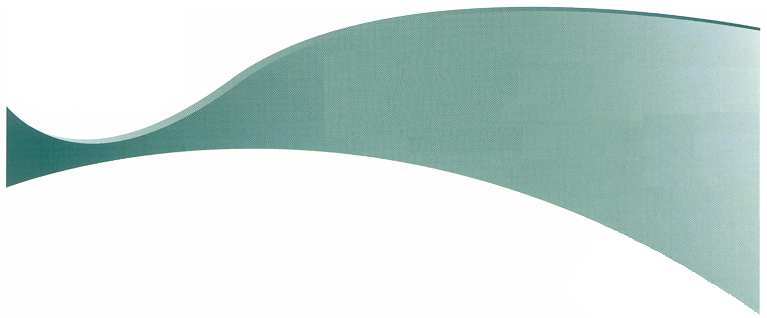
**National Medical Laboratory Information System**

**(MedLIS)**

**MedLIS Data Sharing Agreement**



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# 1. Introduction

The MedLIS project will create a national electronic laboratory record for patients by designing, building and implementing a standard national laboratory information system in all HSE funded laboratories in the country. The Order communications modules involve all clinical users i.e. every health care provider that requests or reviews laboratory tests in hospitals and in the community setting e.g. GPs, nursing homes, health care clinics etc. Access to this national database will be restricted to health care providers having a legitimate reason and all access will be fully auditable, in accordance with data protection guidelines. MedLIS will deliver the following benefits:

* Facilitate a single national patient centred laboratory record by designing, building and deploying a standard national laboratory information system in every HSE funded laboratory in the country (43)
* Provide electronic storage of the entire patient laboratory record on a single hardware platform
* Delivery from a single data centre with 24/7 support & data recovery
* Provide real-time user-friendly access to this data irrespective of where the patient is located and where the patient’s tests were carried out
* Support “end-to-end” electronic communication of requests and results between hospital doctors, primary care clinicians and the laboratory services
* Enable tracking, routing and resulting of specimens
* Support automated interfaces with other relevant information systems, including Patient Administration, Clinical Portals and Clinical Information Systems, and
* Ensure a source of comprehensive management information to allow optimum management and planning of resources

Beginning in Q1 2021 MedLIS will be rolled out on a phased basis to the 43 acute hospitals

The purpose of this Agreement is to define the data protection roles and responsibilities for the system and the data uploaded, stored and processed by MedLIS.

# 2. Definitions

In this Agreement, unless the context otherwise requires:

***Aggregate data*** shall mean data collected from multiple sources and complied into data summaries or summary reports.

***Anonymised data*** shall mean data which has been manipulated to irreversibly remove all personal identifiers from the data so that it is impossible to identify an individual whom the data relates to.

***Anti-malware software*** shall meanany software program designed to prevent, detect and remediate malicious programming (i.e. viruses, spyware, adware, key loggers, ransomware etc.) on individual computing devices and IT systems.

***Computer Device*** shall mean any fixed, mobile or handheld device that is capable of accepting, processing and storing data. Including but not limited to desktop computers, mobile computer devices, smart devices etc.

***Consent*** of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her

***Data Controller*** *or* ***Controller*** means the natural or legal person, public authority, agency or other body, which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law.

***Data Processor*** *or* ***Processor*** means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

***Data Protection Acts*** means the Data Protection Acts 1988 and 2003 (as amended) and the European Communities (Electronic Communications, Networks and Services) (Privacy and Electronic Communications) Regulations 2011 (S.I. 336/2011) and every statutory modification, re-enactment, replacement and/or amendment thereof for the time being in force (or, where the context so admits or requires, any one or more of such Acts) and all orders and regulations/statutory instruments made thereunder;

***Data Subject***means an individual who is the subject of personal data;

***Delete***for the purposes of this agreement means removing all data which is electronically held in such a way that it can never be retrieved from the device on which it is held;

***Demographic Data*** shall meanthat is statistically socio-economic in nature, such as an individual’s age, gender, education level, marital status, occupation, religion, date of birth etc

***EEA (European Economic Area)*** shall mean the free trade area agreed between the 28 EU member states and the three EFTA States (Iceland, Liechtenstein, and Norway)

***Encryption / Encrypt:*** The process of converting (encoding) information from a readable form (plain text) that can be read by everyone into an unreadable form (cipher text) that can only be read by the information owner and other authorised persons.

