



Gaining Secure Remote Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspectors

DLV-GEN-WI-012

Gaining Remote Access to Electronic
Systems for Monitors, Auditors and Regulatory
Inspectors using Secure Remote Access– V3

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[Non-Trust IT Research Monitor Request Form](#)

[Monitors, Auditors and Regulatory Inspectors Approvers list \(access to the EHR\)](#)

Install Guide for Citrix Receiver for Windows

Install Guide for Citrix Receiver for Windows 10

Install Guide for Citrix Receiver for Mac

1. Secure Remote Access

The One Time Code Pin allows external Monitors/Auditors/Regulatory Inspectors secure access to the Trust's Electronic Health Record (eRecord) remotely to verify source data for research.

Principles of Remote Access using the One Time Code

- 1) Maximum data security:
 - Access is disabled when not required
 - No passwords are stored by researchers
 - Read-only access to eRecord provided for Monitors/Auditors/Regulatory Inspectors
 - Two-factor authentication system requiring both password and pin number
- 2) Minimum administration:
 - Account is set up in advance
 - Access is enabled and then disabled by IT Service Desk only for the required days
- 3) Full audit:
 - Audit report listing all patients' records accessed by Monitor/Auditor/Regulatory Inspector is available after every visit

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Procedure/Method

As soon as the study/trial team is notified of a remote monitoring visit or regulatory body inspection, they must request access to the eRecord for participants in the study, using the One Time Code Pin. IT will need 5 days' notice for new accounts.

1. Send a copy of (Appendix 1) [Non-Trust IT Research Monitor Request Form](#) to the designated Monitor, Auditor or Regulatory Inspector. The completed form must include their date of birth and be signed in **wet ink** (scanned signatures pasted onto the form will not be accepted by IT). **Tick the box on the form that request is for Secure Remote Access.**

NB: Regulatory Inspectors will not need to provide their date of birth or sign the form. The requirement for confidentiality concerning inspection information by inspectors performing their statutory duties is set out in law in the Human Medicines Regulations 2012, Regulation 332.

The Designated Approver must sign the form to verify the request for access is appropriate.

2. The study team must confirm that the applicant holds an employment contract with the Sponsor, CRO or authorised delegate.
3. The team must verify the identity of the applicant by review of a government issued photographic identification e.g., passport, national identity card, driving licence etc.
4. Confirm the duration of the monitoring visit/inspection, which electronic health record system they need access to and the account expiry date.
5. On receipt of the completed forms and confirmation of the duration of the visit, submit the completed forms to the **Designated Approver** for authorisation. Authorisation can only be given by **Designated Approvers** IT will not accept requests from anyone else.
6. A **Designated Approver** (see Appendix 2) must:
 - a. ensure that the forms have been signed and an end date is provided



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- b. submit the completed forms with the expiry date to nhsnewcastle@service-now.com
- c. ensure the email subject is **Research Monitor New Account Request** (If anything other than this text is entered into the **Subject Line**, a ticket will **NOT** be logged).
- d. An expiry date **MUST** be provided for the account. Without this, the account will not be enabled.

This process will automatically log a ticket to the **Service Desk** and the **Designated Approver** will receive 2 emails from the Service Desk (one is generic and the other contains the reference number for the request).

If an email containing a reference number has not been received within 10 minutes of sending the email, please contact the IT Service Desk.

7. When the account is created, the Designated Approver requesting it (Team Lead or Matron) will be provided with Monitor's login details (username and initial password).

The monitor/auditor/inspector will receive an email confirming their read-only access to eRecord via Remote Access One Time Pin. The email will include the following:

- A username
- An initial password (after initial login, Monitor will be prompted to change it)
- A 4-digit One Time PIN code
- A confirmation of the minimum requirements for operating systems (Windows, Windows 10, and Mac)
- The Install Guides for installing Citrix Receiver

Installing Citrix Receiver

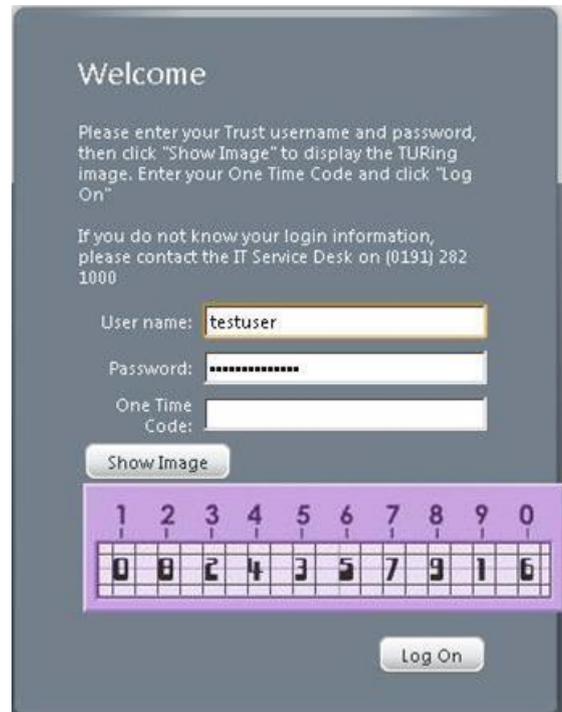
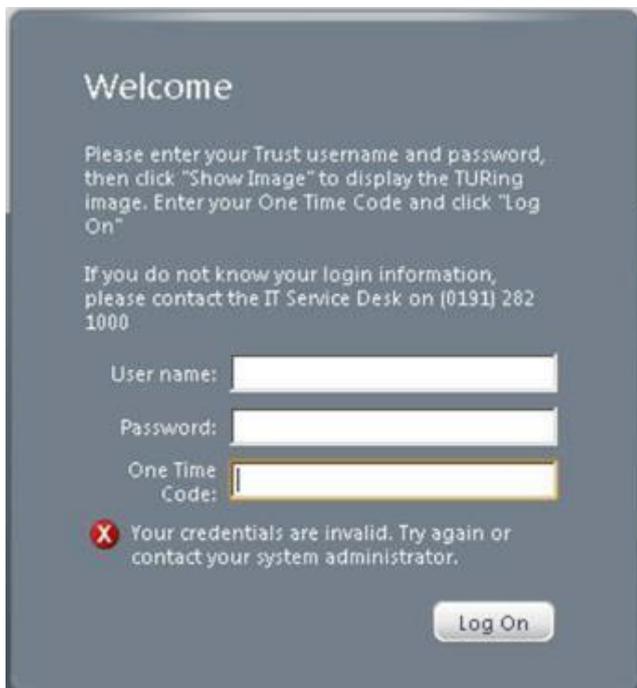
To install Citrix Receiver, the Monitor/auditor/inspector will need to go to <https://remotecare.nuth.nhs.uk> in their browser of choice and follow the instructions for the preferred operating system from the Install Guides (see Appendix 3, 4 or 5).

