Describe briefly the most recent revision made to this policy, procedure or protocol & why:
New Procedure

Purpose/Policy Statement:
CJD is caused by an infectious agent known as a prion. Expanded decontamination practices beyond Universal Precautions are expected to minimize infection occurrences by this agent in laboratory staff.

1. Suspected cases of CJD are from patients demonstrating the following clinical symptoms:
   - CJD
   - rapidly progressive dementia
   - dementia with seizures, especially myoclonic seizures
   - dementia associated with cerebellar or lower motor neuron signs

2. All specimens shall be clearly labeled at the collection site as WARNING/BIOHAZARD/CJD and placed immediately into 10% Neutral Buffered Formalin (NBF) fixative.

3. The diagnosis of CJD on brain biopsy is not categorized as an emergency diagnosis. There is no justification for a frozen section in suspected cases of CJD and no frozen section will be performed.

4. Following 24 hour fixation in 10% NBF, decontamination of suspected prion-containing tissue is achieved by post-fixation in 95% Formic Acid for two hours before being returned to either formalin or glutaraldehyde.

5. Brain biopsies are small enough that no dissection at the grossing bench is required.

6. The least disruptive method for processing is manual. This avoids a decontamination procedure for the entire automated processing system after handling one case.

7. No autopsy will be performed at Salem Hospital on a patient demonstrating the following clinical symptoms:
   - CJD
   - rapidly progressive dementia
   - dementia with seizures, especially myoclonic seizures
   - dementia associated with cerebellar or lower motor neuron signs
   These autopsy cases will be sent to Oregon Health Sciences University for post mortem examination.

Definitions:
- n/a
**STEPS / KEY POINTS**

**PROCEDURE:**
1. Fix specimen (small brain biopsies) in 10% NBF for at least 24 hours.
2. Transfer the tissue to 95% Formic Acid for at least 2 hours to complete denaturation.
3. Process tissue manually as follows:

<table>
<thead>
<tr>
<th>10-hour processing schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MANUAL DEHYDRATION and CLEARING</strong></td>
</tr>
<tr>
<td>60% EtOH</td>
</tr>
<tr>
<td>95% EtOH</td>
</tr>
<tr>
<td>95% EtOH</td>
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<tr>
<td>100% EtOH</td>
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<tr>
<td>100% EtOH</td>
</tr>
<tr>
<td>Xylene</td>
</tr>
<tr>
<td>Xylene</td>
</tr>
<tr>
<td><strong>TISSUE PROCESSOR INFILTRATION</strong></td>
</tr>
<tr>
<td>Paraffin</td>
</tr>
<tr>
<td>Paraffin</td>
</tr>
<tr>
<td>Paraffin</td>
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<tr>
<td>Paraffin</td>
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</tbody>
</table>

**NOTE:** Following each solution use, treat each reagent with an equal volume of fresh Concentrated Sodium Hypochlorite for 60 min. prior to disposal. Decontaminate all non-disposable accessories as in Step 5 below.

1. Extra care when cutting blocks is prudent: utilize maximum PPE. Following microtomy, immediately contain secured paraffin shavings in a biohazard bag for incineration.
2. Following microtomy, decontaminate all non-disposable accessories by immersion in 2N Sodium Hydroxide solution for one hour. Decontaminate all work surfaces with 2N Sodium Hydroxide; allow the solution to stand for five minutes before drying. These treatments may also be followed with recommended autoclave sterilization at 134°C for 20 min. or 132°C for 1 hour.
3. Contain broken slides in a biohazard bag for incineration.
4. Surface seal paraffin blocks, store in a heat-sealed pouch and label **WARNING / BIOHAZARD / INFECTIOUS / CJD**.

**CALCULATIONS:** N/A

**CALIBRATION:** N/A

**QUALITY CONTROL:** None.

**PROFICIENCY TESTING:** None.

**RESULTS:** N/A

**PROCEDURE NOTES:**
Use Concentrated commercial-grade Sodium Hypochlorite on all work surfaces and non-disposable accessories that will not be destroyed by corrosion; additionally use 2N Sodium Hydroxide as a secondary decon-tamination step; follow these treatments with recommended autoclave sterilization at 134°C for 20 min. or 132°C for 1 hour.

**LIMITATIONS OF PROCEDURE:** None
Equipment/Supplies (If Applicable):

SPECIMEN: Brain biopsy tissue from patients with undiagnosed encephalopathy or dementia.

MATERIALS, REAGENTS:

Concentrated Sodium Hypochlorite (chlorine bleach)  95% Formic Acid

<table>
<thead>
<tr>
<th>Equipment/Supplies</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Alcohol</td>
<td>95%, 100%</td>
</tr>
<tr>
<td>2N Sodium Hydroxide</td>
<td>1 L</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>800 gm</td>
</tr>
<tr>
<td>Xylene</td>
<td></td>
</tr>
<tr>
<td>Paraffin</td>
<td></td>
</tr>
</tbody>
</table>

DISPOSABLE PERSONAL PROTECTIVE EQUIPMENT (PPE)

“It Kit” (Infectious Tissue kit) Marketing International #5750

Lab coat
Apron
Gloves
Goggles
Mask
Faceshield
Ventilation hood with HEPA filter cartridge

Form Name & Number or Attachment Name (If Applicable):
surgpath23

Author Position:
Histology Supervisor

Review/Revision Authority (Position Not Individual Name):
Medical Director, Operation Manager, Histology Supervisor, Pathologist Assistant

Expert Consultant Position/s (Not Individual Name/s):
n/a

References (Required for Clinical Documents):

MANUFACTURER’S PACKAGING BROCHURE/INSERT: NONE.

Is there a Regulatory Requirement? Yes ☐ No ☐
If yes, insert requirement information here:

Review History (No Changes):
n/a
Revision History (Note changes in area under header):
n/a

Computer Search Words:
n/a

Policy, Procedure or Protocol Cross Reference Information:
n/a