### Handling Specimens Suspected for Prion Disease (CJD)
Department of Clinical Laboratories
The Ohio State University Wexner Medical Center

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<th>Original Date Adopted:</th>
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<tr>
<td>Gross Room</td>
<td>Policy</td>
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<td>GR1-41, Revision 3</td>
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<th>Document Author:</th>
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<td>All Gross Room laboratory personnel</td>
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### Approval**:
Surgical Pathology Director  
New York Laboratory Medical Director  
University Hospitals Laboratory Medical Director

### *Approval and Acknowledgements*
Refer to Q-Pulse system and Document Details report for laboratory directors(s) electronic signature approval, employee acknowledgment and effective date
1. **PRINCIPLE**
   To safely handle and gross a specimen in the Gross Room with suspected prion disease, [e.g. Creutzfeldt-Jakob disease (CJD)]. Transmissible Spongiform Encephalopathies (TSEs) are fatal degenerative brain diseases that occur in humans and certain animal species. They are characterized by microscopic vacuoles and the deposition of amyloid (prion) protein in the grey matter of the brain.

2. **SPECIMEN COLLECTION:**
   Refer to the *Specimen & Container Labeling Requirements* policy

3. **REAGENTS/SUPPLIES:**
   3.1. **Materials** – ink, paper towels, gauze, formalin neutralizing pad, tissue paper/tissue bags, applicators
   3.2. **Instruments/Tools** – forceps, scalpel, long handled knives, scissors, ruler, probe, spatula, cassette basket/lid in formalin bucket, instrument holders/cups
   3.3. **Reagents/Chemicals** – saline/water, acetone/vinegar, formalin, disinfectant/cleanser

4. **SPECIAL SAFETY PRECAUTIONS**
   4.1. Transmissible Spongiform Encephalopathies (TSE) are not known to spread by contact from person to person, but transmission can occur during invasive medical interventions
   4.2. Infectivity is found most often and in high concentration in the central nervous system (e.g. brain, spinal cord, and eye)
   4.3. Low infectivity tissue includes CSF, kidney, liver, lung, lymph nodes, spleen and placenta. **Most other tissue, including blood, has no detectable infectivity.**

<table>
<thead>
<tr>
<th>Risk of Infection</th>
<th>Tissue</th>
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<tr>
<td>High</td>
<td>Brain (including dura mater), spinal cord, eye (e.g., corneas), pituitary tissue</td>
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<tr>
<td>Low</td>
<td>CSF, liver, lymph node, kidney, lung, spleen, placenta, olfactory epithelium</td>
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<tr>
<td>None</td>
<td>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 and milk</td>
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4.4 Cutaneous exposure of intact skin or mucous membranes (except those of the eye) poses negligible risk
4.5 Lab personnel grossing specimens must observe Standard Precautions including personal protective equipment (PPE) appropriate for a Biosafety Level 2 environment
4.6 Single-use protective clothing should include:
   4.6.1 Gloves
   4.6.2 Disposable laboratory coat/protective apron and sleeves
   4.6.3 Face shield
4.7 For tissues, secretions, or excretions with *low or no detectable infectivity* (see chart above), no special requirements beyond Standard Precautions are required for the handling of body fluids or body-fluid contaminated linen, equipment or environments
4.8 No frozen sections will be performed on tissue confirmed or suspected of TSE
5. QUALITY CONTROL:
   5.1 To avoid cross contamination with subsequent cases, the following precautions should be taken for tissue types that pose a low or high risk of infectivity:
   5.1.1 Cut surgical specimens on a clean chuck/diaper placed on top of a clean cutting board, but preferably, within the lid of the container as to not contaminate any laboratory surfaces
   5.1.2 Use disposable forceps and scalpel/razor blade
   5.1.3 Change gloves when case is complete
   5.2 For tissues, secretions, or excretions with low or no detectable infectivity (see chart above), no special requirements beyond Standard Precautions are required for the handling of body fluids or body-fluid contaminated linen, equipment or environments.

