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Office of Origin: Hospital Epidemiology and Infection Control

I. PURPOSE

- To prevent transmission of prions to personnel, other patients or the community
- To describe appropriate confinement, containment, safe handling, disinfection, and disposal of contaminated materials and tissues generated during the course of hospitalization

II. REFERENCES

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III. POLICY

Appropriate precautions are taken to safely manage materials from any patient with suspected or confirmed prion disease and transmissible spongiform encephalopathy (TSE) in order to prevent transmission and avoid exposure to personnel, other patients, or the community. At UCSF, the most commonly-seen Human Prion Diseases include: sporadic Creutzfeldt-Jakob disease (sHuman Prion Disease), familial Creutzfeldt-Jakob disease (fHuman Prion Disease), and Gertsmann-Straussler-Scheinker disease (GSS).

IV. PROCEDURES

A. Routine Care Of Patients

1. Patients with Human Prion Disease can be cared for using Standard Precautions.
2. A private room is not required for infection control purposes.
3. Patient waste will be handled in accordance with hospital policy (Environment of Care Manual 3.1.0).
4. Liquid body substances such as blood, urine, bile, vomitus, or other secretions/excretions, and stool are disposed of in the sanitary sewer (toilet, hopper, or lab sink) in a manner that limits splash.
5. Feeding utensils, feeding tubes, suction tubes, or items used in skin or wound care, and bed linens are handled as per routine.

B. Non-Routine Care of Patients

1. Lumbar Puncture of patient in whom Human Prion Disease is confirmed or is in the differential diagnosis

a. Room Set-up

i. The patient will be in a procedure room or a room with roommate absent during a lumbar puncture procedure.

ii. Order a Human Prion Disease Lumbar Puncture Kit that contains the supplies needed for the procedure from Material Services. Human Prion Disease Lumbar Puncture Kit contains:

a) Infection Control Procedure for Patients with Human Prion Disease
b) Disposable Lumbar Puncture Tray
c) 4 long-sleeved fluid repellant disposable gowns
d) 4 masks with face shield
e) 2 alternative eye protection goggles
f) 2 face masks without face shield
g) Signage for patient room "Procedure in Progress Do Not Enter"
h) One quart size sharps container
i) Occlusive dressing material to cover LP site: 2 sterile 2x2's and 2 (two) 10 cm x 8 cm transparent dressings
j) 3 yellow chemical hazardous waste bags for disposal materials contaminated with any materials used during the LP procedure.
k) 3 OEH&S Hazardous Waste Tags, one for each bag, are located in the kit. Contact OEH&S at 415-412-8402 to request pick-up for all Prion-Disease contaminated waste.

iii. Post a sign on the door of the room to indicate "Procedure in Progress Do not Enter"

iv. All personnel assisting with the procedure must wear personal protective equipment.

b. Prevent contamination of work surfaces with Cerebrospinal Fluid (CSF):

i. Cover immediate exposed bed, linen, and bedside table with disposable impermeable barriers.

ii. Set up a sterile field next to patient with a disposable impermeable barrier.

iii. Place a sharps container in close proximity to the LP procedure area. The used lumbar puncture needle and all sharps used during the procedure shall be discarded in this container.

c. Personal Protective Equipment

i. All health care workers performing or assisting with the procedure who may come in contact with CSF must wear the following personal protective equipment:

a) Long sleeve fluid repellant gown
b) Face protection to include eyes, nose and mouth protection (mask with face shield or mask with goggles. Prescription glasses do not provide adequate eye protection).
c) Gloves. MD performing the procedure will wear double sterile gloves.
d) Dispose of all used PPE in yellow chemical hazardous waste bag.

i.) UCSF Office of Environmental Health and Safety (OEH&S) has a specific waste profile set up with chemical waste vendor Stericycle (formerly PSC). This profile specifies that the waste must be incinerated by Stericycle. This is verified and tracked by us on the Hazardous Waste

Manifest. Upon request OEH&S can provide verification that Human Prion Disease waste was treated appropriately by incineration.

d. Transport of specimen(s) to the lab

i. CSF may be infectious and must be handled with care. CSF will be bagged in leak-proof specimen bags and labeled "Human Prion Disease Precautions."
ii. Document where specimen will be delivered, who will be transporting the specimen, and notify the lab receiving the specimen that it has been collected.
iii. Lab personnel shall use universal precautions when handling specimens (see laboratory procedures below).

e. Post-Procedure Waste

i. Gown: Remove patient's gown if contaminated with CSF during the procedure and discard in yellow chemical hazardous waste bags (not to be confused with yellow personal effects bags).
ii. Dressing: Discard any dressing used to cover the lumbar puncture site in yellow chemical hazardous waste bag.
iii. Sharps: Discard the sharps container and all disposable items into yellow chemical hazardous waste bag. See IV.B.1.c.(d) i) for incineration responsibilities.
iv. Linen: Remove disposable barriers covering the linen. Discard any linen contaminated with CSF in the yellow chemical hazardous waste bag. Linen that has not been contaminated with CSF during the procedure can be placed in the in-room covered linen container for usual reprocessing
v. Complete and affix Hazardous Waste tag to each yellow bag and discard into **white barrels marked Human Prion Disease Waste Only**.
   a) White barrels are permanently located in ACC, OR, 12GCRC, and 8L dirty utility room. A white barrel is also located at 675 Nelson Rising Lane, Suite 130 Neurosciences Clinical Research Unit for LP procedures. No other white barrels are permanently located on 3rd floor Radiology Parnassus, Mission Bay, or Mount Zion. For units without access to white barrels or secure storage, contact Hospitality Services at 353-1283 to request a white barrel for a specific procedure.
   Contact OEH&S to request pickup
      - Parnassus M-F 7:30a-4:30: 415-412-8402.
      - Mission Bay M-F 7:30a-4:30p 415-514-4107
      - Weekends/holidays both Parnassus and Mission Bay: 415-412-8402
      - Maintain in a secured area until picked up by OEH&S.
   b) For units without access secure storage:
      - Discard contaminated linen as directed above.
      - Contact Hospitality Services to pick-up the white barrel
      - Hospitality Services will notify OEH&S to request pickup
      - Hospitality Services will store white barrel with yellow chemical hazardous waste bag in its Stericycle Storage Unit until OEH&S is able to pick up.

