Standard Operating Procedure		**61.001**	
Supervised Industry Access to the NHS for innovation purposes			
Version	3.0		
Prepared by	Roma Armstrong	Signature	Date
Approved by	Alastair Roberston	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 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 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, specifying the role of industry personnel working on an NHS site for a specific registered project.

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, confidentiality, 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 Observing NHS practice (Clinical Observership) – indirect access to patients

The simplest request from industry is to observe NHS practice so that the company can understand NHS processes and how these can be improved. Because there is only indirect

access to patients, Clinical Observership has no bearing on patient care. Since Clinical Observership is fully supervised, no formal pre-engagement checks (such as Disclosure or Occupational Health) are required. Critically if the company needs to observe consultations with individual patients and carers, verbal assent must be obtained and captured in the patient record. Understanding confidentiality requirements is an absolute requirement, and evidence of understanding will be captured in the Letter of Access. The process to be followed is summarised below:

- The date should be agreed with industry 2-4 weeks in advance
- A Letter of Access contract (Appendix A) must be signed prior to the visit
- The NHS supervisor specified in the Letter of Access should warn the clinical team and General Manager well in advance of the proposed visit.
- The NHS supervisor specified in the Letter of Access should meet the industry representative at reception, give a visitor's badge and escort and supervise throughout the visit

5.2 Clinician supervised direct access to patients (and carer)
This option is where direct access to patients is required but with no bearing on patient care (interviews, focus groups, discussion). This approval route is for scoping work only. Collaborative research projects must be approved through the usual ethics and R&I route.

As above, because access to patient (and carer) is fully supervised no formal pre-engagement checks (such as Disclosure or Occupational Health) are required. But it is critical that verbal assent is obtained from patients (and carers), and captured in the patient record. Understanding confidentiality requirements is an absolute requirement, and evidence of understanding will be captured in the Letter of Access.

The same process specified in 5.1 above, should be followed but the different project requirements captured in the Letter of Access.

5.3 Clinician supervised access to staff groups
Direct access to staff groups is often required to understand existing services, NHS needs and the utility of proposed changes (interviews, focus groups, discussion). This approval route is for scoping work only. Collaborative research projects must be approved through the usual IRAS R&I route.

As above, because access to staff is fully supervised no formal pre-engagement checks (such as Disclosure or Occupational Health) are required. Staff participation is completely voluntary in this scenario. The process to be followed is summarised below:

- The date should be agreed with industry 2-4 weeks in advance so that staff members have time to agree to participate
- The NHS supervisor arranging the visit should warn the clinical team and General Manager well in advance of the proposed visit.
- The NHS supervisor arranging the visit should meet the industry representative at reception, give a visitor's badge and escort and supervise throughout the visit

5.4 Supervised Access to NHS IT systems
In some cases Industry will require supervised access to IT systems eg Clinical Portal, Trak, Radiology, safe haven. This means that Industry may be able to view identifiable patient data - but not download identifiable data

As above, because access to NHS IT systems is fully supervised no formal pre-engagement checks (such as Disclosure or Occupational Health) are required. Understanding confidentiality

requirements is an absolute requirement, and evidence of understanding will be captured in the Letter of Access. The process to be followed is summarised below:

- The date should be agreed with industry 2-4 weeks in advance
- A Letter of Access contract (Appendix A) must be signed prior to the visit
- The NHS supervisor specified in the Letter of Access should warn the eHealth, radiology or safe haven team well in advance of the proposed visit
- Caldicott Guardian is the minimum level of approval for the proposed work. In some 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.
- The NHS supervisor specified in the Letter of Access should meet the industry representative at reception, give a visitor's badge and escort and supervise throughout the visit

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	02/12/2019	Revised letter of access
3.0	04/10/2021	Updated to change R&D to R&I

Appendix A

Example Letter of Access Agreement

Industry Partner – *xxx*

Project Title – *xxx*
R&I Number– *GSH/19*
Health Board – *NHS Greater Glasgow & Clyde (NHSGGC)*
Supervised access – *YES*
Name of Supervisor within NHSGGC – *XXX*
Name of Clinical Lead in NHSGGC – *XXX*

Brief Description of Work:

This Letter of Access confirms your right to supervised access through NHS GGC 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.

We are satisfied that the work to be undertaken forms part of a Collaborative Working Agreement and Caldicott Guardian Approval has been granted for this work.

For the avoidance of doubt, as the signatory to the Agreement, it remains the Employing Institution's 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.
- Co-operate with the NHSGGC in discharging their duties under the Health and Safety at Work Act 1974, and other health and safety legislation and to take reasonable care for the health and safety of themselves and others while on Host Board premises
- Observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other member of staff, and act appropriately, responsibly and professionally at all times
- 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 Heath and Community Care, or any guidance that may succeed it.
You should ensure that, where you are issued with an identity or security card, or any other equipment or form of access, these are returned or revoked upon termination of this arrangement.
Please ensure that, while you are on the premises of NHSGGC, that you wear your official NHS ID Badge at all times, and are able to prove your identity if challenged.
Please note that NHSGGC accepts no responsibility for damage to or loss of personal property.
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 (Canon)

NHS Board	☐A&A ☐D&G ☐FV ☒GGC ☐Lan ☐NWTCB
	XXX
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 considered to be a legal visitor to the premises of the Host Board. 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: