

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Policy for the Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in the hospital and community setting

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1. Introduction

Transmissible spongiform encephalopathies (TSEs), sometimes known as prion diseases, are rare, fatal degenerative brain diseases, which occur in humans and certain other animal species. The commonest human TSE is Creutzfeldt-Jacob Disease (CJD). This occurs in various forms:

- Sporadic CJD
- Variant CJD (vCJD)
- Familial CJD
- Iatrogenic CJD

Other more rare human TSEs include:

- Gerstmann Straussler Scheinker syndrome (GSS)
- Fatal familial insomnia (FFI)
- Kuru

Classic (sporadic) CJD occurs worldwide with a frequency of approximately one per million population per annum. vCJD is thought to have resulted from oral exposure to the bovine spongiform encephalopathy (BSE) agent and is currently rare with approximately 176 cases in the UK up to December 2011. The abnormal prion proteins are present in certain tissues before patients show any symptoms and some carriers may remain asymptomatic. Consequently there is a risk of contamination of instruments used during invasive procedures such as surgery and endoscopy.

Prions are highly resistant to standard methods of disinfection and sterilisation, and therefore a special approach must be adopted in the care of patients, disposal of clinical waste and handling of surgical instruments and other medical devices.

As non-CJD diseases are extremely rare this guidance will refer to CJD specifically. However the principles and guidance will be the same for other prion diseases.

2. Policy Scope

The Trust expects that all staff who work in the clinical ward environment and community will adhere to the principles of this policy. This policy provides instruction on risk assessment and management of TSE in relation to Infection Prevention and Control (IPC).

3. Aim of policy

The aim of this policy is to prevent the transmission of CJD, variant CJD (vCJD) and other human TSEs / prion diseases in healthcare settings. Additionally this policy identifies care that should be given to individuals affected by the disease.

Information is provided on the clinical care of patients with or at risk of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeld-Jacob Disease (CJD), the identification of patients at risk and measures required for surgical procedures and endoscopy, including instrument quarantine.

This policy is based on national guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee¹.

4. Duties

- 4.1 All Trust employed staff, agency and locum staff are responsible for adhering to this policy.
- 4.2 Staff are responsible for reporting breaches of this policy to the CJD Committee (a sub-committee of the Infection Prevention and Control Committee) and should complete Datix information following any incident.
- 4.3 Ward Sisters/Charge Nurses, Community staff are responsible for ensuring implementation within their area, and for ensuring all staff working within the area, adhere to the principles at all times.
- 4.4 The Infection Prevention and Control Team (IPCT) is responsible for providing expert advice in accordance with this policy, for supporting staff in its implementation and assisting with risk assessment where complex decisions are required.

5. Definitions

Definitions are given throughout the policy

6. CJD Policy

6.1 Patient risk groups

See Appendix 1.

6.1.1 Symptomatic patients

A definitive diagnosis of **CJD or vCJD** can only be made on brain biopsy or at post mortem. Patients with neurological symptoms are classified according to established, published criteria as definite, probable or possible CJD or vCJD. For details see Department of Health TSE guidance Part 4¹. Depending on the route of transmission CJD cases may also be classified as familial (inherited) or iatrogenic (healthcare acquired).

Iatrogenic CJD

Worldwide in the past CJD has been associated with the administration of hormones prepared from human pituitary glands (e.g. growth hormone, gonadotrophins) and with the use of dura mater grafts. These are no longer used. Transmission has also been identified following neurosurgical procedures.

Iatrogenic vCJD

As of November 2011 there have been no known transmissions of vCJD via surgery or use of tissues or organs. This remains a potential risk. Since 2003 four cases of presumed person-to-person transmission via transfusion of non leucodepleted red blood cells have been reported in the UK (3 clinical, one asymptomatic), and a case of probable transmission via plasma products (asymptomatic).

All cases where CJD is suspected should be reported by the responsible clinician (usually a neurologist) to the National CJD Research and Surveillance Unit (NCJDRSU) in Edinburgh and to the local Health Protection Unit so that any necessary action can be taken². Further details available at <http://www.cjd.ed.ac.uk/>.

Clinicians, ward and community staff caring for patients in whom the diagnosis of a CJD/vCJD is being considered or investigated are urged to contact the IPCT as soon as possible. In particular, it is imperative that, once the diagnosis has been suggested, clinical procedures using equipment intended for re-use on other patients are not carried out without prior discussion with the IPCT.

6.1.2 At risk asymptomatic patients

Patients are considered at increased risk of CJD/vCJD based on their family or medical history, e.g.:

A family history of CJD

Past surgery which may have involved a dura mater graft

Past treatment with human derived growth hormone or gonadotrophins

Blood or blood components from 80 or more donors since 1980

A number of patients will have also been identified as 'at increased risk' by the CJD Incidents panel, for example due to having received blood from someone who later went on to develop vCJD. These patients and their GPs will normally have been notified of their status.

For a full list of patient groups potentially at risk of CJD/vCJD, see Appendix 1.

See Section 6.3; Appendix 3 and 4 for screening procedures for the identification of patients at risk from CJD/vCJD prior to invasive procedures.

6.2. Tissue infectivity

See Appendix 2.

It is believed that the most infective material is that obtained from the central nervous system and eye. Tissues classified as '**high risk**' are:

- Brain
- Spinal cord tissue
- Posterior eye

Other tissue is thought to be less infective, and is classified as '**medium risk**'

- Olfactory Epithelium
- Spinal ganglia
- Lymphoid tissue (vCJD only)

Tissues with no evidence of infectivity are described as '**low risk**', e.g. blood, saliva, body secretions, or excreta.

For classification of infectivity in various tissues, see Appendix 2

6.3 Identification of patients at risk from CJD/vCJD

It is important to identify instruments that may have been contaminated by prions. Due to the fact that there is currently no fully effective mechanism to decontaminate instruments, such instruments must be removed from use. Annex J of the Department of Health TSE guidance¹ deals with this issue specifically.

There is no effective test to identify carriers of prion diseases. Risk is determined prior to surgery/endoscopy by either a single question (all patients) or series of questions (for procedures involving high risk tissues).

All surgical and endoscopy patients should be asked the single question – 'Have you ever been notified that you are at risk of CJD/vCJD?' This question should be

incorporated into pre-assessment and admission documentation as appropriate, in order that potential risk is identified as early as possible.

Neurosurgical patients should also be screened using four additional questions. A specific form is available for this purpose (appendix 3). Screening questions should be asked at pre-assessment or at the earliest opportunity. A patient information leaflet is available explaining the reasons for these questions (appendix 5).

Ophthalmology patients due to undergo surgery involving the posterior eye should be screened using four additional questions. As the majority of procedures in ophthalmology do not involve the posterior eye a specific form is available for use in ophthalmology (appendix 4). This ensures all patients are asked the single question; while the full assessment is performed only for those due to undergo procedures involving the posterior eye. Screening questions should be asked at pre-assessment or at the earliest opportunity. A patient information leaflet is available explaining the reasons for these questions (appendix 5).

If a patient answers 'yes' to one of the questions, their consultant should be immediately informed. This is necessary as instruments may need to be quarantined and for input into the full risk assessment. Further information may be required from the patient, notes or GP. The case must also be referred to the **IPCT**, who will advise further on risk assessment and arrangements for instrument quarantine if required (see section 6.6.4).

Arrangements will be made for instruments used on medium or high infectivity tissues in patients deemed to be 'at risk' following investigation, to be quarantined following the procedure. Where investigations are on-going instruments will be quarantined pending the outcome. In most cases there will be no need to cancel or postpone procedures.

Those neurosurgical or ophthalmology patients answering yes to the question on multiple blood transfusion (i.e. those who may have received more than 50 units of blood products, or received blood products on more than 20 separate occasions), **and where pragmatic clinical risk assessment cannot exclude this possibility**, require a specific risk assessment by the Infection Prevention and Control Team in collaboration with the Blood Transfusion Laboratory to establish whether the actual total number of donor exposures exceeds 80. Together they will fill in the 'Highly transfused risk assessment form' which can be found in Microsoft Word format on the Health Protection Agency Website (www.hpa.org.uk). Patients formally shown to have had more than 80 donor exposures since 1980 are deemed 'at risk' of vCJD.

Those patients who on investigation are assessed as 'at risk' of TSE are still extremely unlikely to have been infected or to ever develop symptoms. A

personalised information leaflet will be provided by the IPCT (consultant virologist) which also contains further sources of information/support. Additionally a specific letter will be sent by the IPCT (consultant virologist) to the GP and copied to the Health Protection Unit (appendix 6). Those patients who on investigation are assessed as 'at risk' of TSE should have their records marked electronically by the **IPCT** to identify the potential risk for future admissions.

In addition to the risk assessment questionnaire, all patients undergoing high risk procedures (on the posterior eye, brain or spinal cord) should have their notes checked for any mention of prion diseases. Medical staff should actively consider the potential for a TSE/prion diagnosis in these patients and if this is considered a possible diagnosis appropriate action should be taken.

6.4 Guidance for Hospital and Clinic Care of CJD/vCJD patients

Note: the methods outlined below are applicable to patients with or at risk of CJD / vCJD unless otherwise stated.

There is no evidence of a risk to staff, relatives or the community from normal social or routine clinical contact with patients with or at risk of CJD/vCJD.

6.4.1 Isolation

For practical and confidentiality reasons patients with a potential diagnosis of CJD/vCJD should ideally be nursed in side rooms. This is not required for 'at risk' patients.

6.4.2 Collection of laboratory samples and other invasive medical procedures

Body secretions and body fluids (including saliva, blood and CSF) are considered low risk for CJD/vCJD. It is therefore likely that the majority of samples taken and procedures performed on the ward will be low risk.

The collection of all samples should involve standard precautions (i.e. avoidance of sharps injuries and other forms of parenteral exposure), and the safe disposal of sharps and contaminated waste by incineration. The procedure should be carried out by competent staff who are aware of the hazards involved. Lumbar puncture should only be carried out by competent staff who are aware of the hazards involved. Disposable gloves and eye protection should be worn. All lumbar punctures on any patient (regardless of a possible diagnosis of TSE) must always be carried out with single-use lumbar puncture kits.

Biopsy and CSF samples from cases of potential CJD should be marked with a 'Biohazard' label, and the laboratory should be

contacted before sending the specimen. Particular care must be given to maintaining patient confidentiality.

If samples are being sent to the National CJD Research Unit this should be arranged directly with them, including courier pick-up. If the sample is to be picked up from a trust laboratory, the laboratory need to be informed that the sample is coming and when the courier is due to collect it.

Any inoculation injury (needlestick) should be handled according to trust [Needlestick Injuries Policy](#), including informing the occupational health department. Contact with small volumes of blood (including inoculation injury) is considered low risk, though it is known that transfusion of large volumes of blood and blood components may lead to vCJD transmission.

6.4.3 Bed linen

Used or soiled bed linen (contaminated with body fluids or excreta) should be removed from the bed and washed and dried in accordance with standard practice See: [Used Laundry Management Policy](#). No additional handling or processing requirements are necessary

6.4.4 Clinical waste

In the ward setting the majority of clinical waste will be low risk and can be disposed of according to standard trust policy. High or medium risk tissues (see appendix 2) and objects contaminated with high or medium risk tissues should be bagged or placed in a sharps bin (as appropriate) and sent for incineration in accordance with the Trust [Waste Management Policy](#). Special collection for incinerated waste must be arranged by the individual department.

6.4.5 Surface decontamination and the management of spillages

The infectious agents associated with TSE are unusually resistant to inactivation by chemicals and other processes. The removal of contaminating material and thorough cleaning of the surface are the most important elements in cleaning up spillages on a hospital ward.

Standard methods should be followed to clear up spillages on the ward, including spillages of blood and CSF, where gloves and an apron should be worn. The spillages should be covered with paper towels to absorb fluid and disposed of as clinical waste The affected area should be disinfected with 1,000ppm hypochlorite unless the spillage is of high/medium risk material. Any area affected by a high/medium risk material spillage must be disinfected with 10,000ppm hypochlorite solution for 30 minutes following paper towel absorption Note: wet puddles should be avoided. If necessary the disinfected area should be cordoned off during this period

(and until dry) in order to avoid people slipping on a damp area. The area should then be cleaned with detergent and warm water and left to dry.

High concentration (20,000ppm) hypochlorite is unlikely to be practical in a ward situation, since it is highly corrosive to many surfaces. However, it can be used in exceptional circumstances to clear up spillages of high risk material (see Appendix 2). In such instances the area must be well ventilated and barred to patient access. The area should then be cleaned with detergent and warm water and left to dry.

There is no need for terminal cleaning over and above the routine standard after patients have left a ward other than the decontamination of any spillage

6.4.6 Childbirth

In the event that a symptomatic or at risk patient is found to be pregnant, childbirth should be managed using standard infection control procedures. The placenta, other associated material and fluids are regarded as low risk and can be handled as per trust policy.

