

## DIAGNOSTIC CLINICAL TESTS AND SCREENING PROCEDURES MANAGEMENT POLICY

(To be read in conjunction with Diagnostic Imaging – Requesting and Interpreting Radiographs by Non Medical Practitioners Policy, Consent and Capacity to Consent to Examination and/or Treatment Policy, Inpatient Handover Policy and Blood Investigations – Non Medical Professionals Requesting Pathological Samples Policy)

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## DOCUMENT CONTROL

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<b>Document objectives:</b> Safe and effective management of clinical diagnostic tests and/or screening procedures.			
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## CONTENTS

<b>Section</b>	<b>Summary of Section</b>	<b>Page</b>
Doc	Document Control	2
Cont	Contents	3
1	Introduction	4
2	Purpose & Scope	4
3	Duties and Responsibilities	4
4	Explanations of Terms used	6
5	Requesting Clinical Tests and/or Screening Procedures	6
6	Obtaining Samples	8
7	Taking Action on Test and Screening Results	9
8	Communicating Test and Screening Results	9
9	Training	10
10	Equality Impact Assessment	10
11	Monitoring Compliance and Effectiveness	10
12	Counter Fraud	11
13	Relevant Care Quality Commission (CQC) Registration Standards	11
14	References, Acknowledgements and Associated documents	11
15	Appendices	12
Appendix A	Flowchart	13
Appendix B	Clinical Audit Standards	14

## **1. INTRODUCTION**

- 1.1 There are many screening and diagnostic tests performed in healthcare everyday on both inpatients and outpatients. Healthcare providers must be assured that the results of these tests inform the clinical decision making process, contributing to a correct diagnosis and appropriate patient care.
- 1.2 Somerset Partnership NHS Foundation Trust aims to ensure that patients receive the best possible care in respect of diagnostic testing and/or screening procedures and that the results are communicated in a timely manner.
- 1.3 Staff should ensure the patient is able to understand the information given to them and are able to give their informed consent. This may necessitate the use of a professional interpreter and the translation of written information. A capacity assessment should be considered for those patients who are unable to consent to the procedure and reference should be made to the relevant Trust policy.

## **2. PURPOSE & SCOPE**

- 2.1 This policy will provide a reference point for clinical staff to have an understanding of the agreed procedures for the requesting, managing, recording and communicating of clinical diagnostic tests and/or screening procedures undertaken within the organisation
- 2.2 The policy will ensure that all diagnostic tests and/or screening procedures are managed to minimise the risk to patients and staff, to improve patient outcome, expedite diagnosis and treatment decisions.
- 2.3 This policy applies to all Somerset Partnership NHS Foundation Trust clinical staff who are involved in diagnostic testing and/or screening procedures.

## **3. DUTIES AND RESPONSIBILITIES**

- 3.1 **The Trust Board via the Chief Executive**  
Responsibility for ensuring compliance with the statutory requirements within the policy lies with the Chief Executive
- 3.2 **Director of Nursing and Patient Safety** of Somerset Partnership NHS Foundation Trust is the Executive Lead responsible for ensuring that the implementation of this policy is monitored as part of the patient safety strategy.
- 3.3 **Lead Officers** will ensure that this policy is accessible, disseminated and read within their areas of responsibility

### 3.4 **Heads of Service/Wards/Departments**

3.4.1 **Heads of Service/Wards/Departments** have a responsibility to ensure that the diagnostic and screening procedures undertaken with their clinical area will follow locally agreed procedures or the Royal Marsden Hospital manual of Clinical Procedures. If there is not an appropriate section within the manual, or Trust Standard Operating Procedure available the department will develop an agreed procedure using the organisation's Policy for the Development and Management of Procedural Documents and in line with the overarching principles of this document.

3.4.2 **Heads of Service/Wards/Departments** must ensure that all staff are aware and adhere to these procedures. They are also responsible for ensuring that any deviation or errors arising are dealt with in the correct manner and reported in accordance with Somerset Partnership NHS Foundation Trust Incident Reporting Policy and Procedures.