***FOIA 2014*** means the Freedom of Information Act 2014 and any amendments to or replacements thereof, including by means of directly effective EU Regulation;

***GDPR*** means the EU General Data Protection Regulation, Regulation (EU) 2016/679, the effective date of which is 25th May 2018;

***Joint Data Controllers*.** Where two or more controllers jointly determine the purposes and means of processing, they shall be joint controllers. They shall in a transparent manner determine their respective responsibilities for compliance with the obligations under this Regulation, in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in [Articles 13](https://gdpr-info.eu/art-13-gdpr/) and [14](https://gdpr-info.eu/art-14-gdpr/) of the GDPR, by means of an arrangement between them unless, and in so far as, the respective responsibilities of the controllers are determined by Union or Member State law to which the controllers are subject. The arrangement may designate a contact point for data subjects;

***Mobile Computer Device*** shall mean any handheld computer device including but not limited to laptops, tablets, notebooks, PDA’s etc.

***Mobile Phone Device*** shall mean anywireless telephone device not physically connected to a landline telephone system. Including but not limited to mobile phones, smart phone devices (for example, Apple iPhones, Windows Mobile enabled devices, Google Android enabled devices, Nokia Symbian enabled devices, Blackberry RIM enabled devices etc). This does not include cordless telephones which are an extension of a telephone physically connected to a landline telephone system.

***Party*** shall mean each organisation that is included and has signed up to this agreement

***Personal Data*** means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;

***Personal Data Breach*** shall meana breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, *Personal Data* transmitted, stored or otherwise *Processed* by the MedLIS;

***Processing*** and ***Process*** means any operation or set of operations which is performed on personal data or on sets of personal data, whether by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

***Privacy Impact Assessment (PIAs)*** shall mean theprocess that is used by organisations to ensure that individuals’ privacy is appropriately protected within any information system that collects and processes personal data.

***Removable Storage Device*** shall meanany optical or magnetic storage device or media, including but not limited to floppy disks, CD, DVD, magnetic tapes, ZIP disk, USB flash drive (i.e. memory stick/pen/keys), and external/portable hard drives.

***Sensitive Personal Data*** means any personal data as to –

(a) the racial or ethnic origin, the political opinions or the religious or philosophical beliefs of the data subject,

(b) whether the data subject is a member of a trade union  
(c) the physical or mental health or condition or sexual life of the data subject,   
(d) the commission or alleged commission of any offence by the data subject, or   
(e) any proceedings for an offence committed or alleged to have been committed by the data subject, the disposal of such proceedings or the sentence of any court in such proceedings;;

***Smart Device*** shall mean any handheld mobile computer device which is capable of wireless connection (via Wi-Fi, 3G, 4G etc), voice and video communication and, internet browsing (for example: Apple IOS enabled devices (i.e. iPhone & iPad), Google Android enabled devices (i.e. Samsung Galaxy tablet), Windows Mobile enabled devices and, Blackberry RIM enabled devices etc).

## 3.1 Which organisations are party to this Agreement:

1. The **Health Service Executive (HSE)**, a body corporate with perpetual succession established by the Health Act 2004, which has its principle administrative offices at Dr. Steevens Hospital, Steevens Lane, Dublin 8, and
2. The **Mater Misericordiae University Hospital** which has its principle administrative offices at Eccles Street, Dublin 7
3. **Beaumont Hospital,** which has its principle administrative offices at PO Box 1297Beaumont Road, Dublin 9
4. **Children’s University Hospital**, which has its principle administrative offices at Temple Street, Dublin 1
5. **St. Vincent’s University Hospital,** which has its principle administrative offices atElm Park, Dublin 4
6. **St. James’s Hospital**, which has its principle administrative offices at James’s Street, Dublin 8
7. **Tallaght Hospital,** which has its principle administrative offices in Tallaght, Dublin 24.
8. The **Coombe Women & Infants University Hospital**, which has its principle administrative offices at Cork St, Dublin 8,
9. The **National Maternity Hospital**, which has its principle administrative offices at Holles Street, Dublin 2, and
10. The **Rotunda Hospital**, which has its principle administrative offices at Parnell Square, Dublin 1.
11. The **Mercy University Hospital, Cork** which has its principle administrative offices at Grenville Place, Cork
12. **Our Lady’s Children’s Hospital,** which has its principle administrative offices in Crumlin, Dublin 12