6.4.7 Procedure after death

The **IPCT** must be informed of the death of a definite, probable, possible or known at risk patient. The removal of the body from the ward to the mortuary should be carried out using normal infection control measures. The deceased patient must be placed in a cadaver bag prior to transportation to the mortuary, in line with normal procedures for bodies where there is known infection risk. The Infection Prevention and Control notification sheet must be completed and accompany the deceased to the mortuary (see also Trust Policy: [IPC Care of Cadaver Policy](#)).

Relatives of the deceased may wish to view or have some final contact with the body. Such viewing, and possible superficial contact, such as touching the face, need not be discouraged, **but must occur prior to post mortem examination.**

6.4.8 Organ transplants

To minimise the risk of transmission of CJD/vCJD, organ donations should be rejected from patients with definite, probable or possible CJD/vCJD; those with degenerative neurological conditions of unknown cause and patients classified as 'at risk' from CJD/vCJD.

6.5 Care of CJD/vCJD Patients in Domiciliary Settings

Note: the methods outlined below are applicable to patients with or at risk of CJD / vCJD unless otherwise stated.

There is no evidence of a risk to staff, relatives or the community from normal social or routine clinical contact with patients with or at risk of CJD/vCJD.

People should not be dissuaded from routine contact with CJD/vCJD patients as both CJD and vCJD are not thought to present a risk through normal social or routine clinical contact.

No special measures over and above standard infection control precautions are generally required for caring for CJD/vCJD patients in the community, as it is unlikely that procedures will be adopted that will lead to contact with high or medium risk tissues.

6.5.1 Caring for symptomatic patients at home

Those caring for patients at home should be advised of the standard infection control practices that would apply to any patient. They should be provided with disposable gloves, paper towels, waste bags and sharps containers, as appropriate.

Late stage CJD/vCJD patients may experience tissue breakdown and the development of extensive pressure sores. These lesions should be dressed regularly, using standard infection control precautions, and contaminated dressings disposed of as clinical waste.

6.5.2 Spillages

It is assumed that all spillages in the community will be of low risk material, for example blood and urine. Standard infection control precautions should be followed to clear up spillages of material from patients with, or “at increased risk” of, CJD/vCJD in the community. Spillages should be cleared up as quickly as possible, keeping contamination to a minimum. Disposable gloves and an apron should be worn when removing such spillages. The surface should then be washed thoroughly with detergent and warm water. Use disposable cloths and discard after use. If a re-usable cloth is used then wash thoroughly after use (e.g. washing machine cycle)

You must wash your hands with soap and water after dealing with blood and / or bodily fluids.

6.5.3 Linen

No special requirements are needed when washing a patient’s linen in the home setting. A patient/service user’s clothes and bed linen can be washed as normal by hand or in a domestic washing machine.

Fouled linen should be washed in a separate cycle from other family clothes, if washed by hand then gloves and apron should be worn.

6.5.4 Clinical waste

Orange clinical waste bags and sharps containers should be supplied and used for the disposal of clinical waste and used sharps generated in the patient/service users home. In the domiciliary setting waste contaminated with urine, faeces, *etc.*, is usually double bagged and disposed of as normal household waste. The healthcare worker providing the care must risk assess the waste to identify if it is to be collected; if the waste is of a large quantity e.g. a third of a bag of such waste is being generated per week, then this may need to be classified as clinical waste:

Clinical waste should be stored safely in an area that is inaccessible to animals, children and does not draw attention to the patient/service user. Provision should be made with the contracted waste provider for collection on an agreed date and time.

6.5.5 Sample Collection and Labelling

Body secretions and body fluids (including saliva and blood) are considered low risk for CJD/vCJD. It is therefore likely that all of the samples taken and procedures performed in the community will be low risk. Prior to taking a sample contact must be made to the local laboratory for advice on correct labelling required.

The collection of all samples should involve standard precautions (i.e. avoidance of sharps injuries and other forms of potential exposure), and the safe disposal of sharps and contaminated waste by incineration. The procedure should be carried out by competent staff who are aware of the hazards involved.

6.5.6 Equipment:

Single use disposable equipment should be used where practicable. Instruments which are not disposable must either be discarded or undergo special decontamination procedures. Contact the local Infection Prevention and control team for details.

6.5.7 After Death

When a patient/service user, who is known, suspected or at risk of CJD or vCJD dies, the current evidence is that the body should be removed from the community setting, nursing/residential home or hospice using normal standard infection control measures.

The current recommendations are that the body is placed in a cadaver bag prior to transportation to the mortuary, in line with normal procedures where there is a known infection risk.

6.6. Invasive clinical procedures (Surgery and endoscopy)

See also trust guidance on general measures required regardless of CJD/vCJD status and risk:

[Theatres local interpretation of NICE IPG 196 – Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob Disease \(CJD\) via interventional procedure](#)

The guidance below is based on the Department of Health TSE Guidance Annex E and F¹.

Brain Biopsy

This portion of the policy also applies to **brain biopsy procedures** (preferably open block biopsy) carried out on patients with unexplained progressive dementia, ataxia or neuropsychiatric syndromes. Single use instruments must be used if possible. Re-usable instruments must be quarantined (section 6.6.4), but can be released at a later date if an alternative diagnosis is confirmed.

6.6.1 Rationale

Invasive clinical procedures, including surgery and endoscopy, performed on patients who are categorised as a case of definite, probable or possible CJD/vCJD, or at risk of CJD/vCJD pose a particular problem. Prions are inherently resistance to commonly used disinfectants and methods of sterilisation. This means that there is a possibility of transmission of prion diseases to other patients, even after apparently effective methods of decontamination or sterilisation have been used. For this reason, it may be necessary to destroy instruments after use on such a patient, or to remove the instrument from further use until the diagnosis is either confirmed, or an alternative diagnosis is established. The instrument can be used for the same patient on another occasion if necessary.

It is particularly important that patients with illness potentially due to CJD/vCJD, or at risk of CJD/vCJD disease are identified prior to the procedure. Failure to do this may result in exposure of individuals on whom the equipment is subsequently used.

6.6.2 General points

- Think before carrying out such a procedure. Does it really need to be performed? Is there an equally acceptable alternative? Remember that in doing so instruments may have to be destroyed, or set aside for a significant/prolonged period of time. However, the quality of care for the patient should remain the primary concern.
- The IPCT must be informed before invasive clinical procedures are undertaken on any definite, probable or possible case, and on any patient potentially 'at risk' of CJD/vCJD.

- Procedures on such patients, and the practicalities of instrument handling, storage, cleaning and decontamination, or disposal, should be planned carefully in advance.
- The laboratory should be informed before sending CSF or medium/high risk tissue samples on patients who may have a prion disease. The possibility of a diagnosis of CJD should be clearly stated in the written or electronic request.
- In all cases to minimise the loss of instruments, single-use disposable instrument should be used whenever possible, but only if this does not affect the quality of care.
- All staff directly involved in procedures on patients in the risk groups, or in the subsequent re-processing or disposal of potentially contaminated items, should be aware of the specific precautions, and adequately trained.
- Sufficient notice should be allowed for the necessary preparations, which should include informing SSD.

6.6.3 Precautions during invasive clinical procedures (surgery and endoscopy) on definite, probable, possible, or at risk patients

Definite or probable patients

Wherever appropriate and possible, the intervention should be performed in an operating theatre, and the procedure should be performed at the end of the list to allow normal cleaning of the theatre before the next session. If a procedure is performed on a ward it should take place in the treatment room. Involve only the minimum number of staff required.

The following protective clothing should be worn:

- Liquid repellent operation gown, over a plastic apron
- Gloves
- Mask
- Visor or goggles

This protective clothing should be treated as single-use and disposed of by incineration after use.

Instruments (single-use or otherwise) and other medical devices that are contaminated with tissue of high or medium infectivity (see Appendix 2) must be destroyed by incineration. The Infection Control team will advise where there is doubt as to whether contamination of instruments or medical devices has occurred.

Instruments and other medical devices that have been in contact with tissue of low infectivity can be cleaned, decontaminated and reused as normal.

Some expensive items such as drills, may be prevented from being contaminated by using shields, guards or covering, so that the entire item need not to be destroyed. The drill bit, or other parts in contact with high/medium risk tissue and the protective covering, would then need to be incinerated. In practice it may be difficult to ensure protective covering and advice should be sought from the IPCT.

Possible patients

Precautions are as for definite or probable cases (section 6.6.3) with the following differences.

- Instruments that are, or may be, contaminated with tissue of high or medium infectivity (see Appendix 2) need not be incinerated, but will be quarantined (see section 6.6.4) until the diagnosis is confirmed or an alternative diagnosis made.

At risk asymptomatic patients

Precautions as for definite and probable cases (section 6.6.3) with the following differences:

- Instruments and other medical devices that are, or may be, contaminated with tissues of high or medium infectivity (see appendix 2) that have been used on at risk asymptomatic patients must be quarantined (Section 6.6.4) and reused only on the same patient.
- The protective clothing described in section 6.6.3 should be worn by staff carrying out the procedures although the protective clothing may be reprocessed if not designated single-use. If protective clothing is contaminated then it should not be reprocessed but should be disposed of through the clinical waste stream.

6.6.4 Quarantining of surgical instruments

The user, the individual's clinician, the SSD supervisor and the Infection Prevention and Control Team are all jointly responsible for ensuring the correct instruments/endoscopic equipment is identified for quarantine, reprocessing and subsequent storage in a safe and secure place. The final decision on whether to quarantine instruments/endoscopic equipment and on release for re-use or incineration must be made by the Consultant Virologist supported by the IPCT.

On occasions it may be unclear as to whether a patient has been exposed to a CJD/vCJD, or whether a certain procedure is classified as high, medium or low risk, and decisions need to be made about whether instruments used on the patient need to be quarantined. In such cases the IPCT will seek expert advice from the CJD panel.

The quarantining procedure for both surgical and endoscopy instrumentation is clearly identified in appendices 7 and 8 respectively.

Further information is also available in Department of Health TSE Guidance Annex E and F ¹.

Access to quarantine cupboards on each trust site

Royal Victoria Infirmary: Key code access available from IPCT and Operating Theatres Matron/bleep holder.

Freeman Hospital: Keys held by Infection Prevention and Control and Security

6.6.5 Instrument cleaning, decontamination, and waste disposal

Please refer to Sterile Services Department (SSD) Standard Operating Procedures relating to the cleaning and decontamination of surgical instruments potentially contaminated with CJD/vCJD. These will be reviewed on a regular basis and also specifically when further DOH guidance is made available and at the time of review of this policy

6.6.6 Endoscopic cleaning, decontamination and waste disposal

Only central reprocessing units within the Trust have the facilities to manage individual scopes identified for quarantining therefore management of these scopes outside of these departments is prohibited. Please refer to the Endoscopy Unit Standard Operating Procedures relating to the cleaning and decontamination of scopes potentially contaminated with CJD/vCJD. These will be reviewed on a regular basis and also specifically when further DOH guidance is made available and at the time of review of this policy.

6.6.7 EEG

EEG electrodes used within the Trust are non invasive and therefore do not pose a risk. If any non single use invasive EEG electrodes are proposed for introduction in the future then Infection Prevention and Control must be contacted.

6.6.8 Waste disposal in Theatres and Endoscopy

High or medium risk tissues (see Appendix 2) and objects contaminated with high or medium risk tissues should be bagged or placed in a sharps bin (as appropriate) and sent for incineration in accordance with the Trust waste policy. Normal procedures apply for low risk waste.

6.6.9 Surface Decontamination and management of spillages

See section 6.4.5

6.7 Laboratories

The agents of TSE are classed as hazard group 3 pathogens, and all clinical specimens from definite, probable, possible or at risk patients should be handled at containment level 3. However, the option of derogation does apply and, based on local risk assessment, certain containment level 3 precautions can be dispensed with.

All Trust laboratories must ensure that appropriate risk assessments have been made and that procedures are in place for the safe handling of specimens from TSE patients. Such procedures must be applied to all specimens from definite, probable, possible, or risk patients, and must include procedures for the inactivation and safe disposal of clinical specimens.

More detailed information can be found in the Department of Health TSE Guidance Annex K¹.

6.8. Post mortems

Pathology departments must ensure that appropriate procedures are in place for the safe performance of post mortem examinations. It is recommended that post mortems are only carried out in one post mortem room to reduce the risk of potential infection; the post mortem room at the Royal Victoria Infirmary is recommended because the neuropathology department is on that site.

More detailed information can be found in the Department of Health TSE Guidance Annex H¹. Specific guidance for the further management of the deceased in relation to undertakers and embalmers is also detailed in Annex H1.

7. Training

All staff working on Trust premises, including Trust employed staff; agency and locum staff are responsible for accessing IPC Policies in order to assist in the management of their patients. It is the responsibility of the departmental lead to ensure that training is offered to all relevant staff in relation to TSE. Specific support is available in order to meet training needs through the IPCT.

8. Equality and Diversity

This policy meets the needs of all individuals including that of children

9. Monitoring and Review

Standard / process / issue	Monitoring and audit			
	Method	By	Committee	Frequency
To achieve full risk assessment preoperatively in high risk areas	Retrospective audit of risk assessment management	IPCT and departmental leads in high risk areas	CJD Committee IPCC	Annually
Ensure compliance of policy at departmental level in relation to care of individuals and any instrumentation used on those individuals	Real time monitoring of care given and management of instrumentation	IPCT and departmental leads	CJD Committee IPCC	Case by case basis

10. Consultation and review

This policy has being reviewed by the members of the IPCT and CJD Group

This policy will be reviewed every three years by IPC Doctor for CJD/CJD Committee or as and when significant changes make earlier review necessary

11. Implementation and review

This Policy is the amalgamation of the Acute and Community IPC Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt- Jacob Disease (CJD)

Sisters/Charge Nurses and Clinical Leads should ensure that staff are aware of this policy and ensure that the Standard Principles of Infection Prevention and Control are followed in the management of patient/service users with a known TSE

12. References

1. Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee. Transmissible spongiform encephalopathy agents: safe working and the prevention of infection. 2003. (Web site: <http://www.dh.gov.uk/ab/acdp/tseguidance/index.htm>). Individual sections updated regularly.

2. National Creutzfeldt-Jakob Disease Surveillance Unit, Neuropathology Laboratory, Western General Hospital, Crewe Road, Edinburgh EH4 2XU. Telephone 0131 332 2117; fax 0131 343 1404. (<http://www.cjd.ed.ac.uk>)
3. National Institute for Health and Clinical Excellence. Patient safety and reduction of risk of transmission of Creutzfeldt-Jacob disease (CJD) via interventional procedures. November 2006. <http://www.nice.org.uk/>
4. Reducing the risk of exposure of patients to the agent of CJD through brain biopsy procedures. Letter from the Chief Medical Officer. May 2004. (web site: <http://www.dh.gov.uk>)

13. Associated documentation

Trust Policies

(Accessed via Policies & Procedures, Trust intranet)

- [IPC Care of Cadaver Policy](#)
- [Hand Hygiene Policy](#)
- [Needlestick Injuries Policy](#)
- [Notifiable Diseases](#)
- [Standard Precautions](#)
- [Used Laundry Management Policy](#)
- [Waste Management Policy](#)

Appendix 1: Categorization of Patients by Risk

Patient groups	
Symptomatic patients	<ul style="list-style-type: none"> • Patients who fulfill the diagnostic criteria for definite, probable or possible CJD or vCJD (see Annex B for diagnostic criteria) • Patients with neurological disease of unknown aetiology, who do not fit the criteria for possible CJD or vCJD, but where the diagnosis of CJD is being actively considered
Patients “at increased risk” from genetic forms of CJD	<ul style="list-style-type: none"> • Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD. • Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD; • Individuals who have or have had two or more blood relatives affected by CJD or other prion disease
Patients identified as “at increased risk” of CJD/vCJD through iatrogenic exposures	<ul style="list-style-type: none"> • Recipients of hormone derived from human pituitary glands, e.g. growth hormone, gonadotrophin. In the UK the use of human-derived gonadotrophin was discontinued in 1973, and use of cadaver-derived human growth hormone was banned in 1985. However, use of human-derived products may have continued in other countries after these dates. • Individuals who underwent intradural neurosurgical or spinal procedures before August 1992. These patients may have received a graft of human-derived dura mater and should be treated as being “at increased risk” unless evidence can be provided that human-derived dura mater was not use. Patients who received a graft of human-derived dura mater <u>before August 1992</u> are “at increased risk” of transmission of sporadic CJD. • Individuals who have had surgery using instruments that had been used on someone who went on to develop CJD/vCJD, or was “at increased risk” of CJD/vCJD; • Individuals who have received and organ or tissue from a donor infected with CJD/vCJD or “at increased risk” of CJD/vCJD; • Individuals who have been identified prior to high risk surgery as having received blood or blood components from 80 or more donors since January 1980; • Individuals who have received blood from someone who went on to develop vCJD; • Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD; • Individuals who have been treated with certain implicated UK sourced plasma products between 1980 and 2001

Adapted from Department of Health TSE Guidance. Part 4¹

Appendix 2

DISTRIBUTION OF TSE INFECTIVITY IN HUMAN TISSUE AND BODY FLUIDS

The table below presents current information on the distribution of infectivity in tissue and body fluids in CJD and vCJD, based on data from experimental studies, where available, and on information from other studies of natural TSE disease in humans and animals.

Tissue	CJD Assumed level of Infectivity	VCJD Assumed level of Infectivity
Brain	High	High
Spinal cord	High	High
Cranial nerves (entire optic nerve and intracranial portions of others)	High	High
Cranial ganglia	High	High
Posterior eye	High	High
Olfactory epithelium	Medium	Medium
Spinal ganglia	Medium	Medium
Tonsil	Low	Medium
Gut associated lymphoid tissue	Low	Medium
Appendix	Low	Medium
Spleen and thymus	Low	Medium
Other lymphoid tissue	Low	Medium
Dura mater (reclassified December 2010)	Low	Low
Anterior eye and cornea	Low	Low
Peripheral nerve	Low	Low
Skeletal muscle	Low	Low
Dental pulp	Low	Low
Gingival tissue	Low	Low
Blood and bone marrow	Low	Low
CSF	Low	Low
Placenta	Low	Low
Urine	Low	Low
Other tissue	Low	Low

Adapted from department of Health TSE Guidance, annex A1¹

Appendix 3: CJD/vCJD Risk Assessment Form (neurosurgery)

The Newcastle upon Tyne Hospitals 
 NHS Foundation Trust

Affix patient identification label in box below or complete details

Surname	Patient i.d.No.
Forename	D.O.B. DDMMYYYY
Address	NHS No.
	Sex. Male / Female
Postcode	

CJD / vCJD ASSESSMENT Questionnaire

Note: this form does not need to be completed prior to procedures that are completed solely with single use instruments

CJD is a very rare fatal brain disease caused by a protein that is not destroyed by the systems used to clean surgical instruments. Although there have been no cases of transmission of vCJD via surgical instruments, we are required to safeguard against this risk. Answering yes to any of the questions does not necessarily mean surgery may be cancelled.

1) Are you closely related to anyone who has or has had vCJD/CJD?

NO YES UNKNOWN

If yes please specify

2) Have you ever received growth hormone or gonadotrophin fertility treatment?

NO YES UNKNOWN

If yes, 1) was it in the UK..... 2) was it before 1985?.....

3) Have you had surgery on your brain or spinal cord before August 1992?

NO YES UNKNOWN

If yes please specify

Please continue overleaf

4) Have you ever been notified that you are at risk of vCJD/CJD?

NO YES UNKNOWN

If yes please specify

5) Since 1980, have you had multiple transfusions of blood or blood components (e.g. red cells, plasma, platelets)?

NO YES UNKNOWN

If yes do either of the following apply:

1) More than 50 units of blood or blood components given?.....

2) Transfusions given on more than 20 separate occasions?.....

If the information has been provided by the next of kin please state:

Name : Relationship:

Details of member of staff completing form:

Name:

Signature: Date:

Designation: Ward:

NOTE TO STAFF: If answer to any of the above is YES, refer to Infection Prevention and Control Team immediately and bring to the attention of the clinician in charge of the patient. Regarding question 5 only patients who may have received transfusion of more than 50 units or on more than 20 separate occasions require further investigation.

In addition for all patients undergoing procedures on high risk tissues (Neurology and Ophthalmology), check medical notes and referral letter for any mention of vCJD/CJD.

If the Infection Prevention and Control Team were contacted please document advice given and the outcome.

.....
.....
.....

**THIS FORM MUST BE FILED IN THE CLINICAL SECTION
OF THE PATIENT NOTES**

Affix patient identification label in box below or complete details

Surname	Patient I.D. No.
Forename	D.O.B. DDMMYYYY
Address	NHS No.
Postcode	

CJD / vCJD Ophthalmology Assessment Questionnaire

Note: this form does not need to be completed prior to procedures that are completed solely with single use instruments

CJD is a very rare fatal brain disease caused by a protein that is not destroyed by the systems used to clean surgical instruments. Although there have been no cases of transmission of vCJD via surgical instruments, we are required to safeguard against this risk. Answering yes to any of the questions does not necessarily mean surgery may be cancelled.

1) Have you ever been notified that you are at risk of vCJD/CJD?

NO YES

If yes please specify

Note to staff: Please discuss with the clinician and then contact Infection Prevention and Control to discuss if answered yes. If the answer is unknown it can be assumed that no action is required.

2) Does the planned procedure/surgery that the patient is undergoing involve posterior eye? (If unsure, please discuss with medical staff)

NO If **NO** – sign and complete details in box of page 2 of this form (**DO NOT** ask questions 3-6)
 YES If **YES** – questions 3-6 **MUST** be asked

3) Have you ever received growth hormone or gonadotrophin fertility treatment?

NO YES UNKNOWN

If yes, 1) was it in the UK..... 2) was it before 1985?.....

4) Have you had surgery on your brain or spinal cord before August 1992?

NO YES UNKNOWN

If yes please specify

5) Are you closely related to anyone who has or has had vCJD/CJD?

NO

YES

UNKNOWN

If yes please specify

.....

6) Since 1980, have you had multiple transfusions of blood or blood components (e.g. red cells, plasma, platelets)?

NO

YES

UNKNOWN

If yes do either of the following apply:

1) More than 50 units of blood or blood components given?.....

2) Transfusions given on more than 20 separate occasions?.....

If the information has been provided by the next of kin please state:

Name : Relationship:

Details of member of staff completing form:

Name:

Signature: Date:

Designation: Ward:

NOTE TO STAFF: If answer to any of the above is YES, please discuss with the clinician in charge of the patient and inform the Infection Prevention and Control Team. Regarding question 6 only patients who may have received transfusion of more than 50 units or on more than 20 separate occasions require further investigation.

In addition, for all patients undergoing procedures on high risk ophthalmology tissue (back of eye), check medical notes and referral letter for any mention of vCJD/CJD.

If the Infection Prevention and Control Team were contacted please document advice given and the outcome.

.....

.....

**THIS FORM MUST BE FILED IN THE CLINICAL SECTION OF
THE PATIENT NOTES**

Appendix 5: Patient Information Leaflet

Information for patients on the CJD/vCJD assessment questionnaire

Part of your routine assessment before operations on the brain, spinal cord or the back of the eye includes some questions to find out whether you could have an increased risk of Creutzfeldt-Jakob disease (CJD). We ask you:

- **Are you closely related to anyone who has or has had vCJD/CJD?**
- **Have you ever received growth hormone or gonadotrophin treatment?**
- **Have you had surgery on your brain or spinal cord before August 1992?**
- **Since 1980, have you had multiple transfusions of blood or blood components (red cells, plasma or platelets)?**

What is CJD?

Creutzfeldt-Jakob disease (CJD) is a rare brain disorder that affects about one in a million people each year. CJD is thought to be caused by the build up in the brain of an abnormal form of a protein called a 'prion'. There are different types of CJD, including variant CJD (vCJD). vCJD is caused by eating meat from cows infected with BSE.

How can CJD spread from person to person?

A person who is infected with CJD may have abnormal prion protein in their body for years before becoming ill. If that person has an operation, or donates blood, tissues or organs, during that time, the abnormal prion protein that causes CJD could spread to other patients.

Why are we asking you about CJD before your operation?

The abnormal prion protein that causes CJD is very hard to remove or destroy. If surgical instruments are used on a patient who is infected with CJD they may still have prion protein on them, even after they have been properly washed and disinfected. They could then spread CJD to other patients. This is particularly important for operations on the brain, spinal cord and the back of the eye as these parts of the body contain the largest amount of abnormal prion protein.

What have these questions got to do with CJD?

CJD has been spread in several ways and different groups of people may have an increased risk of CJD.

- We ask whether there is anyone in your family who has had CJD because some types of CJD can be passed on through families. These types of CJD are caused by faulty genes and may be passed from parent to child.
- We ask whether you have been treated with growth hormone or gonadotrophin infertility treatment because these used to be prepared from pituitary glands. Some of these hormone treatments have been linked to CJD infection - these hormones are no longer used.

- We ask whether you have had surgery on the brain or spinal cord because some of these operations used to use grafts of 'dura mater' (the tough lining round the brain and spinal cord). Some of these grafts have been linked to CJD infection - these grafts are no longer used.
- We ask whether you have had a large number of blood transfusions as this could be related to an increased risk of variant CJD (vCJD). vCJD is the type of CJD which is caused by eating meat from cows infected with BSE. vCJD can be spread through blood transfusions. We don't know how many blood donors are infected with vCJD, even though they appear to be healthy, or how easily vCJD might spread through blood transfusions. This means that the risk of vCJD to someone who has received blood is very uncertain. It is only worth considering if patients have received extremely large amounts of blood. Even then the risk is still very uncertain.

What happens if I answer 'Yes' to any of these questions?

If you answer 'Yes' to any of these questions, medical staff will now examine your medical records in more detail to determine whether or not you may have an increased risk of CJD.

What will happen then?

If you do have an increased risk of CJD special precautions will be taken with the surgical instruments used in your operation. Please remember that the overall risk of CJD spreading by these routes is generally **very low**. These questions are an extra measure to prevent CJD spreading through surgery. **This should not affect the medical care you receive now or in the future.**

Can I have a blood test to see if I am infected with CJD?

Unfortunately there is no blood test available yet which could show if you have CJD.

Where can I find out more?

If you have any further questions or concerns please let ward staff know.

The following organisations also offer further information and support.

- Health Protection Agency website: www.hpa.org.uk/cjd
- CJD Support Network website: www.cjdsupport.net
- National CJD Surveillance Unit website: www.cjd.ed.ac.uk
- National Prion Clinic website: www.nationalprionclinic.org/

Information produced by Sheila Waugh (consultant virologist)

Adapted from: Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection; Annex J. July 2009.

Appendix 6: Outline of letter to be sent to GP by Consultant Virologist on behalf of IPC team. (based on annex J DOH TSE guidance¹)

Dear Dr

RE: Patient Name:

Date of Birth

NHS Number:

The above patient recently attended the Royal Victoria Infirmary / Freeman Hospital. As part of the pre-surgical assessment for neurosurgery or posterior eye surgery we ask a number of questions regarding potential risk factors for Creutzfeldt Jacob Disease (CJD) / variant CJD (vCJD). This is required by the Department of Health guidance 'Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection; Annex J. updated 2010'.

The patient answered 'YES' to the question:

- **Are you closely related to anyone who has or has had vCJD/CJD?**

Some types of CJD can be passed on through families. These types of CJD are caused by faulty genes and may be passed from parent to child. As the patient states that they have at least two blood relatives who have developed CJD they are regarded as at potential increased risk of developing the inherited form of CJD

OR

The patient answered yes to the question:

- **Have you had surgery on your brain or spinal cord before August 1992?**

In the past some operations on the brain or spinal cord used grafts of 'dura mater' (the tough lining round the brain and spinal cord). Some of these grafts have been linked to CJD infection - these grafts are no longer used. The patient states they had a neurosurgical procedure in 19xx. Further investigations suggest that this procedure may have involved a dura mater graft, although we cannot be certain. The patient is therefore considered to be at increased risk of CJD.

OR

The patient has answered yes to the question:

- **Since 1980, have you had multiple transfusions of blood or blood components (red cells, plasma or platelets)?**

Some types of CJD can be spread through blood transfusions. We don't know how many blood donors are infected with CJD, even though they appear to be healthy, or how easily CJD might spread through blood transfusions. This means that the risk of

CJD to someone who has received blood is very uncertain. It is only worth considering if patients have received extremely large amounts of blood (over 80 donor exposures). Even then the risk is still very uncertain.

Further investigation indicates that the patient has in excess of 80 donor exposures and is therefore considered as at increased risk of vCJD.

OR

The patient has answered yes to the question:

- Have you ever received growth hormone or gonadotrophin treatment?

Growth hormone or gonadotrophin (often used in fertility treatment) used to be prepared from human pituitary glands. Some of these hormone treatments have been linked to CJD infection - these hormones are no longer used.

Further investigation suggests that the patient may have received pituitary-derived growth hormone/gonadotrophin in the past and is therefore considered at increased risk for CJD.

CJD is extremely rare and the chance of the patient being infected or developing symptoms is still likely to be extremely low. We have to ask these questions so that special precautions can be taken with the surgical instruments used in the operation to prevent CJD spreading through surgery. This should not affect the medical care the patient receives now or in the future.

We have informed the patient of the potential increased risk and I have enclosed a copy of the written information given to the patient. Further information is available from the following sources:

- Health Protection Agency website: www.hpa.org.uk/cjd
- CJD Support Network website: www.cjdsupport.net
- National CJD Surveillance Unit website www.cjd.ed.ac.uk/
- National Prion Clinic website: www.nationalprionclinic.org

INCLUDE FOR BLOOD TRANSFUSION RISK

We are required to inform the CJD section of the Health Protection Agency for patients identified as at increased risk due to multiple transfusions. They may contact you directly regarding this.

INCLUDE FOR INHERITED RISK

The Department of Health guidance (annex J www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm Guidance) also states the following: 'Patients who are at increased risk of genetic forms of CJD may benefit from discussions with the National Prion Clinic, based at the National Hospital for Neurology and Neurosurgery, Queen Square, London: <http://www.nationalprionclinic.org/>'

INCLUDE FOR HORMONE RISK

The Department of Health guidance (annex J www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm) also states the following: Patients who are at increased risk of sporadic CJD due to receipt of human derived growth hormone or gonadotrophin may benefit from discussions with the UCL Institute of Child Health, London. Contact: L.Davidson@ich.ucl.ac.uk, 020 7404 0536.

Patients identified as at increased risk from of CJD or vCJD are asked to take certain precautions to reduce the risk of spreading the infection to others. These are:

- Not donating blood (most organs and tissues can still be donated)
- Informing healthcare staff if they need to undergo an invasive surgical, medical or dental procedure;
- Informing a family member or someone close to them, in case they need emergency surgery or endoscopy in the future

The individual's GP is asked to record the patient's CJD risk status in their primary care records. This information should also be included in any referral letter should the patient require invasive surgical, medical or dental procedures.

Should you need to discuss this further please contact Dr Sheila Waugh (consultant virologist) on 0191 244 8948 or The HPU on 0844 225 3550.

Yours sincerely

Sheila Waugh
(Consultant Virologist)

Cc HPU, surgeon.

Instrument Quarantine Form

Patient Details :(affix Hospital addressograph)

Name:

DOB:

Patient's identified Ward and Hospital Site:

Details of Procedure:

Surgical Procedure Performed:

Date of Procedure:

Operating Theatre and Hospital site:

Name and Designation of Person Performing Procedure (Consultant):

Instrument Quarantine Action for Pre assessment/Theatres

1. Ensure that the Infection Prevention and Control team are aware that non disposable instruments have been identified for quarantining.
2. Ensure that the Sterile Service Department are aware of instruments that require reprocessing and quarantining.
3. Ensure Consultant is aware.

Instrument Quarantine Theatres

Theatres:

1. Where ever possible use disposal instruments. Any clinical waste generated must be segregated and sent for incineration.
2. Photocopy tray list. One for unused instruments left in din basket and one for used instruments (see 5 and 6).
3. Separate instruments prior to the procedure from the tray that will not be used (leave in din basket provided with tray). Send this incomplete tray to SSD identifying on the tray list those instruments present. Please note reason for incomplete tray on instrument list.
4. All instruments used in the procedure must be placed in the din basket provided in the SSD BLUE APPROVED TRANSPORT BOX (BTB006) (Yellow Ties).
5. Place the instruments used in the din basket in to the BLUE APPROVED TRANSPORT BOX (BTB006).
6. Complete documentation including tray list and tray numbers identification on reverse of this document.
7. Place this form into a plastic sleeve; attach to the BLUE APPROVED TRANSPORT BOX (BTB006) with biohazard tape to the side of the box with the patient details uppermost.
8. Arrange to be sent to the Infection Prevention and Control Quarantine cupboard or if pre arranged direct to SSD for reprocessing prior to quarantining. These instruments must be segregated from other instrumentation at all times.
9. Security holds the access key to the quarantine cupboard at FRM .Key code for RVI available from senior theatre staff. Contact the Infection Prevention and Control team in working hours to confirm actions taken.

Name of person responsible for the above (print):

Signature: Date:.....Designation:.....

Instrument Quarantine Form

Patient Details

Name:
Hospital Number:

Instruments (theatre staff):

List all theatre tray numbers used in procedure including any supplementary instruments. Ensure a photo copy of tray list is attached. Please write clearly

Number of BLUE APPROVED TRANSPORT BOXES (BTB006) relating to this individual case:

Preparation of Instrument for transfer to Infection Prevention and Control Quarantine Cupboard

Name of person arranging storage in Quarantine Cupboard (print):
Signature: Date:.....Designation:.....

Preparation of Instrument Transfer to SSD for reprocessing

Name of person transferring instruments to SSD (print):
Signature: Date:.....Designation:.....

Instrument Quarantine Sterile Service Department

1. Check all instruments identified on quarantine tray list accompanying this document.
2. Reprocess as identified on SOP.
3. Identify whether instruments autoclaved or not. Autoclave Yes/No
4. Ensure thermal disinfection cycle undertaken following washer disinfector use on this/these individual trays.
5. Contact Infection Prevention and Control to arrange re Quarantining of BLUE TRANSPORT (BTB006) BOX and contents.
6. Ensure this documentation remains with the BLUE TRANSPORT BOX (BTB006)

Name of person responsible for the above (print):
Signature:..... Date:.....Designation:.....

Instrument Quarantine Infection Prevention and Control

Arrange collection from SSD to quarantine instruments]

Name of person responsible for the above (print):
Signature: Date:.....Designation:.....

Countersignature of Infection Prevention and Control once verification of quarantine made

Name of person responsible for the above (print):
Signature: Date:.....Designation:.....

Release of Instruments from quarantine for:

1. Specific identified patient reuse YES/NO
2. Release into general circulation as now low risk identified YES/NO
3. Instrument to be incinerated YES/NO

Name of person responsible for the above (print):
Signature: Date:.....Designation:.....

Endoscope Quarantine Form

Patient Details :(affix Hospital addressograph)

Name:

DOB:

Patient's identified Ward/department and Hospital Site:

Hospital Number:

Details of Procedure:

Endoscopic Procedure Performed:

Date of Procedure:

Name and Designation of Person Performing Procedure (i.e. Consultant):

Endoscope Quarantine (Endoscopy Unit)

Endoscope Unique Serial Number:.....

10. Use disposable equipment wherever possible. Any clinical waste generated must be segregated and sent for incineration.
11. For scope reprocessing: Follow the protocol for use of Flexible Endoscopes with patients having received UK Plasma Blood Products or that have been identified as potentially at risk of CJD or vCJD.
12. Place this completed form into a plastic sleeve; attach to the outside of the scope lockable box with biohazard tape to the top of the box with the patient details uppermost.
13. Arrange to be sent to the Infection Prevention and Control cupboard for CJD Quarantine by contacting the security services at NGH and FRM and Leases wing reception at the RVI for key access or contact Infection Prevention and Control direct . This scope must be segregated from other scopes at all times.

Name of person responsible for the above (print):

Signature: **Date:**.....**Designation:**.....

Endoscope Quarantine Infection Prevention and Control ONLY

Release of Instruments from quarantine for:

4. Specific identified patient reuse YES/NO sees below.
5. Release into general circulation as now low risk identified YES/NO
6. Instrument to be incinerated YES/NO

Name of person responsible for the above (print):

Signature: **Date:**.....**Designation:**.....

Endoscope for Reuse on Identified Patient Only

Arrange collection from Quarantine Cupboard and delivery to Endoscopy (to be undertaken by Infection Prevention and Control).

Name of person responsible for the above (print):

Signature: **Date:**.....**Designation:**.....

NB: Complete a new for any scope that is reused on an identified patient

THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
IMPACT ASSESSMENT – SCREENING FORM A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	Policy for the Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in the hospital and community setting.	Policy Author:	Dr Sheila Waugh
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)	No	This policy does not directly or indirectly affect any of the groups listed.
	• Race *	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender *	No	
	• Culture	No	
	• Religion or belief *	No	
	• Sexual orientation including lesbian, gay and bisexual people *	No	
	• Age *	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems *	No	
	• Gender reassignment *	No	
	• Marriage and civil partnership *	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable?		
4(a).	Is the impact of the policy/guidance likely to be negative? (If "yes", please answer sections 4(b) to 4(d)).	No	
4(b).	If so can the impact be avoided?		
4(c).	What alternatives are there to achieving the policy/guidance without the impact?		
4(d)	Can we reduce the impact by taking different action?		

Comments:	Action Plan due (or Not Applicable): N/A
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Name and Designation of Person responsible for completion of this form: Dr Sheila Waugh (Consultant Virologist)..... Date: 12/01/2012.....

Names & Designations of those involved in the impact assessment screening process:.....

..(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman/Walkergate, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.