### 3.5 **All clinical staff employed by Somerset Partnership NHS Foundation Trust are responsible for:**

- carrying out the designated duties as outlined within the Royal Marsden Hospital Manual of Clinical Procedures or their departmental procedure;
- ensuring that they have had appropriate training to enable them to request, perform interpret and / or report on the designated diagnostic test or screening procedure;
- to ensure they have correctly identified the patient and correctly identified the diagnostic test and/or screening procedure and obtained and recorded informed consent;
- to record actions taken when dealing with a diagnostic test and/or screening procedure, managing and recording any adverse events during the process;
- the staff member receiving the diagnostic and/or screening results will document in the patients clinical notes and notify the requestor of their return;
- The clinical team that requested the diagnostic testing and/or screening procedures is responsible and accountable for tracing, validating, documenting, acting upon, and informing the patient and /or clinicians with ongoing responsibility for the patient e.g. general practitioner;
- when screening or diagnostic tests involve direct patient contact/collection of bodily fluids all staff are required to implement standard infection prevention and control precautions and adhere to the Somerset Partnership NHS Foundation Trust Hand Hygiene Policy. Infection Prevention and Control Policies can be accessed via the

Somerset Partnership NHS Foundation Trust Intranet site or further guidance may be sought via the Somerset Partnership NHS Foundation Trust Infection Prevention and Control Team.

## 4 EXPLANATION OF TERMS USED

- 4.1 **Diagnostic test:** Procedures such as laboratory testing and radiographic imaging routinely performed on patients or specified categories of individuals in a specific situation assisting clinicians to reach a diagnosis.
- 4.2 **Screening:** examination of people with no symptoms to detect underlying disease.
- 4.3 **Verification:** refers to acquisition, interpretation, communication and action of the test result(s) to referrer and patient.
- 4.4 **Skilled:** the competent clinician.
- 4.5 **Interpretation:** refers to the understanding and explanation of a test result in relation to reaching a diagnosis or differential diagnosis.
- 4.6 **Referrer:** the person who instigated the request for the test or screening procedure.
- 4.7 **Collector:** the person carrying out the diagnostic test or screening procedure.

## 5 REQUESTING CLINICAL TESTS AND/OR SCREENING PROCEDURES

- 5.1 Clear communication and good record keeping is essential to avoid confusion over whether a test or screening procedure has been undertaken. Repeating investigations which have already been done should be avoided unless retesting will contribute to the diagnostic picture.
- 5.2 The following principles must be applied:
- clinical diagnostic tests or screening procedures must be of diagnostic value;
  - consideration must be given as to whether diagnosis can be made on clinical presentation alone;
  - Somerset Partnership NHS Foundation Trust will have identified the procedures for the clinical diagnostic tests and/or screening procedures;
  - there will be identified healthcare staff with the authority and competence to authorise/proceed with the test or screening procedure;

- informed consent will be obtained as per the organisations Consent and Capacity to Consent to Examination and Treatment policy and should involve a verbal discussion and the use of patient information fact sheets and/or an interpreter where appropriate;
- systems are in place to ensure that the sample(s) (where applicable) have been taken, correctly identified, labelled, prepared, transported and despatched to comply with agreed protocols of the service;
- only clinical staff competent to do so will interpret the results of diagnostic tests and/or screening procedures and the results will be documented in the patient's clinical records;
- diagnostic tests and/or screening procedure results will be received within agreed time frames by the appropriate clinician / electronic system;
- the mechanism by which the dissemination of the diagnostic test and/or screening procedure result is made, i.e. by paper or by electronic means will be agreed;
- all patients who undergo a clinical diagnostic test and/or screening procedure will be informed of their results where clinical intervention may be required;
- all patients who receive a screen positive or high risk result, will have access to an appropriately trained healthcare professional to discuss treatment options;
- all outcomes and their subsequent follow up will be recorded in the clinical patient record. This will include the clinician responsible for this action;
- all clinical diagnostic tests and/or screening processes are the subject of clinical audit standards.

5.3 Consideration must be given to the type of diagnostic test and/or screening procedure requested and the impact on the patient.

5.4 The diagnostic test and/or screening procedure required and its purpose must be fully explained to the patient, carer or relative to minimise any potential distress.

5.5 All departments must identify an appropriate clinician to undertake the identified diagnostic test and/or screening procedure and who can provide a skilled interpretation.

5.6 The clinical team that requested the diagnostic testing and/or screening procedures is responsible and accountable for tracing, validating,

documenting, acting upon, and informing the patient and /or clinicians with ongoing responsibility for the patient e.g. general practitioner.

5.7 To assist in the early identification of failures to follow up on any reports, it is recommended that the patient should also be given the following guidance:

- to ask when and how they will be informed of test results;
- be aware of how to get their results;
- to have the relevant health professionals contact details and be able to access them if required;
- to ensure that their, and their next of kin's, contact details are recorded in their health records and that contact arrangements are clear.

## **6 OBTAINING SAMPLES**

6.1 It is the responsibility of the requestor or healthcare professional with the delegated responsibility to collect samples (e.g. the phlebotomist) to ensure that they have identified the patient correctly and that informed consent has been gained. They must ensure that the sample is in the correct container and it is correctly labelled. If a laboratory service is requested, healthcare staff must ensure that the information includes:

- the recording of the correct patient's identification details, including their NHS number;
- the request for the correct diagnostic test and/or screening procedure is clearly stated on the request form;
- the details of the requesting clinician and/or clinical team for return of the diagnostic test and/or screening procedure result.

6.2 If the patient is required to provide their own sample the requester must inform the patient of the correct sampling and storage requirements.

6.3 Where the procedure does not require a laboratory analysis e.g. point of care testing, the undertaking and outcome of this activity must be documented in the patient's clinical records and if appropriate, the requestor informed of the outcome.

6.4 All staff involved must understand the part they play in this process and with the verification of results; informing patients and documenting the results in the patient's clinical records, informing the clinician with ongoing responsibility for the patient, e.g. general practitioner.



## **7 TAKING ACTION ON TEST AND SCREENING RESULTS**

- 7.1 It is the requester's responsibility to ensure that they follow up the receipt of results and act upon them appropriately and in a timely manner. If an image or other test result indicates a life threatening or clinically significant condition it is expected that the referring clinician will respond immediately on receipt. If the result arrives out of normal working hours, or the requesting clinician knows that they may be unavailable to receive the report e.g. off site or off duty, there must be arrangements (see 7.2) in place for handover of the case by the requester and these arrangements recorded.
- 7.2 If the patient was an inpatient and has been discharged, the team responsible for that patient must ensure that appropriate action is taken which may mean recalling the patient or informing the patient's GP of the result. Recall systems must be in place, correct patient contact details, e.g. landline and mobile telephone numbers must be verified as correct. All temporary addresses must be recorded in the clinical notes. The patient's general practitioner will be informed.
- 7.3 It is the responsibility of the requesting clinician to interpret and act on the results of diagnostic test and/or screening procedures and form a diagnosis or differential diagnosis along with a management plan. Missed or incorrect diagnosis must be reported in accordance with Somerset Partnership NHS Foundation Trust Incident Reporting Policy and involve a senior clinician.
- 7.4 The recipient of the results is responsible for recording the results, securing the results into the patient's healthcare record and documenting any changes to the clinical management plan.

## **8 COMMUNICATING TEST AND SCREENING RESULTS**

- 8.1 The person who completes/interprets or verifies a diagnostic test and/or screening procedure must ensure that results are communicated to the referrer/requestor of the diagnostic test and/or screening procedure, and, in the case of a life threatening situation or clinically significant result, that the referrer/requester, or nominated senior clinician, will be advised immediately
- 8.2 The accurate contact details of the referrer/requester must be included on the request form. The member of staff contacting the referrer/requester must document in the patient's clinical record, the date and time the information was given along with their name and designation. Where clinically significant results indicate urgent assessment and prompt management, the nominated senior clinician needs to be informed
- 8.3 It is the responsibility of the clinician requesting the diagnostic test and/or screening procedure to inform the patient of the results as soon as possible where clinically indicated. If the results are unfavourable, consideration must be given as to how these are communicated to the patient.

## **9. TRAINING**

- 9.1 The Trust will work towards all staff being appropriately trained in line with the organisation's Staff Mandatory Training Matrix (training needs analysis). All training documents referred to in this policy are accessible to staff within the Learning and Development Section of the Trust Intranet.

Heads of Service/wards/departments are responsible for ensuring that staff carrying out diagnostic testing and/or screening procedures are appropriately trained and competent to do so, and for liaising with the training department to negotiate training or to evidence the competencies required.

## **10. EQUALITY IMPACT ASSESSMENT**

All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity Lead who will then actively respond to the enquiry.

