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<th>Document name:</th>
<th>Policy for the Management of Patients known or at High Risk of Creutzfeldt-Jakob Disease (CJD) and other human prion diseases</th>
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<td>Executive Management Team</td>
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<td>Developed by:</td>
<td>Infection Prevention and Control Team</td>
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<td>Director leads:</td>
<td>Director of Nursing, Clinical Governance and Safety, acting as Director of Infection Prevention and Control</td>
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<td>Contact for advice:</td>
<td>Infection Prevention &amp; Control Team,</td>
</tr>
</tbody>
</table>
Index

1. **Introduction** .................................................................................................................. 4
   1.1 Creutzfeldt-Jakob Disease ......................................................................................... 4
   1.2 Variably Protease-sensitive Prionopathy (VPSPr) ..................................................... 4
   1.3 Variant Creutzfeldt-Jakob Disease ............................................................................ 5
   1.4 Cgertman-Straussler-Scheinker syndrome (GSS) and Fatal Familial Insomnia (FFI) ........................................................................................................ 5
   1.5 Kuru ........................................................................................................................... 5
   1.6 Transmission of CJD and related disorders ............................................................... 5
   1.7 Occupational exposure .............................................................................................. 5

2. **Purpose and scope of the policy** ..................................................................................... 5

3. **Definitions** .................................................................................................................... 6

4. **Duties and responsibilities** ............................................................................................ 6
   4.1 Chief Executive ......................................................................................................... 6
   4.2 Trust Board ............................................................................................................... 6
   4.3 Executive Management Team (EMT) ....................................................................... 6
   4.4 Clinical Governance & Clinical Safety Committee (CGCSC) .................................. 6
   4.5 Director of Infection Prevention and Control ........................................................... 7
   4.6 Infection Prevention and Control Trust Action Group (IPC TAG) ......................... 7
   4.7 Infection Prevention and Control Team (IPCT) ....................................................... 7
   4.8 Business Delivery Units .......................................................................................... 8
   4.9 Matrons/Practice Governance Coaches .................................................................. 8
   4.10 Unit / Department Managers ................................................................................ 8
   4.11 Link Professionals .................................................................................................. 9
   4.12 Staff ....................................................................................................................... 9
   4.13 Volunteers, Agency Staff, External Contractors and visitors/members of the public .............................................................................................................. 9
   4.14 Occupational Health ............................................................................................... 9

5. **Principles of this policy** .................................................................................................. 9
   5.1 Glossary of terms & abbreviations ............................................................................ 9
   5.2 Identifying patients at risk of CJD or related disorder .............................................. 9
   5.3 Recommended CJD risk questions ........................................................................... 11
   5.4 The need for a comprehensive pre-surgery assessment ........................................... 12
   5.5 Diagnostic criteria .................................................................................................... 12
   5.6 Classification criteria ............................................................................................... 12
   5.7 Individuals who do not fulfil any of the criteria ....................................................... 14
   5.8 Categorisation of body tissues depending upon risk of infectivity ........................... 14
   5.9 Hospital care of individuals with CJD / vCJD .......................................................... 15
   5.10 Occupational Exposure ......................................................................................... 17
   5.11 After Death .............................................................................................................. 19
6. Developmental Process ...........................................................................................................21
   6.1 Identification of need ........................................................................................................21
   6.2 Stakeholder Involvement .................................................................................................21
   6.3 Equality impact assessment ............................................................................................20
7. Dissemination and implementation arrangements (including training) .........................21
   7.1 Dissemination ................................................................................................................21
   7.2 Implementation .................................................................................................................21
   7.3 Training ............................................................................................................................21
8. Process for monitoring compliance and effectiveness ..........................................................22
   8.1 Monitoring compliance .....................................................................................................22
   8.2 Further advice and support .............................................................................................22
9. Review and revision arrangements (including version control) .........................................23
   9.1 Process for reviewing the policy .....................................................................................23
   9.2 Version control ...............................................................................................................23
   9.3 Archiving .........................................................................................................................23
10. References and further reading ..........................................................................................23
11. Any other documents which should be referred to ............................................................23

Appendix A – Equality Impact Assessment Tool .......................................................................25
Appendix B – Version Control Sheet ........................................................................................27
Policy for the Management of Patients known or at High Risk of Creutzfeldt-Jakob Disease (CJD) and other human prion diseases

1. Introduction
Creutzfeldt-Jakob Disease (CJD) and related disorders, belong to a group of diseases known as Transmissible Spongiform Encephalopathies (TSEs) or human prion diseases. These are fatal degenerative brain diseases which occur in humans and some animal species.

The Human CJD Related Disorders which are also covered by this policy include:

- Creutzfeldt-Jakob disease (CJD)
- Classical sporadic familial iatrogenic and variant CJD (vCJD)
- Gerstmann-Straussler-Scheinker syndrome (GSS)
- Fatal familial insomnia (FFI)
- Kuru

The causative agent is remarkably resistant to conventional sterilisation and disinfection techniques. It is thought that CJD is caused by infectious proteins known as ‘prions’ which are rogue forms of a normal protein found in the brain.

Whilst the evidence to date does not suggest that CJD or related disorders are spread from person to person by close contact, it is known that transmission can occur in specific situations associated with medical interventions e.g. hormones sourced from human pituitary glands or neurosurgery with inadequately decontaminated instruments. Consequently, certain procedures need to be followed to identify patients who present a greater than average risk of carrying a CJD or related agent and thereafter managing their care appropriately, whilst reducing the risk of on-going transmission to staff and other patients.

1.1 Creutzfeldt-Jakob Disease
This is a rare and fatal neurological condition that affects the nervous system. It is associated with a change in a protein called the ‘prion protein’. This abnormal form of the protein accumulates in the brain and results in the death of nerve cells. The commonest form of CJD is classical sporadic, which affects approximately one per million of the population per annum across the world. The usual age of onset for classical sporadic CJD is late middle age (average age 63 years). About 85% of all cases are classical sporadic, most of the rest occur as familial diseases. Iatrogenic CJD is the result of transmission through medical and surgical procedures including injections with human pituitary hormones, dura mater grafts and very rarely by neurosurgical instruments.

1.2 Variably Protease-Sensitive Prionopathy (VPSPr)
VPSPr is a recently described human prion disease, which appears to be a rare sporadic disorder affecting patients in an age range similar to those affected by sporadic CJD.

The transmissibility of VPSPr is currently under investigation; preliminary results appear to indicate that it is transmissible experimentally to rodents, but the transmission characteristics are still being determined.
There is very little data on the detection of abnormal prion protein outside the CNS in VPSPr, so as for other prion diseases where these data are lacking (e.g. many genetic forms of prion disease) it seems reasonable to assume a similar tissue distribution to sporadic CJD, since there is no evidence to indicate that VPSPr is a BSE-related disorder.

1.3 Variant Creutzfeldt-Jakob Disease

Variant CJD (vCJD) is a new form of human TSE, which was first recognised in 1996. This new disease is associated with the same transmissible agent that is responsible for Bovine Spongiform Encephalopathy (BSE). Experimental studies have shown that the BSE agent is not related to sporadic CJD. There have been over 100 confirmed or probable cases of vCJD in the UK. Variant CJD is thought to have resulted from the consumption of contaminated bovine (beef) food products.

1.4 Gerstmann-Sträussler-Scheinker syndrome (GSS) and Fatal Familial Insomnia (FFI).

These types of TSEs are exceptionally rare, affecting around one person in 10-100 million per year. These diseases are associated with mutations in the prion protein gene and are inherited thus related members of a family may be affected. In GSS and FFI the disease is usually more prolonged then in CJD, and generally starts at an earlier age. GSS patients suffer predominately from problems of balance and in coordination; FFI is characterised by abnormal sleeping patterns.

1.5 Kuru

Kuru was found in the Fore tribe of New Guinea and was first reported in 1957. It was associated with funeral rites involving ritual contact with, preparation of, and consumption of the entire body including the brains of victims of which some of these would have had Kuru. Occurrence of kuru has been markedly reduced following the abolition of cannibalism, although some case may still arise from historical exposure.

1.6 Transmission of CJD and related disorders

There is no evidence that any type of CJD and related disorders are spread from person to person through normal social contact. However, a number of cases of CJD have been transmitted through certain medical treatments e.g. corneal graft operations and treatments with hormones prepared from human pituitary glands and dura mater.

1.7 Occupational exposure

There have been no confirmed cases of transmission by occupational exposure. If a TSE were to develop as a result of occupational exposure, it may only become apparent decades later. Control of Substances Hazardous to Health (COSHH) Regulations requires employers to keep a list of employees exposed to TSE agents for 40 years following the last known-exposure. Such a list is only necessary when there is a deliberate intention to work with the agent or in the case of an incidental exposure if a risk assessment shows there is significant risk. For routine clinical care of people with CJD or a related disorder however, this should not be necessary. If a significant incident occurs the details should be recorded in the individual's occupational health record.

2. Purpose and Scope of the Policy

The Trust has a legal requirement to comply with the Health and Social Care Act (DH 2008). This states that healthcare providers are required to have in place effective
systems to manage patients with, or at high risk of CJD, vCJD, and other human prion diseases.

The Trust must ensure the correct employment of procedures related to transmission of CJD, in order to minimise the risk of transmission.

The policy cannot anticipate every situation therefore professional judgement should be used to identify when a risk assessment is needed to protect those who are vulnerable and / or at risk. The process will enable staff to identify the level of vulnerability and the risks posed to individuals.

This policy should be read in conjunction with other Trust Infection Prevention and Control policies and procedures, in particular Hand Hygiene, Infection Prevention and Control and Decontamination policies.

3. Definitions
This document is a policy, which clearly specifies its’ purpose and scope.

4. Duties and responsibilities
South West Yorkshire Partnership NHS Foundation Trust (SWYPFT) has a duty and is committed to reducing the risk of the transmission of CJD and other TSE’s. Infection prevention and control is everybody’s responsibility. Trust staff are responsible for demonstrating compliance with this policy. The following specific duties apply:

4.1 Chief Executive
The Chief Executive has overall responsibility for reducing the risk of transmission of CJD, vCJD and related disorders by ensuring that there are arrangements within the organisation to manage patients with or at high risk of the disorders.

He/she is responsible for ensuring that all Directors, the Executive Management Team, BDUs and all other staff understand and accept their responsibilities in relation to this policy.

He/she is responsible for ensuring that IPC is embedded at all levels of the organisation.

4.2 Trust Board
Trust Board is responsible for signing off the approval, dissemination and implementation of this policy.

4.3 Executive Management Team (EMT)
The Executive Management Team is responsible for approving the contents of the policy.

4.4 Clinical Governance & Clinical Safety Committee (CGCSC)
The Clinical Governance & Clinical Safety Committee is responsible for the dissemination and implementation of this policy on behalf of Trust Board. They will review relevant Infection Control data.
4.5 **Director of Infection Prevention and Control**
The DIPC will report directly to the Chief Executive and the Board, and not through any other officer.

He/she will challenge inappropriate clinical hygiene practice, as well as antibiotic prescribing decisions.

He/she will be an integral member of the organisation’s clinical governance and patient safety teams and structures.

He/she will assess the impact of all policies and plans on infection, and make recommendations for change.

He/she is the lead director responsible for engaging relevant stakeholders in the development of the policy.

He/she will ensure appropriate arrangements are in place for managing any resource implications, including dissemination, implementation and training.

He/she is responsible for ensuring the most current version of the policy is in use and obsolete versions have been withdrawn from circulation.

He/she will submit the infection prevention and control assurance framework objectives for the coming year to Trust Board for approval.

He/she will produce an annual report on the state of HCAI in the organisation, and release it publicly.

4.6 **Infection Prevention and Control Trust Action Group (IPC TAG)**
The IPC TAG will review new legislation and guidance and ensure that its implications are fully understood within the Trust.

It will commission a revision of the existing policy accordingly and oversee the dissemination and implementation of the revised policy. Commissioning and development of this policy may be undertaken in liaison with the Health and Safety TAG, Drugs and Therapeutics Sub - Committee, and the Estates TAG.

The IPC TAG will receive quarterly reports from the IPCT in order to monitor compliance with relevant IPC policies.

4.7 **Infection Prevention and Control Team (IPCT)**
The IPCT will develop, disseminate, implement and review this policy.

The IPCT will provide education to clinical staff on effective decontamination.

The IPCT will advise on the appropriate infection prevention and control measures for infected and symptomatic service users.

The IPCT will support, advise and provide information to the service user, carer and relatives as appropriate
The IPCT will co-ordinate audit activity to monitor compliance with this policy.

The IPCT will ensure that Directors of BDUs are made aware of issues which occur within their care groups as they arise.

The IPCT will also provide other timely reports to Trust Board, EMT, BDUs, Modern Matrons and any other relevant groups throughout the year. These will include lessons learnt, performance management and changes to policy and procedures.

The IPCT will provide advice relating to effective practice to prevent the transmission of CJD, vCJD and related disorders.

The IPCT will lead by example and challenge poor practice.

4.8 Business Delivery Units
BDUs will be consulted in the development of the policy.

BDUs will ensure that the policy is implemented within their areas.

BDUs will ensure that business plans capture any resource implications identified to prevent the effective implementation of this policy.

BDUs will ensure that adequate resources and facilities are made available to fulfil the policy requirements.

BDUs are responsible for ensuring that all their staff complete mandatory IPC training sessions.

BDUs will ensure staff compliance with this policy.

4.9 Matrons/ Practice Governance Coaches
Modern Matrons have a key responsibility for the environment in which care is provided. They have a pivotal role in supporting the IPCT to ensure effective implementation of, and compliance with IPC policies

4.10 Unit / Department Managers
Managers will ensure that all staff for whom they have line management responsibility are aware of, and comply with this policy.

Managers will seek advice as soon as possible from the IPCT with regard to any relevant issues related to this policy.

Managers will ensure records of mandatory IPC training are sent to the Learning & Development Centre for collation.

Managers will lead by example.
4.11 Link Professionals
They will actively promote compliance with this policy.
They will actively take part in promotional events where appropriate.
They will reinforce good practice by attending the Link Professionals meetings/updates.
They will lead by example.

4.12 Staff
Infection prevention and control is everyone’s business. All staff are responsible for taking reasonable care of themselves, service users and any other people affected by their acts or omissions in accordance with Health and Safety at Work Act 1974. Staff have an individual responsibility to ensure they are working within legal and ethical boundaries. It is each member of staff’s responsibility to seek out guidance and help in implementing this policy where they have difficulty. If any member of staff is aware of difficulties in following the policy they must alert their line manager as soon as is practical.

All staff must be aware of this policy and how it impacts on their practice.
All staff must be aware of the risks to others as a consequence of non-compliance with this policy.

Individual staff are responsible for accessing and complying with this policy.

4.13 Volunteers, Agency Staff, External Contractors and visitors/members of the public
Visitors, agency staff and external contractors are expected to comply with reasonable instructions given by staff who are seeking to protect them from the risk of infection.

Occupational Health will monitor staff health.

5 Principles of this policy

5.1 Glossary of terms & abbreviations.
All abbreviations have been included in the text of this policy at it’s first use.

5.2 Identifying patients at risk of CJD or related disorder
When considering measures to prevent transmission to service users or staff in the healthcare setting, it is useful to make a distinction between symptomatic individuals, i.e. those who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD, and asymptomatic individuals, i.e. those with no clinical symptoms, but who are potentially at risk of developing one of these diseases, e.g. having a medical or family history which places them in one of the risk groups (Table 1 details below the classification of the risk).
<table>
<thead>
<tr>
<th>Patient Groups and Classification of Risk</th>
<th>Symptomatic patients</th>
<th>Patients “at increased risk” from genetic forms of CJD</th>
<th>Patients identified as “at increased risk” of vCJD through receipt of blood from a donor who later developed vCJD</th>
<th>Patients identified as “at increased risk” of CJD/vCJD through iatrogenic</th>
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</thead>
<tbody>
<tr>
<td><strong>Symptomatic patients</strong></td>
<td>Patients who fulfill the diagnostic criteria for definite, probable or possible CJD or vCJD. 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.</td>
<td>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.</td>
<td>Individuals who have received labile blood components (whole blood, red cells, white cells or platelets) from a donor who later went on to develop vCJD.</td>
<td>Recipients of hormone derived from human pituitary glands, <em>e.g.</em> growth hormone, gonadotrophin, are “at increased risk” of transmission of sporadic CJD. 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.</td>
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<tr>
<td><strong>Patients “at increased risk” from genetic forms of CJD</strong></td>
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<tr>
<td><strong>Patients identified as “at increased risk” of CJD/vCJD through iatrogenic</strong></td>
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<tr>
<td><strong>Exposures</strong></td>
<td>Individuals who underwent intradural brain or intradural spinal surgery before August 1992 who received (or might have received) a graft of human-derived dura mater are “at increased risk” of transmission of sporadic CJD (unless evidence can be provided that human-derived dura mater was not used). 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 an organ or tissue from a donor infected with CJD/vCJD or “at increased risk” of CJD/vCJD. Individuals who have been identified as having received blood or blood components from 300 or more donors since January 1990; Individuals who have given blood to 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 1990 and 2001.</td>
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<tr>
<td><strong>Patients identified as “at increased risk” of vCJD through receipt of blood from a donor who later developed vCJD</strong></td>
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<tr>
<td><strong>Patients identified as “at increased risk” of CJD/vCJD through iatrogenic</strong></td>
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<tr>
<td><strong>Exposures</strong></td>
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<tr>
<td><strong>Patient Groups and Classification of Risk</strong></td>
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In most routine clinical contact, no additional precautions are needed for the care of individuals in the risk groups. However, when certain invasive interventions are performed, there is the potential for exposure to the agents of TSEs. In these situations it is essential that control measures are in place to prevent the iatrogenic transmission of TSEs (see 5.6)

It is essential that clinicians ask CJD risk questions to all service users about to undergo a surgical or endoscopic procedure that may involve contact with tissues with high or medium level infectivity (See the list below) as part of the pre-surgery assessment.

**Brain**
- Spinal ganglia
**Spinal cord**
- Olfactory epithelium
**Cranial nerves**
- Tonsil
**Cranial ganglia**
- Appendix
**Posterior eye**
- Spleen
**Pituitary gland**
- Thymus
**Lymph nodes and gut-associated lymphoid tissues**
- Adrenal gland

If effective pre-surgery assessment is not carried out, there is a danger that the CJD status of an individual will not be determined and this may result in failure to take the appropriate infection control precautions. If this is the case, there is the potential for a CJD incident to occur and this may result in exposing subsequent service users to CJD infectivity.

Each area/department will need to undertake a risk assessment to determine whether they need to identify patients in risk groups.

### 5.3 Recommended CJD risk questions:
- Has the patient ever been diagnosed as suffering from CJD or related disorder
- Does the patient have a neurological disease, as yet of unknown etiology, but the diagnosis of CJD or a related disorder is being actively considered?
- Does the patient have a family history of CJD or related disorder?
- Has the patient received hormones derived from the human pituitary glands e.g. Growth hormone, Gonadotrophin (This practice stopped in U.K in 1985 but the use of human derived products may have continued in other countries)
- Has the patient had neurosurgery or removal of spinal tumour or cyst before August 1992.
- Has the patient been informed by Public health England, CJD incident Panel or their local health care team that they are potentially at risk of CJD or a related disorder?
- Has the patient had any transfusions of blood components since January 1980 (red cells, plasma, cryoprecipitate or platelets). This does not include autologous transfusion, plasma products such as intravenous immunoglobulin, albumin, coagulation factors and anti-D.

If yes please ask supplementary questions. Have they:
- Received more than 80 units of blood or blood components? Or
- Received blood or blood components on more than 20 occasions?
If the answer to any of the above questions is “Yes”, contact the infection prevention & control team for full assessment.

5.4 The need for a comprehensive pre-surgery assessment
In addition to asking the CJD risk questions, the following actions should also be carried out before any surgical procedure involving tissues with high or medium level infectivity, to ensure that a comprehensive pre-surgery assessment is completed. The clinician undertaking the pre-surgery assessment should:

- Check the service user’s medical notes and/ or referral letter for any mention of CJD status.
- Consider whether there is a risk that the service user may be showing the early signs of CJD, i.e. consider whether they may have an undiagnosed neurological disease involving cognitive impairment or ataxia.

These actions, in conjunction with the CJD risk questions, will minimise the chance of a CJD incident occurring and therefore greatly reduce the risk of transmission of CJD to subsequent service users.

**Emergency Surgery**
In the event that an individual is about to undergo emergency surgery and is physically unable to answer questions, the next of kin or carer should be asked the CJD risk questions before surgery takes place. If they are unavailable, the questions must be answered as soon as possible after the operation by the individual, next of kin, or carer.

5.5 Diagnostic criteria
Individuals suspected as suffering from CJD or a related disorder can be categorised, using internationally accepted diagnostic criteria, into three groups: Definite, Probable or Possible CJD, or related disorder as appropriate.

Suspected cases are classified according to this criteria by a neurologist from the National CJD Surveillance Unit (NCJDSU), on an on-going basis.

The classification is recorded at 4 “key” stages:

- At notification;
- When the patient was first seen, in life, by a neurologist from the NCJDSU;
- The highest classification on the sole basis of clinical information (i.e. not including neuropathological information);
- When a NCJDSU review is completed (i.e. when the case-file is closed). The completed case file may, or may not, include neuropathological data.

The date of any change of classification and the reason for such a change is recorded as necessary.

5.6 Classification criteria
**Sporadic CJD**
**Definite:**
Laboratory confirmation is required for a diagnosis of definite sporadic CJD.
**Probable**
Probable sporadic CJD patients will have rapidly progressive dementia, and at least two of the following four symptoms:

- myoclonus
- visual or cerebellar problems
- pyramidal or extrapyramidal features
- akinetic mutism

Plus typical electroencephalogram (EEG) changes.

Or

clinical criteria for possible sporadic CJD (see below) and a positive assay for 14-3-3 protein in the cerebrospinal fluid (CSF).

**Possible**
Possible sporadic CJD patients will have rapidly progressive dementia, two of the symptoms listed in the above paragraph (a)-(d) above and a duration of less than 2 years.

**Iatrogenic CJD**
Progressive cerebellar syndrome in a pituitary hormone recipient or sporadic CJD with a recognised exposure risk (e.g. dura mater transplant, medical intervention) will be classified as iatrogenic CJD.

A definite diagnosis of iatrogenic CJD still require a neuropathological examination.

**Familial CJD**
Patients with familial CJD will have:

- definite or probable CJD, plus definite or probable CJD in a close blood relative (i.e. a parent, child or sibling)
- or a neuropsychiatric disorder plus a disease-specific mutation in the prion protein gene.

**Variant CJD (vCJD)**

**Definite**
Definite vCJD patients will have a progressive neuropsychiatric disorder and neuropathological confirmation of the disease.

**Probable**
Probable vCJD patients can be classified under two sets of criteria

For both sets of criteria they will have progressive neuropsychiatric disorder for longer than 6 months, where routine investigations do not suggest an alternative diagnosis and there is no history of iatrogenic exposure.

In addition the individual will have at least four of the following five symptoms:

- early psychiatric symptoms (depression, anxiety, apathy withdrawal, delusions)
• persistent painful sensory symptoms (including both frank pain and/or unpleasant dysesthesia)
• ataxia
• myoclonus, chorea or dystoniae
• dementia

An EEG will not show the typical appearances of sporadic CJD, or no EEG has been done but there is a symmetrical high signal in the posterior thalamus on a MRI brain scan (Zeidler et al 2000). These individuals would have had no history of potential iatrogenic exposure.

Or Tonsil biopsy which is positive

**Possible**
Possible vCJD sufferers will have progressive neuropsychiatric disorder of a duration greater than 6 months where routine investigations do not suggest an alternative diagnosis, and no history of potential iatrogenic exposure. They will also have at least four out of five of the symptoms listed in the probable vCJD section and an EEG does not show the typical appearance of sporadic CJD or no EEG has been performed.

5.7 **Individuals who do not fulfil any of the criteria**
The NCJDSU have designated three additional categories for patients who are referred to the Unit but who do not meet the criteria for possible CJD. These can be summarised as:

**Diagnosis unclear** – the diagnostic criteria for definite, probable or possible CJD are not met, nor is there a reasonable alternative diagnosis. CJD, therefore, remains a possibility.

**CJD thought unlikely** – information indicates that a clinical diagnosis of CJD is very unlikely because of atypical disease features, and/or an atypical course, and/or atypical clinical investigation results and/or a reasonable alternative diagnosis is made but is not confirmed.

**Definitely not CJD** – information indicates that CJD is not the diagnosis and there is an alternative definite diagnosis proven on the basis of clinical examination, clinical investigations or pathology.

5.8 **Categorisation of body tissues depending upon risk of infectivity**
At present, there is no evidence of infectivity in saliva, body secretions or excreta.

Although Prions have not been detected in the CSF in either sporadic or variant CJD experimental transmission of infectivity has been achieved from CSF in sporadic CJD indicating that levels of infectivity are likely to be much lower than in the central nervous system (CNS).

Blood is considered to be low risk tissue.

In the main, most infectivity is likely to be concentrated in the central nervous tissue. In vCJD, infectivity is also likely to be present in lymphoid tissue, albeit at a lower level.
## Risk Status of Different Tissues

<table>
<thead>
<tr>
<th>CJD other than vCJD</th>
<th>vCJD</th>
</tr>
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<tbody>
<tr>
<td><strong>High</strong></td>
<td><strong>High</strong></td>
</tr>
<tr>
<td>- Brain</td>
<td>- Brain</td>
</tr>
<tr>
<td>- Spinal cord</td>
<td>- Spinal cord</td>
</tr>
<tr>
<td>- Cranial nerves</td>
<td>- Cranial nerves</td>
</tr>
<tr>
<td>- Cranial ganglia</td>
<td>- Cranial ganglia</td>
</tr>
<tr>
<td>- Posterior eye</td>
<td>- Posterior eye</td>
</tr>
<tr>
<td>- Pituitary gland</td>
<td>- Pituitary gland</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td><strong>Medium</strong></td>
</tr>
<tr>
<td>- Spinal ganglia</td>
<td>- Spinal ganglia</td>
</tr>
<tr>
<td>- Olfactory epithelium</td>
<td>- Olfactory epithelium</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td><strong>Low</strong></td>
</tr>
<tr>
<td>- Anterior eye</td>
<td>- Anterior eye</td>
</tr>
<tr>
<td>All other tissues including blood and</td>
<td>All other tissues including</td>
</tr>
<tr>
<td>dental tissues</td>
<td>blood and dental tissues</td>
</tr>
</tbody>
</table>

### 5.9 Hospital care of individuals with CJD / vCJD

#### General Ward Procedures

Available epidemiological evidence does not suggest that normal social or routine clinical contact with someone who has CJD or vCJD presents a risk to healthcare workers, relatives and others in the community.

Isolation of individuals with CJD or vCJD is not necessary, and they can be nursed in an open ward using standard infection control precautions in line with those used for all other service users.

#### Non-Invasive Procedures

For non-invasive procedures (e.g. X-Ray or other imaging procedures), no specific precautions are required other than those that would normally be applied to all individuals.

#### Invasive procedures

An invasive procedure is defined as one where there is a risk of exposure to body tissues. Only trained and experienced staff who are aware of the hazards may undertake invasive procedures that may lead to contact with high or medium risk tissue. The following points must be observed:
- single-use disposable equipment should be used wherever practicable and all other small items of equipment contaminated whilst undertaking invasive procedures and obtaining specimens should be destroyed.
- blood, biopsy and lumbar puncture samples from known or suspected individuals should only be taken by trained personnel who are aware of the hazards involved.
- where procedures are performed at the bedside e.g. a lumbar puncture, care should be taken to ensure the environment can be readily cleaned should a spillage occur.

The following precautions should be taken for procedures involving high or medium risk tissues on known or suspected individuals.
- wherever appropriate and possible, the intervention should be performed in an operating theatre at the end of a list and treated as an ‘infected case’.
- only the minimum number of healthcare personnel required should be involved.
- protective clothing, including impermeable disposable operating gown, gloves, mask and goggles, or full face visor should be worn by theatre personnel, and should be disposed of as “infectious / hazardous” waste.
- a one way flow of instruments should be maintained.

Sample labelling
Samples must be marked with a ‘Biohazard’ (Danger of Infection) label, and it is advisable to inform the laboratory in advance that a sample is being sent.

Blood samples
The collection of blood specimens should involve the same precautions used for all work of this type with any individual, i.e. avoidance of sharps injuries and other forms of accidental exposure. Disposable gloves and eye protection (where splashing may occur) should be worn. Single-use disposable equipment should be used where possible.

Biopsy samples
The collection of biopsy samples should involve the same precautions used for all work of this type with any individual, although particular care must be taken with lymphoid tissue specimens. Disposable gloves, aprons and eye protection (where splashing may occur) are to be worn. Single-use disposable instruments should be used where possible.

Lumbar puncture
When performing a lumbar puncture, disposable gloves, aprons and eye protection must be worn. Single-use disposable equipment must be used for all elements of the procedure. CSF is considered to be a low risk body fluid.

Childbirth
In the event that an individual with, or at risk of, CJD or a related disorder becomes pregnant, it is important to ensure that patient confidentiality is properly maintained, and that any action taken to protect public health does not prejudice individual patient care. Childbirth should be managed using standard infection control procedures. Instruments should be handled following the advice elsewhere in this document for low risk tissues. The placenta and other associated material and fluids will be treated as infected, and disposed of as infectious / hazardous waste by incineration. If the material is needed for investigation, the precautions for dealing with infected tissue will be followed.
**Spillages**
The infectious agents associated with CJD and related disorders, are unusually resistant to inactivation techniques. Dilution is the most important element in cleaning up spillages in a healthcare environment. For further guidance refer to the management of Blood and Other Body Fluid Spillages Policy

**Infectious / Hazardous Waste**
Infectious / hazardous waste must be disposed of in line with locally approved arrangements.

**Bed linen**
Used or fouled bed linen (contaminated with body fluids or excreta) should be removed from the bed and washed and dried in accordance with current standard practice and advice. No other handling or processing requirements are necessary.

5.10 **Occupational Exposure**
Although cases of CJD/vCJD have been reported in healthcare workers, there have been no confirmed cases linked to occupational exposure. However, it is prudent to take a precautionary approach.

The highest potential risk in the context of occupational exposure is from exposure to high infectivity tissues through direct inoculation (e.g. as a result of “sharps” injuries, puncture wounds or contamination of broken skin), and exposure of the mucous membranes (e.g. conjunctiva, lips) must also be avoided.

Compliance with standard infection control precautions, in line with the Trust policy will help to minimise risks from occupational exposure.

Healthcare personnel who work with individuals with definite, probable or possible CJD or vCJD, or with potentially infected tissues, should be appropriately informed about the nature of the risk and relevant safety procedures.

For any accident involving “sharps”, or contamination of abrasions with blood or body fluid(s), wounds should be gently encouraged to bleed, gently washed (avoid scrubbing) with warm soapy water, rinsed, dried and covered with a waterproof dressing, or further treatment given appropriate to the type of injury. Splashes into the eyes or mouth should be dealt with by thorough irrigation. The accident should be reported via Datix.
List of workers exposed to Transmissible Spongiform Encephalopathic agents

Under certain circumstances COSHH requires employers to keep a list of employees who are exposed to HG3 or 4 agents. The decision to keep a list depends on the local risk assessment. This should be carried out by senior manager responsible for the area concerned with advice from the occupational health Physician or Microbiologist. For TSE agents a list is only required where employees deliberately work with the agent. For example:

- those involved in laboratory research work and veterinary clinical work with a TSE agent.
- staff performing invasive clinical procedures on individuals known or suspected to be suffering from CJD of any type, particularly where there is a risk of exposure to central nervous tissue, eye tissue or other tissues known to contain CJD infectivity.
- laboratory staff handling tissue specimens from individuals with CJD of any type, in either routine or specialist neuropathology laboratories.
- staff undertaking post-mortem examinations of individuals who have died of CJD of any type or where CJD of any type is suspected.

The routine clinical care of service users with CJD or a related disorder is unlikely to pose a significant risk of exposure to CJD of any type, and staff working with such individuals would not need to be included on such a list.

In cases of unintentional exposure, a list may be required if the risk assessment shows that there is a significant risk.

The risk is deemed to be significant if more than basic hygiene measures are necessary to protect staff or if the control measures listed in COSHH are specifically applied. The list should be kept where there is a likelihood of exposure and not simply when there has been a known incident or accident, although it should also include details of these.

Recording details of incidents or accidents on this list is not the same as the requirement to report certain diseases and accidents to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

The information that should be recorded includes the type of work done and, where known, any specific exposure, accident or incident.

Because of the long latency period of TSE agents and their serious long-term sequelae, the list must be kept for 40 years after the last known exposure.

This list is in addition to the health record (which is required for the purposes of health surveillance under COSHH) and must be made available to any doctor appointed to carry out health surveillance, e.g. the occupational health physician. It must also be available to any employee who is specifically responsible for health and safety.

Surface decontamination and the management of spillages:

Disposable gloves and apron must be worn when removing any spillage or surface contamination, and these must be disposed of as infectious / hazardous waste (orange bag). Face protection should also be used if there is a risk of splashing.
For minor spillages of low risk materials such as blood and urine from definite, probable or high-risk cases, the surface must be disinfected using standard infection control precautions. Spillages of larger volumes of low risk fluids should be cleaned up as per Trust policy, using the appropriate spill kits provided.

For decontamination of surfaces in contact with high or medium risk material from definite, probable or high risk cases, sodium hypochlorite containing 10,000ppm available chlorine should be used. Needs may differ according to different circumstances and a full risk assessment is required.

All materials used in the cleaning operation must be disposed of as infectious / hazardous waste into an orange bag, which is then incinerated by the contractor.

5.11 After Death
Normal infection prevention and control procedures apply. The deceased must be placed in a cadaver bag with ‘Danger of Infection’ label applied and moved to the mortuary using standard infection control precautions. If a post mortem is not to be carried out, no further additional precautions are required, other than those applied for any other individual.

Where a post mortem examination is required, Pathologists proposing to undertake the procedure should seek specialist advice. A theoretical risk of contamination with infectious tissue arises after a post mortem examination in which the cranium has been opened. For this reason, contact with the body should be minimised following post mortem.

Undertakers should use the general precautions required for handling intact bodies. Following post mortem examination it is advisable to minimise contact, particularly in circumstances where penetrating injuries could arise. It is advisable to avoid embalming. Cosmetic work on bodies may be undertaken observing the precautions routinely used when dealing with human cadavers.

Funeral arrangements
Families often find it helpful to start making funeral arrangements before the individual dies. This gives them more time to make the arrangements according to their wishes. The key worker should discuss these issues with the family sensitively, before the death. Undertakers may be reluctant to handle cases of CJD or may apply unnecessary restrictions due to a perceived risk of transmission. These problems may be resolved if anticipated and discussed with them beforehand. If necessary the key worker may liaise with the undertaker on behalf of the family.

Viewing the deceased
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 or kissing, need not be discouraged even if a post-mortem has taken place.

Environmental concerns
There is no need to discourage burial of an individual with known or suspected CJD or vCJD, and no special arrangements for burial are required. Similarly, there is no need for any extra precautions to be taken for cremation
Transporting the body
No additional precautions are needed for transporting the body within the UK. If there is a need to transport the body internationally, it will be necessary to comply with the IATA Restricted Articles Regulations and any additional requirements of the individual carrier, which should be discussed on a case-by-case basis.

Sources of information:

**National CJD Surveillance Unit**
Western General Hospital
Crewe Road
Edinburgh EH4 2XUT
Tel: 0131 5371980
Fax: 0131 5373075

**CJD Support Network**
National CJD Co-ordinator
CJD Support Network
Birchwood
Heath Top
Ashley Heath
Market Drayton
Shropshire
TF9 4QR
Tel: 01630 673 993

**The Prion Unit**
The prion Unit at St Mary’s Hospital, London specialises in the care of patients suffering from all forms of CJD. It provides assessment, diagnosis and ongoing support for patients suffering from CJD.

Clinical Nurse Specialist
Prion Unit
Department of Neurology
St Mary’s Hospital
Praed St
London W2 1NY
Tel: 0171 886 6883

**Human BSE Foundation**
The Human BSE Foundation is a voluntary organisation run by families of vCJD patients aimed at helping relatives, friends and carers of vCJD patients by providing support, information and practical advice.
6. Developmental process.
6.1 Identification of need.

This policy is intended to meet the needs of the organisation as a whole.

6.2 Stakeholder involvement.
The organisation recognises that policies need to be developed in consultation and communication with a range of stakeholders. The following list identifies some of the individuals or groups who have been consulted in the development of this policy. This is not an exhaustive list.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Level of involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Management Team</td>
<td>Approval</td>
</tr>
<tr>
<td>Director of Infection Prevention and Control</td>
<td>Initiation, lead, development, receipt, circulation</td>
</tr>
<tr>
<td>Infection Prevention and Control Trust Action Group</td>
<td>Commissioning, development, consultation, dissemination, implementation, monitoring.</td>
</tr>
<tr>
<td>Infection Prevention and Control Team</td>
<td>Development, consultation, dissemination, implementation, training, audit</td>
</tr>
<tr>
<td>Health and safety Trust Action Group</td>
<td>Consultation, development, implementation, monitoring</td>
</tr>
<tr>
<td>Drugs and Therapeutics Sub-Committee</td>
<td>Consultation, development, dissemination, implementation,</td>
</tr>
<tr>
<td>Business Delivery Units (BDUs), Modern Matrons, practice governance coaches, Managers</td>
<td>Consultation, disseminate, implement, monitor</td>
</tr>
</tbody>
</table>

6.3. Equality impact assessment.
The Trust aims to ensure its policies and procedures promote equality both as a provider of services and as an employer. Please see appendix A for equality impact assessments.

7. Dissemination and implementation arrangements (including training)
7.1 Dissemination
This policy is available in read only format via the document store and web page on the Trust intranet. Staff are informed of any changes to the policy via the weekly update, communication from the IPCT via the home page of the Intranet, and using other forms of media.
7.2 **Implementation.**
Advice to assist implementation of this policy is available from the Infection Prevention and Control Team.

7.3 **Training**
IPC training is mandatory for all identified staff. This will be as advised by the annual training needs analysis (TNA) identified by the Learning and Development Lead.

BDUs and Service managers are responsible for ensuring that all their staff attend mandatory IPC training sessions.

The IPCT will offer training in a number of formats e.g. face to face, e-learning, DVD, to accommodate the diversity of the service.

8. **Process for monitoring compliance and effectiveness**

8.1 **Monitoring compliance**
Arrangements and processes are in place to audit compliance and effectiveness, and this is reported up through the organisation. Arrangements for monitoring compliance with this policy are evidenced through the following legislation and guidance:

The Health and Social Care Act: Code of Practice for health and adult social care on the prevention and control of infections and related guidance (DH, 2010)


Health and Safety at Work Act 1974

8.2 **Further Advice and Support**
Please see contact details in appendix 1 for further advice.
9. **Review and revision arrangements (including version control)**

9.1 **Process for reviewing the policy**

The review date for this policy will be March 2017 and two yearly thereafter unless otherwise indicated by an identified need for change.

9.2 **Version Control**

This policy has been updated and is version 2.

9.3. **Archiving**

The Integrated Governance Manager will be responsible for maintaining a corporate record of this policy, and notifying the Lead Director when the policy is due for review.

10. **References and further reading.**

The Health and Social Care Act: Code of Practice for health and adult social care on the prevention and control of infections and related guidance (DH, 2010)


Health and Safety at Work Act 1974


11. **Any other documents which should be referred to**

This document should be read in conjunction with the Trusts:

- Confidentiality policy
- Health and Safety policy
- Waste Management policy
- COSHH guidance
- Moving and Handling policy
- Incident Management and patient safety policy
- Occupational Health policy
- Mandatory training policy
- All other infection prevention & control policies.
For further advice contact the IPC Team on the contacts below

Infection Prevention and Control Staff Contact Details

- Alison Thomas, Lead Infection Prevention & Control Nurse
  Alison.thomas@swyt.nhs.uk
- Adele Watson, Senior Infection Prevention & Control Nurse
  Adele.watson@swyt.nhs.uk
- Julie Hartley, Senior Infection Prevention Practitioner,
  Julie.hartley@swyt.nhs.uk
- Katy Symon, Infection Prevention Practitioner,
  Katy.Symon@swyt.nhs.uk
- Yvonne Sambrook, Infection Prevention & Control Nurse
  Yvonne.sambrook@swyt.nhs.uk

Barnsley Hospital NHS Foundation Trust Consultant Microbiologist

- Consultant Microbiologist, BHNFT
  Tel: 01226 730000

Calderdale, Kirklees and Wakefield In-Patients Services Microbiologist

- Consultant Microbiologist
  Tel: 0844 8110101
### Appendix A - Equality Impact Assessment Tool

*To be completed and attached to any policy document when submitted to the Executive Management Team for consideration and approval.*

<table>
<thead>
<tr>
<th>Equality Impact Assessment Questions</th>
<th>Evidence based Answers &amp; Actions:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Name of the policy that you are Equality Impact Assessing</td>
<td>Policy for the Management of Patients known or at High Risk of Creutzfeldt-Jakob Disease (CJD) and other human prion diseases</td>
</tr>
<tr>
<td><strong>2</strong> Describe the overall aim of your policy and context?</td>
<td>The overall aim of the policy is to provide staff with clear and practical evidence based information that they can translate into their working practice within the context of the requirements of the H&amp;S Care Act (2008).</td>
</tr>
<tr>
<td></td>
<td>Who will benefit from this policy?</td>
</tr>
<tr>
<td></td>
<td>All staff</td>
</tr>
<tr>
<td><strong>3</strong> Who is the overall lead for this assessment?</td>
<td>Director of Nursing, Clinical Governance and Safety (designated Director of Infection Prevention and Control)</td>
</tr>
<tr>
<td><strong>4</strong> Who else was involved in conducting this assessment?</td>
<td>Senior Infection Prevention Practitioners and Infection Prevention Practitioners</td>
</tr>
<tr>
<td><strong>5</strong> Have you involved and consulted service users, carers, and staff in developing this policy?</td>
<td>The Executive Management Team and staff teams were consulted during the development of the original Policy</td>
</tr>
<tr>
<td></td>
<td>What did you find out and how have you used this information?</td>
</tr>
<tr>
<td></td>
<td>It was identified that staff required clear and unambiguous information that was easily accessible. This was taken into account when developing the policies</td>
</tr>
<tr>
<td><strong>6</strong> What equality data have you used to inform this equality impact assessment?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>7</strong> What does this data say?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>8</strong> Have you considered the potential for unlawful direct or indirect discrimination in relation to this policy?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>9</strong> Taking into account the information gathered. Does this policy affect one group less or more favourably than another on the basis of:</td>
<td>Where Negative impact has been identified please explain what action you will take to mitigate this. If no action is to be taken please explain your reasoning.</td>
</tr>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>Race</td>
<td>N</td>
</tr>
<tr>
<td>--------</td>
<td>---</td>
</tr>
<tr>
<td>Disability</td>
<td>N</td>
</tr>
<tr>
<td>Gender</td>
<td>N</td>
</tr>
<tr>
<td>Age</td>
<td>N</td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td>N</td>
</tr>
<tr>
<td>Religion or Belief</td>
<td>N</td>
</tr>
<tr>
<td>Transgender</td>
<td>N</td>
</tr>
</tbody>
</table>

10. What measures are you implementing or already have in place to ensure that this policy:
   - promotes equality of opportunity,
   - promotes good relations between different equality groups,
   - eliminates harassment and discrimination

   N/A

11. Have you developed an Action Plan arising from this assessment?

   If yes, then please attach any plans at the back of this template

   N/A

12. Who will approve this assessment and when will you publish this assessment.

   Executive Management Team
   When revised policy is approved by Trust Board

If you have identified a potential discriminatory impact of this policy, please refer it to the Director of Corporate Development or Head of Involvement and Inclusion together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact the Director of Corporate Development or Head of Involvement.
Appendix B - Version Control Sheet

This sheet should provide a history of previous versions of the policy and changes made

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Status</th>
<th>Comment / changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>May 2012</td>
<td>Director of Nursing, Clinical Governance and Safety (designated Director of Infection Prevention and Control)</td>
<td>Final</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>March 2013</td>
<td>Director of Nursing, Clinical Governance and Safety (designated Director of Infection Prevention and Control)</td>
<td>Final</td>
<td>Minimal changes to ensure needs of all business delivery units.</td>
</tr>
<tr>
<td>3</td>
<td>March 2015</td>
<td>Julie Hartley Infection Prevention and Control Nurse</td>
<td>Final</td>
<td>Updated to include change in guidance from the Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection Policy: Part 4 January 2014 document. Updated CJD panel, support organisation and IPC Team contact details</td>
</tr>
</tbody>
</table>
12.3. Checklist for the Review and Approval of Procedural Document

*To be completed and attached to any policy document when submitted to EMT for consideration and approval.*

<table>
<thead>
<tr>
<th>Title of document being reviewed:</th>
<th>Yes/No/Unsure</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Title</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the title clear and unambiguous?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Is it clear whether the document is a guideline, policy, protocol or standard?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Is it clear in the introduction whether this document replaces or supersedes a previous document?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>2. <strong>Rationale</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are reasons for development of the document stated?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>3. <strong>Development Process</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the method described in brief?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Are people involved in the development identified?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Is there evidence of consultation with stakeholders and users?</td>
<td>EMT</td>
<td></td>
</tr>
<tr>
<td>4. <strong>Content</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the objective of the document clear?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Is the target population clear and unambiguous?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Are the intended outcomes described?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Are the statements clear and unambiguous?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>5. <strong>Evidence Base</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the type of evidence to support the document identified explicitly?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Are key references cited?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Title of document being reviewed:</td>
<td>Yes/No/Unsure</td>
<td>Comments</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------------</td>
<td>----------</td>
</tr>
<tr>
<td>Are the references cited in full?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Are supporting documents referenced?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>6. Approval</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the document identify which committee/group will approve it?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>7. Dissemination and Implementation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there an outline/plan to identify how this will be done?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Does the plan include the necessary training/support to ensure compliance?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>8. Document Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the document identify where it will be held?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Have archiving arrangements for superseded documents been addressed?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>9. Process to Monitor Compliance and Effectiveness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Is there a plan to review or audit compliance with the document?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>10. Review Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the review date identified?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Is the frequency of review identified? If so is it acceptable?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>11. Overall Responsibility for the Document</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is it clear who will be responsible implementation and review document?</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>