f. Standard Post-procedure Room Cleaning

i. **No CSF contamination has occurred**: Standard room and surface cleaning is appropriate.
ii. **CSF-Contamination**: Work Surface Clean-up Procedure

i) Any person in the room may identify a potentially contaminated CSF spill, and all have equal responsibility to order a contaminated clean-up procedure.
ii) Obtain Human Prion Disease Spill Kit from Hospitality Services, by calling 353-1283.
   i.) Human Prion Disease Spill Kit contains:
      a) One copy of this policy
      b) Three fluid repellant gowns
      c) Three masks with face shields
      d) Three alternative eye protection goggles and masks
      e) Blue high-risk gloves (2 medium and 1 large)
      f) Three pairs of fluid repellant leg and shoe covers
      g) Six yellow chemical hazardous bags
      h) Six OEH&S chemical hazardous waste tags
      i) Information sheet to contact OEH&S for waste pick-up
      j) Two liters 1N sodium hydroxide (for surface cleaning—see below)
      k) Two liters 2N sodium hydroxide (for use in suction canisters)
      l) One box extra strength shop rags
      m) One mop head
      n) MSDS sheet for sodium hydroxide
   ii.) White waste barrel is available by request from Hospitality
   iii.) Designated barrels are located in ACC, OR, 8th floor, GCRC
iii) PSA's will wear fluid repellant gowns, eye, nose and mouth protection, leg and shoe covers, and blue high-risk gloves for cleaning the room.
iv) Use 1N sodium hydroxide to wipe down all surfaces that have come in contact with the CSF, including the bed, bed rails and bedside table.
   i.) 1N sodium hydroxide will be poured onto rags to damp wipe.
   ii.) Damp wipe area generously with the 1N sodium hydroxide solution and let sit undisturbed for one hour.
   iii.) If CSF fluid has splashed onto floor, clean floor by carefully pouring small amounts of 1N sodium hydroxide directly onto floor at floor level, taking care not to splash. Use all of the 1N sodium hydroxide
      1) Allow to air dry for one hour.
      2) Rinse area thoroughly with water.
      3) Clean the floor and surrounding area according to standard procedure.
      4) Discard the empty container into a yellow hazardous waste bag.
      5) CAUTION:
         - Do not use mop bucket.
         - Do not use spray bottles, in order to prevent creating breathing hazard,
         - Sodium hydroxide must not come in contact with strong acids, flammable liquids and solvents, e.g., acetone.
v) Double bag all cleaning equipment, e.g., rags and mop heads that have come in contact with 1N sodium hydroxide into separate yellow hazardous waste bags.
vi) Complete and affix Hazardous Waste tag to each yellow bag and discard into white barrels marked Human Prion Disease Waste Only, located in ACC, OR, 8th floor, GCRC. Contact OEH&S to request pickup 415-412-8402. Maintain in a secured area until picked up by OEH&S.

2. Clinical Laboratory

a. Handling CSF specimens

i. All CSF specimens will be considered potentially infectious for Human Prion Disease and will be handled the same as CSF specimens from patients known or suspected to be infected with Human Prion Disease.
   a) At a minimum, staff will wear gloves and lab coats at all times when working with CSF specimens and slides.
   b) Where the potential for splash exists, work will be done behind a plexiglass shield, within a biosafety cabinet or face shields will be worn (protective eye wear and mucosal protection).
   c) One pair each of medium and large scrubs will be available in the Chemical Spill Materials cabinet in L554 (Chemistry). If lab coat or personal clothing is contaminated with the splash, remove garment and place in a red biohazard bag, which will then be placed in a red-lined Pathology Waste container. Scrubs are available at **each laboratory site.**

ii. In each section, a work area will be defined for handling CSF specimens. The area will be covered with an absorbent barrier drape, which will be changed once per shift or after a CSF spill.

iii. All CSF specimens will be spun down in disposable, capped containers. Specimens received in Central Processing that require centrifugation will be spun down in the original plastic, capped collection tube, then distributed in capped tubes to the sections (Chemistry, Immunology) or poured off for Send Out. ~~Specimens received in Central Processing will be spun down in the original plastic, capped collection tube, then distributed in capped tubes to the sections (Chemistry, Immunology) or poured off for Send Out. When preparing smears, specimens received in Hematology and Microbiology will be pipetted into disposable plastic funnels, capped and spun down in the cytocentrifuge in each section. If a sample is re-spun in Immunology, it will be spun down in a capped, disposable tube or funnel.~~

iv. Used CSF funnels and collection tubes, and all remaining CSF after testing is completed will be placed in the pathological waste tub (including from patients with known or suspected Human Prion Disease).

v. All equipment (e.g. inside cover of cytocentrifuge) and work areas used to process CSF specimens will be wiped down once every shift with 20,000 ppm or 2% sodium hypochlorite (most commercial household bleach contains 5.25% or about 50,000 ppm sodium hypochlorite. To produce 20,000 ppm sodium hypochlorite, make a 1:1.5 dilution of bleach with water (1 part bleach + 1.5 parts water)) and allowed to dry for 10 minutes. The work area will be re-covered with a barrier drape.

vi. Due to the need to wipe down microscopes, the number of scopes used to review CSF slides will be kept to a minimum. Reusable supplies (e.g. counting chambers) will be soaked in full strength household bleach for one hour after use on CSF specimens.

b. Each section will process CSF specimens as follows:

i. **Chemistry:**
   a) Pour CSF into disposable cup and run sample through automated analyzers.
   b) Sample will then be discarded in regulated pathological waste.
   c) When required, unused CSF will be returned to Central Processing for distribution to Immunology.

ii. **Immunology:**
   a) CSF specimens will be pipetted into open disposable well of automated analyzer or tubes for analysis.
   b) After testing, the specimen will be discarded in regulated pathological waste.
   c) CSF specimens will also be placed onto non-disposable slides, rotated 8 minutes, then read on the CSF microscope.
   d) The non-disposable slides will be soaked in full strength bleach for one hour.
   e) The barrier drape on the rotator surface will be changed after each use and the rotator lid wiped down with a 20,000 ppm or 2% sodium hypochlorite towelette and air dried for 10 minutes.
   f) The CSF microscope will be wiped down according to manufacturer's recommendations.

