

Standard Operating Procedure		61.002	
Un-supervised Industry Access to the NHS			
Version	3.0		
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Approved by	Alastair Robertson	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category

NHS GG&C General

2. Staff Category

- West of Scotland Innovation Team
- Industry Collaboration Innovation Team
- NRS Safe Haven Team
- Clinical Research Imaging Facility Team
- NRS Biorepository Team

3. Scope

This procedure applies to all scenarios that require un-supervised industry access to the NHS and offers proportionate and easily applied governance routes, depending on the level of access required.

4. Purpose

This framework to facilitate un-supervised industry access to the NHS for innovation purposes is comparable to the UK Research Passport system developed to support access to the NHS for academic researchers, and utilises similar concepts such as the sharing of Employer pre-engagement checks and provision of individual Letters of Access.

This SOP is intended to act as a document to give clear instructions on how to assess industry requirements and provide a governance route appropriate to the industry request providing clear understanding about responsibility, accountability, patient safety, and duty of care.

5. Procedures

As with the Research Passport system, the onus is on the industry substantive employer to provide and verify the necessary information regarding their employee's suitability to carry out innovation related activities in the NHS.

5.1 Un-supervised Access to NHS data for innovation purposes

In some cases Industry will require un-supervised access, usually through VPN, to approved NHS data for innovation purposes. In most cases, this will be to support ground truth analysis, machine learning and algorithm development. This means that Industry will be able to view but not download pseudo-anonymised NHS data. In some cases, access to NHS data that is potentially identifiable may be approved. This is most likely to occur when analysis of extremes and outlier data is being undertaken.

For this type of access to be approved, a Collaboration Agreement or Contract must always be in place. This will cover all confidentiality aspects.

- Caldicott Guardian is the minimum level of approval for the proposed work. In most cases Project ethics & R&I approval through the Local Privacy Advisory Committee or Public Benefits and Privacy Panel will be in place. Part of this approval process is to ensure that the researchers have appropriate privacy training and analytical expertise to conduct the innovation work.
- A Letter of Access (Appendix A) must be fully signed off before access is given. Different access rules apply for large companies that are signed up to N3 Terms & Conditions and smaller companies that need to meet NHSGGC's Third Party Access policy.

6. Referenced documents

None

7. Related documents

None

8. Document History

Version	Date	Description
1.0	25/06/2019	Release of first version
2.0	2/12/2019	Revised Letter of Access
3.0	26/01/2022	Update from R&D to R&I

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Appendix A - Example Letter of Access

Industry Partner –XXX

Project Title – XXXX

Project R&I Number– GSH/19/

Health Board – NHS Greater Glasgow & Clyde (NHSGGC)

Unsupervised access – VPN only – N3 Terms & Conditions **YES/NO**

- Third Party Access **YES/NO**

eHealth Lead within NHSGGC – XXX

Name of Clinical Lead in NHSGGC – XXX

Brief Description of Work:

We are satisfied that the work to be undertaken forms part of a Collaborative Working Agreement and that Local Privacy Advisory Committee or Public Benefits & Privacy Panel approval has been granted for this work.

This Letter of Access confirms your right to VPN access through NHSGGC for the purpose above and on the terms and conditions set out below. The right of access commences **XXX** and finishes on **XXX** unless terminated earlier in accordance with the clauses below. Critically **XXX** is able to view data by VPN for analysis purposes but is not permitted to download any NHS Project data. [Replacement text only when Azure is used: Critically, **XXX** is able to view, process, and download data to virtual machines within NHSGGC's Microsoft Azure tenancy for analysis purposes but is not permitted to download any NHS Project data to local **XXX** machines.] All outputs, including but not limited to data, models, algorithms, software and graphs generated by **XXX** must be checked by the NHS **prior** to release to **XXX**. As stated in the Project Agreement, **XXX** is responsible for all Data Protection Losses suffered or incurred by NHSGGC arising out of or in connection with any failure by **XXX**, or any of their employees, to comply with any of the obligations of NHS Access. In the event of a deliberate breach of the conditions relating to the use of project data (as to which matter the Data Controller will be the final judge) **XXX** will forfeit their rights to use any or all of the outputs generated through use of project data.

For the avoidance of doubt, as the signatory to the Agreement, it remains the Employing Institution's (**XXX**) responsibility to inform NHSGGC of any relevant issues that would affect access to the NHS.

In particular, while undertaking research/ innovation through NHSGGC, you will:

- Remain accountable to your Employing Institution (**XXX**) but are required to follow the reasonable instructions of R&I and clinical colleagues in NHSGGC in relation to the terms of this Letter of Access.
- Ensure that all information regarding patients or staff remains secure and strictly confidential at all times.
- Ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (<https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice>) and the **Data Protection Act 2018**. Furthermore they should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.
- If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the NHSGGC HR department prior to commencing your research/ innovation role at NHSGGC.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your permission for access, you are required to co-operate fully with any investigation by the Host Board in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings. You must act in accordance with NHSGGC policies and procedures, which are available to you upon request, and the Research Governance Framework for Health and Community Care, or any guidance that may succeed it.

NHSGGC may terminate your permission to attend their premises at any time either by

- giving seven days' written notice to you, or
- immediately without any notice if you are in breach of any of the terms or conditions described in this letter, or
- if you commit any act that they reasonably consider to amount to serious misconduct, or to be disruptive and/or prejudicial to the interests and/or business of the Host Board, or
- if you are convicted of any criminal offence.

Your Employing Institution is responsible for your conduct while working in an NHS Host Board and may in the circumstances described above instigate disciplinary action against you.

Research/ Innovation Staff and Employing Institution (XXX) Declaration

A copy of this Declaration must be signed by the Research/ Innovation Staff member who is being issued with an NHS Letter of Access and the nominated representative of the Employing Institution (XXX)

NHS Board	<input type="checkbox"/> A&A <input type="checkbox"/> D&G <input type="checkbox"/> FV <input checked="" type="checkbox"/> GGC <input type="checkbox"/> Lan <input type="checkbox"/> NWTCB
	XXX Representative
Name:	
Job title:	
Tel:	
Email:	

DECLARATION: Representative of the Employing Institution (XXX)

- As the nominated representative of the Employing Institution (XXX), I confirm that the above Research Staff member is suitable to be issued with an NHS Letter of Access.
- I confirm that the Employing Institution (XXX) retains full responsibility for ensuring compliance with all applicable clauses in the Agreement, and in particular for ensuring that our Research Staff member is aware of, and agrees to comply with, those clauses that apply directly to them.

Employing Institution (XXX) nominated representative

Signature: _____ Date: _____
 Name: _____ Role: _____

DECLARATION: Research/ Innovation Staff Member

- I accept the offer of an NHS Letter of Access, and agree to comply with its terms.
- I agree to ensure that my XXX representative is made aware of any issues that impact on my suitability to carry out my role - in particular, but not limited to, any changes to my health or criminal records check status.

Research/ Innovation Staff member

Signature: _____ Date: _____
 Name: _____ Role: _____

In signing this Letter of Access, you confirm that you have read and agree to comply with the terms contained within the Agreement.

- **You are not entitled to any form of payment or access to other benefits provided by Host Board to their employees, and this agreement does not give rise to any other relationship between you and the Host Board.**

If your current role or involvement in research and innovation changes, or any other circumstances change that would impact on your ability to carry out your role, you must inform your Employing Institution.

You must also inform your nominated contacts and the R&I Office in NHSGGC where you provide support for research and innovation studies.

NHS GGC nominated representative

Signature:

Date:

Name:

Role: