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Statement No.: WITN3866001
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INFECTED BLOOD INQUIRY

EXHIBIT "WITN3866012"

This is the exhibit marked "WITN3866012" referred to in the witness statement of Dr Alexandra Rice.

Instructions for handling tissues from Patients with or at risk of CJD or VCJD

Introduction

Transmissible spongiform encephalopathies (TSEs) are a rare group of uniformly fatal diseases caused by unconventional agents and prions, the most common of which is Creutzfeldt - Jakob disease (CJD) which accounts for 95% of all TSE's.
All TSE's are invariably progressive and fatal once clinical symptoms appear, and there is no known treatment or prophylaxis. Confirmation of diagnosis can only be made at post mortem. Human TSE's have a pre-clinical phase which may last for many years during which time no symptoms of the disease are evident.

Equipment and Materials:

- Yellow sharps bin for discard by incineration
- Yellow vat4 bin for separate disposal of human tissue by incineration
- UN3291 disposal label @ T:\Histopathology\Proformas\Histology\UN3291 DISPOSAL LABEL.doc)
- Cut-resistant gloves
- Disposable scalpel
- Disposable forceps
- Disposable gown
- Disposable gloves
- Disposable lung knife
- Orange clinical waste bags
- Class 1 Microbiological safety cabinet
- Disposable gown
- Laboratory coat
- Safety Goggles

Equipment required for the clean-up operation

- Spill kits or disinfectant of choice
- Safety masks
- Disposable gloves
- Emergency Eye-wash
- Safety goggles
- Disposable safety gowns
- Disposable paper hand towels
- Clinical waste bag

CHEMICALS/REAGENTS:
10% formal-saline
2M sodium hydroxide
96% > 100% formic acid

OCT compound
Formal acetic alcohol fixative in a slide-mailer (used as a disposable coplin)

HAZARD:
Untreated tissues constitute a potential DANGER OF INFECTION HAZARD
Formalin, formic acid and sodium hydroxide constitute a potential CHEMICAL HAZARD
Dissection and microtome knives constitute a potential SHARPS HAZARD

Precautions:

Appropriate PPE (laboratory coat, gloves and safety glasses) must be worn.

Health and Safety:

The risk assessment and procedure should address the possible emergencies and their effects with the aim of prevention, containment or minimisation and safe clean up.

- HISTINST29 – Spillage Procedures

For specific risks and hazards refer to COSHH sheets on Q-Pulse

STANDARDS:

1. The procedures described in this document are based on guidelines laid down in Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex K @ http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_096930.pdf. This guide is aimed at pathologists and biomedical scientists involved in handling such cases and aims to ensure they are aware of risk factors for CJD or vCJD prior to carrying out any of the procedures described below. In addition to the document above all involved should read and have a personal copy of T:\Histopathology\Health & Safety\Useful docs\CJD infectivity - Brown et al.pdf.
2. A tripartite risk-benefit assessment must be jointly conducted by the surgeon/clinician, reporting Pathologist and a nominated Biomedical Scientist (BMS) prior to the patient being accepted for histological assessment. This will ensure that all agree on the precise nature of samples to be forwarded to Histopathology and the level of analysis, if any,that will be provided.
3. **Frozen section must not be done on either medium or high risk tissues for patients with, or at risk of, CJD or vCJD.** Frozen section in such cases is usually restricted to lung nodules. Lymph nodes are considered a medium risk and therefore should **NOT** be processed for frozen section.
4. The request form must be labelled with an Inoculation Risk sticker and attached to the exterior of the double bag. Clinical information on the request form should state the patient classification with regard to CJD of vCJD.
5. This document is designed to offer extra protection to the Pathologist/BMS and should be used in conjunction with established reception / registration / processing. Any request which does not conform should be brought to the attention of the nominated BMS.
6. No laboratory procedures will be performed on any specimen until it has been given a unique laboratory number on the Computer System (See RB.HI.HSOP.05 Booking in specimens).

7. The safety cabinet and cryostat must not be used for any other case or by any other person until fumigated with formalin, the waste removed and all surfaces treated with 2M sodium hydroxide.
8. The microtome used for microtomy must not be used for another case or by another person until it has been decontaminated and the waste disposed.
9. Non-disposable instruments and cut-resistant gloves should be autoclaved or decontaminated with 2M sodium hydroxide left for a minimum of 60 minutes.
10. All persons involved with the procedures described below should complete a personal log of the contact with ?vCJD / vCJD contaminated tissues.
11. No tissue to be released to the BRU biobank team or any other researcher.

PROCEDURES:

Handling tissues at source and reception of tissues

1. All tissues, excluding those for urgent frozen section, must be fixed in the theatre in a suitable container containing 10% formalin to the volume of 20 times the mass of tissue. Slice into specimen at 5mm intervals to aid fixation. Containers must be double bagged and labelled with an Inoculation Risk sticker. The request form must also bear an Inoculation Risk sticker and attached to the exterior of the bags. The container(s) and request form must be clearly labelled with either CJD risk or vCJD risk.
2. A nominated BMS will ensure a Safety Cabinet is made ready to receive such a case and clearly labelled *"Reserved for sole use by nominated persons handling the current CJD / vCJD case".* Following fumigation, all previous cases are removed together with unnecessary items. Ensure that the following items are available: disposable scalpel, disposable forceps, disposable lung knife, 2M sodium hydroxide, 96%>100% formic acid, yellow vat4 bin labelled with a UN3291 disposal label (located @ T:\Histopathology\Proformas\Histology\UN3291 DISPOSAL LABEL.doc), several orange clinical waste bags, gown, gloves and cut-resistant gloves. Handling of other surgical tissues for inflation, frozen section, sampling for bio-bank, etc are dealt with in an alternative Safety Cabinet and frozen sections are cut using a separate cryostat.
3. The nominated BMS must be informed of the imminent arrival of tissue from a patient with, or at risk, of CJD or vCJD.
4. On arrival, place specimen containers in the Safety Cabinet. If routine histology diagnosis is required then place containers to rear of cabinet and allow and fix for 48 hours.
5. Register case on WinPath and label request form and container(s).
6. Add an important note (i.e.NOT2) test library code on WinPath and enter the nature of risk. All persons handling tissue should also be recorded here.
7. Process according to relevant section below – either "Performing an urgent frozen section" or "Processing for paraffin section" described below.

Performing the urgent frozen section

1. A nominated BMS will ensure a cryostat is made ready to receive such a case and clearly labelled *"Reserved for sole use by the nominated persons for handling the current CJD / vCJD case".* All unnecessary items are removed.
2. Remove container from double bag inside the safety cabinet and place on an orange clinical waste bag which will act as the preparation surface. Using disposable forceps/scalpel

remove tissue from container and place sample in OCT compound on cryostat chuck. Excess tissue is returned to original container.

3. Transfer chuck to cryostat and cut two frozen sections.
4. A second BMS presents a disposable slide mailer containing Formal acetic alcohol fixative so that the cryotomist can immerse the slide(s) without contaminating the slide mailer. Ensure the slides are completely immersed in the fixative. The second BMS to complete the frozen section procedure and forward slides and form to Pathologist for reporting.
5. Once reported the nominated BMS returns chuck to cabinet, allows OCT to thaw, and places tissue in a labelled cassette in a container of 10% formal-saline and place to rear of cabinet and allowed to fix for a minimum of 48 hours. Tissue surplus to frozen section also fixed in 10% formal-saline for 48 hours at the rear of the safety Cabinet.
6. Excluding disposable sharps, all waste items in the safety cabinet are wrapped in the clinical waste bag and all work surfaces and pots are wiped down with 2M sodium hydroxide left for a minimum of 60 minutes.
7. After use of cryostat, wrapped waste, gown and gloves are double bagged in clinical waste bags presented at the Safety Cabinet interface. The secured bag is sealed in a large yellow waste container to await disposal by incineration according to trust waste disposal policy.
8. Disposable sharps are decontaminated with 2M sodium hydroxide left for a minimum of 60 minutes. These are placed into a separate sharps bin, double-bagged followed by disposal by incineration according to trust waste disposal policy.
9. Process according to section "Processing to paraffin wax" described below.

Processing to paraffin wax

1. Place an orange clinical waste bag over the work surface inside the Safety Cabinet - this will act as the preparation surface.
2. Label a duplicate specimen pot and fill with formic acid.
3. Remove tissues from original pot and place in duplicate, immersing tissue in the formic acid.
4. Leave for a minimum of one hour.
5. Dispense with formic acid via the Safety Cabinet sink along with copious amounts of running tap water. Wash tissue is water for a minimum of 60 minutes before replacing with 10% formalin.
6. Take minimum number of samples and place in labelled processing cassette(s) using disposable instruments.
7. Add absorbent material such as saw dust to the formalin in the original pots and ensure it has completely absorbed the formalin. Replace lid.
8. Process cassettes to paraffin wax and embed in a routine manner.
9. Excluding disposable sharps, all waste items are wrapped in the clinical waste bag and all work surfaces and pots are wiped down with 2M sodium hydroxide left for a minimum of 60 minutes.
10. Wipe work surfaces and pots with water.
11. Disposable sharps are decontaminated with 2M sodium hydroxide left for a minimum of 60 minutes. These are placed into a separate sharps bin and double bagged to await disposal by incineration according to trust waste disposal policy.
12. After use, wrapped waste, original pots with sawdust, gown and gloves are double bagged in clinical waste bags presented at the Safety Cabinet interface. The secured bag is sealed in a large yellow waste container to await disposal by incineration according to trust waste disposal policy.

Cutting paraffin sections and staining

1. A nominated BMS cuts sections on a microtome. The case is cut as a non-routine case and not cut along with other surgical cases.
2. Sections are mounted on glass slides according to standard laboratory protocols and stained as required.
3. After use, waste, block trimmings, tissues and gloves are double bagged in clinical waste bags. The secured bag is sealed in a large yellow waste container to await disposal by incineration according to trust waste disposal policy. Ensure the bin bears the "Pathological specimen .....separate incineration. UN3291" label.
4. Disposable sharps are decontaminated with 2M sodium hydroxide left for a minimum of 60 minutes. These are placed into a separate sharps bin and double bagged to await disposal by incineration according to trust waste disposal policy.
5. Wipe down microtome with xylene to remove any wax and then wiped over with 2M sodium hydroxide left for a minimum of 60 minutes.
6. Wipe down microtome with water.

NB. This decontamination step is an additional safeguard - performed for reassurance of the involved BMS staff as the tissue blocks have already been rendered non-infective by formic acid pre-treatment.

Closure

1. Once the nominated Pathologist is satisfied that no more work is required the specimen pots and surplus tissue can be disposed.
2. Saw dust is added to the formalin in the pot(s).
3. After absorption of all formalin the pot/tissue/sawdust is sealed and double bagged in clinical waste bags.
4. The secured bag is sealed in a yellow waste bin to await disposal by incineration according to trust waste disposal policy. Ensure the bin bears the "Pathological specimen .....separate incineration. UN3291" label.

Related Documentation:

- RB&H NHS Trust's Waste Disposal Policy
- RB&H NHS Trust's Disinfection Policy
- HISTINST29 – Spillage Procedures

References:

Refer to Risk assessment and COSHH files on Q-Pulse