Royal Cornwall Hospitals
NHS Trust

Scope of Practice for Mainstream Germline, Genomic R208, R444.1, Testing in the Breast Care Unit Policy

V1.0

September 2024

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

Genetics is a relatively new science with regards to panel testing for disease and is becoming more relevant in clinical settings with the introduction of mainstreaming genomic testing via blood samples in mainstream clinics such as the cancer setting.

Breast cancer is a common cancer with approx. 550 diagnoses a year in our small unit (Trust data 2023), but an average of 59,000 diagnoses, in the UK a year (Cancer Research 2024).

The impact on the Genetics services that initially consented, tested, and counselled patients for BRCA (Breast Cancer genes) and other breast cancer related gene alterations as well as other cancers and rare conditions found in the National genetic test directory for inherited disease, caused an unacceptable delay on assessment and testing with laboratories taking years to turnaround some results.

Mainstreaming has reduced the current wait time from months to weeks by early testing in the breast cancer unit by competent Breast Care Nurses, who will assess, inform, consent, test, give results and support as part of the patients care pathway and refer to the clinical genetic service if a positive or variant of unknown significance result is found.

This has reduced the workload in the Clinical Genetic Services and Genetic Laboratories by filtering the need for patient appointments and improved the pathway for patients with early breast cancer to influence their surgical or Oncological pathways for themselves and their families at an earlier stage.

Therefore, mainstreaming genomic testing in clinics will become an important part of upcoming healthcare practice.

There are already changes to drugs and eligibility since the start of this service in February and there are more plans soon to further grow and improve this service for the patients, their families and for us as a team and a hospital.

2. Purpose of this Policy/Procedure

2.1. This guidance is to set out the protocols for the Nurse led, Mainstream Germline/Genomic Clinics with the Breast Care Unit at the Mermaid Centre.

2.2. This policy is to guide appropriately qualified Breast Care nurses to manage patients that have been referred to the Genomic testing clinic within the Mermaid Centre via Surgeon, Oncologist or Breast Care Nurses (BCN) on a referral through Maxims when available.

2.3. Maxims referral service name is: *Outpatient service Mermaid Mainstreaming Genomic Service.*

3. Scope

3.1. The scope of practice is to cover all BCN's who work in the Mermaid Centre Breast Unit, Genomic testing clinic.

3.2. The BCN will assume accountability for their own actions as per Nursing and Midwifery Council Guidelines (NMC2019). www.nmc.org.uk/standards/code/read-the-code-online/

4. Definitions/Glossary

4.1. A **Breast Care Nurse** is an experienced Registered Nurse who manages the complete information giving, consent, testing, results, and referrals for their patient, during genomic testing.

Working amongst all specific areas of Breast care practice and are involved in delivering specialist care to patients and in this case Genomic clinic.

They also contribute to the evidence base and development of other staff, act as an expert resource for knowledge, information and demonstrate team leadership.

4.2. **Genetics** – A study of genes and how they are inherited.

4.3. **Genomics** – The study of an organism's genome, its genetic material and how that information is applied.

- **Consent** – Consent is a legally defined decision given by someone who is competent, who has been adequately informed (and has adequate understanding), who is free from undue influence enabling them to make a voluntary decision. Whenever possible, patients should have time to consider the information given, they should be given time to discuss information with family and friends if they wish. (NHS health research authority).

4.4. **Time** – there are no fixed guidelines on time, complexities guide the time required, BCNs must consider what appropriate length of time is appropriate to ensure that consent is informed and voluntary. (NHS health research authority).

4.5. **Olaparib** – PARP inhibitors are a type of drug used in early breast cancer to treat patients with a BRCA gene alteration potentially causing the associated breast cancer.

4.6. **Talazoparib** – Parp inhibitor like Olaparib however to be used in the Metastatic setting.

4.7. **BRCA1/2 gene alterations – BR**east **CA**ncer genes help to repair damaged DNA, (Tumour suppressor genes) One copy from each parent. When there is a change, this is when cancer can develop (Higher risk of breast or ovarian cancer) but they are not the cause of cancer just, unable to stop it developing.

4.8. **BRCA inheritance** – Each child from a BRCA positive parent has a 50% chance of inheriting it, siblings are at risk of a positive gene alteration also. (See appendix 10).

4.9. **First/Second/Third Generation**

First – parents, siblings, and Children. 50%.

Second – Grandparents, Aunts, Uncles and Cousins. 25% of genetic material transferred through inheritance.

Third - First Cousins 12.5% of genetic material transferred through inheritance.

4.10. **Genetic Counselling –** A process of helping people understand and adapt to the genetic, medical, psychological, and familial implications of genetic contributions to disease.

4.11. **Somatic –** All cells in the body other than those that lead to the formation of Gametes (sex cells).

5. Ownership and Responsibilities

5.1. Role of the Managers

Line managers are responsible for: Line managers are responsible for: ensuring professional standards, registration and Code of Practice are adhered to.