iii. **Hematology**:
   a) CSF specimens will be pipetted onto a counting chamber and read.
   b) After cytocentrifugation, all CSF slides will be processed on the strainer.
   c) Microscopes used to review CSF slides will be wiped down according to manufacturer's recommendations.
   d) All non-disposable supplies (e.g. counting chambers) will be soaked in full strength household bleach for 1 hour after use on CSF specimens.

iv. **Microbiology**:
   a) The areas for handling CSF specimens will be covered with an absorbent barrier drape.
   b) When preparing smears, spun CSF specimens will be pipetted onto a slide, dried on a heating block and stained.
   c) The slide will then be read on a designated microscope and stored in a designated slide box.
   d) Gloves will be worn when using the microscopes or when handling and staining CSF slides.
   e) Disposable supplies will be used when plating CSF specimens and the supplies discarded in the pathological waste tubs after use.
   f) The following work areas will be cleaned with 10% household bleach once per shift or after a CSF spill and the absorbent barrier drape changed: specimen processing biological safety cabinet, antigen testing area (work surface of plexiglass shield, heating block, slide rotator surface, and rotator lid), work area adjacent to the microscope for reading CSF smears, and PCR biological safety cabinet in pre-PCR room.
   g) The microscope will be cleaned according to manufacturer's recommendations. Non-disposable supplies, such as Cryptococcus antigen latex agglutination slides, will be soaked in full strength bleach for one hour after use with CSF specimens.

v. **CSF Spills**
   a) After any CSF spill, the area of contamination will be cleaned.

b) If the spill is contained on the barrier drape, the work area and equipment (where practical) will be cleaned with 10% household bleach and air dried for 10 minutes.
c) If the spill occurs other than on the barrier drape, the area will be flooded with full strength household bleach and allowed to air dry.
d) Materials used to clean the spill (cloth or paper towel, absorbent barrier etc.) will be placed in the regulated pathological waste tub.
e) If an exposure occurs, refer to section XIII, Occupational Exposure.

3. Pathology (refer to Pathology Department's internal policy)

a. Tissue Handling

i. All tissue samples identified as "high" infectivity or risk (see Table 1) will be treated as potentially infectious and will be handled as follows.
   a) Personal Protective Equipment:
      - All staff will wear, at minimum, gloves and a lab coat at all times when working with these specimens.
      - work will be done behind a plexiglass shield, within a biosafety cabinet or face shields (protective eye wear and mucosal protection) will be worn in conditions under which aerosolization may occur,.
   b) The work area for these tissues will be defined and protected by a disposable barrier drape.
   c) When possible, disposable supplies will be used in the preparation of these tissue samples and will be discarded in the pathological waste tubs.
   d) Sharps used in the preparation of specimens will be discarded in an approved sharps container and then into the pathological waste tub.
   e) After testing, tissue specimens from all sections will be placed in 1N NaOH for 1 hour. Following treatment in 1N NaOH, tissue may be disposed directly into the pathological waste tubs with no further autoclaving.

b. Decontamination after Tissue Specimen Preparation

i. After processing the specimen, the barrier drape will be removed and discarded in the pathological waste tubs.
ii. The work area and all equipment (when feasible) will be wiped down with 10% household bleach and allowed to air dry.
iii. Non-disposable supplies (such as tissue grinders) will be soaked in full strength bleach for one hour.

c. Contamination of the work area:

i. Should contamination of the work area occur, the barrier drape will be discarded in the pathological waste tubs, and the area flooded with full strength household bleach and allowed to air dry.
ii. Materials used to clean the spill (cloth or paper towel, absorbent barrier etc.) will be placed in the pathological waste tubs.
iii. One pair each of medium and large scrubs will be available in the Chemical Spill Materials cabinet in L554 (Chemistry)

4. Imaging

a**. MRI Scan, Fluoroscopic or CT Guided Lumbar Puncture**

i. If procedure is done with anesthesia, an attending anesthesiologist, a registered nurse from Radiology, and the technologist will have the proper supplies for infection control as described in this policy, before the induction of anesthesia.
ii. The exam table will be covered with disposable drapes.
iii. If lumbar puncture is being performed, limit the number of people in the room to those who are essential.
iv. Anesthesia equipment or supplies will be discarded in accordance with recommended anesthesia procedures. (see #7. Anesthesia)
v. After the scan, the table and radiologic equipment will be cleaned by the technologist in accordance with the recommended procedure for cleaning as described above.

5. Perioperative Care For Patients With Suspected Or Confirmed Human Prion Disease

a. All patients with a diagnosis of suspected or confirmed Human Prion Disease require a higher level of infection control precautions in the Operating Room.
b. Surgeons (attending or resident) booking a case must document all suspected or confirmed Human Prion Disease cases in the scheduling system.
c. If the diagnosis is not documented, the scheduling coordinator will contact the surgeon for clarification.
   i. For example, if a Burr hole procedure is booked for 'Brain Biopsy: other' i.e., not for tumor), then it must be clarified with the Neurosurgery service that Human Prion Disease is not on the differential. The scheduling coordinator shall notify the charge nurse immediately if a tonsil biopsy or procedure not involving the neurosurgical service is ordered on a Human Prion Disease patient. Cases should be scheduled early in the day to allow adequate time for cleaning and processing of specimens in surgical pathology.

6. Pre-Operative Handling Confirmed or Suspected Prion-Infected Patients in Preoperative Areas

a. Notifications

i. Scheduling staff or OR front desk staff will notify the pod manager for Neurosurgery.
ii. Pod manager will notify (see Appendix 1 #10 for phone extensions):
   a) Pre-op
   b) PACU
   c) OR Charge Nurse
   d) SPD Manager or Assist manager
   e) Instrument Coordinator/Lead Tech
   f) OR support supervisor
   g) Infection Control
   h) Pathology
   i) OEH&S
iii. The circulating nurse will place the appropriate signage on OR doors.

b. Human Prion Disease Cart

i. The circulating nurse will obtain the Human Prion Disease cart containing supplies from the central storage area in Perioperative Services. Contents include:
   a) a copy of this policy,
   b) yellow chemical waste bags,
   c) blue high-risk gloves,
   d) disposable sterile gowns,

e) face shields,
f) shoe covers,
g) disposable BP cuffs (both pediatric and adult)
h) 1N (normal) sodium hydroxide solution
i) 2N (normal) sodium hydroxide solution
j) isolation sign
k) tags and notification forms for OEH&S.

ii. OR hampers and kick buckets will be lined with yellow chemical hazardous waste bags.
iii. The attending surgeon will determine unit location where the patient will be sent post-operatively.

c. Non-essential Equipment

i. The circulating nurse will remove all non-essential equipment from the room.

