University Hospitals of Morecambe Bay NHS Foundation Trust

Document Type: **Procedure**	**Unique Identifier:** THEAT/LOCSSIP/002
Document Title: **Local Safety Standards for Invasive Procedures (LocSsip) for:** **Verification Safety Standards for Implantation of an Intra-Ocular Lens**	**Version Number:** 1 **Status:** Ratified
Scope: The MTD Theatre Operating Team consisting of : Clinicians, Scrub and Circulating Practitioners and Clinical Support Workers	**Classification:** Departmental
Author / Title: Sue Wroe, Trust Lead NatSsips, Quality & Governance	**Responsibility:** Theatre Matron
Replaces:	**Head of Department:** Daniel Bakey Faye Bennet
Validated By: Surgery & Critical Care Procedural Group	**Date:** 11/10/2017
Ratified By: Surgery & Critical Care DGAG Chair's Action	**Date:** 30/10/2017
Review dates may alter if any significant changes are made	**Review Date:** 01/10/2020

Which Principles of the NHS Constitution Apply? **Please list from principles 1-7 which apply** 1,2,3,4 Principles	**Which Staff Pledges of the NHS Constitution Apply?** **Please list from staff pledges 1-7 which apply** 1,2,3 Staff Pledges

Does this document meet the requirements of the Equality Act 2010 in relation to Race, Religion and Belief, Age, Disability, Gender, Sexual Orientation, Gender Identity, Pregnancy & Maternity, Marriage and Civil Partnership, Carers, Human Rights and Social Economic Deprivation discrimination? **Yes**

Document for Public Display: No

Reference check Completed by Paul Tickner……Date 17/11/17
To be completed by Library and Knowledge Services Staff

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BEHAVIOURAL STANDARDS FRAMEWORK

To help create a great place to work and a great place to be cared for, it is essential that our Trust policies, procedures and processes support our values and behaviours. This document, when used effectively, can help promote a workplace culture that values the contribution of everyone, shows support for staff as well as patients, recognises and celebrates the diversity of our staff, shows respect for everyone and ensures all our actions contribute to safe care and a safe working environment - all of which are principles of our Behavioural Standards Framework.

Behavioural Standards Framework – Expectations 'at a glance'

1. SUMMARY

Across the NHS in 2015 to 2016 a total of 26 wrong lens implants were reported and classified as a never event. Never events are serious largely preventable patient safety incidents that should not occur if existing national standards for invasive procedures known as **NatSsips** are implemented into everyday practice for all cataract surgeries by all procedural staff.

The insertion of an intraocular lens (IOL) involves a complex range of steps in the patients care pathway. In context this pathway and the potential for error often starts when the patient agrees to have surgery with an IOL implant in the outpatients clinic. Ideally correct lens insertion concludes when the correct lens is implanted in the operating theatre at the time of surgery.

2. PURPOSE

The LocSsip (Local Safety Standards for Invasive Procedures) identifies where the areas of vulnerability are, which relate to where a wrong lens insertion in the patient's perioperative episode could occur.

LocSsips which are devired from the National Framework provide a unified standard for use by all the University Hospital Morecambe Bay (UHMB) ophthalmology clinicians and theatre teams for:

- Health Care Professionals at pre-operative assessment and on the day clerking by the operating surgeon.
- The theatre procedural team at 5 'Steps to Safer Surgery' by identifying the underpinning behaviours of lens confirmation processes at:
  - pre brief checks,
  - patient lens selection and lens implantation steps.
  - Tracking and traceability.

3. SCOPE

The operating surgeon is ultimately accountable for the correct lens being implanted. However, various tasks associated with lens identification and verification are delegated to other members of the peri-operative team during the surgical procedure. The delegated team member is subsequently responsible for **leading** the team through the tasks of documenting, reviewing, and confirming the correct lens selection before it is opened for implantation by ensuring the adhereance to the LocSsips safety steps outlined in this document.

4. PROCEDURE

4.1 Clear Documentation and Pre-Operative Recording

The potential for incorrect lens implantation can start as early as when the patient is consented in clinic.
To ensure the operating surgeon and theatre team select the correct implant during the surgical procedure the following must occur.