It is the responsibility of the Clinical Lead Breast Care Nurse and genomics lead BCN in the Mermaid Unit to support those undertaking genomic clinic and ensure all training and education has been completed prior to BCN's performing any associated information, consenting, genomic testing, support, and signposting.

5.2. Role of the Surgical Clinical Governance Group

The Surgical Clinical Governance Group is responsible for: approving changes in practice following consultation with Surgical Audit Group, Guided by Southwest genomic laboratory (SWGLH) and the National test directory. www.england.nhs.uk/genomics/the-national-test-directory/.

5.3. Role of Individual Staff

Individual staff are to have attended the Trusting workshop and preferably completed bitesize Health England modules for the knowledge to inform patients appropriately.

- Genomics education programme - https://www.genomicseducation.hee.nhs.uk
- Consent training on ESR portal RCHT.
- Awareness of the relevant Acts of Parliament with regards to Tissue taking, storage and consent. www.legislation.gov.uk/ukpga/2004/30 - Human tissue act 2004.
- www.gov.uk/government/publications/consent-privacy-policy/consent-policy - consent.
- BCN's have a duty of care towards their patients and must therefore ensure they work within the NMC Code of Practice and in accordance

with local governance. They must maintain competency of their practice as part of professional development requirements.

- Work within their own professional competencies as documented in the NMC code of conduct.

5.4. **BCN led Genomic Clinical skills may include.**

- Information giving.
- Communication skills.
- Consenting for testing.
- Venipuncture.
- Support and referrals.
- Documentation.
- Running of mainstream genomic testing clinics.
- Managing workloads in other clinics to accommodate genomics discussion and consent.
- Organisation of interpreting, receiving, informing, and documenting results.
- Health promotion and audit.
- Education and training.
- Research and development.
- Team/professional leadership.
- Basic counselling skills.

6. Standards and Practice

6.1. **Identifying Patients:**

6.1.1. Patients are identified in MDT and clinical interactions when a patient falls into the eligibility criteria for R208, R444.1 and R346. (See appendix 4).

6.1.2. Consultant/Dr/BCN to highlight possible patients for R208, R444.1 and R346 in MDT.

6.1.3. For R444.1 Patients identified or approached in Oncology clinic by a BCN, if possible.

6.2. **Referral Via Maxims**

Refer patients to R208/R444.1 testing in the Mermaid Centre under the patient internal referral tab. The name of this service is, *Outpatient service Mermaid Mainstreaming Genomics Service.*

Please give as much information as possible on age, eligibility, diagnosis, and family history. Please add a link to the latest letter regarding the patient. Although favorable, it does not matter if you have not given an information booklet yet as we can send that out with the appointment if needed.

6.3. **Information Giving:**

Basic genetics and heritability.

- Ensure that the patient has enough time to read and understand the information leaflet produced by SWGLH (see appendix 11).
- Patients are not to be rushed into a decision and feel that they have come to their decision without coercion.
- Give information leaflet to take away at diagnosis appointment, (see appendix 11), with awareness of all information and emotional load distress.
- In the event of an Oncologist requesting R444.1, full information about Parp inhibitor treatment must be communicated to the patient from the oncology team prior to approaching with R444.1 information. (see appendix 11). Organise appointments at the earliest genomic clinic for consent discussion and testing.
- Mention R208 genomics referral to second Friday Genomics clinic leaving a weekend to take in diagnosis and think about genomic testing.

6.4. **Clinical Assessment:**

To carry out a comprehensive assessment of capacity to make informed decisions about genomic testing and the implications genomic testing holds for themselves and their families both now and in the future, under the Mental Capacity Act (2006).

www.gov.uk/government/publications/mental-capacity-act-code-of-practice

At MDT and in all clinic situations, assess patients' eligibility for genomic testing.

6.5. **Supportive Role:**

Supporting patients with informed decision-making and informed consent in the most appropriate pathway for the patients understanding of genomics.

Managing risk in patients where capacity might be in question and seeking appropriate support for the patient in respect of their age, gender, culture or religion.

Enable patients to feel confident with their decision.

6.6. **Informed Consent:**

6.6.1. Using clinical judgement to assess understanding of discussion had, regarding the implications of genomic testing on themselves, their treatment pathway and their family's health risks of breast and ovarian cancer both now and in the future.

6.6.2. Use expert knowledge to answer questions, understanding where to source answers, if out of BCN knowledge base:

- Peninsular Clinical Genetic counsellors. ubh-tr.clinicalgeneticsuhb@nhs.net
- Matilda Bradford Exeter Lead Genetic. counsellor.matildabradford@nhs.net
- Sadie Mitchell, Local lead genomic nurse. rduh.genomicpractitioner@nhs.net
- Tracie Miles, Associate Director of Nursing and Midwifery NHS South-West Genomic Medicine Service Alliance, Mainstream Genomic Nurse lead. tracie.miles@nhs.net
- Southwest Genomic laboratories hub. (3 Patient Identifiers are required to discuss patients. SWGLHenquiries@nbt.nhs.uk/ rduh.exetergenomicslaboratory@nhs.net

6.6.3. Offering support and referrals to MDT to ensure patients holistic needs are met.

6.6.4. Ensure patients understand the process of testing one vial and storing the other for further genes added to the panel in the future, to help test family in the future, research, quality assurance.

6.6.5. R208 panel testing for BRCA1 and 2, PALB2, RAD15C, RAD15D, ATM and CHEK2 is tested currently other gene alterations can be added as they are discovered.

6.6.6. R444.1 panel is only BRCA 1 and BRCA 2 tested.

6.6.7. Awareness that Insurance could be affected by a positive result.

6.6.8. Understand that a patient has the right to decline or disengage and cancel consent and testing/storage at any time.

6.6.9. Understand that once the results are communicated, they are confidentially stored in health records but cannot be unknown once released.

6.6.10. Signpost and provide contact details to ask questions and seek support.

6.6.11. Complete consent form using it as a guide to the implications of testing. Consent forms are found on the BCN shared drive under R208 or visit SWGLH.

6.7. The future of genomics in the Mermaid Centre

6.7.1. The Mermaid Centre will be trialling a new digital consent project for genomic testing once the software is ready, to make consenting and information giving more responsive to the patient and the unit, reducing the amount of paper used.

6.7.2. Digital Maxims blood forms are currently being finalised to remove paper waste and make the clarity of information and the efficiency of blood transport to the labs for testing.

6.7.3. We are waiting for Breast Genomic competencies to be produced and trialled within the Mermaid Centre (please see section 6.11).

6.8. Testing

6.8.1. BCN's should continue to be confident and competent to assess capacity and informed, non-coerced, consent, to offer testing in patients over 18 years old.

6.8.2. Competency and skilled in venepuncture.

6.8.3. Is able and has the authority to request appropriate Genomic testing using the R208, R444.1 or R346 protocols (see appendix 3) currently on paper request but moving to Maxims.

6.9. In Genomic Clinic

6.9.1. Wash hands.

6.9.2. Apply tourniquet and clean the skin with skin prep swab.

6.9.3. Using aseptic technique, take two lavender EDTA blood vials of blood from the patient.

6.9.4. Remove torniquet and clean and dress area.

6.9.5. Label with patient's identification labels prior to Maxims requesting approval.

6.9.6. Place paper blood request form in the sample bag with the double wrapped sample until the maxims blood requests are ready for use.

6.9.7. Send to RCHT lab with instruction on blood form for Exeter lab, to be processed and DNA extracted to send to Bristol for testing.

6.9.8. In the case of R444.1, in time sensitive patients and occasional ward patients, which may not be responding to chemotherapy. It may be essential to take a blood sample and send for storage under the R346 protocol. Breast care Nurses will have to call the patient and discuss

consent and information in a genomic clinic.

6.9.9. Patients can then remote consent if willing to go ahead once informed consent is gained. BCN to sign the form stating.

"***Remote consent given to continue to testing (R444.1/R208) of bloods currently stored under the R346 protocol"*** *BCN to sign date and stamp consent form.*

"Remote consent gained to cancel the process and destroy the samples currently stored in the R346 protocol." *BCN to sign, Date, and stamp consent form**.***

6.9.10. Clinical judgement to assess if consent is clear using this protocol without face-to-face cues and in-depth discussion, this is only suitable in an emergency.

6.9.11. In either case, this process takes approximately 8 weeks.

6.9.12. BCN to request that admin book patients into genomic results clinic as face to face, for giving of the results, if it is positive patients are assessed for referral to clinical genetics and holistic support.

6.9.13. Appointment specific letters are pre-set onto PAS system and automatically generated when an appointment is made.

6.9.14. Request Invite letter to book appointment for consent clinic. (see appendix 6).

6.9.15. Request Testing letter to book appointment for summary and results clinic. (See appendix 7).

6.9.16. Request storage letter for storage of blood until decision is made. (see appendix 8).

6.10. **Results**

6.10.1. Lab Results are sent to rcht.mermaidgenomicsresults@nhs.net.

6.10.2. If results are not ready, re-organise appointment with patient.

6.10.3. Collaborate with the lab to receive and process results.

6.10.4. Communicate results and further actions as below.

6.10.4.1. **Positive Result** – They have the tested gene alteration, this may mean alterations to ongoing surgical plan for prophylactic reasons, Referral to genetics for in depth discussion, referrals to other screening and discussion of family risk and support.

6.10.4.2. **Variant of unknown significance (VUS)** – There is a change to the DNA, but this is not understood at this time, this could be a normal familial alteration or a gene alteration that may be found in the future that we do not realise the importance of yet.

Referral to genetics for in depth discussion, referrals to other screening and discussion of family risk and support.

6.10.4.3. **Negative result** – Inform patient by phone to inform of result and offer BCN support to continue with planned treatment. The likelihood of a genetic cause is significantly reduced, and most patients will not need to see clinical genetics.

6.10.5. If the patient has significant personal or family history of cancer, referral to clinical genetics may still be appropriate.

6.10.6. Refer any breast cancer <30, or any HER2+ breast cancer <35. Referral may also be appropriate based on multiple primary cancers in patient or family history (on the same side) including multiple relatives with young diagnoses; significant family history of breast, ovarian, sarcoma or thyroid cancers. If the significance of cancer history is unclear, approach clinical genetics for advice and guidance in the first instance.

6.10.7. Communicate results to consultants to inform their treatment options Via MDT and upload results onto Maxims.

6.10.8. Currently results letters are populated and sent by BCN (see appendix 9).

6.10.9. A template letter, regarding results is completed by the BCN using dragon accounts, once set up and uploaded onto Maxims.

6.11. **Referral to Genetics:**

6.11.1. BCNs are able and has the authority to refer to the appropriate healthcare professional, groups and agencies via Maxims or email and work collaboratively with them.

6.11.2. Clinical genetics will support the patients with complex discussions and support the patient and the family throughout next stages.

6.11.3. Referral via email to clinical genetics rduh.pcgreferrals@nhs.net

6.12. **Further responsibilities:**

6.12.1. Registered with the NMC.

6.12.2. Experienced Breast Care Nurse.

6.12.3. Fully accredited in Breast Care Nursing.

6.12.4. To support and participate in audit, complete the database to keep data to improve our service if a business case is needed in the future.

BCN shared drive, R208 database.

6.12.5. Continual professional development and teaching within the Surgical Breast Team.

6.12.6. Provide clinical leadership and to promote a culture of learning within the Surgical Breast Team

6.13. **Multi-disciplinary Relationships:**

6.13.1. Breast care nurses are expected to build and maintain relationships with their Surgical, Oncological and Genetic colleagues and all members of the multi-disciplinary team including research, and GP's.

6.13.2. Communicate with other members of the breast and genetic team for updating knowledge and skills.

6.14. **Acquiring and Assuring Maintaining Competency:**

6.14.1. Breast care Nurses must ensure that they obtain sufficient experience to maintain their standards.

6.14.2. May undertake further in house training to acquire competencies in a wider range of procedures as dictated by departmental clinical requirements.

6.14.3. Trusting workshop (Dame Lesley Fallowfield).

6.14.4. The MDT meeting alongside Audit, will act as a forum for development.

6.14.5. Ongoing mentorship and clinical training are also available.

6.14.6. Health England online learning portal. https://www.england.nhs.uk/genomics/the-national-genomic-test-directory.

6.14.7. A Competency framework is currently being formulated to ensure knowledge is gained and continued to learn to provide a good standard of information to allow for informed consent to genomic testing and the implications to the patient's treatment and the health of the family. This will be trialled in the mermaid centre.

6.15. **Documentation:**

6.15.1. Documentation in line with RCHT protocol and in line with NMC guidelines.

6.15.2. Episodic notes are required for the Genomic clinics with an outcome and identification stickers.

6.15.3. Referrals made using Maxims referral system (once set up).

6.15.4. Documentation on Somerset Cancer Register.

6.15.5. Admin to send pre-populated letters from PAS at appointment letter stage.

6.15.6. BCN to Write a letter on Dragon software, with approved licence and training.

7. Dissemination and Implementation

This document will be shared on the Documents library.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Clinical performance will be monitored and audited through examination of data, presentations at Audit and discussion with the surgical team.
Lead	Clinical Lead Breast Care Nurse for Mermaid Centre, Lead Genomics BCN for Mermaid Centre.
Tool	Audit, peer review.
Frequency	6 monthly.
Reporting arrangements	To Clinical Lead Breast Care Nurse for Mermaid Centre, Lead Genomics BCN for Mermaid Centre be informed of results.
Acting on recommendations and Lead(s)	Both a Clinical Lead Breast Care Nurse for Mermaid Centre, Lead Genomics BCN for Mermaid Centre re responsible for acting on any recommendations.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned immediately. A member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant team members and departments.

9. Updating and Review

The document is to be reviewed after 1 year unless practice dictates otherwise.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Scope of Practice for Mainstream Germline, Genomic R208, R444.1, Testing in the Breast Care Unit Policy V1.0
This document replaces (exact title of previous version):	New Document
Date Issued/Approved:	May 2023
Date Valid From:	September 2024
Date Valid To:	September 2027
Author/Owner:	Sara Trotman, Breast care nurse
Contact details:	01872 25 2880
Brief summary of contents:	To define the scope of practice for BCNs within Genomic service within the Mermaid Breast Unit
Suggested Keywords:	Breast, genomics, Breast care.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Dual Chief Nursing Officer / Deputy CEO (RCHT)
Approval route for consultation and ratification:	Breast Surgical Clinical Governance Meeting Group
Manager confirming approval processes:	Ian McGowan
Name of Governance Lead confirming consultation and ratification:	Rachel English
Links to key external standards:	RCN. NMC Nursing Practice. NMC Code of Professional Standards.

