infectious agent or prion. The CJD prion is hardy and resistant to heat, formaldehyde, glutaraldehyde, ionizing radiation, freezing, drying, and organic detergents. Because it resists routine cleaning, disinfection, and sterilization procedures used in hospitals, diligent adherence to the following recommended practices is essential.

## III. Policy

### A. Definitions for High-Risk CJD Patients

1. Patients with known or suspected prion diseases (e.g., CJD, Gertsmann-Straussler Sheinker [GSS] disease, fatal familial insomnia [FFI syndrome]).
2. Rapidly progressive dementia consistent with possible prion diseases.
3. Patient is undergoing brain biopsy when a specific lesion has not been demonstrated (e.g., via MRI, CT).
4. Familial history of CJD, GSS, or FFI.
5. Patients known to carry a mutation in the PrP gene involved in familial Transmissible Spongiform Encephalopathies (TSEs).

### B. Infection Control Measures

These should be based upon epidemiological evidence linking specific body tissues or fluids to transmission of CJD. (See Appendix 1 for a table summarizing the comparative frequency of infectivity in organs/tissue/body fluids of humans with CJD and other TSE.)

1. General Precautions for Patients with Known or Suspected CJD
  - a. Standard Precautions should be followed utilizing appropriate personal protective equipment. Gloves should be worn for handling blood and body fluids. Masks, gowns, protective eyewear should be worn if exposure of skin or mucous membranes to

blood/body fluids is anticipated. Double gloving is recommended for operating room and anatomic pathology personnel at risk of sharps injury.

- b. A private room for the patient is not necessary for infection control purposes.
  - c. No special precautions are required for handling laundry, food trays or utensils.
  - d. Disposable instruments should be discarded in the appropriate receptacle.
  - e. Since standard decontamination of tissue samples (e.g., formalin) or specimens may not inactivate CJD, all tissue samples should be handled using Standard Precautions (i.e., gloves). The tissue and specimens should be labeled "BIOHAZARD" and "suspected CJD" prior to being sent to the laboratory.
  - f. No special precautions are required for disposal of body fluids. Such fluids may be disposed of via a sanitary sewer in accordance with applicable regulations.
  - g. Regulated medical waste (i.e., bulk blood, pathological materials, biologic materials, and sharps) should be managed according to the Infection Control Policy: Guidelines for Disposal of Regulated Medical Waste IC0054.
  - h. When a patient dies, ensure that the morgue and funeral home are notified that the patient has known or suspected CJD. No excess precautions are taken at burial.
  - i. Patients with known or suspected prion disease should not serve as donors for organs, tissues, blood components, or biologic products (e.g., interferon). Recipients of pituitary hormones or dura mater transplants should not be donors. Transfusion services should include this factor in predonation surveys.
2. Cleaning and Disinfection of Contaminated Environmental Surfaces
    - a. High Risk Tissue (brain, spinal cord, posterior eyes, pituitary tissue) and Low Risk Tissue (cerebrospinal fluid, liver, lymph node, kidney, lung, olfactory epithelium, spleen) Contamination
      - i. Thoroughly clean surface with a detergent. Follow with decontamination with a 1:10 dilution of bleach and water.
    - b. No Risk Tissue or Fluid Contamination (refer to Appendix 1)
      - i. Use standard disinfection procedures (i.e., any EPA-registered disinfectant/detergent or a 1:10 dilution of bleach and water).
  3. Decontamination of CJD Contaminated Medical Devices: Decontamination methods are based upon the type of contamination (i.e., high risk tissues, low risk tissues/fluids, no risk tissues/fluids), and the potential risk of infection involved in the use of the items.
    - a. Categories of Risk of Patient-Care Items
      - i. Critical Items: Items that enter sterile tissue or contact the vascular system. High risk of infection if contaminated. These items must be sterilized between patients. Includes surgical instruments and implants, and some endoscopes.
      - ii. Semicritical Items: Items that come into contact with mucous membranes or skin that is not intact. These items require at least high-level disinfection using wet pasteurization or chemical disinfectants. Examples: most endoscopes, respiratory therapy equipment.
      - iii. Noncritical Items: Items that touch only intact skin. Examples: floors, walls, blood pressure cuffs, patient furniture.
    - b. Decontamination Procedures

