|  |  |  |  |
| --- | --- | --- | --- |
|  | **Risk Assessment (Subject):**  **APPENDIX 1**  **Remote Monitoring Risk Assessment** | **EDGE ID:** | **Assessor:** |
|  | Monitor access for Edge |  |  |
|  |  |  |  |
|  | **Department/Ward:** | **Date:** | **Signature:** |
|  |  |  |  |

**A validation of the Edge monitor access account has shown the following hazards: (see section 1 on page 2)**

* Documents are automatically downloaded to the electronic device when opened and the document maintains in the electronic device download history. There is also a risk that the download history is maintained on a shared server or cloud, accessible by multiple users.
* Monitor user account allows the user to upload documents to any areas within the project on Edge.
* Monitor can add or delete patients on project and is also able to edit patient details such as demographics and patient status.
* Trial participant
* Monitor
* Study Site (LRI LGH GH)
* Monitor will be required to follow their organisation’s policy relating GDPR and Information Governance.
* Monitor’s organisation has a schedule program to clear the download history from the server
* Document Sharing process document that outline the remote monitoring process and the responsibility for the study team and the monitor
* EDGE audit report details any changes to any areas of the project on EDGE
* The monitor access can only view project that the site EDGE administrators has allocated, therefore if any changes are made it would only be limited to the allocated projects
* An existing user guide for the same level of access as the monitor access. This will guide the monitor to functions that they only required for monitoring purpose

**Evaluation of Risk: (see section 4)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Consequence** | **Score** | | | **Likelihood** | **Value** | | | **Control Potential** | **Tick** |
|  | **Low** | **1** | | | **Rare** | **1** | | | **Easy** | X |
|  | **Minor** | **2** | | | **Unlikely** | **2** | | | **Medium** |  |
|  | **Moderate** | **3** | | | **Possible** |  | **3** |  | **Hard** |  |
|  | **Major** |  | **4** |  | **Likely** | **4** | | | **Very Hard** |  |
|  | **Catastrophic/death** | **5** | | | **Certain** | **5** | | |  |  |

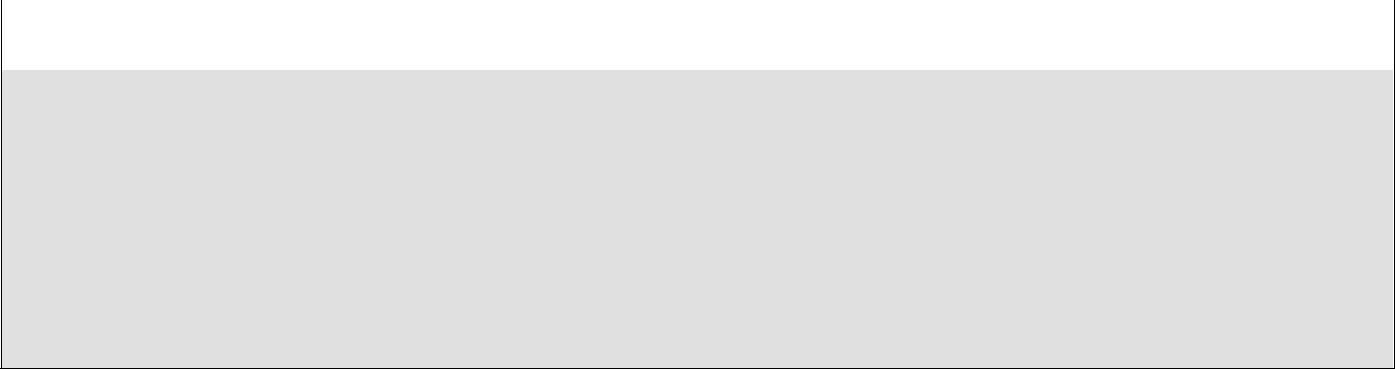
**Consequence x Likelihood = risk rating score 12**

**Actions Required: (see section 5)**

Create audit plan. More extensive auditing will be carried out to ensure there have been no changes to patient records such as files being deleted or uploaded – an audit report can be produced which shows any changes to patient records.

Amend the EDGE user guide specifically to the functions that the monitor is required to ensure that the monitor will only follow those instructions when using EDGE.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **To be actioned by:** | **Assessment Review Date:** | |
|  |  | **(see section 6)** | |
|  |  |  |  |

**all GDPR queries please contact the UHL privacy team.**

PrivacyUnit@uhl-tr.nhs.uk

**1. Hazard**

Look only for hazards which you could reasonably expect to result in significant harm under the conditions in your workplace. Use these examples as a guide:

* Clinical Care
* Process/procedures
* Policy
* Slips, trips and falls
* Manual handling
* Fire (eg from flammable materials)
* Chemicals
* Moving parts of machinery
* Work at height
* Ejection of material
* Pressure systems
* Vehicles
* Electricity
* Dust
* Fumes
* Noise
* Poor Lighting
* Extremes of temperature;
* Environmental
* Exposure to infections (biological hazards)
* Violence/Aggression

**2.** **People At Risk**

There is no need to list individuals by name – just think about groups of people doing similar work or who may be affected, eg:

* Nurses
* Doctors
* Porters
* Office staff
* Maintenance personnel
* Contractors
* People sharing your workplace
* Operators
* Cleaners
* Members of the public including patients.

Where an individual is particularly vulnerable the generic risk assessment must be modified to give an individual assessment of risk. eg:

* Staff with disabilities or medical conditions
* Inexperienced staff
* Lone workers
* Night workers
* Pregnant workers

**3.** **Existing Controls**

For the hazards listed, what precautions already been taken:

* Meet the standards set by a legal requirement?
* Comply with a recognised industry standard?
* Represent good practice?
* Reduce risk as far as reasonably practicable?
* Adequate information, instruction or training?
* Adequate safe systems of work or procedures?
  1. **Evaluation of Risk Table:**

The risk may be evaluated by using the equation Consequence x Likelihood. This will produce a risk rating. Identify the ease within which any controls could be introduced.

**5. Action Plan**

Where the risk is not adequately controlled, indicate what more you need to do (the action list).

Does the risk need to escalated to the Risk Register?

Amended June 2021

**6.** **Review and Revision**

Set a date for review of the assessment. On review check that the precautions for each hazard still adequately control the risk. If not indicate the action needed. Review will be required:

* At least annually
* As a result of an accident/near miss
* Change in process/equipment/personal
* Change in legislation