This Agreement shall be managed by the following authorised officers from each of the participating organisations:

1. The Health Service Executive

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The Mater Misericordiae University Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Beaumont Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Children’s University Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. St. Vincent’s University Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. St. James’s Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Tallaght Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The Coombe Women & Infants University Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The National Maternity Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The Rotunda Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The Mercy University Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Our Lady’s Children’s Hospital

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. GP Practice Name

Mr / Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ph: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# 4. Privacy Impact Assessment

## 4.1 Draft MedLIS Data Privacy Impact Assessment

In 2017 MedLIS worked with Deloitte to create a draft MedLIS Data Privacy Impact Assessment (DPIA) [ML-QP-0019]. This has been shared with all the organisations in phase 1 and has been updated following review by the HSE DPO.

# 5. Legal basis for processing

## 5.1 What is MedLIS’s legal basis for processing.

It is not possible to undertake medical care without collecting and processing personal data and data concerning health. In fact, to do so would be in breach of the Medical Council’s ‘Guide to Professional Conduct and Ethics for Doctors’. Therefore the following articles within GDPR and Data Protection law are applicable

* Article 6 (1)(c) ‘processing is necessary for compliance with a legal obligation to which the controller is subject’
* Article 6 (1)(d) ‘processing is necessary to protect the vital interests of the data subject or of another natural person’.
* Article 6 (1)(e) ‘processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller’
* Article 9(2)(h) which states that special categories of personal data, including health data, may be processed if the processing is necessary for “the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services”.
* Article 9(2)(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;
* Data Protection Act 2018, Section 52(1) (a) – ‘for the purposes of preventative or occupational medicine’, Section 52(1) (d)’ for the provision of medical care, treatment or social care’ and/or Section 52(1) (e) for the management of health or social care systems and services’ which allows patient information to be used for clinical audit provided that appropriate measures are taken to safeguard the fundamental rights of the data subject.
* GDPR Article 5(1)(a) states that personal data shall be “processed lawfully, fairly and in a transparent manner in relation to the data subject”. Therefore, it is necessary to notify patients of how their data will be processed. It is intended that this will be done by means of a Patient Information leaflet which states the purposes for the processing of their personal data, and any secondary purposes which may apply (e.g. for statistics and research purposes).

## 5.2 Responsibility of each controller

Each organisation has a responsibility to ensure that uploading of Personal Data by them onto MedLIS and subsequent processing of the Personal Data can be justified under the Data Protection Acts and the GDPR as stated above e.g. The processing is required for the purpose of medical treatment undertaken by health professionals, **including assessing** **the working capacity** **of employees and the** **management of health or** **social care systems and** **services.**

# 6. Privacy Notice

6.1 Privacy Statements at an organisation level

Each organisation shall ensure they amend (where necessary) their individual Privacy Notice / Patient Information leaflet to incorporate the information within the MedLIS patient information leaflet below and include any additional processing of their patients personnel data that is not accounted for in the MedLIS Patient Information Leaflet.

6.2 Informing Patients

Each party shall ensure that all new and returning patients are given a copy of the MedLIS Patient Information Leaflet (Appendix A) when they attend their hospital (following implementation by that hospital) for their treatment and care. Additionally, the MedLIS Patient Information Leaflet will be available in GP practices, and on the HSE Website.

# 7. Data Controllers

7.1 Who are the data controllers

All Parties shall be considered Joint Data Controllers for all Personal Data which is processed and retained by MedLIS and will be legally responsible for complying with their obligations as Data Controllers under the Data Protections Acts and GDPR.

7.2 Processing Personal Data

As Joint Data Controllers all Parties will be jointly responsible for determining the purposes and means forprocessing of Personal Data processed by MedLIS.

7.3 Healthcare data outside of MedLIS

Each Party shall remain the sole Data Controller for any Personal Data that they Process outside of MedLIS and independently of the other Parties.

# 8. Data Processors

8.1 MedLIS was developed by Cerner Ireland on behalf of the HSE and they will continue to provide on-going support and maintenance of the system and as such will fulfil the role of Data Processor.

8.2 Each party shall not appoint any additional Data Processors for MedLIS without having first obtained the written approval of the other parties.