- i. High Risk Tissue (brain, spinal cord, posterior eyes, pituitary tissue) and Low Risk Tissue (CSF, kidney, liver, spleen, lung, placenta, nasal/olfactory epithelium, lymph nodes) and Critical/Semicritical Items from high-risk patients:
- Contact should be made with Central Processing Department (CPD) prior to sending instruments in this category for cleaning and disinfection, to inform them they will be receiving instruments that are from a patient known **or** suspected to have CJD.
  - The items should be labeled “CJD” so the CPD employee receiving them will know they are the ones that will require special processing.
  - Keep instruments moist (either wet by immersion in water or a detergent with prionicidal activity or, if not possible, by use of a wet cloth draped over the instruments or use of a transport gel/foam) after use and during storage/transport prior to decontamination in Central Processing. This will retard adherence of material to the medical device.
  - The CJD instruments should be decontaminated and reprocessed as soon as possible using the following 3 steps:
    1. Wearing gloves, place instruments in an autoclave at at 134° C for 18 minutes in a prevacuum sterilizer.
    2. After autoclaving, place the CJD instruments only in the Belimed washer/disinfector. Note that this washer/disinfector uses fresh water for all cycles therefore at completion it is ready for use with other instruments.
    3. After removal from washer/disinfector, assemble/package instruments and autoclave at 134° C for 18 minutes in a prevacuum sterilizer.

Note: No other instruments/devices may be in the washer basket or sterilizer with CJD exposed instruments.

- Discard devices that are impossible to clean.
- Immediate-use steam sterilization should not be used for reprocessing.
- Items requiring low temperature sterilization (e.g., ethylene oxide, hydrogen peroxide gas plasma) should be discarded.
- Contaminated items not processed according to these recommendations should be recalled and appropriately reprocessed (e.g., medical devices used for brain biopsy prior to diagnosis).

- ii. No Risk Tissue (refer to Appendix 1) and Critical/Semicritical Medical Device: These devices can be cleaned and disinfected or sterilized using conventional protocols or heat or chemical sterilization, or high-level disinfection as appropriate. Endoscopes, in general, would be contaminated only with low or no-risk materials and hence, standard cleaning and high-level disinfection protocols would be adequate for reprocessing.

#### 4. Percutaneous Exposure to High Risk Tissues (Brain, Spinal Cord, Eyes)

- a. Percutaneous exposure to high risk tissues may be followed by washing with detergent and copious water (avoid scrubbing), rinsing and drying. Although scientifically unproven, it has been suggested in the literature that the wound should be immediately cleansed with a 1N sodium hydroxide solution for 5-10 minutes, followed by extensive rinsing with running water. However, this solution must not be used on or near the

- mucous membranes of the face. Mucous membrane exposure should be managed by irrigating the mucous membrane thoroughly with saline for several minutes. Major injuries (e.g., large wound or deep laceration) should not be immersed in the solution.
- b. 1N sodium hydroxide may be obtained by calling Hospital Epidemiology (984-974-7500) during normal business hours or by paging the Infection Preventionist (IP) on call after hours, on weekends and holidays (123-7427). If indicated after consultation with an IP, the solution should be kept in a secure place (i.e., out of the reach of children) such as the clean utility room on the patient's unit. The solution will be clearly labeled as to content, directions for use, and expiration date. Sodium hydroxide is a hazardous substance. Protective eyewear and gloves should be worn during use. 1N sodium hydroxide should be returned to Hospital Epidemiology when no longer needed.
  - c. A freshly prepared 0.5% or 1:10 dilution of sodium hypochlorite (i.e., household bleach) may be used instead of the 1N sodium hydroxide solution. Cleanse the wound with bleach and water solution for 5-10 minutes, followed by extensive rinsing with running water. This solution should not be used on or near the mucous membranes of the face. Major injuries (e.g., large wound or deep laceration) should not be immersed in the solution. Sodium hypochlorite may be obtained from Central Distribution.
  - d. After cleansing of the wound, the injured employee should contact the appropriate occupational health service (Hospital Employees-Occupational Health Service at 984-974-4489 or Needlestick Hotline at 984-974-4480 after hours; University Employees contact University OHS at 984-974-9119 or Healthlink at 984-974-6302 after hours). For large wounds or deep laceration after hours, employees should be seen in the ED as soon as possible.
5. For further information, contact Hospital Epidemiology at 984-974-7500 for any questions or problems that may arise while caring for a patient with suspected or known CJD. The Infection Preventionist on call 24/7 may be contacted on pager 123-7427.
  6. Although autopsies are not currently performed on known/suspected CJD patients at UNC Health Care System there is a CJD Autopsy Protocol (Appendix 2) as a reference for research or for future reference.
  7. Communication
    - a. Hospital Epidemiology, Central Processing, Microbiology, and Perioperative Services should be notified prior to any neurosurgical procedure on a patient with known or suspected prion disease or a High Risk CJD patient (section IIIA). The attending physician is responsible for communicating with Hospital Epidemiology and other involved departments (e.g., Perioperative Services, Neurophysiology, Pathology) when a patient with known or suspected CJD is scheduled for any invasive procedure in which there may be exposure of personnel or instruments to potentially infective tissue.
    - b. Prion sterilization procedures will be used on all contaminated neurosurgical instruments from patients undergoing a brain biopsy when a specific lesion has not been demonstrated (e.g., via MRI, CT). This is to minimize the possibility of use of potentially contaminated neurosurgical instruments from patients later diagnosed with CJD. Since only the neurosurgical attending would be aware of patients meeting this criterion, Hospital Epidemiology, Central Processing and Perioperative Services must be notified when suspected cases are scheduled for the operating room.
    - c. Follow-Up by Hospital Epidemiology: Upon notification that a patient with known or suspected CJD has been admitted for an invasive procedure in which there may be exposure of personnel or instruments to the potentially infective substances, Hospital Epidemiology personnel will do the following:

