

Governance Checklist for Tallaght University Hospital 2025

Legal, Statutory and Regulatory Obligations applicable to Tallaght University Hospital's activities which include but are not limited to the following.

Ethics Legislation - SIPO

Languages (Amendment) Act 2021

Employment Equality Act 1998

Employment Equality (Abolition of Mandatory Retirement Age) Bill 2022

Employment Equality (Pay Transparency) Bill 2022

Safety, Health & Welfare at Work Act (Night work and Shift work) regulations, 2000 S.I No 11 of 2000

European Working Time Directive and Amendments: Directive 93/104/EC, Directive 2000/34/EC, Directive 2003/88/EC

Health & Social Care Professionals (Amendment Act) 2019

National Vetting Bureau Acts 2012.

National Vetting Bureau (Amendment) Bill 2022

Gender Pay Gap Information Act 2021.

Public Service Pay and Pensions Act 2017.

Accounting Standards for Voluntary Hospitals 1999

HSE Annual Compliance Statement

Charities Act 2009 - Charities Regulator

Charities (Amendment) Bill 2024

Companies Act 2014

European Union (Award of Public Authority Contracts) Regulations 2016

Quality in Public Procurement (Contract Preparation and Award Criteria) Bill 2021

Value Added Tax Consolidation Act 2010

Criminal Justice (Theft & Fraud Offences) Act 2001

Fraud & Corruption Statement

Criminal Justice (Money Laundering & Terrorist Financing) (Amendment) Act 2021

Gender Balance on Boards Directive (EU) 2022/2381

Code of Professional Conduct and Ethics 2012

Scope of nursing and Midwifery Practice Framework 2015

Ethics and Standards for student nurses and midwives.

Nurses and Midwives social media and social networking guidance 2013.

Registered Nurses and Midwives Medication Administration Guidance 2020.

Practice Standards for Nurses and Midwives with Prescriptive Authority 2018.

Nursing Authority Radiological Procedures 2020.

Nursing and Midwifery Act 2011

Patient Advocacy/Complaints Management

Health Act 2004 (complaints) regulations S.I 652 of 2006

National Safer Better Care Standards(HIQA) - compliance

Mental Health Commission; HIQA(2017) national Standards for the Conduct and Review of Patient Safety Incidents

National Treasury Agency (NTMA) Amendment Act 2000 & 2014 (KPI's)

Civil Liabilities & Courts Act (Part 4) 2017

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.

Assisted Decision Making (Capacity) Act 2015 & Assisted Decision Making (Capacity) – (Amendment) Act 2022

Coroners (Amendment) Act 2024

The Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022

Protected Disclosure Act 2014 & Protected Disclosure (Amendment) Act 2022

Medical Practitioner's Act 2007 Section7(20(i) Advanced Healthcare directives

Health Act (Provision of Information) Act 1997

Disability Act 2005

Data Protection Act 2018

Freedom of Information Act 2014

EU GDPR

European Communities (Data Protection and Privacy in Telecommunications) Regulations (2002)

National Information Security Directive – National Cyber Security Centre

National information Security Directive II – National Cyber Security Centre

Health Information Bill 2024.

Communications Regulations Act 2002

Al Liability Directive & Product Liability Directive

Health Identifiers Act 2014

European Health Data Space

Health Act 2007

Health Acts 1947 to 2020

Health (Miscellaneous Provisions) (No.2) Act 2022

Health (Amendment) Act 2023

Health (Waiting Lists) Bill 2024

Irish Medicines Board (Miscellaneous provisions) Act 2006

Food Safety Authority of Ireland Act 1998

Waste Management (Hazardous Waste) regulations 1998 S.I No 147 & 163 of 1998

Waste management Amendment Act 2001

Safety, Health and Welfare at Work Act 2005

Health & Safety Authority: Guide to the Safety health and Welfare at work (General Applications) regulations 2007

Building Regulations 2009

Medicinal Products(Prescriptions & control of supply) (Amendment) Regulations 2007 S.I No 201 of 2007

Misuse of Drugs (Amendment) regulations 2007 S.I No 200 of 2007

Misuse of Drugs (Amendment) Act 2016

Misuse of Drugs Regulations 2017

Children First Act 2015 - now falls to HIQA to audit

Child Trafficking and Pornography (Amendment) Act 2004 & 1998.

Research/clinical trials:

For Clinical Trials the following legislation exists:

- 1. Control of Clinical Trials Act 1987&1990.
- 2. Council Directive 2001/20/EC transposed into Irish law EU Regulation SI No. 190 of 2001

Amended SI No. 878 of 2004

- 3. Council Directive 2005/28/EC transposed into Irish law EU Regulation SI No 374 of 2006
- 4. 2001/20/EC will be repealed in 2021 when new clinical trial regulation No 536/2014 is implemented.
- 5. Data Protection Act Heath Research Regulations.

Research and Innovation Bill 2024

HSE Records Management Standards 2014

HSE Records Retention Policy 2014

HSE Code of Practice for Healthcare Records Management 2013

| Statistics Act 1993 |
|--|
| Medicinal Products (Prescription and Control of Supply) |
| Infectious Diseases Regulations 1981 & Amendments 2007 & 2020 |
| Criminal Damages Act (1991) |
| Intellectual Property Miscellaneous Provisions Act 2014 |
| |
| Copyright and Related Rights Act (2000) |
| The Pharmacy Act 2007 |
| Public Health (Tobacco Products and Nicotine Inhaling Products) Act 2023 |
| Medical Ionising Radiation – EU regulations |
| HIQA- Ionising Radiation (Medical Exposures) |
| HIQA- Prevention and Control of Healthcare-associated Infections |
| HIQA- Medication Safety |
| HIQA Information Governance Standards |
| HSE Safeguarding Vulnerable Persons at Risk |

Inspection/Regulatory Bodies

- HSE
- **Data Protection Commissioner**
- Office of the Information Commissioner
- Coroner
- Irish Medical Council
- CORU
- Nursing & Midwifery Board Ireland
- Gardaí
- HAS
- **BDO**
- **INAB Lab Accreditation**
- HIQA
- Pharmaceutical Society
- Environment Protection Agency Health Products Regulatory Authority
- National Office for Research Ethics Committees