Information Category	Detailed Information
Related Documents:	RCHT Standards of Documentation and Record Keeping. RCHT Infection Control. Cornwall and Isles of Scilly Medicines Management Policy.
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/Breast

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
May 2024	V1.0	Initial issue	Sara Trotman, Breast Care Nurse

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy/policy/proposal/service function to be assessed:	Scope of Practice for Mainstream Germline, Genomic R208, R444.1, Testing in the Breast Care Unit Policy V1.0
Department and Service Area:	General Surgery and Cancer Services / Breast
Is this a new or existing document?	New
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Sara Trotman, Breast Care Nurse
Contact details:	01872 25 2880

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To define the Scope of Practice for the Breast Care Nurses within the nurse led Genomic testing Clinic.
2. Policy Objectives	Clearly state training requirements and procedures which following suitable training, the Breast Care Nurse is permitted to perform.
3. Policy Intended Outcomes	To recognize the Genomic pathway and holistic care whilst, allowing the genomic skilled Breast care Nurse to practice within agreed boundaries.
4. How will you measure each outcome?	Monitored through audit, patient satisfaction, and peer review
5. Who is intended to benefit from the policy?	Staff, patients, and consultants.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/visitors: No • Local groups/system partners: No • External organisations: Yes • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Breast Surgical Clinical Governance Meeting Group. NHS Southwest Genomic Laboratory hub. Peninsula Genetic service.
6c. What was the outcome of the consultation?	Approved
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Sara Trotman, Breast Care Nurse.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Paper Bloods Request

Permissions from South West Genomic Laboratory Hub

NHS South West Genomic Laboratory Hub

Genomic Test Request

BRISTOL GENETICS LABORATORY
T: 0117 414 6168/6167/6174
nbn-tr.geneticsenquiries@nhs.net

EXETER GENOMICS LABORATORY
T: 01392 408229
rde-tr.ExeterGenomicsLaboratory@nhs.net

Please return completed request form with all samples to the following SWGLH Laboratory (tick as appropriate)

Bristol Genetics Laboratory, Pathology Sciences, Southmead Hospital, Bristol, BS10 5NB

Exeter Genomics Laboratory, Royal Devon and Exeter NHS Foundation Trust, Barrack Road, Exeter, EX2 5DW

Patient first name	Relevant clinical and family information (please include lab identifiers)
Patient last name	
Date of birth *(dd/mm/yyyy)* / Gender	
NHS number	
Postcode	
Ethnicity	
Hospital number / Clinical Genetics number	
Test request Please include NHSE R/M code (https://www.england.nhs.uk/publication/national-genomic-test-directories/)	
For fetal samples	
Gestation / EDD / Multiple pregnancy?	

Samples (For sample requirements please see https://www.nbt.nhs.uk/south-west-genomic-laboratory-hub/swglh-sample-test-information)

Blood (EDTA)	Chorionic Villus		Collection date / time
Blood (LitHep)	Fresh Tissue	Tissue Origin	
Fetal Blood	FFPE Tissue		
Amniotic Fluid	Buccal/Saliva		

Responsible clinician / consultant	Additional contact
Name Department address Phone Email	Name Department address Phone Email
Report copy to	
Name	Email
CONSENT: In submitting this sample, the clinician confirms that informed consent has been obtained for (a) testing and storage (b) the use of this sample and the information generated from it to be shared with members of the donor's family and their health professionals (if appropriate). The patient should be advised that the sample may be used anonymously for quality assurance and training purposes. Signature:	

Appendix 4. Patient eligibility. R208 and R444.1.

R208 Eligibility (Surgical)

- Breast/Ovarian cancer +/- Individual +/- Family History if one of the following exists.
- Breast cancer, Hi grade DCIS, grade 1,2,3 under 40 years old.
- Bilateral cancer under 60 years old. (Updated from 50).
- Triple negative breast cancer under 60 years old.
- Male breast cancer of any age or type.
- Breast cancer under 45 years old with a 1st degree relative with Breast Cancer under 45 years old.
- Breast cancer of any age with Ashkenazi Jewish ancestry.
- Breast cancer of any age with at least one grandparent from the Scottish Shetland / Orkney islands (New eligibility).

R444.1 Eligibility for Olaparib (Oncological)

- Patients with triple negative breast cancer who have received neo-adjuvant chemotherapy:
  With *residual invasive disease of the breast, resected lymph nodes or both at the time of surgery.*
- Patients with triple negative breast cancer who are having adjuvant chemotherapy:
  - **With** *Node-positive cancer* **or**
  - **With** *Node-negative cancer and a primary tumour of 2cm or greater.*
- Patients with hormone-receptor positive, HER2-negative breast cancer who have received neo-adjuvant chemotherapy:
  With *residual invasive disease of the breast, resected lymph nodes or both at the time of surgery AND a CPS + EG score of 3 or more based on pre-treatment clinical and post-treatment pathological stage, receptor status and histological grade.*
- Patients with hormone-receptor positive, HER2-negative breast cancer who are having adjuvant chemotherapy:
  With *4 or more pathologically confirmed positive lymph nodes.*

R444.1 Eligibility for Talazoparib for Metastatic Breast Cancer (Oncological).