- If the power is calculated in clinic the logging of the power on the biometry sheet must always be done by circling the chosen power on the biometry sheet in black ink.
- The HCP (HealthCare Professional) who has calculated the lens must initial the document.
- Any previous biometry documention present in the notes has the potential to cause an error leading to a never event. It is therefore imperative that previous documentation should be clearly crossed through i.e. **X** and signed by the HCP
- In cases where a patient is having **2nd** cataract eye surgery at both the outpatient clinic and on the day pre-operative examination, the operating surgeon must confirm the consented operative eye, and ensure that any biometry relating to the **1st** eye has been or is crossed through and signed i.e. **X** plus the HCP's signature.

4.2 On the day Pre-Operative Examination

Recalculation of Lens Power at pre-operative examination on the day of the scheduled operation

- Patients are pooled for cataract surgery, some have lens powers calculated at the outpatient appointment and some are calculated at the pre-operative examination on the day of surgery.

- If the 'on the day operating surgeon' decides to recalculate the lens power of a patient who had previously been calculated in clinic, the following must occur:

  - The operating surgeon must amend any existing biometry sheet for this patient .
  - The previously selected size must be crossed through with a clear **X** and the operating surgeon must insert their initials.
  - The theatre team must be verbally informed at pre brief, that there is an amended biometry sheet for this patient and the change be reitereated and confirmed at 'Time Out' that this particular patient has an amended power.

- If there is no a change of lens power at pre-operation examination , or this is the first time the lens power is being calculated the operating surgeon must ensure that the logged lens power is clearly legiable prior to any patient transferring to theatre.

4.3 Check 1: Operating Theatre

Confirmation of Lens availability for the scheduled list.
This must be discussed at Step 1 of the 5 Steps to Safer Surgery (List Pre-Brief).

- Each theatre suite where cataracts are performed has a designated ophthalmology theatre, and a lens bank.
- The theatre scrub & circulating team are responsible prior to the start of the list that there are sufficient numbers of lens implants and sizes available for the scheduled list. This information must be communicated at pre-brief to the operating surgeon ensuring any lack of stock or lens issues are highlighted.
- The check of the lens stock must include presence of lens sizes and the integrity of the lenses (i.e. the lenses are in-date and sterility is intact).
- The operating surgeon must acknowledge the information and confirm he/she is satisfied that the number and choice of lenses available for the operating list are satisfactory.
- If a lens power is not available and can be recalculated then the surgeon must revisit the patient on the ward and amend the biometry document as defined in **section 4.2. Lens Power Changes at pre-clerking at on the day operation** of this document.
- In cases whereby a specific power is not present, but is the only option for a patient and cannot be replaced with a planned substitution. The team should consider sourcing the necessary lens from one of the Trusts other sites.
- A list order change may be necessary to avoid a patient cancellation in this situation to allow time for the lens to be received.
- No patients' surgery must ever be commenced if an implant and or instruments are not available and transfer of their arrival is awaited.

- Cancelation of surgery due lack of lens stock must be reported on the Trust's C.I.R. (Clinical Incident Report) system. It will then be investigated in line with the Trust's incident reporting management standards (see Section 6 for link).
- Lack of stock must be discussed at pre-brief and actions logged.

4.4 Check 2: Individual Patient Lens Confirmation Checks that are Performed (Time Out)

N.B. Individual patient and lens check which can be performed prior to scrubbing or when scrubbed but must be pre-incision (TIME-OUT)
It is not the final lens check before implantation.

- The UHMB Cataract W.H.O. checklist must be used for all patients having cataract surgery.
- Each patient during their surgery must have their name, side and RTX number logged on the Theatre Yellow Implant Board prior to the start of surgery. Staff must ensure that when each patient enters the operating room for their surgery the board is free of previous patient data.
- Using the operative patients biometry sheet, and ideally before the operating surgeon surgeon and practitioner scrubs, the surgeon, scrub and circulating practitioner together confirm the IOL lens power, dioptre and type required (i.e. 21.5 Dioptre, target minus 0.37.and the IOL lens proposed refractive outcome target).
- The lens power information must then be written on the yellow theatre implant board, along with which eye is being operated upon (Left or Right).
- The information is confirmed as correct..
- The implant at this stage can be segregated from stock and stored with the patient's biometry sheet on the holding trolley for this patient.

