University Hospitals of Morecambe Bay NHS Foundation Trust

Document Type: **Procedure**	**Unique Identifier:** ENDO/LOCSSIP/002
Document Title: **Local Safety Standards for Invasive Procedures (LocSsip) for:** **4 Steps For Patient Safety (Endoscopy)**	**Version Number:** 2
	Status: Ratified
Scope: Multi-Disciplinary Teams that are involved in the patients' interventional procedure episode	**Classification:** Departmental
Author / Title: Sue Wroe Governance Project Lead NatSsips Quality & Governance	**Responsibility:** Endoscopy
Replaces: New	**Head of Department:** Matron Simon Glover
Validated By: Medicine Procedural Documents Group	**Date:** 04/08/2016
Ratified By: Medicine DGAG	**Date:** 16/09/2016
Review dates may alter if any significant changes are made	**Review Date:** 01/08/2019
Which Principles of the NHS Constitution Apply? 1,2,3,4	**Which Staff Pledges of the NHS Constitution Apply?** 1,2,3
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 Joanne Phizacklea……..Date…22.11.2016……. **To be completed by Library and Knowledge Services Staff**	

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1. SUMMARY

Delivering patient care through a process of logical, timed and co-ordinated safety standards provides a quality framework for all patients who undergo interventional procedures at UHMB. The safety standards in this LocSsip (Local Standards Safety for Interventional Procedures) document are for teams to apply and use with the safety checklist/s when undertaking interventional procedures in the Trusts Endoscopy Units or Procedural rooms.
When used together the LocSsip and the Checklist provide a quality framework of safety standards for interventional procedures which work towards eliminating '**never events'**.

Harm free and compassionate care is a fundamental element of the University Hospital Morecambe Bay (UHMB) vision. All healthcare staff who participate in a patients' journey have a common goal which is to prevent harm and deliver safe patient care to the highest standards.

A wrong interventional procedure, or the incorrect patient, is rare. However, should any of these untoward events occur, experience has shown that they have a devastating impact on both patient and staff, which could affect the patient outcome.

The standards within this document have been developed to reduce the likelihood of these occurrences known as '**never events'** occurring. Local Safety Standards work in harmony with the principles of the World Health Organisation (W.H.O.) saving lives initiative and when combined and supported through the use of checklists facilitate teams to deliver consistently high safe standards of patient care.

Further benefits of delivering care through these standards and the checklist process supports:

- Effective team communication and team harmony,
- A Systematic process for verification of the correct patient,
- An assurance that the correct procedure is consented for ,
- An assurance that (if applicable) that the correct site procedure occurs,
- Correct insertion of the right implant or device occurs,
- Specimens are verified for correct patient assignment which ensures correct patient diagnosis.
- An opportunity to reflect and continuously improve at local level is facilitated through the use of debriefing.

Audit, benchmarking, feedback and an open learning culture are crucial elements to successful and effective procedural teams. A clinical audit program of qualitative and quantities audits will provide teams with a mechanism to measure, benchmark and learn to improve.

2. PURPOSE

The purpose of the UHMB Safe Standards for Interventional Procedures is to foster a Safety Culture by ensuring patient safety through universal best practice The 'LocSsips' in this document with robust use and adherence to the 'Time Out' Checklist ensures consistent, safe, and effective care for all patients undergoing an interventional procedure

in the Endoscopy Unit.

3. SCOPE

LocSsips are to be embedded in the culture and are crucial standards that must be applied consistently for all patients who attend for an interventional procedure across all the Trusts hospital sites. UHMB requires that **all staff** who are involved in the clinical interventional pathway embrace and participate in :-

- Safety Briefings
- Sign in/ Time out
- Sign out
- Debriefs

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The Procedural team leader for the list should ensure a hard paper copy of the checklist is completed and retained in the patient notes. This is a mandatory standard of record keeping and may be required for audit.