7. Anesthesia

a. Procedure

i. Intraoperative anesthesia care will be provided by an Attending only; residents or CRNA's will not be involved.
ii. All anesthesia caregivers must wear Personal Protective Equipment:
a) Long sleeve fluid-resistant gown
b) Eye, nose and mouth protection (e.g., mask with face shield or mask with goggles. Prescription glasses do not provide adequate eye protection)
c) Double gloves
iii. With the exception noted in **7.a.iii. g)**, all equipment that comes in contact with the patient's airway shall be disposed of
a) Disposable laryngeal mask airways (LMA) must be used
b) Disposable laryngoscope blades and handles , or handles covered with a protective jacket must be used.
c) Difficult airway equipment: In the case of a difficult airway where traditional laryngoscopy / LMA are not successful, disposable difficult airway equipment must be used, i.e., Retrograde Wire Intubation.
d) All equipment that comes in contact with the patient's airway must be immediately placed into the yellow chemical hazardous waste bags for pickup by OEH&S. for incineration.
e) Rigid Scopes (Wu, Bullard, Upsher), video laryngoscopes, and fiberoptic intubating equipment should NOT be used, as incineration is the recommended treatment for critical and semi-critical instruments used in patients with known or suspected Human Prion Disease.
f) Equipment is not to contact any other surface.
g) **Exception**: pre-identified and approved critical, heat-sensitive equipment that contacts LOWER Infectivity tissue will be cleaned and disinfected using procedures identified in **Section #10**.
h) Non-airway Equipment: Shall be processed following guidance in Table 1.

b. Anesthesia Machine

i. A HEPA grade filter must be attached directly to the endotracheal tube.
ii. The gas sampling line leading to the respired gas analyzer must be connected only to the sampling port on the circuit side of the HEPA filter.

iii. The machine surface must be cleaned as per routine anesthesia procedure
iv. Disposal of anesthesia equipment that contacts patient's blood or secretions
   a) Non-Sharps: Place in double yellow chemical hazardous waste bags for disposal.
   b) Sharps: Place a dedicated sharps container next to the patient and dispose immediately following use. At the end of case, close and lock this sharps box and place it in a yellow chemical hazardous waste bag.
   c) All yellow chemical hazardous waste bags shall be tagged with the words "Human Prion Disease Precautions."
   d) Transport all yellow chemical hazardous waste bags to the OR staging area to be placed in the white barrel labeled Human Prion Disease waste only for OEH&S pick up.

8. Intra-Operative Procedure

a. Personal Protective Equipment (PPE) includes:
   a. long sleeve disposable gowns
   b. eye, nose and mouth protection
   c. gloves

b. The scrub team will wear:
   i. head protection,
   ii. fluid-impervious sterile gowns
   iii. double gloves,
   iv. face shields
   v. shoe covers.

c. Instrumentation:
   i. For surgical set-up (see Preference Card)
   ii. Obtain the dedicated Human Prion Disease instrument set which includes disposable items
   iii. Immediate Use Steam ("Flash") sterilization is contraindicated. For emergent instrument issues, page SPD Supervisor
   iv. Empty entire 500 ml bottle of 2N sodium hydroxide into suction canister before any procedures.

d. Handling of Specimens:
   i. The circulating RN will invert the specimen bag to cover his/her hand while the scrub nurse is passing off the specimen.
   ii. The circulator will invert the bag over the cup once the specimen is obtained.
   iii. All specimens will be -bagged and labeled with a sticker stating "Human Prion Disease Precautions."
   iv. The circulating RN will notify Pathology to pick up the specimen in the OR at the time of surgery and that Human Prion Disease precautions are required. Specimens will be picked up immediately and not stored in the OR Pathology refrigerator. Specimens may be stored briefly in the surgical pathology refrigerator prior to final transport to the lab.

9. Post-Operative Procedure

a. At the conclusion of the case, the circulator will notify PACU that the patient is ready for transport and that standard precautions are required for caring for patients with Human Prion Disease.
b. All linen used in the Operating Room including bed sheets, bath blankets and towels and any disposable materials *exposed to any patient fluids* must be placed in the yellow chemical waste bags. These bags must be placed in the white Human Prion Disease waste tub in the specified area for Human Prion Disease waste for pick up by OEH&S for incineration.
c. All linen used in the Operating Room including bed sheets, bath blankets and towels and any disposable materials *that has not had any contact with the patient's fluids* can be treated as routine soiled linen and placed in the routine soiled linen bags for routine processing.
d. Pre-approved, heat sensitive airway equipment with contact limited to lower infectivity tissue will be kept moist and labeled for special handling in SPD.

10. Surgical or Procedural Instrument Handling

a. Invasive Procedures On High And Lower Infectivity Tissue In Patients With Confirmed Or Suspected Prion Disease

i. Single-Use Disposable Instruments are Preferred When Feasible
ii. Instruments that contact such tissues (see Table 1) must be treated as indicated. Hence, the risk of prion disease in the clinical diagnosis must be discerned prior to the procedure.
a.) **Patients with *Definite*** (pathology-proven) or ***Probable*** **prion disease** (determined by Neurology service):
i.) Instruments must be destroyed by incineration if they contact HIGH or LOWER risk tissues.
ii.) Instruments that contact tissue with NO DETECTABLE INFECTIVITY can be reprocessed using routine procedures.
iii.) **Patients with *Possible*** **prion disease** (patients in which prion disease is in the differential diagnosis, as determined by the Neurology Service): Instruments must be destroyed by incineration if they contact HIGH risk tissues (see Table 1).
iv.) Contact with LOWER risk tissue: Instruments may be cleaned, then quarantined pending final diagnosis. If prion diagnosis is confirmed, instruments must be destroyed by incineration
v.) Instruments that contact tissue with NO DETECTABLE INFECTIVITY risk (see Table 1) can be reprocessed using routine procedures tissue.
b.) **Patients with Asymptomatic Genetic or Iatrogenic prion disease:**
i.) Instruments must be destroyed by incineration if they contact HIGH or LOWER risk tissues
ii.) Instruments that contact tissue with NO DETECTABLE INFECTIVITY risk (see Table 1) can be reprocessed using routine procedures tissue.
iii. Exception to Destroy by Incineration: Pre-approved, critical, heat-sensitive equipment that contacts only LOWER INFECTIVITY tissue can be disinfected by soaking in 2N NaOH for 1 hour following cleaning in enzymatic cleaner.
a.) SPD is responsible for pre-approval.