The lens must not be be implanted until the steps in check 3 are completed and verified.

4.5 Check 3: Final Check Prior to Implantation

- Due to the complexity of surgery and the requirement of the operating surgeon to maintain visual contact with the patient's operative eye, the final lens check is a delegated task that is undertaken between the scrub and circulating practitioner.
- A final check occurs between scrub and the circulating practitioner to ensure the biometry sheet corresponds to the implant board for the patient being operated upon.
- This final check of lens size must also include a lens integrity check, which consists of:
    - No damage to the box which could compromise the lens integrity.
    - A gamma radiation dot or sterilisation date is present.
    - The lens expiry date for implantation does not exceed the date of which the lens is being implanted.
- When verified as being both in tact and the correct size, the selected lens is opened and passed into the scrub field.

If at the final implant check, any team member has any concerns they must raise them and speak up.

- Once the lens is implanted, the circulating practitioner must ensure the following

occurs:

- Attachment of the implant identification label into the patient's records.
- Ensure that the implanted lens details are recorded into the Theatre Operating Room Management Information System.
- Add a set of labels to the theatre lens implant book, with a patient addressograph.
- Reordering of the implant(s) may be undertaken at the end of the list for all patients collectively.

4.6 Intra-Operative Complications Leading to Reassessment of Lens Power for Implantation

- On the rare occasion an intraoperative complication may occur, i.e. vitreous loss, or a capsular tear, the following must occur .
- Operating surgeons must consider escalation if a complication occurs, as they may require advise or further support.
- **<u>If the situation/complication requires the operating surgeon to undertake reassessment and recalculation of the lens power from the original caluculation and lens selection, the following must occur:</u>**
  - An additional Time Out should occur as soon as is safe to do so and the theatre team must be clearly informed of the change to the original operative plan to now implant a different size of I.O.L . Ensure the type and size are specified.
  - The new lens now required must clearly be stated by the operating surgeon, the previous lens must be erased off the yellow board and the new sizes must be writtenon the yellow board.
  - The final lens checks of 4.5 of this standard must then occur.
  - If the original lens has already been opened, during surgery it must be safetly isolated so it can be returned into its original packaging and stored safely until the end of the list. Care must be taken that this opened lens cannot be confused with any other lenses.
  - As it will be unsterile it will need to be reordered and a note logged in the implant book that the lens was not implanted in a patient but opened in error.
  - If the original lens sticker had already been applied to the patients notes this must be struck through and documented as not implanted and signed by a registered healthcare practitioner.
    The new lens label will be secured in the patients notes.
  - Any electronic logging will also be amended or contain a free text reference to the new size.
  - The operation notes will clearly state the complication that has occurred, any actions taken, including consultant escalation andany onward referral to a tertiary centre if this has occured.

The decision to implant a different size lens is justifiable and not a wrong lens implant if discussed and documented at this stage.

N.B. operation notes cannot be amended relating to or discovering a non-planned size of IOLs after the patient is transferred from the procedural room or dischared from theatre as the operative episode is completed. Any discovery after the event must be report as a CIR (Clinical Incident Report) on the Trust's Safeguard system.

5. ATTACHMENTS	
Number	**Title**
1	Description of NatSsips translated into the UHMB LocSsip
2	Cataract Time Out Sheet
3	Equality & Diversity Impact Assessment Tool

6. OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
Corp/LocSsip/001	LocSsip For: • Surgical Site Marking • 5 Steps to Safer Surgery using the W.H.O. Theatre Time Out' Checklist http://uhmb/cs/tpdl/Documents/CORP-LOCSSIP-001.docx
Corp/Proc/022	Reporting and Management of Incidents including Serious Incidents http://uhmb/cs/tpdl/Documents/CORP-PROC-022.docx

7. SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS **References in full**	
Number	**References**
1	The Royal College of Opthalmologists (2010) Cataract Surgery Guidelines. [Online] Available from: https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2010-SCI-069-Cataract-Surgery-Guidelines-2010-SEPTEMBER-2010.pdf [Accessed: 17.11.17]
2	NHS England (2014) Surgical Never Events taskforce report. [Online] Avaiable from: https://improvement.nhs.uk/resources/surgical-never-events-taskforce/ [Accessed 17.11.17]
3	Moorfields Eye Hospital (2014) Cataract Service Patient Information. [Online] Available from: http://www.moorfields.nhs.uk/sites/default/files/uploads/documents/Cataract%20service%20booklet%20-%20Oct%202014.pdf [Accessed: 17.11.17]
Bibliography	
NICE guideline 77 - Cataracts in adults: management https://www.nice.org.uk/guidance/ng77/chapter/Recommendations#preventing-wrong-lens-implant-errors	

8. DEFINITIONS / GLOSSARY OF TERMS	
Abbreviation or Term	**Definition**
I.O.L.	Intra occular lens
NatSsips	National Safety Standards Invasive Procedures
LocSsips	Local Safety Standards Invasive Procedures.
W.H.O.	World Health Organisation
HPC	Healthcare Professional
C.I.R.	Clinical Incident Report.

9. CONSULTATION WITH STAFF AND PATIENTS

Enter the names and job titles of staff and stakeholders that have contributed to the document

Name	Job Title	Date Consulted
Sue Howard	Matron Westmoreland General Surgery	11th & 28th July 2017
Faye Bennet	Matron Theatres Furness General Hospital	11th & 28th July 2017
Daniel Bakey	Matron Theatres Royal Lancaster Infirmary & Westmorland General Hospital	11th & 28th July 2017
Laura Armitstead	Governance Lead Surgery & Critical Care	11 th & 28th July 2017
Christiana Shrimpton	Consultant Opthalmologist	11th & 28th July 2017

10. DISTRIBUTION PLAN	
Dissemination lead:	Daniel Bakey – RLI & WGH Theatre Matron Faye Bennett – FGH Theatre Matron
Previous document already being used?	No
If yes, in what format and where?	N/A
Proposed action to retrieve out-of-date copies of the document:	N/A
To be disseminated to:	
Document Library	Governance Team
Proposed actions to communicate the document contents to staff:	Include in the UHMB Friday Corporate Communications Roundup – New documents uploaded to the Document Library

11. TRAINING

Is training required to be given due to the introduction of this policy? *Yes / No * Please delete as required