4. PROCEDURE

4.1 The 4 Steps To Patient Safety

4.1.1 <u>STEP 1</u> List Safety Briefing

- Prior to commencement of any elective, procedural list a 'Safety Briefing' which involves key members of the team as a minimum (ideally all the team) must take place.
- The purpose of the brief is to discuss the sessions' list schedule of planned interventional procedures.
- The area used should be quiet and free from interruptions.
- The brief may be led by any designated member of the team
- All staff members of the procedural team are named for the session and roles identified.
- The procedural list must be visible throughout the session for staff in all areas involved in the procedural list. (This includes holding areas for patients)
- Any patient data can only be in view of staff.
- Any anticipated milestones or challenges must be considered, and plans put in place if necessary.
- Equipment checks should have already been performed and any issues highlighted, and actions put in place to address if required.
- Procedures involving implantation of devices must be discussed and availability of devices verified for the list.
- The list operator must confirm that they approve the device availability.
- If it is necessary to change the list order, a new printable list must be produced and communicated. (All staff should be familiar with the List Change LocSsip and follow the safety steps outlined in the LocSsip for doing so.)

4.1.2 STEP 2 Procedural Sign In (2A) and 'Time Out' (2B) (A combined Safety Step)

Sign in and Time Out are safety processes whereby the prompts on the checklist ensure verification of the correct patient, procedure and which implants/devices maybe required.
Conscious and coherent patients will actively be encouraged to participate in these processes.

Sign In 2A

- The Sign in verification process must be performed by two team members; one will be the Operator and one other team member.
- The process must have both team members performing the checks and giving the safety task their full attention to confirm sign in. No other task should be undertaken until this is completed.
- The questions will be undertaken verbally by both in a clear, precise and audible tone, with the patient, their family or carer encouraged to participate if present, and acknowledged in the same manner.

Time Out 2B

Time out must be undertaken with all the team present and everyone must engage and give their full attention to the task.

- The verbal questions from the checklist must be led by a trained Healthcare professional in a clear and audible manner.
- All Team members must 'stop and pause' (hence this part of the safety process is known as 'time out') whilst the checklist questions are asked and responded to the appropriate questions when asked.
- If there is an interruption, the 'time out' must be suspended and recommenced.
- Every team member is valuable and should feel comfortable and at ease to raise any questions or concerns they have relating to the case at this time.
- The patient should once again be included where possible in the time out.
- Team members must not enter or leave the procedural room during this time.

4.1.3 STEP 3 Sign Out

Sign Out After when the procedure is completed.

All patients who have undergone an interventional procedure must undergo safety checks at the end of the procedure before leaving the procedural room.
Any team member who has been involved in the procedure should not leave the room until this is completed and verified as correct

- The nominated Healthcare professional leading time out will request that all the team is present and ask the team to 'stop and pause'.
- The set questions on the designated section of the Checklist are then directed to the appropriate team member/s, who will verbally respond to the questions being asked.
- Any specimen/s obtained will be procured, reconciled and transferred to the standards of Labelling and Transfer of Patient Specimens from Endoscopy Units (see section 6)
- Implant/device record keeping logs for traceability with confirmation of the devices labels must be confirmed securing of stickers must be confirmed.
- The decontamination traceability label of the endoscope which has been used will have been verified in an earlier check for decontamination but for traceability this must be secured in the patient notes.
- Finally prior to transfer to the recovery/discharge area the team will review any key plans or concerns for the handover.
- **A member of the procedural team must participate in the patient handover to the recovery/discharge area**
- The 'Time Out' sheet is then signed by a registered healthcare professional and retained in the patient's notes as evidence.