Patients with HER2 negative locally advanced or Metastatic breast cancer:

- Patients should have been previously treated with an Anthracycline and/or a Taxane in the neo/adjuvant setting unless patients were not suitable for these treatments.

- Patients with hormone receptor (HR) positive breast cancer should have been treated with a prior endocrine-based therapy or be considered unsuitable for endocrine-based therapy.

R346 Storage of blood only

- Initially prepared for testing but not tested until the decision is made to continue or decline testing.

Appendix 5. Consent Form

NHS South West Genomic Laboratory Hub

Name:
Date of Birth:
MRN Number:
NHS Number:
(OR AFFIX HOSPITAL LABEL HERE)

MAINSTREAM CONSENT FORM FOR GENETIC TESTING AND STORAGE

I have discussed genetic testing and I agree to my blood sample being used for the following reason:	
Diagnostic genetic test for genes associated with inherited breast cancer (and DNA storage)	☐
OR	
DNA storage only ***If the patient is having DNA stored without testing, ignore the additional sections and proceed to Statement of Patient / Practitioner to consent for storage alone.***	☐

Family implications	The results of my test *may* have implications for other members of my family. I agree that results may be shared with doctors looking after my relatives - as appropriate.	☐
Uncertainty	The results of my test may reveal genetic variation whose significance is not yet known. I acknowledge that interpretation of my results may change over time as such evidence is gathered.	☐
DNA storage	I understand that my DNA may be used to help with tests for other family members, or anonymously for quality control purposes.	☐
Data storage	Data from my genetic test will be stored to allow for possible future interpretations.	☐
Health records	Results from my genomic test and my test report will be part of my Patient Health Record.	☐
I understand that if I am found to have a gene alteration, I will be referred to Clinical Genetics.		☐
I understand that if I am found to have a gene alteration, this may inform my risk of developing another cancer such as ovarian cancer.		☐
Other areas discussed (e.g. research, insurance)		☐

Should I be unable to receive my result, I agree with it being shared to benefit the care of my family. In this situation, I would like my result communicated to:	
Full name:	Relationship:
Date of birth:	Address:

Patient's full name:	
Patient's signature:	Date:

Health practitioner section	
Health practitioner's full name:	Role:
Signature:	Date:

Appendix 6. Invite to Genomics clinic letter

Mermaid Centre
Direct Line: 01872 252880

Date

Name
Address
Address
Address
Postcode

Dear……

Your NHS number……
Your hospital number…….

Following on from our discussion in clinic, you may be eligible for genetic testing after your recent breast cancer diagnosis.

The following appointment has been made for you to see one of our Breast Care Nurses in the Genomics Clinic, at the Mermaid Centre, Treliske Hospital, Truro.

FRIDAY (insert written date) at (add time) pm.

At this appointment we will discuss this further and if appropriate, consent you to have a genetic blood test taken and stored.

If you think you may be able to claim help with travelling expenses, a form is available from our reception for you to take to the General Office for re-imbursement. The General Office does require evidence of the benefit you receive.

If this not convenient for you, please call us at the Mermaid Centre as soon as possible on 01872 252880.

Yours sincerely
Mermaid Centre

Appendix 7. Post consent, for testing letter.

Mermaid Centre
Direct Line: 01872 252880

Date

Address
Address
Address

Dear

Your NHS number:
Your hospital number:

It was a pleasure to see you in the Mermaid R208 genomic Clinic on…….. We had a conversation regarding hereditary genetic variants which may put you at a higher risk of breast cancer.

We talked about genetic testing, using your blood sample to see if you had this gene present in your DNA. You have read the information leaflet or watched the short videos and signed the consent form, you have consented to taking of 2 vials of blood to be sent to the lab for processing and testing.

We have discussed the possible implications to you and your family in the future. If you have the gene, we will refer you to the Genetics counsellor to talk about your result, how it affects you and next steps in more detail.
The results could take 6 – 8 weeks to come back and therefore we have booked you an appointment in 8 weeks' time to discuss them.

While you are waiting for your results, feel free to contact the breast care nurses for support or advice for any aspect of care. Unfortunately, we will not have any updates regarding genomics before your results are ready and if these are delayed, we may have to rebook your appointment.

Please come to the Mermaid genomics clinic on Friday…… at……for your results.
We wish you the best for your results.

If this not convenient for you, please call us at the Mermaid Centre as soon as possible on 01872 252880.

Yours sincerely
Mermaid Centre

To complete a short questionnaire about your latest visit, please visit www.oc-mermidian.com/OCQ/u/RCHT192 and tell us how we are doing. These questionnaires help us to improve where needed and see what is going right. Alternatively, if you would like a paper copy, please let us know.

OFUA/MM20 Breast Surgery

Appendix 8. post consent clinic storage letter.

Mermaid Centre
Direct Line: 01872 252880

Date

Address
Address
Address
Postcode

Dear,

Your NHS number:
Your hospital number:

It was a pleasure to see you in the Mermaid R208 genomic Clinic on……
We had a conversation regarding hereditary genetic variants which may put you at a higher risk of breast cancer.

We talked about genetic testing, using your blood sample to see if you had this gene alteration present in your DNA. You have read the information leaflet or watched the short videos and signed the consent form.

You have consented to taking of two vials of blood to be sent to the lab for storage until you are decided on whether to have the test.

If you decide against it, then your samples can be destroyed at your request.
If you would like to proceed to the testing of your blood sample, please inform us, to discuss this further.

We wish you the best.

Yours sincerely

Mermaid Centre

To complete a short questionnaire about your latest visit, please visit www.oc-meridian.com/OCQ/u/RCHT192 and tell us how we are doing. These questionnaires help us to improve where needed and see what is going right. Alternatively, if you would like a paper copy, please let us know.

OFUA/MM19
Breast Surgery

Appendix 9. Results clinic letter

Mermaid Centre
Direct Line: 01872 252880

Date

Name
Address
Address
Address
Postcode

Dear……

Your NHS number……
Your hospital number…….

It was a pleasure to speak with you in …… (**insert clinic / on the phone**), following on from your genetic testing after your recent breast cancer diagnosis, due to having a breast cancer and …… (**enter eligibility criteria**).

The result of this test is ……. (**Positive, Negative, or Uncertain outcome**).

This means that you (**Do / do not**) have a genetic variant associated with your breast cancer.

(**For a positive result insert paragraph below**.)
You have been advised that you will be referred to the genetic counsellor who will be able to support and guide you through the next steps and the implications for you and your family.

Your consultant is aware of your genetic diagnosis and may want to see you about further treatment or surgery.

This information will be kept in your confidential medical file. However, it important to note that if you are asked about genetic testing for insurance purposes, it is important to declare this legally.

OR

(If negative insert paragraph below.)
You have been advised that you will be discharged from the genomic clinic and will continue the planned treatment pathway for your breast cancer diagnosis.
(If unknown relevance, insert paragraph below)

You have been advised that you will be referred to the genetic counsellor who will be able to further support you, explain if further tests are required to understand the variance discovered in your genes and guide through this result. You are likely to continue with the current treatment plan.

We took two vials of blood; one was stored in case a significant new gene is relevant to you in the future. The other one was tested. If you would prefer not to store any blood for the future, this will also be disposed of at your request.

Please contact the Mermaid centre if you would like to have a conversation with a breast care nurse.

If you think you may be able to claim help with travelling expenses, a form is available from our reception for you to take to the General Office for re-imbursement. The General Office does require evidence of the benefit you receive.

Yours sincerely

Mermaid Centre

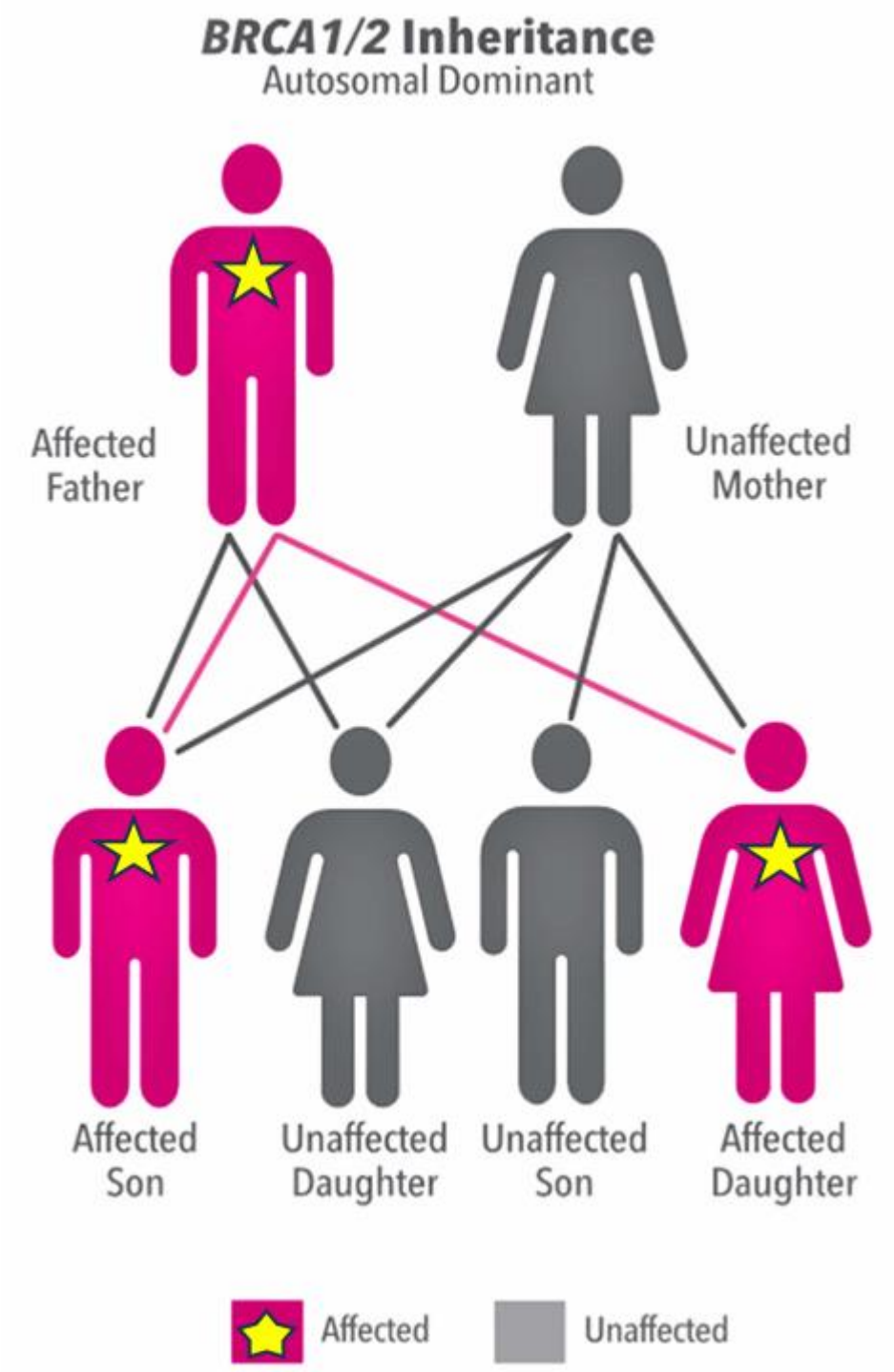
To complete a short questionnaire about your latest visit, please visit www.oc-meridian.com/OCQ/u/RCHT192 and tell us how we are doing. These questionnaires help us to improve where needed and see what is going right. Alternatively, if you would like a paper copy, please let us know.

Please scan this QR code on your smart phone to complete a short questionnaire about your latest visit, it helps us to improve where needed and see what is going right.

We value your opinion.

or type www.oc-meridian.com/OCQ/u/RCHT192 in your browser and tell us how we are doing that way.

Appendix 10. Inheritance Diagram

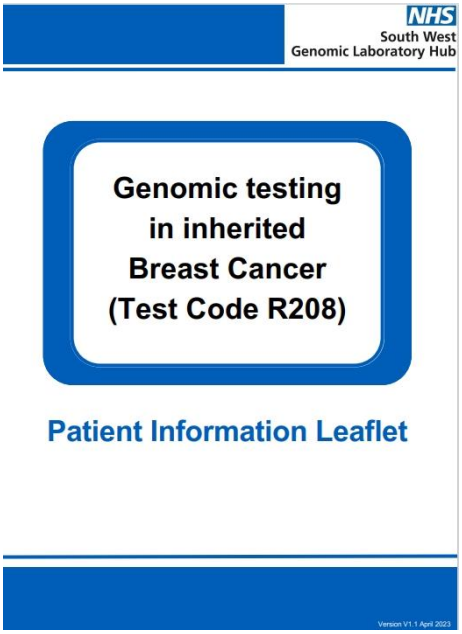


Permissions https://healthjade.com/brca-testing/

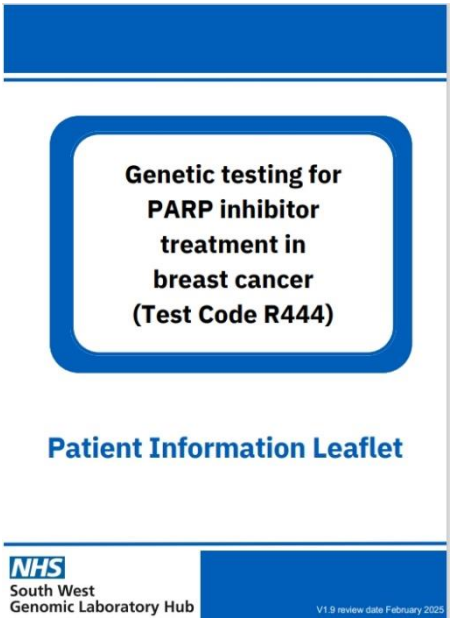
Appendix 11. Information Leaflets

Information leaflets for patients to be given prior to testing with time to read and discuss with relatives, written and supplied by Southwest Genomic laboratories Hub.

R208 information leaflet.



R444.1 Information leaflet



Appendix 12. References

Cancer Research UK (2024) Online resource, www.cancerresearchuk.org/healthprofessional/cancer-statixtics/statistics-by-cancer-type/breast-cancer accessed online April 2024.

NHS health research authority (2024) online resource www.hra-decisiontools.org.uk accessed online April 2024.

Trust Data (2023) information on a trust job post within the unit, www.beta.jobs.nhs.uk accessed online April 2024.