b. Exposed Instruments

i. The circulating nurse/anesthesia tech is responsible to:

a) Identify and ensure correct disposal of equipment exposed to HIGH Infectivity Tissue;
b) Hand off to SPD Lead Tech or Supervisor:
    i) Contaminated instruments being sent to SPD will be bagged in a yellow bag and labeled “Human Prion Disease Quarantine”.
    ii) Equipment exposed to LOWER Infectivity Tissue: SPD follows its internal quarantine procedure to clean, quarantined pending final diagnosis, receive notification of final diagnosis, and release equipment from quarantine and either return to circulation or discard.
    iii) Pre-approved, critical, heat-sensitive equipment exposed to LOWER Infectivity Tissue that requires 1 hour soak in 2N NaOH after cleaning with enzymatic cleaner.

Table 1. Tissue Infectivity and Directions for Handling Equipment used for invasive or surgical procedures in patients with confirmed or suspected prion disease.

	Prion Disease Status of Patient (as determined by Neurology Service)			
			Asymptomatic	
WHO Table on Human Tissue Infectivity	Definite/ Probable	Possible	Genetic risk	Iatrogenic risk
IA. High Infectivity Brain Spinal cord Retina Optic nerve Spinal ganglia Trigeminal ganglia Pituitary gland Dura mater	Destroy by incineration	Destroy by incineration	Destroy by incineration	Destroy by incineration
IB. Lower Infectivity Peripheral Nervous System: Peripheral nerves, Autonomic ganglia Lymphoreticular tissues: Spleen, Lymph nodes, Tonsil, Nictitating membrane, Thymus Alimentary tract: Esophagus, Fore-stomach (ruminants only), Stomach/abomasum, Duodenum, Jejunum, Ileum, Appendix, Colon/caeceum, Rectum Reproductive tissues: Placenta, Ovary, Uterus Other tissues: Mammary gland, Skin, Adipose tissue, Heart/pericardium, Lung, Liver, Kidney, Adrenal, Pancreas, Bone marrow, Skeletal muscle, Tongue, Blood vessels, Nasal mucosa, Salivary gland, Cornea Body fluids, secretions, and excretions: CSF, Blood, Saliva, Milk, Urine, Feces	Destroy by incineration **Exception:** pre-approved, critical, heat-sensitive equipment with exposure only to lower-infectivity tissue may be disinfected by soaking in 2N NaOH for 1 hour.	Clean* & quarantine pending final diagnosis[f] **Exception:** Pre-approved critical, heat-sensitive equipment with exposure only to lower-infectivity tissue may be disinfected by soaking in 2N NaOH for 1 hour.	Destroy by incineration **Exception:** Pre-approved, critical, heat-sensitive equipment with exposure only to lower-infectivity tissue may be disinfected by soaking in 2N NaOH for 1 hour.	Destroy by incineration **Exception:** Pre-approved, critical, heat-sensitive equipment with exposure only to lower-infectivity tissue may be disinfected by soaking in 2N NaOH for 1 hour.
IC. No Detected Infectivity * Reproductive tissues: Testis, Prostate/Epididymis/Seminal vesicle, Semen, Placenta fluids, Fetus, Embryos Musculoskeletal tissues: Bone, Tendon Other tissues: Gingival tissue, Dental pulp, Trachea, Thyroid gland Body fluids, secretions, and excretions: Colostrum, Cord blood, Sweat, Tears, Nasal mucus, Bile	Routine reprocessing	Routine reprocessing	Routine reprocessing	Routine reprocessing

*World Health Organization. WHO tables on tissue infectivity distribution in transmissible spongiform encephalopathies. http://www.who.int/bloodproducts/tablestissueinfectivity.pdf.
As testing continues, more tissues will find their way from Table IC into Table IB (but probably not from either Table IC or IB into Table IA). **See below for cleaning instructions pending final diagnosis

c. Cleaning of Instruments to be Quarantined

i. Do not allow instruments to become dry after use. 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 or foam) after use and during storage or transport prior to decontamination in central processing departments.

ii. Instruments with a large amount of bioburden must be either discarded or decontaminated by hand, with the worker wearing full protective gear.
Full protective gear includes:
a) Long sleeve fluid repellant gown
b) Face protection to include eyes, nose and mouth protection (e.g., mask with face shield).
c) Heavy duty, water repellant work gloves.

iii. All brushing to remove organic material must be done with the instrument(s) submerged in a sink of use-dilution enzymatic cleaner. Keeping items below the surface of the solution will minimize spray from the cleaning equipment.

iv. Following manual removal of bio-burden, complete the decontamination by placing instrument in washer-disinfector and cleaning with a detergent preferably that has been shown to have prionicidal activity.
a) There is no need to decontaminate the washer-disinfector.

v. Once visible decontamination is completed, the instrument(s) will be stored in SPD, and quarantined.

vi. Allow solution in sink to flow down the drain.

vii. Rinse sink and all treated areas thoroughly with water.

d. Cleaning of Pre-approved, Critical, Heat Sensitive Airway Instruments

i. Do not allow instruments to become dry after use. 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 or foam) after use and during storage or transport prior to decontamination in central processing departments.
a.) Dried films of tissue are more resistant to prion inactivation by steam sterilization than are tissues that have been kept moist.

ii. Instruments with a large amount of bio-burden must be either discarded or decontaminated by hand, with the worker wearing full protective gear.
Full protective gear includes:
a)Long sleeve fluid repellant gown
b) Face protection to include eyes, nose and mouth protection (e.g., mask with face shield).
c)Heavy duty, water repellant work gloves.

iii. All brushing to remove organic material must be done with the instrument(s) submerged in a sink of use-dilution enzymatic cleaner. Keeping items below the surface of the solution will minimize spray from the cleaning equipment.

iv. Following manual removal of bio-burden, complete the decontamination by placing instrument in washer-disinfector and cleaning with a detergent preferably that has been shown to have prionicidal activity.
   a) There is no need to decontaminate the washer-disinfector.

v. Once visible decontamination is completed, the instrument(s) will be soaked in 2N NaOH for 1 hour then rinsed with water.
   a) Soak in 2N NaOH in a free-standing basin with bottom spigot that drains directly into a container that can be capped and placed in the yellow bag for removal by OEH&S. Do not allow 2N NaOH to drain into the sanitary sewer.

11. Terminal Cleaning of the Operating Room

a. Personal Protective Equipment
   For cleaning the room, OR PCA's/PSA's will wear:
   i.) Moisture impervious gowns
   ii.) Mask with face shield
   iii.) High-risk gloves
   iv.) Shoe/leg covers if shoe contamination is anticipated
b. Decontaminate all room surfaces that have come into contact with the patient's blood and body fluids with 1N sodium hydroxide solution, including:
   i.) OR bed,
   ii.) Instrument tables,
   iii.) Floor at head of bed
c. Wet surfaces by pouring **1N sodium hydroxide** onto rags to damp wipe.
   i.) DO NOT use spray bottles.
   ii.) Allow to sit undisturbed to air dry.
   iii.) After drying, rinse area thoroughly with water then clean the floor and surrounding area according to standard procedure.
d. To clean floor, pour the entire bottle of **1N sodium hydroxide** directly onto floor at floor level, taking care to not splash. **Do not use mop bucket.**
e. Decontaminate the remainder of the room according to standard procedure
f. Nurse suctions all liquid wastes into one container that has been previously prepared with **2N sodium hydroxide**. Double bag the suction container into yellow hazardous waste bags and place into receptacle provided for liquid waste. [Note that 2N sodium hydroxide is used to deactivate potential prions in liquid wastes (including fluids from the field [i.e., suction fluids]), as these fluids will dilute the 2N sodium hydroxide to approximately 1N sodium hydroxide.]
g. Complete hazardous waste tag for liquid waste and affix to yellow bag.
h. Double bag all cleaning equipment, e.g., rags and mops heads that have come in contact with 1N sodium hydroxide into another yellow hazardous waste bag.
   i.) Do not mix liquid waste with debris.
h. Complete Hazardous Waste tag for debris.
i. Place all yellow hazardous waste bags in the while Human Prion Disease waste barrel and transport to the staging area L401 for pickup by Environmental Health & Safety (EH&S) for incineration.

j. The scrub nurse will assure that the fluid container will be double-bagged in a plastic yellow chemical waste bag and delivered to the Decontamination Area.
k. The circulating nurse will complete and affix Hazardous Waste tag to each yellow bag and discard into white barrels marked Human Prion Disease Waste Only. Contact OEH&S to request pickup 415-412-8402. Maintain barrel in a secured area until picked up by OEH&S.
l. Each bag must have a completed tag but only one form needs to be filled out for all yellow-bagged items. OEH&S will pick up waste M-F 8-5; or the next business day. It is safe to store the properly packaged materials in a secure area until pick-up.
m. At the completion of the procedure, return the Human Prion Disease cart to the central storage area in Perioperative Services for inventory and restocking.
n. The circulator will document in the intraoperative nursing form that the Human Prion Disease protocol was followed.

12. Precautions For Handling The Deceased Patient

a. Upon the death of a patient with confirmed or suspected prion disease, the removal of the body from the unit will be carried out using normal infection control measures.
   i. Place the deceased patient in a sealed body bag prior to moving.
   ii. Where the skull is open or there is CSF leakage, and where sutures do not completely control this leaking, the bag will be lined with materials to absorb any fluid, and the body should be moved in a sealed body bag.
   iii. Infection Control guidelines for autopsies are contained in the UCSF Department of Pathology Human Prion Disease Biosafety Precautions.

13. Occupational Exposure

There is no evidence of occupational transmission of prion disease to healthcare workers.

a. Employee's Responsibilities (Patient Initial Self-Care)

i. Perform first aid as self-care according to the type of exposure/ injury.
   a) ***First Aid* for an unbroken *Skin Exposure*:** Wash with soap and abundant quantities of warm water (avoid scrubbing), rinse, and dry. Apply for 1 minute, 0.1N Sodium Hydroxide (NaOH) or a 1:10 dilution of bleach (sodium hypochlorite).
      i.) When decontaminating with **0.1N** NaOH or sodium hypochlorite, a face shield and eye goggles or eye goggles with mask should be worn for protection. It is important to decontaminate the wound with the appropriate agent for the appropriate length of time in order to denature the protein as soon as possible. See the special precautions for NaOH below.
      ii.) After decontamination, rinse well with soap and water to neutralize the base.
      iii.) Bring the **0.1N** sodium hydroxide MSDS to the ED.
   b) ***First Aid* for lacerations or needlestick injuries**: Gently encourage bleeding; wash (avoid scrubbing) with warm soapy water, rinse, dry and cover with a waterproof dressing. Further treatment (e.g. sutures) should be appropriate to the type of injury.
   c) ***First Aid* for splashes to the *Eye, Nose* or *Mouth***: Immediately flush the area with running water or normal saline. Continue washing for 15 minutes. ***Do not use sodium hydroxide or sodium hypochlorite in or around your eyes.*** Do not rub or keep eyes closed.
      i.) Inform your supervisor of the exposure.

ii.) Remove any garments that may have become soiled/contaminated with prions or NaOH, and place them in a double plastic bag. Close the bag securely, label it as contaminated, and wash your hands thoroughly.

iii.). Identify any equipment involved in the exposure and the mechanism of exposure. Make sure that the area has been secured and that notification of contamination has been posted to prevent other individuals from entering the area.

iv.) If you need immediate care for your injury, proceed to the Emergency Department(ED). When you injury is stable, Contact the Needlestick Exposure Hotline (415-353-7842) to report the exposure. The injured employee will need to follow up in the UCSF Occupational Health Clinic. Be sure to go to the clinic for medical evaluation and complete all necessary workers' compensation paperwork.

b. Supervisor's Responsibilities

i. In case of an accident involving prions, confirm that the appropriate decontamination procedures have been followed and that the appropriate first aid has been administered as described above. Confirm that the spill has been contained and that other employees will not be exposed.

ii. Confirm that the area has been secured and that notification of contamination has been posted to prevent other individuals from entering the area.

iii. Contact the Office of Environmental Health & Safety (OEH&S) clean-up, as needed.

iv. Report the exposure to the Occupational Health Service at 415 885-7580. Briefly describe the circumstances of exposure and leave patient identification information (name and home telephone number).