- i. Investigate if the patient has had or is scheduled to have a brain biopsy or other surgical procedure that may involve contact with potentially infectious tissues. If surgery is scheduled and may involve contact with potentially infectious tissues (i.e., brain biopsy), notify OR personnel and Central Processing Manager to ensure that all reusable instruments are appropriately resterilized. Advise regarding packaging and transport of contaminated instruments to CPD. If a brain biopsy or other procedure involving potentially infectious tissues has been done prior to diagnosis, CPD will be instructed to track all instruments for recall.
- ii. Advise OR personnel preparing specimens for transport to Anatomic Pathology that all specimen containers must be properly labeled and tightly closed. Special procedures for fixing tissues possibly infectious with CJD are required.
- iii. Contact 3 departments:
  - Anatomic Pathology: Notify the Histology Supervisor at 843-1082 of a specimen coming to the lab including the patient's name and differential diagnosis. A formalin-formic acid procedure is required for inactivating virus infectivity in tissue samples from patients with CJD. For further lab guidelines, refer to Appendix 2 of this policy.
  - Neurophysiology: EEG leads contaminated with high risk tissues must be sent to Central Processing Department and are to be sterilized as described above (IIIB3bi). Alternatively, they may be discarded in a needle disposal container. EEG leads that have had only skin contact may be reprocessed in the conventional manner.
  - Central Processing Department: Provide advice regarding safe transport and proper sterilization techniques for reusable critical and semicritical items by CPD staff.
- iv. Provide 1N sodium hydroxide solution if needed for a percutaneous exposure to high risk tissue. This solution is formulated by the Pharmacy in the Special Formulations Department and a bottle is kept in the Hospital Epidemiology lab.
- v. In the event of patient death, Hospital Epidemiology will ensure that the morgue and funeral home are notified that the patient has CJD.

#### **IV. Reviewed/Approved by**

Hospital Infection Control Committee

#### **V. Original Policy Date and Revisions**

Revised on Aug 2004, Sept 2006, Dec 2009, Dec 2012, April 2015

**Appendix 1: Comparative Frequency of Infectivity in Organs/Tissue/Body Fluids of Humans with CJD and other TSE**

<b>Infectious Risks</b>	<b>Tissue</b>
High	Brain (including dura mater), spinal cord, posterior eyes, pituitary tissue
Low	Cerebrospinal fluid, liver, lymph node, kidney, lung, olfactory epithelium, spleen
None	Peripheral nerve, intestine, bone marrow, whole blood, leukocytes, serum, thyroid gland, adrenal gland, heart, skeletal muscle, adipose tissue, gingiva, prostate, testis, placenta, tears, nasal mucus, saliva, sputum, urine, feces, semen, vaginal secretions, milk.

## **Appendix 2: Creutzfeldt-Jakob Autopsy Protocol for Anatomic Pathology Personnel**

Special precautions need to be taken when performing autopsies in cases suspected of having the Creutzfeldt-Jakob agent because a subpopulation of the virus is very resistant to deactivation. This protocol is designed to protect the pathologist as well as prevent contamination of the morgue.

Protective gowns, gloves, shoe covers, masks and eye shields must be worn. Unless otherwise indicated, dissection should be performed within the opened body bag and should be limited to the brain. The dissection will be performed by one of the neuropathology attendings with the aid of a resident or fellow. After organ biopsies are frozen at –70 degrees C for virus identification, the intact brain will be fixed in formalin for at least 10 days prior to cutting. Tissue blocks are agitated in at least 50-100 ml of 95-100% formic acid for 1 hour and then are returned to formalin for 2 days prior to embedding. Alternatively, the necessary diagnostic section from the fresh brain is fixed in formalin for 2-7 days, treated with formic acid for 1 hour and fixed again in formalin for 2 days.

The remains should be kept within a sealed body bag and identified as contagious. All instruments should be placed in a pan and steam sterilized in a gravity displacement sterilizer for 60 minutes at 132 degrees C (134 degrees C in a prevacuum sterilizer for 18 minutes). Disposable items can be discarded in an appropriately marked disposal container (red bag with Biohazard label) and are incinerated.

In the event of a percutaneous exposure to high-risk tissue (brain, spinal cord, eyes), follow the recommendations in this policy.