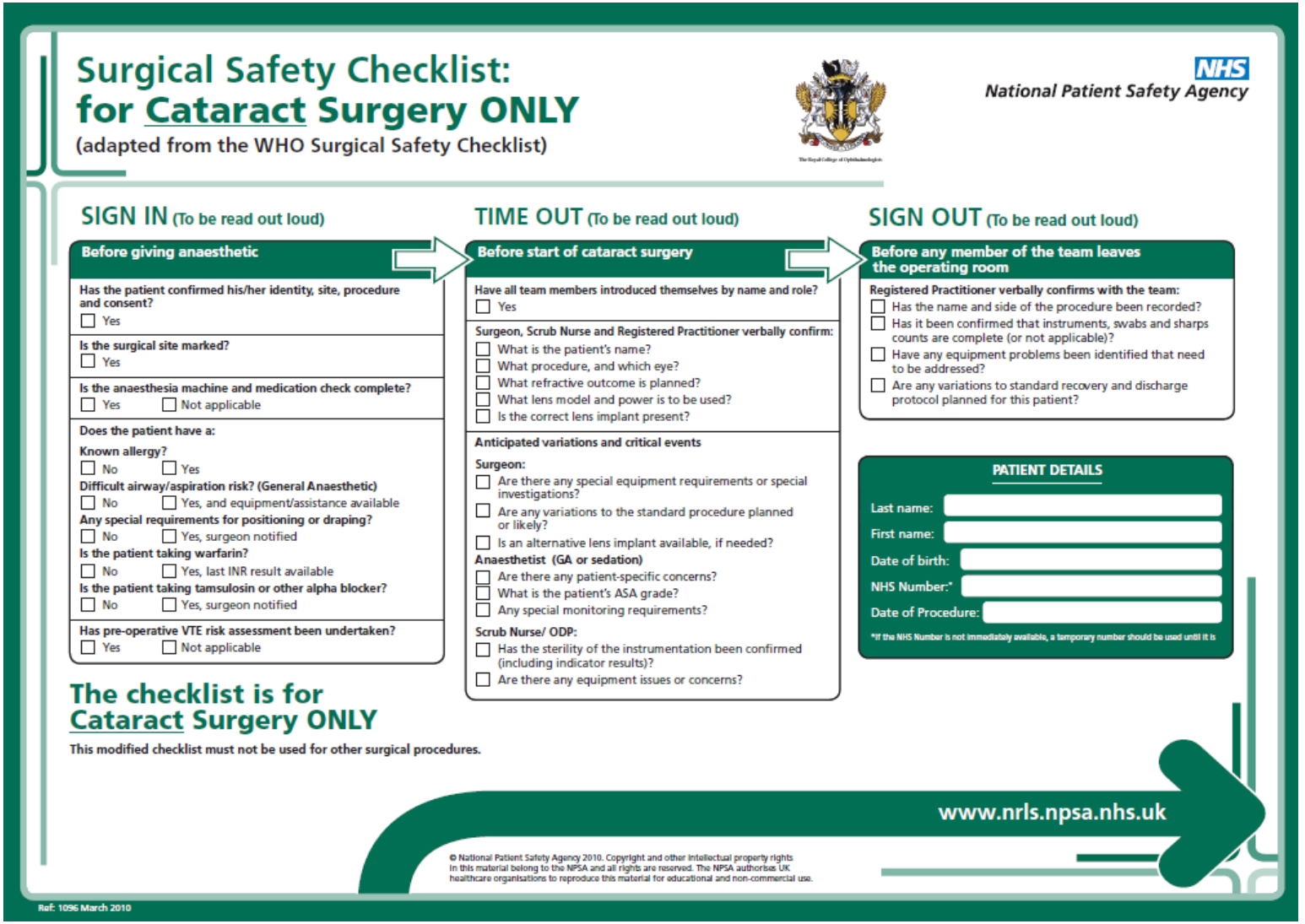
Action by	Action required	Implementation Date
Daniel Bakey & Faye Bennett to delegate to Clinical Theatre Managers And Clinical Leaders	Aduit day training session to clinical leaders Clinical Leaders to train their specific Teams who they hold immediate line Management responsibilities for	Within 1 month of ratification

12. AMENDMENT HISTORY				
Version No.	**Date of Issue**	**Page/Selection Changed**	**Description of Change**	**Review Date**

Appendix 1: Description of NatSsips translated into the UHMB LocSsip

Description of NatSsips which are mandatory inclusion in this LocSsip. The mandatory standards in this document are not all the standards required for prosthesis verification , the only inclusion is what is relevant to this particular standard	By Whom	Where identified	Inclusion achieved
The operating surgeonoperating surgeon must use the safety briefing before the start of the procedural list to confirm the sizes/type of IOL required	Primary Operating Surgeon		Yes
The operating surgeonoperating surgeon must visually inspect and confirm the range of implants with the team prior to the patient being sent to the operating area.	Primary Operating Surgeon		Yes
A record of implants must be made	All Theatre MDT (Surgical)		Yes
The organisation must have in place a process for recording which implants are used for which patients.	All Theatre MDT (Surgical)		Yes
Reconciliation of item used during invasive procedure	Theatre Team		Yes

Appendix 2: Cataract Time Out Sheet



Surgical Safety Checklist: for Cataract Surgery ONLY

(adapted from the WHO Surgical Safety Checklist)

National Patient Safety Agency

SIGN IN (To be read out loud)

Before giving anaesthetic

Has the patient confirmed his/her identity, site, procedure and consent?
- ☐ Yes

Is the surgical site marked?
- ☐ Yes

Is the anaesthesia machine and medication check complete?
- ☐ Yes ☐ Not applicable

Does the patient have a:

Known allergy?
- ☐ No ☐ Yes

Difficult airway/aspiration risk? (General Anaesthetic)
- ☐ No ☐ Yes, and equipment/assistance available

Any special requirements for positioning or draping?
- ☐ No ☐ Yes, surgeon notified

Is the patient taking warfarin?
- ☐ No ☐ Yes, last INR result available

Is the patient taking tamsulosin or other alpha blocker?
- ☐ No ☐ Yes, surgeon notified

Has pre-operative VTE risk assessment been undertaken?
- ☐ Yes ☐ Not applicable

TIME OUT (To be read out loud)

Before start of cataract surgery

Have all team members introduced themselves by name and role?
- ☐ Yes

Surgeon, Scrub Nurse and Registered Practitioner verbally confirm:
- ☐ What is the patient's name?
- ☐ What procedure, and which eye?
- ☐ What refractive outcome is planned?
- ☐ What lens model and power is to be used?
- ☐ Is the correct lens implant present?