v. Confirm that the patient has called for an appointment at the UCSF Occupational Health Clinic for evaluation on the next weekday the clinic is open. Confirm that the patient has been evaluated.

vi. Within 24 hours, send the Supervisor's Report of Injury (SRI) form to UCSF Occupational Health Services.

c. Emergency Department and Occupational Health Responsibilities

i. These exposures are time sensitive. When necessary, treatment should be initiated in the ED should be as soon as possible. The Emergency Physician can consult with the responder covering the Needlestick Exposure Hotline for information and advice.

ii. The Emergency Department and Occupational Health Service need to complete a Doctor's First Report of Occupational Illness (DFR).

iii. The Emergency Department should refer the patient for follow-up to the UCSF Occupational Health Clinic (415/885-7580). The Emergency Department physician should leave a message for Occupational Health that an exposure has occurred. The physician administering care should forward a copy of the DFR to UCSF HR. Here is a link to the form: http://www.dir.ca.gov/dlsr/dlsrform5021.pdf

iv. The UCSF Emergency Department completes a decontamination verification note for use at the Parnassus campus.

V. HISTORY OF POLICY

Revised 4/01, 9/01, 11/01, 3/02, 5/02, 12/02, 4/04, 10/05, 7/10, 4/12, 5/12, 0615, 03/16

2015 Revision Team

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Appendix I

1. Background Information:

Transmissible spongiform encephalopathies (TSEs), or prion diseases, are inevitably fatal neurodegenerative brain and central nervous system diseases affecting humans and animals. Prion diseases affecting humans can be divided into three categories:

1. Spontaneous or Sporadic (sHuman Prion Disease)
   a. Sporadic Human Prion Disease
   b. Sporadic fatal insomnia (<10 cases known in world history)

2. Genetic or Familial
   a. Familial Human Prion Disease
   b. Familial fatal insomnia (FFI)
   c. Gertsmann-Straussler-Scheinker disease (GSS)

3. Acquired
   a. Iatrogenic Human Prion Disease (iHuman Prion Disease)
   b. Variant Human Prion Disease (vHuman Prion Disease) (also called new variant or nvHuman Prion Disease)
   c. Kuru (virtually extinct)

2. Epidemiology

About 85% of Human Prion Disease cases are sporadic, usually sHuman Prion Disease, with no recognizable pattern of transmission. 10% - 15% of Human Prion Diseases are genetic, and less than 1% is acquired. The incubation period for sporadic and genetic cases is unknown. Cases of iHuman Prion Disease, particularly those with defined exposure events to high-risk tissue, appear to develop symptoms between 1.5 years to >2 decades after exposure. Human Prion Disease is present worldwide with an incidence of about 1 case per million people each year. In the U.S., there are approximately 250-400 cases per year, and about 20 cases per year in California.

sHuman Prion Disease typically affects people between 55 and 75 years of age. Death in Human Prion Disease patients occurs within 6-12 months post onset and is often due to pneumonia or other complicating conditions of dementia. There is no proven treatment or prophylaxis. However, treatment studies are underway. http://memory.ucsf.edu/research

Variant Creutzfeldt-Jakob disease (vHuman Prion Disease) was diagnosed in the United Kingdom (U.K.) in 1996. Since then, as of June 2014, there have been more than225 cases of vCJD, almost all occurring in the U.K. The following countries, however, have reported cases: France, Italy, Portugal, Oman, Japan, Republic of Ireland, Canada, and Hong Kong. Until 2014, no cases of vCJD have been acquired in the Western Hemisphere, including the United States (U.S) and Canada. Three patients in the U.S. and one in Canada with vCJD are thought to have acquired it elsewhere. In 2014, a probable vCJD case was identified in the U.S, but its country of potential origin is unknown. .

Evidence suggests that vHuman Prion Disease is acquired through ingestion of bovine spongiform encephalopathy (BSE, or "mad cow disease")-tainted meat. Two cases of confirmed BSE in domestic cows have been identified in the U. S. as of June 2005. The first case, in December 2003, was from a

cow imported from Canada. The second animal, killed in November 2004 and confirmed with BSE in June 2005, is believed to have originated in the U.S. It is unclear whether BSE is a food borne hazard in the U.S. Although Human Prion Disease is not a reportable disease in most states, the CDC monitors incidence of Human Prion Disease in the U.S. While the U.S. Department of Agriculture has conducted active surveillance efforts for BSE since May 1990, there is controversy about whether these efforts are adequate.

3. Human Prion Disease Signs And Symptoms

sHuman Prion Disease is the most common form of Human Prion Disease, characterized by rapidly progressive dementia, motor dysfunction, visual symptoms (e.g., double vision, visual misperception and distortion), behavioral changes, myoclonus, and a variety of other neurologic signs and symptoms. MRI often reveals classic abnormalities in sHuman Prion Disease as well as in some genetic and acquired forms of Human Prion Disease. Electroencephalograms may show characteristic periodic sharp waves, but often not until later stages of the disease.

Genetic forms of Human Prion Disease can present exactly like sHuman Prion Disease with rapid onset of neurological symptoms, classic MRI findings, and death within months of onset. Genetic forms of Human Prion Disease can also present as slowly progressive ataxia or Parkinsonian illness progressing over years. In about 60% of genetic Human Prion Disease, there is no known family history, although careful family history will often reveal previously misdiagnosed Parkinson's or Alzheimer's disease.

vHuman Prion Disease may be more readily transmitted than other forms of Human Prion Disease. vHuman Prion Disease typically presents with a prodrome of several months' duration characterized by profound psychotic illness, followed by onset of neurologic disease. Neurologic symptoms often include movement disorders (dystonia, myoclonus and ataxia), persistent painful sensory symptoms, and dementia.

For more information about Human Prion Disease, view http://memory.ucsf.edu

4. Characteristics Of Prions

The causative agents of TSEs are prions (*pree*-ahns), small protease-resistant proteins which are resistant to the conventional methods of sterilization and decontamination. However, because prions are proteins, they can usually be inactivated by procedures that denature or hydrolyze proteins such as exposure to sodium hydroxide or autoclaving at very high temperatures for prolonged periods of time. If prions come into contact with certain materials, such as metal and glass, they can be much more difficult to inactivate.

5. Distribution of Prions In Humans

Infected brain tissue, dura mater, spinal cord, and cornea are highly infectious (see table below for presumed infectious risk of human tissues and fluids). Due to the hardiness of the causative agent, special precautions must be taken when handling items that have come into contact with these highly infectious tissues. Although cerebral spinal fluid (CSF) has not been shown to readily transmit Human Prion Disease, because of its contact with highly infectious tissues, at UCSF it has been decided to err on the side of caution for handling CSF. Procedures for handling CSF are detailed in **Section III.2a.**

6. Modes Of Transmission

The transmissibility of prions has been demonstrated by inducing disease in laboratory animals. The most effective method of infection of animals was by intra-cerebral inoculation of prions, with intra-

peritoneal and percutaneous inoculation being significantly less effective, and ingestion of prions the least effective.

A. Iatrogenic:
Iatrogenic transmission is exceedingly rare (313 cases total as of June 2005). It has occurred after transplantation of Human Prion Disease-infected corneas (3 cases), dura mater grafts (>136 cases), and stereotactic depth electrodes previously used on infected individuals (3 cases). Iatrogenic Human Prion Disease has been described in patients who received injections of human pituitary-derived hormones (168 cases).

B. Occupational:
There is no evidence of occupational transmission of Human Prion Disease to healthcare workers.
Although cases of Human Prion Disease have been reported in approximately 24 healthcare workers, this incidence does not exceed what would be expected by chance alone. The highest theoretical risk is from occupational exposure to high infectivity tissue through needlestick, splashing of the mucous membranes or unintentional ingestion. All healthcare personnel who work with patients with known or suspected prion diseases must adhere to standard precautions. TRANSMISSION OF Human Prion Disease HAS NOT BEEN ASSOCIATED WITH ENVIRONMENTAL CONTAMINATION OR FOMITES.

7. Surgical or Procedural Instrument Handling Decision-Making
A. Risks for Transmission
Instruments used in neurosurgical and invasive procedures in patients with confirmed or suspected Human Prion Disease have been implicated in the transmission of prion disease in both animal studies and human cases. Additionally, there is theoretical risk from other surgical procedures. Therefore, critical decision-making about whether to destroy, disinfect and quarantine, or disinfect and reprocess instruments must be determined based upon the risk of transmission of Human Prion Disease to patients on whom those instruments would subsequently be used. Some equipment, such as fiberoptic endoscopes and delicate ophthalmic equipment, cannot be adequately disinfected after use on a patient with confirmed or suspected Human Prion Disease without destroying the equipment.

Many specific risk groups for the iatrogenic transmission of vHuman Prion Disease are not known. However, blood transfusion from a patient with vHuman Prion Disease is a known risk. Individual patients who have been potentially exposed to vHuman Prion Disease via surgical instruments used on a patient who went on to develop vHuman Prion Disease may be at higher risk than from surgical equipment exposed to other forms of prion disease, such as sHuman Prion Disease or gHuman Prion Disease. The level of prions in the lymphoreticular system in patients with vHuman Prion Disease is much higher than in patients with other forms of prion disease (i.e., sHuman Prion Disease or gHuman Prion Disease). Therefore, contact with these tissues in a vHuman Prion Disease patient theoretically has a higher risk of transmission. An epidemiological investigation and risk assessment should be undertaken in the case of exposure to potentially contaminated instruments or tissues.

Categories of tissue infectivity are not the same as categories of risk, which require consideration not only of the level of infectivity in tissue, but also of the amount of tissue to which a person or animal is exposed, and the route by which infection is transmitted.
World Health Organization. WHO tables on tissue infectivity distribution in transmissible spongiform encephalopathies. http://www.who.int/bloodproducts/tablestissueinfectivity.pdf.

Risk Categories for Iatrogenic Transmission of Prion Disease is dependent on at least three factors:
- The type of prion disease (i.e., Human Prion Disease vs. vHuman Prion Disease)
- Risk category of tissue or fluid (see Table 1)
- Material of equipment being used (prions adhere more readily to stainless steel and glass)

8. Sodium Hydroxide (NaOH) Information
Sodium hydroxide (NaOH) is caustic but fortunately it is slow-acting and can be rinsed out with water. If left on skin or clothing for an extended time, **0.1N** sodium hydroxide will eventually cause a skin burn. Burn may appear after an aching sensation, and in milder cases a skin rash may appear. Other symptoms are cold and clammy skin with cyanosis or pale color. Aerosolized exposure to sodium hydroxide may cause lacrimation (tearing), blurred vision, and photophobia as well as chemical conjunctivitis and corneal damage.

Personnel need to be trained and observe safety guidelines when working with **1N sodium hydroxide**. With the recommended precautions, it can be used safely. **1N sodium hydroxide** is caustic (basic) and has a pH > 14. It must not come in contact with strong acids, flammable liquids and organic halogens. Consult the 1N sodium hydroxide MSDS that must be readily available.

9. Sodium Hypochlorite (NaOCl) Information
Sodium hypochlorite (NaOCl) is a chemical compound consisting of sodium, oxygen, and chlorine that has been used for centuries for bleaching and disinfecting.

10. Neuro Pod Manager Notifications

Pre-op	**3-1648**
PACU	**3-1292**
OR Charge Nurse	**3-1580**
SPD Manager or Assist manager	**3-1084**
Instrument Coordinator/Lead Tech	**3-1084**
OR support supervisor	**3-1249 or 3-1399**
Infection Control	**Amy Nichols 3-4346 or office 3-4343**
Pathology	**3-1608**
OEH&S	**6-1300**

11. Signage and Tags
See the following sample for CJD Waste signage and Hazardous Waste Removal tag.

HAZARDOUS WASTE

University of California, San Francisco Medical Center
501-555 Parnassus Ave, San Francisco CA 94143

Room Number: _____

Accumulation Start Date: _____

Composition: Materials containing tissues decontaminated with 1 N sodium hydroxide.

Physical State: Solid, Liquid
Hazardous Properties: Corrosive

Shipping Name: Waste Corrosive Liquid, Basic, Inorganic, N.O.S., (Sodium Hydroxide) 8 UN3266 PG III ERG (154)
PSC 14122

EH&S Use Only:

EH&S Pick-up Date: _____

EH&S Tracking Number: _____

For Pick-up Call 412-8402. EH&S Main Office: 476-1300

CJD WASTE ONLY

Composition: Materials containing tissues decontaminated with 1 N sodium hydroxide