4.1.4 <u>STEP 4</u> List De Briefing

National Safety Standards of compliance with debriefing state this can only occur after the last patient on the list has been transferred out of the procedural room to the recovery/discharge area.
The following is the minimum standard that must occur at the debrief:

- The Operator, (this is staff member who has undertaken the procedural interventions on the list) must be present.
- The debrief may be led by any confident team member.
- As many members of the procedural team as possible must attend and if a team member cannot attend, they should have noted any key points for consideration at the debrief that arose throughout the list;

All members of the team attending debrief should feel comfortable enough to contribute to the debrief discussion and raise any concerns or questions.
Any questions included in the debrief are professional and not personal and are to designed to facilitate reflection, share learning, and make improvements where appropriate.
The leader of the debrief should always ensure that what went well during the list is discussed at this feedback session.
Debrief templates are encouraged to be localised, however all debriefing templates must be approved in line with the Trust Governance Processes, for procedural documents.
Examples of questions for discussion and consideration should include:

- Communication – *any issues for* improvements*?*
- Team Harmony – *for example was the best use of skills utilised?*
- Planning - *were there any planning issues, i.e. list order, missing stock how can we improve?*
- Equipment failures *what were the issues? Has the problem been resolved? What action is required? Will it impact on a forthcoming list? Who is taking responsibility to ensure actions and relevant communication are followed through?* See section 4.2.6 of these standards.
- The need to raise a C.I.R. – *is there one?*
- Identification of training or development that could benefit the team

The above list is not inclusive and wider learning and sharing may be an outcome from any Endoscopy Department debrief.

Debriefs should be retained for analysis by the departmental clinical manager. The purpose of which will allow:

- Debriefs can be reviewed monthly
- lessons learned must be shared with MDT team at Staff meetings

The Governance Lead in conjunction with the Matron will ensure that quarterly reports of any themes are produced and the learning outcomes are included in the Divisions' of learning lessons bulletin.

4.2 Non-routine Issues with Malfunctioning Equipment

If medical equipment is thought to be the cause of an incident, it is important to follow these steps:

- Quarantine - The Medical Device and all associated equipment/consumables should be removed from service. The settings of the device should not be changed or adjusted.
- Record - One of the most important pieces of detail to include in the Trust incident report is the correct identification of the equipment through asset number, make, and model, type of equipment, site and location. Without this a technical investigation cannot commence.
- Evaluate - If a technical investigation or evaluation is required, then the originator or manager should request this through the Medical Engineering Department.

It is Trust policy that Medical Device Users should report incidents internally and any decision relating to reporting an incident to the MHRA will be approved by The Trust Medical Device Department with the Risk Office.

5. ATTACHMENTS	
Number	**Title**
1	Description of NatSsip
2	UHMB Endoscopy Unit Individual Patient Procedural Safety Checklist
3	UHMB Endoscopy Unit Safety Brief / Debrief
4	Equality & Diversity Impact Assessment Tool

6. OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
Corp/Proc/022	Reporting and Management of Incidents including Serious Incidents http://uhmb/cs/tpdl/Documents/CORP-PROC-022.docx
Corp/Strat/001	Risk Management Strategy http://uhmb/cs/tpdl/Documents/CORP-STRAT-001.docx
Corp/Pol/089	Medical Devices Management http://uhmb/cs/tpdl/Documents/CORP-POL-089.docx
Corp/Proc/057	Consent to Examination or Treatment – Adults & Children http://uhmb/cs/tpdl/Documents/CORP-PROC-057.docx

7. SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS

References in full

Bibliography

National Patient Safety Agency (NPSA) (2009) WHO Surgical Safety Checklist (accessed 22.11.16)

NHS England (2015) NatSsips National Safety Standards for Invasive Procedures (accessed 22.11.16)

8. DEFINITIONS / GLOSSARY OF TERMS

Abbreviation or Term	Definition
W.H.O	World Health Organisation
C.I.R.	Clinical Incident Report
N.B.	Note Well
M.B.H.T.	Morecambe Bay Hospital Trust

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
Suzanne Langley	Unit Manager Endoscopy FGH
Rosalind Fawcett	Unit Manager Endoscopy RLI
Albert Davies	Consultant Gastroenterologist
Victoria Hodder	Nurse Endoscopist
Lindsay Kelsall	Clinical Lead Nurse
Diane Smith	Service Manager

10. DISTRIBUTION PLAN

Dissemination lead:	Suzanne Langley Roz Fawcett
Previous document already being used?	No
If yes, in what format and where?	
Proposed action to retrieve out-of-date copies of the document:	N/A
To be disseminated to:	
Document Library	
Proposed actions to communicate the document contents to staff:	o Include in the Divisional Monthly Newsletter o Table at local departmental meetings o Clinical leads to disseminate to Clinicians New documents uploaded to the Document Library

11. TRAINING		
Is training required to be given due to the introduction of this procedural document? No		
Action by	**Action required**	**Implementation Date**
Unit Managers	Trial of documentation	22/8/16

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

Appendix 1: Description of NatSsip

Description of NatSsip 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/How	Where identified	Inclusion achieved
Pre list Safety briefing for interventional procedures as identified by NatSsip NatSsip Standard 4.7	Procedural team plus other key members	Page 4	Yes
Sign in standards NatSsip Standard 4.8	Operator and 1 other plus patient.	Page 5	Yes
Time Out Standards NatSsip 4.9	Procedural team	Page 5	Yes
Sign Out Standards NatSsip 4.12	Procedural team to handover team	Page 6	Yes
Debriefing Standards (to include feedback mechanism for anyone not present to raise concerns) NatSsip 4.13	All	Page 6 & 7	Yes
Mechanism for communication , audit and learning NatSsip 4.13	All	Page 7	Yes

Appendix 2 – UHMB Endoscopy Unit Individual Patient Procedural Safety Checklist

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UHMB ENDOSCOPY UNIT INDIVIDUAL PATIENT PROCEDURAL SAFETY CHECK-

Endoscopy Treatment Room ..... Date.....am / pm Operator ..... Room lead.....

Sign In/Time Out

All Endoscopy team prior to start of the procedure. STOP & PAUSE

Can all team members introduce themselves and the role they will be undertaking in this procedure. ☐

Can the patient confirm, their name, date of birth, the procedure and their own signature on the consent form ☐

Wristband (confirm name , DOB and RTX) ☐

Confirm the patient information matches the procedural schedule ☐

Can the 'Operator' also state the intended procedure .....

Are there any allergies (Please state) ☐.....

Do we require an implant device for this patient , confirm availability ☐

Is all equipment available for this procedure before we start. ☐

Confirm diathermy integrity placement & site (Insert here) .....

Prior to procedural start confirm the following observation's.

Pulse ..... BP..... SO2..... .....

Is there any other important information that the procedural team need to be aware of relevant to this case. .....

Affix patient label here

BOXES/ DASHES ON THIS SHEET MUST BE COMPLETED TO CONFIRM THAT THE TASK HAS OCCURRED, if the task does not need to occur then insert N/A

Signature of Sign In/Time Out lead-

Sign Out

Endoscopy Team procedural signout.

Can the 'Operator' confirm the name of the procedure undertaken? .....

Can the operator confirm the endobase report is complete ☐

Are all specimens labelled? ☐ (two team members verify)

Are Implant devices recorded . ☐ (includes labels attaching to care pathway)

Confirm that all equipment decontamination labels are in the ICP. ☐

Any key concerns for recovery or post-procedural management of the patient?

.....

Any concerns to be logged on the list debrief. ☐

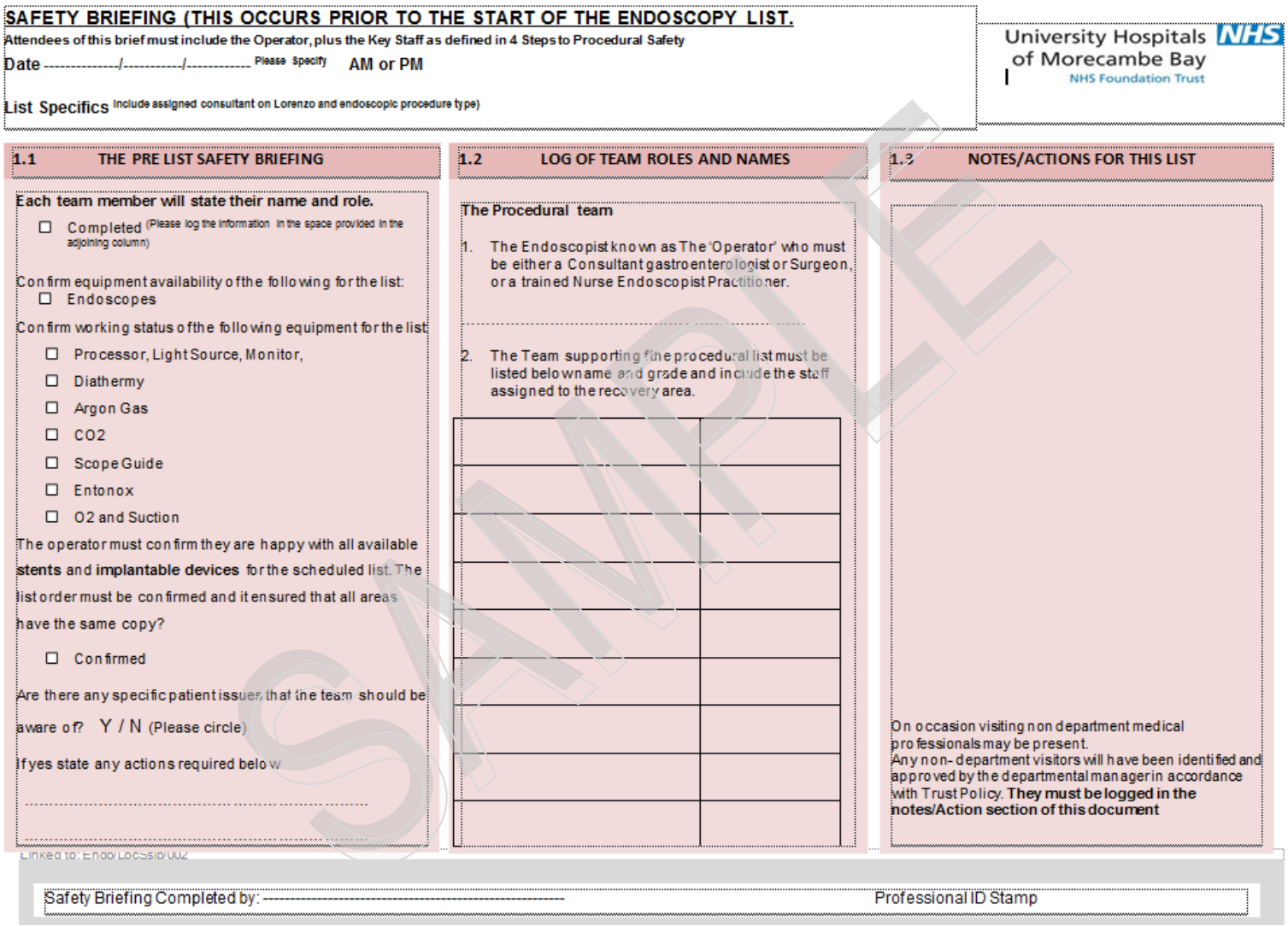
.....

Have there been any untoward incidents with this patient do we need a CIR logging? ☐

Who will log the CIR .....

Signature of Sign Out Leader..... .....

Appendix 3 – UHMB Endoscopy Unit Safety Brief / Debrief



SAFETY BRIEFING (THIS OCCURS PRIOR TO THE START OF THE ENDOSCOPY LIST.