8.3 All additional Data Processors will be required to sign a copy of the HSE Service Provider Confidentiality Agreement prior to them gaining access to MedLIS.

([http://www.hse.ie/eng/services/publications/pp/ict/HSE-Service-Provider-Confidentiality- Agreement-v3-0.pdf](http://www.hse.ie/eng/services/publications/pp/ict/HSE-Service-Provider-Confidentiality-%09Agreement-v3-0.pdf))

# 9. Purposes for processing data

9.1 MedLIS shall collect and process Personal Data for the following primary purposes:

* To help with patient diagnoses in order to plan and provide patients treatment and care;
* To allow 24 hr access to a patients record regardless of their location;
* To record the patient’s results;
* To ensure appropriate information is available if a patient needs to be referred to another health care professional or to another part of the health service; To provide diagnostic, screening and therapeutic data
* To monitor differences over time
* To aid in monitoring a patient’s response to therapy
* To maintain a record of the patient’s laboratory data
* To allow health care providers be fully informed in order to aid in designing care plans and treatment
* To allow each Party ensure their patient’s concerns can be properly investigated by that Party if a complaint is raised.

9.2 Each Party may use the aggregate data from MedLIS for the following purposes:

* To help plan and assess Laboratory ordering and Laboratory services at a national level, as applicable.
* To help plan Laboratory ordering and Laboratory services for the future at a national level, as applicable.

9.3 Each Party may use the data from MedLIS which relates to that Party’s direct provision of care, for the following purposes:

* To help plan and assess that Party’s current Laboratory ordering and Laboratory services, as applicable;
* To help plan that Party’s Laboratory ordering and Laboratory services for the future, as applicable

9.4 Each Party may use anonymised data from MedLIS for educational purposes to help train and teach health care students and staff.

# 10. Description of data stored on the (MedLIS)

10.1 MedLIS will Process the following categories of data, Demographic Data, Personal Data, Sensitive Personal Data and Special Categories of Data concerning each Parties

patients and employees. This will include the following:

* Personal details such as patient’s name, address, date of birth, contact telephone number, PPSN, Eircode and next of kin etc.
* The patients General Practitioners (GP) name, address and contact telephone number.
* Data about the patient’s health and lifestyle relevant to their Laboratory requests.
* Data about any relevant medical treatment and care the patient may have received in the past.
* Laboratory test results, notes and reports about the patient’s health.
* Medical images (for example x-rays, gross descriptions, post mortems electrophoresis etc) which may have been taken as part of the patient’s diagnosis treatmentand care.
* Laboratory photographs/ images which may have been taken as part of the Laboratory testing/reporting
* Personal details of the health care professionals involved in the patient’s treatment and care (i.e. names of the clinical team, medical registration number etc).

# 11. Processing of data

11.1 Each Party shall comply fully with the Common Law of Confidentiality, the Data Protection Act 2018, GDPR and all other relevant legislation.

11.2 Each Party shall ensure that personal data stored within MedLIS will not be transferred or processed outside the European Economic Area (EEA) without the Party, having first informing the other Parties in writing of their intention and, ensuring the

appropriate safeguards are in place to satisfy the Data Protections Act 2018 and GDPR. In the event of the UK leaving the EU provisions will be made in line with legislation

# 12. Access to MedLIS

12.1 All access to MedLIS shall be managed in accordance with the HSE Access Control Policy (<http://www.hse.ie/eng/services/publications/pp/ict/Access_Control_Policy.pdf>).

12.2 Each Party shall ensure that Personal Data stored on MedLIS is only made accessible by them to their employees, agents, representatives, contractors and Data Processors on a strict need to know basis and for the purpose of the Patient’s care.

12.3 Each Party shall ensure that all their employees, agents, representatives, contractors and Data Processors which have access to any Personal Data stored on MedLIS have received appropriate GDPR training, appropriate MedLIS training, are aware of the auditing nature of the system and are fully aware of the disciplinary action for breach of data confidentiality and are aware of the confidential nature and responsibilities placed on those processing such information. GDPR training is mandatory as a pre-requisite to MedLIS training.

# 13. Hosting

13.1 The MedLIS System shall be hosted by the HSE on its own network and all the system servers shall be located in Ireland within secure ISO 27001 accredited data centres.

# 14. Security

14.1 All Parties shall be jointly responsible for maintaining the security and privacy of Personal Data stored on the MedLIS.

14.2 All Parties have individual and joint responsibilities under the Data Protection Act and GDPR, and each Party shall ensure that all their employees, agents, representatives, contractors and Data Processors are trained in this regard and understand their responsibilities to ensure their personal compliance as well the Parties individual and joint compliance in this area.

14.3 Each party shall be responsible for implementing appropriate technical and organisational controls within their own organisation to protect against accidental or unlawful, loss, alteration, unauthorised disclosure of, or access to, Personal Data which is transmitted, stored or otherwise processed by MedLIS.

14.4 As MedLIS is hosted on the HSE network, the HSE shall be solely responsible for the following:

1. The security of the network;
2. The management and security of the servers hosting MedLIS;
3. The scheduled backup of MedLIS and the management and security of all backup media.

14.5 Each Party shall ensure all Computer Devices used by their employees, agents, representatives, contractors and Data Processors to connect to the HSE network always have, reputable up to date Anti-Malware Software and the appropriate security patches installed.

14.6 Each Party shall ensure that all their employees, agents, representatives, contractors and Data Processors which have access to MedLIS have been instructed to keep all their MedLIS logon accounts and passwords confidential and not to share these with others.

14.7 Each Party shall ensure that Personal Data from MedLIS is not copied by their employees, agents, representatives, contractors and Data Processors onto Mobile Computer Devices, Mobile Phone Devices, Removable Storage Devices or Smart Devices unless the Personal Data is Encrypted, or the device used to store the Personal Data on is Encrypted. The encryption standards used by each party must match or better those outlined in the HSE Encryption policy.

(<http://www.hse.ie/eng/services/Publications/pp/ict/Encryption_Policy.pdf>)

# 15. Personal Data Breach

15.1 Each Party shall notify the MedLIS national back office as soon as is practical, and at a maximum within 24 hours, after they become aware of any Personal Data Breach within their organisation concerning MedLIS.

15.2 Once a Party notifies the other Parties of a Personal Data Breach, the Party responsible for the Personal Data Breach shall, within 24 hours, provide the MedLIS national back office with all the available information surrounding the Personal Data Breach.

15.3 Once the MedLIS national back ofice has received all the available information surrounding the Personal Data Breach they shall decide on a plan regarding how they will fulfil their obligations to notify the Data Protection Commissioners and Data Subjects of the Personal Data Breach in accordance with Articles 33 and 34 of GDPR.

15.4 As the Parties are Joint Data Controllers for MedLIS, no one party shall notify the Data Protection Commissioners Office and/or Data Subjects of a Personal Data Breach concerning MedLIS prior to all the MedLIS national back office agreeing a plan as outlined in Clause 15.3

# 16. Restrictions on the use of data

16.1 All Parties shall ensure that Personal Data stored on MedLIS will only be used for the purpose(s) specified at the time of disclosure(s) and as defined in clause 9.1 of this Agreement.

# 17. Disclosure of data to third parties

17.1 Each Party shall ensure that Personal Data stored on MedLIS is only released and disclosed to other health and governmental agencies and departments in accordance with the relevant legislation (for example, FOIA 2014 / Data Protection Act 2018 / GDPR / Health (Provision of Information) Act 1997 / Health Acts 1947 to 2007 / Infectious Diseases Regulations 1948 & 1981 etc) or as required pursuant to an enactment, rule of law or by order of a court.

17.2 Each Party shall ensure that personal data stored on MedLIS is only released and disclosed to the general public in accordance with the relevant legislation (for example, FOIA 2014 / Data Protection Act / GDPR) or as required pursuant to an enactment, rule of law or by order of a court.

17.3 If one Party to this Agreement receives a data subject access request, and Personal Data is subsequently identified as having originated from another Party, it will be the responsibility of the receiving Party to contact the Party that supplied the data to determine whether the supplier wishes to claim an exception under the provisions of either the Data Protection Acts, GDPR or FOIA 2014. The receiving Party must be mindful of the fact that they have 40 days under the Data Protection Act, one month (30 days) under GDPR and 20 working days under the FOIA 2014, to respond to such requests.

# 18. Data Quality

18.1 Each Party shall be responsible for the quality and accuracy of the data, personal (as per minimum demographic dataset) or otherwise, they upload onto MedLIS.