6. TEST PROCEDURE:
   6.1 The following will occur in the operating room for suspect CJD cases:
   6.1.1 When a case potentially contaminated with prions (CJD) is scheduled in the OR, the circulating nurse will call Pathology to alert them of the procedure
   6.1.2 When specimens are collected, they are placed in appropriately labeled containers including “potentially contaminated with prions (CJD)” written after the tissue description, as well as, have a bright sticker labeled “potentially contaminated with prions (CJD)” applied elsewhere on the container
   6.1.3 The specimen order is entered into IHIS and “potentially contaminated with prions (CJD)” is typed into the description box next to the tissue description. A bright sticker labeled “potentially contaminated with prions (CJD)” is also applied to the requisition.
   6.1.4 When manually filling out a frozen section form, the pre-op diagnosis should state “potentially contaminated with prions (CJD)” and a bright sticker labeled the same will be applied to the frozen section requisition.
   6.2 No frozen section will be performed on tissue suspected for TSE. Any frozen section form completed with a sticker and pre-op diagnosis of “potentially contaminated with prions (CJD)” should induce a hard stop.
   6.3 Discussion with the neuropathologist on-service (or director of neuropathology) or the Director of Anatomic Pathology (if the neuropathologist is not available) should occur before deciding whether the specimen should be partly processed here or the entire specimen should be sent to the CJD Surveillance National Prion Disease Pathology Surveillance Center in Cleveland, Ohio
   6.3.1 If all tissue is not to be sent to the surveillance center, snap freeze 30% of the specimen and store in the -80 freezer until results are received from the surveillance center.
   6.3.1.1 Write the measurements and description of the entire specimen on a frozen section form and store with the frozen tissue. Indicate on the form how much tissue was sent to the surveillance center.
   6.3.1.2 To snap-freeze, do not dip the tissue into the liquid nitrogen container. Under the hood, ladle the liquid nitrogen over the mold filled with the OCT and tissue over a metal receptacle (empty dewar or metal tray).
   6.3.2 A result from the surveillance center must be received before CJD-suspected tissue will be processed at OSU Wexner Medical Center
   6.3.3 If negative results are received from the surveillance center, submit the tissue for processing
   6.3.4 If positive results are received from the surveillance center, the tissue will be disposed as per instructions listed in the Clean-Up Procedure below
6.4 If any part of the specimen is to be sent to the surveillance center, then the testing form should be printed from Q-Pulse, thoroughly completed and the specimen should be packaged and shipped as per instructions on www.cjdsurveillance.com.

7. **CLEAN UP PROCEDURE:**

7.1 TSE agents exhibit an unusual resistance to conventional chemical and physical decontamination methods. They are not adequately inactivated by most common disinfectants, or by most tissue fixatives, and some infectivity may persist under standard autoclaving conditions.

7.2 For tissues, secretions, or excretions with low or no detectable infectivity (see chart above), no special requirements beyond Standard Precautions are required for the handling of body fluids or body-fluid contaminated linen, equipment or environments.

7.3 For tissues with high risk infectivity (see chart above), proceed with decontamination and waste disposal as follows:

7.3.1 Double-bag the chuck/diaper, non-sharp disposable instruments and protective clothing. Tie off the outer bag by gathering and twisting the neck of the liner and hand knot (gooseneck tie)

7.3.2 Label the bag "suspected CJD waste" and immediately transport the bag to the Morgue for proper disposal

7.3.3 Once in the morgue, the double-bagged CJD waste bag will be placed into a biohazard bag-lined corrugated box and be sent for incineration

7.3.4 Discard the disposable scalpel/razor in the sharps container

7.3.5 Flood and/or soak any non-disposable instruments and surfaces with household bleach (6.15%) for one hour, followed by a water rinse

8. **REFERENCES:**

   Lab Safety-29

9. **RELATED DOCUMENTS**

   Refer to Q-Pulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms