Policy

Pathology Sample & Request Card Labelling

This policy applies to all tests and investigations with the exceptions: of Cross-match, Group & Save, Antenatal Transfusion Investigations and Cord & Maternal Bloods which are covered under EDC0012

Pathology, Samples, Specimens, Request Cards, Labelling

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<th>CPDI061</th>
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<tr>
<td>Version:</td>
<td>Version 4.0</td>
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<tr>
<td>Developed in Consultation with:</td>
<td>Pathology Management Team Pathology Users Divisional Governance Committee Trust Governance Department</td>
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<td>Ratified by:</td>
<td>Diagnostic and Clinical Support Divisional Governance Committee</td>
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<tr>
<td>Document Author:</td>
<td>Jane Fielding: Interim Performance &amp; Quality Manager, Pathology</td>
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## Main Revisions from previous issue

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<td>CPDI061</td>
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<td>Previous Version Number:</td>
<td>Version 3.1</td>
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| Chapters, sections and pages which have been changed | Scheduled review  
Section 5.1 - simplified so that all information is contained in one table  
Section 5.8 – expanded  
Replace reference to CPA Standards with BS EN ISO 15189:2012 |
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1. Introduction

1.1 Between February 2006 and January 2007, the National Patient Safety Agency (NPSA) received over 24,000 reports of patients being wrongly identified and mismatched with their care.

Reducing and, where possible, eliminating these errors is central to improving patient safety. Many of these errors result in little or no harm but can be distressing for patients and for staff. Some result in serious, lasting harm, such as chronic pain, undiagnosed conditions and even death.

The NPSA has a program of work on safer patient ID and matching patients correctly with samples, specimens, records and treatment.

Figures obtained by the Freedom of Information Act also reveal that between 2008 and 2009 almost 366,000 NHS specimens were mislabelled or ‘mixed up’ including a total of forty-six during this time period where this resulted in patient death or delay in treatment.

1.2 In 2011 a new standard was included in the NHS Litigation Authority (NHSLA) Risk Management Standards for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability services and independent Sector providers of NHS Care. It became a requirement that the Trust has documents that include:

- The process for requesting a test
- The action to be taken following the diagnostic test results including timescales.
- The process for recording who is informed of the diagnostic test results
- The process for recording actions
- The process for monitoring compliance with this standard

1.3 Clinical Pathology Accreditation (UK) is the body that accredits Pathology departments using the standard BS EN ISO 15189:2012. This includes a standard dedicated to Pathology Request cards and in order for the department to meet this standard it is essential that the following is included on the Trust request card.

ISO 15189:2012 standard 5.4.3
the request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:

a) Patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier (an alpha and/or numerical identifier such as a hospital number or personal health number)
b) Name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details

c) Type of primary sample and, where relevant, the anatomic site of origin

d) Examinations requested

e) Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes

f) Date and, where relevant, time of primary sample collection

g) Date and time of sample receipt

2. **Purpose**

2.1 The most commonly encountered source of error and incident in Pathology departments is unlabelled and mislabelled samples. On a daily basis dozens of specimens are received either completely unlabelled or the labelled samples do not correspond with the request card accompanying them. In addition to these errors many more samples are later proved not to have been collected from the intended patient. The inconvenience to the patient or staff member in having to collect a second sample does not outweigh the risk of receiving the wrong result.

2.2 The purpose of this policy is to ensure the correct investigations are performed on the right patient. The safety of the patient is the intended outcome of compliance with the policy. All these occurrences create danger for the patient; any of these incidents could lead to incorrect diagnosis, the wrong treatment and in extreme cases cause harm to the patient including death.

2.3 Pathology staff must establish minimum identification criteria prior to performing investigations on a sample. Table 1 outlines the absolute minimum criteria allowed to accept a request, specimens failing to meet these minimum criteria will only be processed in exceptional circumstances.

2.4 In addition to ensuring that the patient demographic is correct it is essential that the name of the healthcare professional requesting the examination is clearly identified on the request card. In a large organisation there can be a number of requestors with the same or similar names, the person making the request is the person responsible for accessing and acting upon the results of that examination. In order to achieve this it is essential that the full name including initials or a unique identification code for the requestor is included on the request card. The Consultant unique identification codes are available on the Pathology pages on the Trust Intranet.

2.5 It is also a requirement that the location for a hard copy of the report is included on the request card; reports are only printed for inpatients for Biochemistry and Haematology requests if the results have not been accessed electronically within a specified time frame. It is essential to avoid further delay that the Pathology department has been informed where to send a copy of this report.
3. **Scope**

3.1 This policy is applicable to all staff requesting Pathology investigations and collecting samples to accompany that request. Pathology requests may be paper based or electronic.

3.2 This policy is applicable to all tests and investigations with the exception of Crossmatch, Group & Save, Antenatal Transfusion Investigations and Cord & Maternal Bloods which are covered under Requesting, Collecting And Labelling Of Blood Samples For Transfusion Tests, Which Generate A Blood Group (EDC 012).

3.3 Please read this document in conjunction with the Trust Infection Control Policy (CPDI022).

3.4 Please read this document in conjunction with the Standard Operational Procedures for Venepuncture and Associated Guidelines for the Phlebotomy Service (DPGDI014).

4. **Roles, Responsibilities and Accountabilities**

4.1 Before accepting a clinical sample, laboratory staff must ensure the minimum required criteria for requestor and sample identification are met. Stringent standards are put in place to ensure the safety of the patient; they are intended to ensure the right investigation is performed on the right sample. Laboratory staff must not endanger the patient by working outside these standards.

4.2 The responsibility for requesting a laboratory investigation lies with an authorised practitioner, normally a clinician. It is the responsibility of the requestor to ensure all samples are correctly labelled and request forms completed to the agreed standard and that the results are accessed and acted upon.

4.3 The completion of request cards and the collection of samples may be delegated; however the clinician delegating this task is accountable for any requests made or samples collected in their name.

4.4 Samples and request cards not meeting the minimum required criteria for identification will not be processed, these samples will be retained for an appropriate period. It is not always possible to inform the requestor by telephone of this outcome. If the request is marked urgent the requestor will be informed where possible.
5. **The policy itself**

5.1 Table 1, outlines the information required to provide a full quality examination of the specimen received. Failure to provide all this relevant information will not result in the request not being processed, but the results and clinical advice given might not be as comprehensive without the relevant information.

In 2009 the NPSA recommended that all NHS organisations use the NHS Number as the primary identifier for all patients (NPSA/2009/SPN002). The Pathology department has consulted with users of the service and has an appreciation that community users do have difficulty obtaining NHS Numbers for some patients. Until this situation improves, users are asked to inform us on the request card that an NHS Number is not available for a patient, the sample will be processed, but the report will contain a comment stating a unique identifier was not available for this patient.

**Completion of Pathology Requests and Sample Containers**

**General Comments:**

Items marked * in the table below are mandatory. Samples may not be analysed if this information is not supplied. In certain circumstances Unique Coded Identifiers may be used e.g. GUM patients, major incidents and where a name is unobtainable. Samples must be labelled and checked in the presence of the patient. Writing on the sample container and request form must be clear and legible
Table 1

<table>
<thead>
<tr>
<th>Sample Required Information</th>
<th>Request Required Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients full Name* or Unique coded identifier**</td>
<td>Patients full Name* or Unique coded identifier**</td>
</tr>
<tr>
<td>Date of Birth* and /or Hospital Number / NHS Number*</td>
<td>Date of Birth* &amp; Gender.</td>
</tr>
<tr>
<td>Date of Collection (and time of collection where relevant)</td>
<td>Hospital number / NHS number * (must be included wherever possible, if a unique identification number is not available for a patient, please state this in the space provided)</td>
</tr>
<tr>
<td><strong>Destination for Report</strong></td>
<td><strong>The Full Surname and initial of the Forename of the Patients Consultant or an approved Healthcare Practitioner with requesting authorisation. Alternatively the unique identification code can be used</strong> and/or <strong>Destination for the report</strong></td>
</tr>
<tr>
<td><strong>Blood Culture bottles should be labelled as follows.</strong></td>
<td></td>
</tr>
<tr>
<td>☀ Full Name*</td>
<td></td>
</tr>
<tr>
<td># Patient Hospital Number*</td>
<td></td>
</tr>
<tr>
<td>🕒 Date and Time of Collection.</td>
<td></td>
</tr>
</tbody>
</table>

*Mandatory Information

Labels generated whilst in the presence of the patient using a unique label printer are acceptable; these must contain all of the required information for sample labeling and must only cover the tube manufacturer’s primary label. This includes the labels generated by the T Quest and HealthViews software. If you are considering introducing any other labelling system please inform the Pathology department. This minimum information is also required when a copy of a report is requested for a different clinician.
5.2 High Risk samples

Hazard Group 3 pathogens (including tuberculosis and typhoid fever) are considered ‘HIGH RISK’ and an appropriate biohazard sticker MUST be attached to the sample and the request form. The Samples for microbiological analysis from individuals known or suspected of having clinical details entered on the request card should be adequate to convey information about the suspected hazard to the staff handling the samples.

Samples that are from patients suspected of having a Viral Haemorrhagic Fever are always classified as ‘HIGH RISK’. There is a separate policy to cover the way that these samples are handled depending on risk factors identified by the Infectious Diseases Consultant in charge of the patient. Please do not attempt to take any patient samples until the Integrated Care Pathway for Patients Assessed as Being at Risk of Viral Haemorrhagic Fever (CPME089) has been consulted.

Specimens from individuals known or suspected of having Blood Borne Viruses categorised as Hazard Group 2 or 3 are NOT classified as ‘HIGH RISK’ in the laboratory as the infectious agents in these samples are not propagated and do not pose a risk to the laboratory staff handling them.

Health and Safety Executive – Safety Notice – HID 5 – 2011: Provision of key clinical information on laboratory specimen request forms states:
Where a laboratory sample or specimen is considered likely to contain a human pathogen, it is important that the appropriate level of laboratory containment is provided in order to ensure the effective control of the risk of exposure / infection.
Specimens processed for microbiological analysis and considered likely to contain Hazard Group 3 or 4 pathogens must be processed within appropriate containment conditions.
Specimens liable to result in propagation or culture of Hazard Group 3 pathogens for example must be processed in a Containment Level 3 laboratory with associated management arrangements.
Specimens should be supplied with relevant clinical details from requesting clinicians. This can be used to inform the assessment and further laboratory processing e.g. the types of organisms that might be present in specimens from a returning traveller or those associated with an outbreak scenario.
In clinical laboratories, specimens are sorted and processed on the basis of the information provided. If clinical details are inaccurate or incomplete or there is delay in disclosing new information to the laboratory then this can result in specimens being processed under insufficient laboratory containment conditions.
Departments that request Pathology investigations must ensure that:

- Clinical details supplied on specimen request forms contain clear information regarding the nature of the test being requested and sufficient detail to inform laboratory staff upon the safety precautions they need to take in order to process the specimen without risk of infection.
- Clinical details include history of recent foreign travel including the date and country or region visited.
- If, during patient intervention, further information becomes available that has implications for the safety of laboratory staff then this is communicated immediately to the laboratory so that appropriate steps regarding containment can be taken.

5.3 Collection of samples

Only staff that have undertaken a Trust venepuncture-training programme or have been assessed as competent should collect blood samples. (DPGDI014)

Staff collecting samples will:

- Where possible establish the identity of the patient by asking them to state their full name, and date of birth
- For all inpatients to confirm identity check the identification bracelet and compare this with the request card.
- If an identification bracelet is not present on an inpatient, the ward manager should be informed and the procedure abandoned until the identification bracelet is present.
- In an emergency situation, where an identification bracelet is not yet present, the case notes accompanying the patient must be used to confirm the patient's identity.
- Check the details on the request card are complete.
- Enter the name or identification code of the person collecting the sample in the space provided on the request card.

The collection of samples, dispersal into containers and labelling of these containers must be carried out as one continuous, uninterrupted event involving one patient only.

The sample container must be accurately labelled or checked in the presence of the patient at the time the sample is collected. Sample containers must not be pre-labelled, due to the risk of collection into the wrong container.

Addressograph labels must not be used to label specimen containers. They can be used on request cards providing additional information to complete the minimum required criteria is hand written.
Labels generated whilst in the presence of the patient using a unique label printer are acceptable; these must contain all of the required information for sample labeling and must only cover the tube manufacturer’s primary label. Any department considering introducing a system should inform the Pathology laboratory; occasionally these labels can be mistaken for addressograph labels.

The exception to this is blood transfusion where sample labels are not acceptable and all samples must be hand written as per Trust Policy EDC 012 Requesting, Collecting and labelling of blood samples for transfusion tests, which generate a blood group.

5.4 **Unconscious patients**
In cases where the unconscious patient has been through the admissions procedure and an identity bracelet has been fitted, it is acceptable to omit the verbal identity confirmation; the person collecting the sample must confirm the patient’s identity on the identification bracelet.

5.5 **Unknown patients.**
The A&E unique identification number, and where possible a hospital number should be generated for the patient. These numbers should be used on all specimens, request cards and included on the patient’s identity bracelet.

5.6 **Major incidents**
Following a major incident or accident generating multiple patients, major incident numbers might be used to identify the patients.

This unique identification number, and where possible a hospital number should be generated for the patient. These numbers should be used on all specimens, request cards and included on the patient’s identity bracelet.

5.7 **Important considerations**
- A member of staff collecting a sample from a patient is accepting responsibility for ensuring that the specimen has been collected from the correct patient and that all the details are accurate.
- It is vital that any inconsistency found in the information used to identify the patient is checked prior to any procedure being undertaken.
- All pre-labelled specimen containers must be discarded immediately.
- Writing on specimen containers and request cards must be legible; alterations must be neat, readable and signed.
- Laboratory staff will not amend details on a specimen or request card.
- Users will not be invited to attend the laboratory to re-label samples.
- Samples will not normally be returned to users for labelling.
5.8 **Samples that cannot be repeated.**

Failure to comply with the requirements of this policy does present serious Governance issues and samples and request cards that do not comply with the minimum identification and requestor criteria will not normally be analysed.

There are some samples that are exceptions to the rule. These may include:
- Bone marrow biopsy
- CSF and other sterile body fluids
- Paediatric samples
- Blood Gas samples
- Dynamic function tests
- Calculus – renal analysis
- Samples collected prior to commencement of therapy e.g. blood cultures
- Samples collected during surgical procedures

These specimens are usually collected during individual procedures, the identity of the patient undergoing the procedure can be established and it is unlikely the sample could have been collected from a different patient.

Under these rare circumstances such samples may be processed, the report will state that the sample did not comply with the minimum identification criteria, the reason it did not comply along with the results of the examination.

Senior or experienced laboratory staff in each laboratory discipline will, based on the above criteria, take the decision regarding the processing of samples that have been incorrectly labelled.

6. **Implementation**

6.1 **Dissemination**

A variety of dissemination methods are in place to make sure that all staff are aware of, have access to and comply with the Trust’s Controlled Documents. These are:

- Inclusion in the Trust Weekly Bulletin
- Inclusion in the Document Management System on the Trust’s Intranet, which all staff are encouraged to use to gain access to Controlled Documents.
- Distribution to relevant Ward and Departmental Managers
6.2 **Training Arrangements**
Directorate Managers /Clinical Leads must ensure that all newly appointed healthcare workers within Pennine Acute Hospitals NHS Trust, including anyone who might make requests or collect specimens for Pathology, receive instruction regarding the requesting of these pathological investigations in their local induction programme. It is vital that all staff are aware of the reasons for compliant sample and request card labelling and the consequences of non-compliance in terms of adverse patient outcome and professional accountability.

6.3 **Financial Impact**
There are no financial implications for this document.

7. **Monitoring Arrangements**
7.1 Please see Appendix 1.

8. **Review Arrangements**
8.1 This document will be reviewed every 3 years or earlier if required by law or changes in guidance. It is the author’s responsibility to do this.

9. **References and Bibliography**

9.1 **Associated Trust Documents**
- Requesting, Collecting And Labelling Of Blood Samples For Transfusion Tests, Which Generate A Blood Group (EDC 012)
- Standard Operational Procedures for Venepuncture and Associated Guidelines for the Phlebotomy Service (DPGDI014)
- Trust Infection Control Policy (CPDI022)
- Integrated Care Pathway for Patients Assessed as Being at Risk of Viral Haemorrhagic Fever (CPME089)

9.2 **Bibliography**
- IBMS Professional Guidance: Patient Sample and Request form identification criteria
10. Abbreviations & Definitions of terms used

**CPA:** Clinical Pathology Accreditation (UK) Ltd

**CSF:** Cerebrospinal Fluid

**GUM:** Genitourinary Medicine

**IBMS:** Institute of Biomedical Science

**NHS:** National Health Service

**NHSLA:** National Health Service Litigation Authority

**NPSA:** National Patient Safety Agency

11. Appendices
Appendix 1 - Arrangements for Monitoring Compliance with this document

The arrangements for monitoring compliance with this document are summarised in the following table:

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<tr>
<td>ISO 15189:2012 5.4.3</td>
<td>the request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following: a) Patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier (an alpha and/or numerical identifier such as a hospital number or personal health number) b) Name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details c) Type of primary sample and, where relevant, the anatomic site of origin d) Examinations requested e) Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes f) Date and, where relevant, time of primary sample collection</td>
<td>The requirement that all paper requests cards or electronic platforms for requesting Pathology examinations allow for the inclusion of all criterions.</td>
<td>Horizontal Audit</td>
<td>Pathology Discipline Quality Lead</td>
<td>Annual</td>
<td>Pathology Governance Group</td>
<td>Pathology Directorate Committee</td>
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<tr>
<td>g) Date and time of sample receipt</td>
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<tr>
<td>5.4.6 e) Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examinations</td>
<td>Regular vertical audits to assess compliance with this policy</td>
<td>Vertical Audit</td>
<td>Pathology Discipline Quality Lead</td>
<td>Quarterly</td>
<td>Pathology Governance Group</td>
<td>Pathology Directorate Committee</td>
<td>Pathology Directorate Committee</td>
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<tr>
<td>5.4.4.1 The laboratory shall have documented procedures for the proper collection of and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff.</td>
<td>Regular audit to ensure instructions for users are available</td>
<td>Horizontal Audit</td>
<td>Pathology Discipline Quality Lead</td>
<td>Annual</td>
<td>Pathology Governance Group</td>
<td>Pathology Directorate Committee</td>
<td>Pathology Directorate Committee</td>
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The Pathology Directorate will ensure that this topic is submitted to the Directorate’s Annual Clinical Audit Forward Programme as deemed appropriate.
Appendix 2 – Completed Equality Impact Assessment Pro-forma

Equality Impact Assessment Pro-forma (Policy*)
*this form should be completed for all procedural documents including, strategies, policies, procedures, protocols, guidelines, & integrated care pathways.

Part One

<table>
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<th>Name of Policy</th>
<th>Pathology Sample and Request card Labelling Policy.</th>
<th>Date of assessment</th>
<th>22/04/14</th>
<th>Is the policy new or for review?</th>
<th>Reviewed</th>
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<td>Area</td>
<td>Pathology</td>
<td>Name of Author(s)</td>
<td>Jane Fielding</td>
<td></td>
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1.1 Briefly describe the aims and objectives and the purpose of the policy

Aim: Adequately labelled patient samples and request cards
Objective: Good quality safe patient care

1.2 Are there any associated objectives or directives of the policy? i.e. Care Quality Commission (CQC), NHS Litigation Authority (NHSLA)

NHSLA Standard 4: Criterion 4

1.3 Who is the policy intended to benefit, and what are the expected outcomes?

The policy is of benefit to any patient that has Pathology investigations. The expected outcome is the right test on the right patient and the results made available to the requestor at the correct location.

1.4 What factors could influence the intended outcomes either positively or negatively?

Failure to follow these requirements

1.5 Who are the main stakeholders in relation to the policy

Staff Service Users

1.6 Who implements and is responsible for the policy?

Pathology Directorate
## Part One (cont)

For each of the nine Equality Categories ask the question below:

<table>
<thead>
<tr>
<th>Human Rights</th>
<th>Age</th>
<th>Disability</th>
<th>Ethnicity (Race)</th>
<th>Religion</th>
<th>Gender</th>
<th>Sexual orientation</th>
<th>Carers</th>
<th>Social Deprivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

1.7 From the evidence, does the policy affect or have the potential to affect individuals or communities differently or disproportionately, either positively or negatively (including discrimination)?

1.8 Is there potential for, or evidence that, the proposed policy will promote equality of opportunity for all and promote good relations with different groups?

1.9 Is there public concern (including media, academic, voluntary or sector specific interest) in the policy area about actual, perceived or potential discrimination about a particular community?

1.10 Is there any doubt about answers to any of the questions?

## Part Two

2.1 In what way does the policy impact on any particular group listed above? Include here what evidence you have collated, whether there are any gaps and what further information is required.

2.2 Adverse Impact - if you have identified potential or real direct or indirect discrimination? If so, can it be justified (e.g., legislation, clinical or social evidence)?

2.3 Positive Impact - does the policy actively promote equality of opportunity and/or good relations between different groups of people?
## Part Three

<table>
<thead>
<tr>
<th>Policy Title (as it appears on the Document Management System) Pathology Sample and Request Card Labelling Policy</th>
<th>Policy Number</th>
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<td>CPDI061</td>
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<th>Ratifying Committee</th>
<th>Date sent to Committee</th>
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<tbody>
<tr>
<td>Diagnostic and Clinical Support Governance Committee</td>
<td>6th May 2014</td>
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</table>

This policy has been assessed as having no or low equality impact. Part 1 is completed.  

| This policy has been assessed as having low to medium impact. Parts 1 and 2 have been completed. Full impact assessment is unnecessary. | Yes |
| This policy has been assessed as having medium to high impact. Parts 1 and 2 have been completed. Full impact assessment is necessary. | N/A |

<table>
<thead>
<tr>
<th>Assessors Name</th>
<th>Designation</th>
<th>Signed*</th>
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<tbody>
<tr>
<td>Jane Fielding</td>
<td>Interim Performance &amp; Quality Manager</td>
<td>Jane Fielding</td>
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<thead>
<tr>
<th>Equality Champion</th>
<th>Directorate</th>
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<tr>
<td>Avis Webber</td>
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