## **11. MONITORING COMPLIANCE AND EFFECTIVENESS**

- 11.1 All cases of non-compliance with local procedures should be reported using Somerset Partnership NHS Foundation Trust Incident Reporting Policy. Any incidents should be brought to the attention of the Heads of Service/wards/departments.
- 11.2 The implementation of this policy will be assessed through the clinical audit programme for healthcare records to demonstrate its effectiveness, see appendix B 'Clinical Audit Standards' relating to this policy.
- 11.3 The policy will be further evaluated by exception reporting through the existing incident reporting arrangements to the Clinical Governance Group.
- 11.4 **Methodology to be used for monitoring**
- internal audits
  - incident reporting and monitoring
  - clinical effectiveness monitoring
- 11.5 **Process for reviewing results and ensuring improvements in performance occur**
- any audit results will be discussed by the appropriate Best Practice Groups, identifying good practice, any short falls, action points and lessons learnt. These groups will ensure that improvements, where necessary, have been implemented, and will raise awareness through 'What's On'

## 12. COUNTER FRAUD

- 12.1 The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.

## 13. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

- 13.1 Under the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)**, the fundamental standards which inform this procedural document, are set out in the following regulations:

Regulation 9:	Person-centred care
Regulation 10:	Dignity and respect
Regulation 11:	Need for consent
Regulation 12:	Safe care and treatment
Regulation 13:	Safeguarding service users from abuse and improper treatment
Regulation 14:	Meeting nutritional and hydration needs
Regulation 15:	Premises and equipment
Regulation 16:	Receiving and acting on complaints
Regulation 17:	Good governance
Regulation 18:	Staffing
Regulation 19:	Fit and proper persons employed
Regulation 20:	Duty of candour
Regulation 20A:	Requirement as to display of performance assessments.

- 13.2 Under the **CQC (Registration) Regulations 2009 (Part 4)** the requirements which inform this procedural document are set out in the following regulations:

Regulation 16:	Notification of death of service user
Regulation 17:	Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983
Regulation 18:	Notification of other incidents

- 13.3 Detailed guidance on meeting the requirements can be found at <http://www.cqc.org.uk/sites/default/files/20150311%20Guidance%20for%20providers%20on%20meeting%20the%20regulations%20FINAL%20FOR%20PUBLISHING.pdf>

## 14. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

### 14.1 References

Care Quality Commission Registration Standards

Royal College of Emergency Medicine, Clinical Effectiveness Committee, Radiology 2012 [www.collegeofemergencymedicine](http://www.collegeofemergencymedicine)

Higgins C (2013 3<sup>rd</sup> edition) Understanding Laboratory Investigations  
Blackwell Publishing

Making the Best Use of Department of Clinical Radiology (7<sup>th</sup> edition) Royal  
College of Radiologists 2012

NHSLA Risk Management Standards 2016

Royal Marsden Hospital, Manual of Clinical Procedures (9<sup>th</sup> edition) online  
2015

#### 14.2 **Cross reference to other procedural documents**

Cleaning of Equipment and Decontamination Policy

Consent and Capacity to Consent to Examination and/or Treatment Policy

DATIX Untoward Event Reporting Guidance

Diagnostic Imaging – Requesting and Interpreting Radiographs by Non  
Medical Practitioners Policy

Identification of Patients Policy

Infection Prevention and Control Policy

Inpatient Handover Policy

Medical Devices Policy

Non Medical Professionals Requesting Blood Investigations

Physiological Observation Policy

Record Keeping and Records Management Policy

Requesting and Interpreting X-rays by Non Clinical Practitioners,

Risk Management Policy and Procedure

Risk Management Strategy

Staff Training Matrix (Training Needs Analysis)

Untoward Event Reporting Policy

Waste - Healthcare (Clinical) Waste Policy

Waste Management (non clinical) Policy

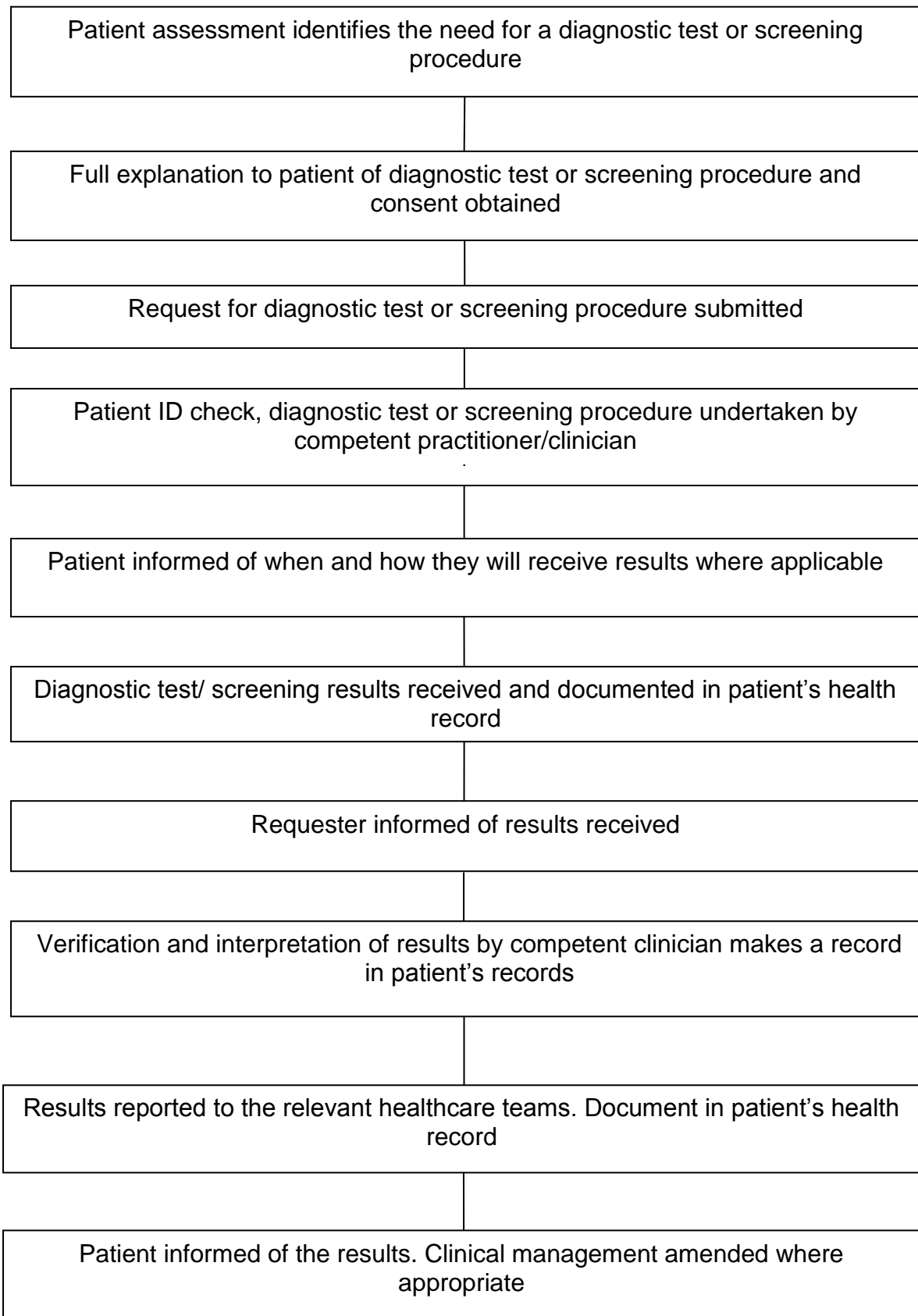
All current policies and procedures are accessible in the policy section of the  
public website (on the home page, click on 'Policies and Procedures'). Trust  
Guidance is accessible to staff on the Trust Intranet.

## 15. **APPENDICES**

Appendix A Flow Chart

Appendix B Clinical Audit Standards

## FLOWCHART



## Clinical Diagnostic Tests or Screening Procedures CLINICAL AUDIT STANDARDS

31/08/2016

**Service area(s) to which standards apply:**

✓	<b>MH Inpatient (CAMHS)</b>	✓	<b>Community CAMHS</b>	✓	<b>CH Specialist Services</b>
✓	<b>MH Inpatient (Adult)</b>	✓	<b>C &amp; YP Integrated Therapy</b>	✓	<b>MH Specialist Services</b>
✓	<b>MH Inpatient (Older)</b>	✓	<b>School Nursing</b>	✓	<b>MH Community Adult</b>
✓	<b>MH Rehab &amp; Recovery</b>	✓	<b>Health Visitors</b>	✓	<b>MH Community Older</b>
✓	<b>Community Hospital</b>	✓	<b>CH Rehab</b>	✓	<b>Learning Disabilities</b>
✓	<b>MIU</b>	✓	<b>Musculo-Skeletal</b>	✓	<b>District Nurses</b>

## Clinical Diagnostic Tests or Screening Procedures

Standard	Policy/ document Reference	Compliance (%)	Exceptions	Definitions <i>(e.g. any interpretations, directions, or instructions on where/how to find information, <b>plus</b> relevant service where applicable)</i>	
<b>REQUESTING CLINICAL TESTS AND/OR SCREENING PROCEDURES</b>					
<b>1</b>	The test ordered and their purpose must be fully explained to the patient, carer or relative to minimise distress.	5.4	100%	No	Recorded in clinical record and care plan
<b>2</b>	Consent must be obtained following explanation to the patient as per Somerset Partnership NHS Foundation Trust Consent Policy, prior to the procedure being carried out	5.5	100%	No	Consent recorded in clinical record and care plan
<b>3</b>	To assist in the early identification of failures to follow up on any reports, the patient should also be given the following guidance: <ul style="list-style-type: none"> <li>• To ask when and how they will be informed of test results</li> <li>• Be aware of how to get their results</li> <li>• To have the relevant health professionals contact details and to access them if required</li> <li>• To ensure that their, and their next of kin's, contact details are recorded in their health records and that contact arrangements are clear and agreed</li> </ul>	5.8	100%	MIU/urgent care service will contact patient only if change in clinical management plan is indicated	MIU radiographic imaging reports will be reviewed within 24 hours of the report being generated.  Recorded in the clinical record.
<b>OBTAINING SAMPLES</b>					

## Clinical Diagnostic Tests or Screening Procedures

Standard	Policy/ document Reference	Compliance (%)	Exceptions	Definitions <i>(e.g. any interpretations, directions, or instructions on where/how to find information, plus relevant service where applicable)</i>
<p>4</p> <p>If a laboratory service is requested, healthcare staff must ensure that the information includes:</p> <ul style="list-style-type: none"> <li>• The correct patient's details, including their NHS number</li> <li>• The request for the correct diagnostic test or screening procedure</li> <li>• The details of the appropriate healthcare staff member for return of the test or screening result and subsequent actioning</li> </ul>	6.1	100%	No	<p>Laboratory staff will not process incomplete requests, failure to process will be recorded in the clinical record</p> <p>Diagnostic imaging professionals will not process incomplete requests and will generate incident reporting</p>
<p>5</p> <p>Where the procedure does not require a laboratory analysis the undertaking and outcome of this activity should be documented in the patient healthcare records and the requestor informed of the outcome.</p>	6.3	100%	No	Recorded in the clinical record and care plan
<b>TAKING ACTION ON TEST AND SCREENING RESULTS</b>				
<p>6</p> <p>It is the requester's responsibility to ensure that they follow up the receipt of results and act upon them appropriately and in a timely manner.</p>	7.1	100%	No	<p>If an image or other test indicates a life threatening condition it is expected that the referring clinician will respond immediately. Clinical interventions and changes in the management plan will be recorded in the clinical record/care plan.</p> <p>If the result arrives out of</p>



## Clinical Diagnostic Tests or Screening Procedures

Standard		Policy/ document Reference	Compliance (%)	Exceptions	Definitions (e.g. any interpretations, directions, or instructions on where/how to find information, <b>plus</b> relevant service where applicable)
					normal working hours, or the requesting clinician knows that they may be unavailable to receive the report (e.g. off site or off duty), there must be robust arrangements in place for handover of the case by the requester and these arrangements recorded.
7	Missed or incorrect diagnosis must be reported in accordance with Somerset Partnership NHS Foundation Trust Incident Reporting Policy.	7.3	100%	No	Will be recorded on DATIX.  MIU/urgent care service continually audits all radiographic imaging results.  Recorded in the clinical record.

## Clinical Diagnostic Tests or Screening Procedures

Standard		Policy/ document Reference	Compliance (%)	Exceptions	Definitions (e.g. any interpretations, directions, or instructions on where/how to find information, <b>plus</b> relevant service where applicable)
<b>8</b>	The recipient of the results is responsible for: <ul style="list-style-type: none"> <li>• Recording the results</li> <li>• Securing the results into the patient's healthcare record</li> <li>• Documenting the subsequent actions taken to implement any clinical actions identified as a requirement of the result.</li> </ul>	7.4	100%	No	Recorded in the clinical record/care plan.
<b>COMMUNICATING TEST AND SCREENING RESULTS</b>					
<b>9</b>	The member of staff contacting the referrer must document in the patient's healthcare record, the date and time the information was given along with their name and designation.	8.2	100%	No	Recorded in the clinical record/care plan.