Anticipated variations and critical events

Surgeon:
- ☐ Are there any special equipment requirements or special investigations?
- ☐ Are any variations to the standard procedure planned or likely?
- ☐ Is an alternative lens implant available, if needed?

Anaesthetist (GA or sedation)
- ☐ Are there any patient-specific concerns?
- ☐ What is the patient's ASA grade?
- ☐ Any special monitoring requirements?

Scrub Nurse/ ODP:
- ☐ Has the sterility of the instrumentation been confirmed (including indicator results)?
- ☐ Are there any equipment issues or concerns?

SIGN OUT (To be read out loud)

Before any member of the team leaves the operating room

Registered Practitioner verbally confirms with the team:
- ☐ Has the name and side of the procedure been recorded?
- ☐ Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)?
- ☐ Have any equipment problems been identified that need to be addressed?
- ☐ Are any variations to standard recovery and discharge protocol planned for this patient?

PATIENT DETAILS

Last name:

First name:

Date of birth:

NHS Number:*

Date of Procedure:

*If the NHS Number is not immediately available, a temporary number should be used until it is

The checklist is for Cataract Surgery ONLY

This modified checklist must not be used for other surgical procedures.

www.nrls.npsa.nhs.uk

Ref: 1096 March 2010

Appendix 3: Equality & Diversity Impact Assessment Tool

University Hospitals of Morecambe Bay NHS Foundation Trust

Equality Impact Assessment Form

Department/Function	Surgery and Critical Care			
Lead Assessor	Sue Howard			
What is being assessed?	Safety standards for implantation of an Intra Ocular lens			
Date of assessment	11/10/17			
What groups have you consulted with? Include details of involvement in the Equality Impact Assessment process.	Equality of Access to Health Group	☒	Staff Side Colleagues	☒
	Service Users	☒	Staff Inclusion Network/s	☒
	Personal Fair Diverse Champions	☒	Other (Inc. external orgs)	☒
	Please give details:			

1) What is the impact on the following equality groups?

Positive:	Negative:	Neutral:
➢ Advance Equality of opportunity ➢ Foster good relations between different groups ➢ Address explicit needs of Equality target groups	➢ Unlawful discrimination, harassment and victimisation ➢ Failure to address explicit needs of Equality target groups	➢ It is quite acceptable for the assessment to come out as Neutral Impact. ➢ Be sure you can justify this decision with clear reasons and evidence if you are challenged

Equality Groups	Impact (Positive / Negative / Neutral)	Comments ➢ Provide brief description of the positive / negative impact identified benefits to the equality group. ➢ Is any impact identified intended or legal?
Race (All ethnic groups)	Neutral	
Disability (Including physical and mental impairments)	Neutral	
Sex	Neutral	
Gender reassignment	Neutral	
Religion or Belief	Neutral	
Sexual orientation	Neutral	
Age	Neutral	
Marriage and Civil Partnership	Neutral	
Pregnancy and maternity	Neutral	
Other (e.g. caring, human rights)	Neutral	

2) In what ways does any impact identified contribute to or hinder promoting equality and diversity across the organisation?	None

3) If your assessment identifies a negative impact on Equality Groups you must develop an action plan **to avoid discrimination and ensure opportunities for promoting equality diversity and inclusion are maximised.**

- This should include where it has been identified that further work will be undertaken to further explore the impact on equality groups
- This should be reviewed annually.

Action Plan Summary

Action	**Lead**	**Timescale**

This form will be automatically submitted for review for Policies and Procedures once approved by Policy Group. For all other assessments, please return an electronic copy to EIA.forms@mbht.nhs.uk once completed.