18.2 Data discovered to be inaccurate or inadequate for the specified reasons (as defined in clause 9.1 of this Agreement) will be brought to the notice of the Party that supplied the data. The Party that supplied data will be responsible for correcting the data and notifying all the other Parties of the corrections.

# 19. Data Retention

19.1 MedLIS shall retain Personal Data no longer than is necessary.

19.2 Each Party will ensure that Personal Data uploaded by them onto MedLIS is retained in accordance with legal retention periods as per the “retention and storage of pathological records and specimens” guidelines and the HSE Record Retention Policy (<http://www.hse.ie/eng/services/list/3/acutehospitals/hospitals/ulh/staff/resources/pppg/rm/recret2013.pdf>).

# 20. Governance

20.1 Governance of MedLIS will ultimately be the responsibility of the HSE Director General with delegated responsibilities to various teams.

20.2 The national joint MedLIS/MN-CMS governance group will oversee the following:

* National changes requested for the system.
* Reporting from the system.
* National audit requests.
* National research requests.
* The back office functions.
* Disciplinary action in relation to data breaches
* The appropriate use of the system from an access and data management perspective (which will be managed and monitored at a more granular level by a joint data governance group).
* The regulation on the activity of interfacing systems.

20.3 The national MedLIS governance group will oversee all research and audit requests for access to data stored within MedLIS at national level. All parties shall have in place an ethics committee to review and authorise any research study for which access to local hospital / Party data is requested. In all cases (i.e. national and local), the applicant(s) may only begin the study or access data within MedLIS, upon receiving the required formal written approval from the appropriate authority.

**21.** Complaints of Misuse of the MedLIS

21.1 In the event that any Party receives a complaint / allegation of the misuse of MedLIS or data stored on the MedLIS by that Party’s employees, agents, representatives, contractors or Data Processors, the Party who received the complaint / allegation will investigate the complaint / allegation and report the findings of their investigation to the national MedLIS back office within 72 hours, unless the investigation finds a Personal Data Breach occurred, in which case the Party will follow the procedure outlined in Clause 15 of this Agreement.

# 22. Monitoring & Review

22.1 This Agreement will be formally reviewed on an annual basis by the authorised officers from each of the participating organisations, unless legislative changes necessitate an earlier review.

22.2 If a new organisation joins the Agreement, a new version of this Agreement shall be issued as soon as is practical, certainly within one month, and circulated to all participating organisations.

22.3 If any organisation is replaced by a successor body or have their relevant powers and responsibilities transferred to another body, a new version of this Agreement shall be issued as soon as is practical, certainly within one month, and circulated to all participating organisations.

22.4 If an organisation leaves the Agreement, a new version of the Agreement shall be issued as soon as is practical, certainly within one month, and circulated to all participating organisations.

22.5 This Agreement may not be supplemented, amended, varied or modified in any manner except by an instrument in writing signed by a duly authorised officer from each of the Parties hereto**.**

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# 23. Dispute Resolution

23.1 In the event of a dispute arising under this Agreement, the authorised officers from each of the participating organisations will discuss and meet as appropriate to try and resolve the dispute within seven (7) calendar days of being requested in writing by any Party to do so. If the dispute remains unsolved, it will then be referred to a senior manager from each of the Parties, who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) calendar days.

23.2 In the event of failure to resolve the dispute through the steps out in clause 22.1, the Parties agree to attempt to settle it by mediation

# 24. Severance & Unenforceability

24.1 If any provision, or part thereof, of this Agreement shall be, or is found by any authority, administrative body or court of competent jurisdiction to be, invalid, unenforceable or illegal, such invalidity, unenforceability or illegality shall not affect the other provisions, or parts thereof of this Agreement, and of which shall remain in full force and effect.

24.2 If any invalid, unenforceable or illegal provision, or part thereof, of this Agreement would be valid, enforceable or legal if some part were deleted, the provision, or part thereof, will apply with whatever modification is necessary to give effect to the intention of the parties as appears from the terms of this agreement.

# 25. Governing Law

25.1 This Agreement will be governed by and construed in accordance with the laws of Ireland, and the parties submit to the exclusive jurisdiction of the Irish courts for all purposes connected with this Agreement*,* including the enforcement of any award or judgement made under or in connection with it.

**IN WITNESS** where of this *Agreement* has been entered into the day and year first herein written.

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