Attendees of this brief must include the Operator, plus the Key Staff as defined in 4 Steps to Procedural Safety

Date ----------/----------/---------- Please Specify AM or PM

List Specifics Include assigned consultant on Lorenzo and endoscopic procedure type)

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1.1 THE PRE LIST SAFETY BRIEFING

Each team member will state their name and role.

☐ Completed (Please log the information in the space provided in the adjoining column)

Confirm equipment availability of the following for the list:

☐ Endoscopes

Confirm working status of the following equipment for the list:

☐ Processor, Light Source, Monitor,

☐ Diathermy

☐ Argon Gas

☐ CO2

☐ Scope Guide

☐ Entonox

☐ O2 and Suction

The operator must confirm they are happy with all available **stents** and **implantable devices** for the scheduled list. The list order must be confirmed and it ensured that all areas have the same copy?

☐ Confirmed

Are there any specific patient issues that the team should be aware of? Y / N (Please circle)

If yes state any actions required below

.....

.....

1.2 LOG OF TEAM ROLES AND NAMES

The Procedural team

1. The Endoscopist known as The 'Operator' who must be either a Consultant gastroenterologist or Surgeon, or a trained Nurse Endoscopist Practitioner.

.....

2. The Team supporting the procedural list must be listed below name and grade and include the staff assigned to the recovery area.

1.3 NOTES/ACTIONS FOR THIS LIST

On occasion visiting non department medical professionals may be present.
Any non- department visitors will have been identified and approved by the departmental manager in accordance with Trust Policy. **They must be logged in the notes/Action section of this document**

Linked to: Endo/LocSsip/002

Safety Briefing Completed by: ---------- Professional ID Stamp

ENDOSCOPY SAFETY DEBRIEF

Team Debrief-the entire team should attend this meeting *at the end* of the list after the last patient has left the treatment room.

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Date ...../...../..... am/pm **Operator** .....

TEAM in ATTENDANCE (Insert Name & Role in the Table)

- The 'Operator' must attend debrief – if the operator is not present this must be logged and the reason of abstinence.
- All members of the team should feel comfortable and able to raise any concerns or questions in this session.
- The prompts in debrief are professional, not personal. They are designed to promote a safety culture and facilitate reflection, share learning and, where appropriate, make improvements

Log any actions in the last column, follow them through and share learning with all departmental staff

SAFETY DEBRIEF DISCUSSION

What went well today? What was really good?

.....

.....

The Following questions are a guide and the outcomes/actions must be logged in the 3rd column of the debrief sheet.

- Did the team communicate effectively?
- Were there any equipment issues?

Consider the following for equipment issues:

- Is the issue fully resolved? OR
- Could a future lists be affected?
- Who will be responsible for ensuring actions and communication?
- Can we make an improvement so it does not happen again?
- Discuss if the team harmonised well? i.e. utilisation of skills
- Were there any planning issues?
- List order? Missing stock?
- Is there a need to raise a Clinical Incident? If yes log in the last column of the debrief with the name of who will enter the CIR on the Trust Incident Reporting System

☐ **Does anyone in the team wish to raise any particular concerns in relation to any of today's list that we have not discussed?**

☐ **Have any Training or Development needs been identified?**

AGREED ACTIONS FROM THE DEBRIEF DISCUSSION

☐ .....

.....

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☐ .....

.....

.....

☐ .....

.....

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☐ .....

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.....

Have these actions been transferred to the Endoscopy Safety Action plan?

Scanned for Audit? Y / N

By ..... **on** ...../...../.....

Debrief completed by **Date** ...../...../.....

Appendix 4: Equality & Diversity Impact Assessment Tool

University Hospitals of Morecambe Bay NHS Foundation Trust

Equality Impact Assessment Form

Department/Function	Endoscopy			
Lead Assessor	Sue Wroe			
What is being assessed?	Local Safety Standard for Invasive Procedures (LocSsip) for: 4 Steps to Patient Safety (Endoscopy)			
Date of assessment	17/11/2016			
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?	

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.