**JRMO Electronic-Health Records Validation Audit Checklist**

Part A - General information

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|  | **Please enter details and provide evidence where applicable** |
|  | **System name:** |  |
|  | **System version:** |  |
|  | **Checklist completed by:** (name and position) |  |
|  | **System Administrator Contact:** |  |
|  | **System function:**(Brief description of what the system is used for) |  |
|  | **Is this a COTS or Bespoke system?**(Commercial off the shelf) |  |
|  | **If COTS** - please provide details of contract, purchasing arrangement, time period, updates delivery, helpdesk availability for this system |  |
|  | **Is this system located on the Barts Health servers?**  | *Please provide specific details.*  |
|  | **Has the system been validated?**  | *Is there evidence of design validation from the supplier available?* *Is there documented evidence that the e-HR system as installed at this site does what it was designed to do and is fit for purpose?*  |
|  | **Has a Barts Health IG department Information Asset Risk Assessment been performed?** If yes - please insert date and outcome and attach a copy of the assessment and data flow. | *If unsure, please contact the Barts Health Information Governance team for confirmation and details.*  |
|  | **Is there anti–virus software installed and regularly updated on the system to ensure and data is protected from virus attacks?** |  *Please state name of documented evidence and processed surrounding this.* |
|  | **Who is responsible for change control?** Including system assessments prior to implementation e.g. software updates, security patches, hardware replacements? | *Please state a named individual and reference documentation in place evidencing this?* |
|  | **Does this system interact with any other Barts Health system?** | *If yes, please list and provide details of validation and documentation on this element*  |

Part B - System assessment

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|  |  | **Yes/No** | **Please complete using narrative explanation and provide evidence** |
| **Access** |
|  | **Unique user ID and passwords** |  | *Password change prompt period (please state unless biometric control is used for user access)* |
|  | **Is the system restricted to :****A) only those systems features, functions that are appropriate to their job?** **B) only that data that are appropriate to their job?** | A)B) | *Does the system have the ability to limit the access of each user, to those systems features and functions needed for that role and user?* |
|  | **Can a list of users who have accounts be created, including their access level and dates of account creation and activation?** |  | *If yes, please state contact details and documented procedure for retrieving this.* |
|  | **Are users instructed not to share their passwords / login?** |  | *If yes, where is this specifically documented?*  |
|  | **Automatically log off after idol periods** |  | *If yes, where is this documented*  |
|  | **Locks user account after several failed login attempts** |  | *If yes, where is this documented?* ***NHS Smartcard Access configuration***  |
|  | **Can access be granted to Non – hospital personnel?** (e.g. monitors, auditors, Inspectors) **Can the system allow read only access to only those patients who have consented to a particular study?** |  |  |
| **Training** |
|  | **Are there documented records to show Training for use of e-HR system** |  | *Please specify who holds these and what the process is for obtaining the records.* |
|  | **Are there documented procedures or instructions for using the system?** |  |  |
| **E-Signatures** |
|  | **Does the system digitally stamp\* user id against each action?**How is this executed?(\* for the purposes of this document this can be taken as an e- signature)  |  |  |
|  | **If yes, is the e-signature recognised as equivalent to the individual’s handwritten signature?** |  |  |
|  | **Is this system compliant with FDA 21 CFR11 (if applicable) - USA requirement?** |  |  |
| **Audit trail** |
|  | **Is there an audit trail for all elements within the system?** |  |  |
|  | **Is the following information included in the audit trail:**1. Action performed on e-record (creation, deletion and modification)?
2. Date and time of operator action?
3. User name of the operator who performed the action?
4. Does the system capture the reason for the change?
5. Is the audit trail readily available and readable?
 | a)b)c)d)e) |  |
|  | **Are there process in place to ensure all records, including audit trails procedures and records, are retained for the required period?** |  |  |
|  | **Does the system have the ability to print accurate and complete copies of the e-HR including audit trails?****Has this element been tested?** |  |  |
| **Retrieval, retention and backup** |
|  | **Are there checks in place to ensure the archived data continue to be available and readable?** |  |  |
|  | **In the event of power outage, is there a power backup available to allow orderly shutdown of the system?** |  |  |
|  | **Is there a process for backing up the data in the system?** 1. What is the frequency of the data backup?
2. Is the data backup sent offsite?
3. Is there a process for restoring data from backup media?
4. Has the backup been tested?
5. Is the backup regularly QC’d?
 | a)b)c)d)e) |  |
|  | **What is the continuing operations process should the system not be available?** |  | *Contingency plan - specify document*  |
|  | **Any other comments?** |  |  |

**Part C – Validation signature**

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| **Document completed by:**Full Name ………………………………………………………………………………………………………………………Signature …………..........……………………………………………………………………………………………….…… Date .……………………………………….………………. |