1. **Secure Remote Access Guide**

Once Citrix Receiver is installed, the Monitor will be able to log in via the remote link. The 4-digit One Time PIN code used as a cypher for the TURING Image that is displayed on the login page:

2. To gain access to the **TURING image**, the Monitor must enter their TRUST username and password and then select the show image button that is available:

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- Each number of the users One Time **PIN code** corresponds to a number in the top row and the number below this number provides you with the **One Time Code** that must be entered. For example, in the screenshot above, this user has a pin of 5678 and is presented with the TURING image of:



The **Monitor's One Time Code** would be **3579**. The Monitor would enter that into the **One Time Code box** select Log On.

- They will then be presented with the Trust Desktop. They will need to select the eRecord icon to access the health records required.



Enabling and Disabling Existing Remote Access Accounts

1. Designated Approvers can nominate additional Trust Approvers, who will be able to enable and disable Existing Swivel Pin accounts (e.g., Clinical Trial Coordinators or Study Lead Coordinator). Approver changes must be enabled through the Informatics Team email: nuth.research.informatics@nhs.net
2. When Monitor/Auditor/Inspector requests the remote access to be granted for specific date(s) the Trust Approver must:
 - Email nhsnewcastle@service-now.com
 - Provide the Monitor/Auditor/Inspector's name, username name and/or DOB (if known).
 - Provide a start date for account to be enabled and an end date after which the account will be disabled (without the end date, the account will not be enabled)
 - Ensure the email Subject Line is **Research Monitor Enable Existing Account** (please note: if anything, other than this text is entered into the subject line, a ticket will **NOT** be logged).
3. This process will automatically log a ticket to the Service Desk and the **Approver**, and **Trust Supervisor** will receive 2 emails from the Service Desk (one is generic and the other contains the reference number for the request).

If an email containing a reference number has not been received by a designated approver within 10 minutes of sending the email, please contact the IT Service Desk.

Please give **24 hours'** notice for enabling existing accounts.

4. When the account has been enabled a 3rd email will be received by the approver to confirm the account has been activated. This may include a temporary password for the monitor (usually dependent on when they last accessed the system). This will need to be sent to the monitor on the day of visit so they can access their account if received.

Monitors/Auditors/Regulatory Inspectors, who no longer require the access to eRecord, should have their accounts deactivated permanently so that the licence can be transferred.



On the day of the monitoring visit:

1. Monitors must be sent the **participant list** using a secure email (entering [SECURE] at the beginning of the email subject. This ensures the email is sent encrypted to the recipient.
2. The email must include the study ID numbers, MRN and the participant's year of birth to cross check against the MRN on eRecord, to ensure the correct patient is selected. No further identifiable information should be provided via email. If there is any confusion (e.g., year of birth doesn't match with the MRN number) the monitor must ring the coordinator to confirm the patient ***Request that the encrypted email is deleted at the end of the monitoring visit.***
3. If a monitor has any trouble accessing their account, they can ring the IT service desk on 0191 2821000
4. The access request and approvals **must be stored in the study site file** (either electronically or printed and placed in the paper Investigator Site File along with the site visit log.
5. When the **remote visit is completed** and access disabled, the study coordinator will receive a full **audit report**, listing all patients' records accessed by Monitor/Auditor/Regulatory Inspector during the remote visit.
6. The audit report is to be reviewed by the study coordinator to confirm Monitor/Auditor/Regulatory Inspector's eRecord activities. Save an electronic copy with corresponding monitoring documents. This should be recorded on an electronic log detailing the dates of the visit, the INC number, date that the audit trail was sent to the team, date it was checked by the coordinator, and a note if there were any deviations from the participant list. Any deviations from the participant list should be reported via Datix, and a manager should be notified.

Please note: Any Monitors/Auditors/Regulatory Inspector who have remote access and attend site for a physical visit will not be able to access eRecord unless their account has been enabled.

*Any problems please email nuth.research.informatics@nhs.net



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Appendices

1. [Access to e-Record, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspectors](#)
2. [Non-Trust IT Research Monitor Request Form](#)
3. [Monitors, Auditors and Regulatory Inspectors Approvers list \(access to the EHR\)](#)
4. [Research Monitors eRecord Working Instruction](#)
5. Install Guide for Citrix Receiver for Windows
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