



**UNIVERSITY OF
LIMERICK**
OLLSCOIL LUIMNIGH

HEALTH RESEARCH POLICY

1 Introduction

1.1 Purpose

Health research plays a key role in helping to realise the strategic priorities of the University of Limerick by driving the translation of research discoveries and knowledge into new ways of treating populations, delivering care, changing behaviour and ultimately improving health, wellbeing and health services. Across the University a range of health related research involving human participants is undertaken from regulated clinical trials to studies that involve human participants in non-regulated studies and is considered under the umbrella term “Health Research” (see 1.3.1) The various categories of health research that this policy relates to include both clinical research involving people, or samples from people for the purposes of improving medical care, as well as health research (as outlined below):

Health research categories¹

Regulated Clinical Trials – these are clinical trials of medicines or medical devices that fall under the remit of the Competent Authority (CA); in Ireland this is the Health Product Regulation Authority (HPRA). Research of medicines or medical devices that fall under the category of regulated clinical trials are required to follow HPRA approval and notification procedures and specific insurance to be sought by the University. Regulated research may be interventional, low-intervention or non-interventional.

Non-regulated clinical trials – a clinical trial that does not included medicines or medical devices and does not fall under specific Legislative framework.

Non-regulated, non-interventional, observational studies There are several different types of non-regulated non-interventional observational studies. In this type of research, the factor or intervention that the researcher is investigating is not controlled or directly applied as part of the study. There are several different types of observational studies which can be of varying risk. Example studies in this category include studies with:

- Non-invasive testing e.g., data collection only using survey instruments, routine outcome measures.
- Invasive but low risks tests e.g., blood samples, swabs Invasive, higher risk tests e.g., tissue biopsy, CT scans.

¹ Based on the Corporate Enabling of Clinical Research Report 2019 and the Health Research Board policy on Clinical Trials)

Classification of Research that Health Research Policy applies to:

Type of study	Regulated Clinical Trial		Non-interventional – Observational study		
Sub- classification	IMP/MP - Interventional - Low Intervention - Non-Interventional	Device - Interventional - Non-Interventional	Non-invasive e.g. survey instrument	Routine Tests incorporated e.g. standard blood tests, swabs, saliva	Invasive clinical tests incorporated. e.g., MRI, biopsy,
Sponsor required?	Yes	Yes	varies	varies	varies
Likely risk level	High	High	Low	Low	Medium

1.2 Scope

1.2.1 To whom does the policy apply?

This policy applies to all University of Limerick staff and students, as well as joint appointees of the University and other institutions/bodies. For the purposes of this policy, adjunct appointees, visiting academics/researchers (e.g., those incoming to the university on sabbaticals from other institutions) will be regarded as honorary Faculty members per University policy elsewhere and as such bound by the principles and requirements that follow.

1.2.2 In what situations does the policy apply?

This policy applies to all staff and students at the University of Limerick who plan to undertake any health research as per the categories in Section 1 including clinical trials. This policy incorporates the Clinical Research Policy for UL Sponsored Regulated Clinical Trials.

1.2.3 Who is responsible for ensuring that the policy (and any associated procedure) is implemented and monitored?

This policy sets out requirements for staff and students at the University of Limerick before, during and after the conduct of health research to ensure good research governance² is adhered to. The Office of the Vice President Research is responsible for ensuring

² Research governance may be defined as the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality both nationally and internationally.

implementation and monitoring of this policy; however, as described below, individual staff, students and other members of the community under the scope of this policy have responsibilities with regard to the carrying out of health research.

1.3 Definitions

The following definitions are informed by the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 and the Data Protection Act 2018 (Section 36(2))(Health Research)(Amendment) Regulations 2021”) [hereafter referred to as the “Health Research Regulations”], HRB Clinical Trials Policy and HSE Research Governance Framework and the new Clinical Trial Regulation (EU) No 536/2014 adopted on 16 April 2014 and became applicable on 31 January 2022, the community code relating to Medicinal products for human use 2001/83/EC, Medical Device Regulation, 2017/745 and In Vitro Diagnostic Medical Device Regulation 2017/746.

1.3.1 Health Research:

Health research is defined in the Health Research Regulations as:

- research with the goal of understanding normal and abnormal functioning, at the molecular, cellular, organ system and whole-body levels.
- research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury.
- research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals.
- research with the goal of improving the efficiency and effectiveness of health professionals and the health care system.
- research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.
- Health research referred to above may include action taken to establish whether an individual may be suitable for inclusion in the research.

1.3.2 Clinical Trials:

“Clinical trial” means a clinical study which fulfils any of the following conditions: (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned; (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

1.3.3 Low-intervention clinical trial:

Means a clinical trial which fulfils all of the following conditions: (a) the investigational medicinal products, excluding placebos, are authorised; (b) according to the protocol of the clinical trial, (i) the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or (ii) the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned.

1.3.4 Non-regulated clinical trials:

A clinical trial that does not fall under specific legislative framework (e.g., trials with intervention arms that do not investigate new treatments).

1.3.5 Sponsor:

In alignment with the HRB's Clinical Trials and Interventions Research Governance Policy, for clinical trials and interventions under this policy, the Sponsor is defined as "the legal entity which has ultimate responsibility for the study and compliance with the regulations, principles and standards of good practice that governs clinical research"³. The Sponsor takes the responsibility for the initiation, management, financing (or arranging the finance) and reporting of the clinical trial and interventions.

The Sponsor responsibilities for Clinical Trials of Investigational Medicinal Products (CTIMPs) are governed by the EU Clinical Trial Regulation EU No.536/2014 or 2001/83/EC for authorised medicinal products.

The Sponsor responsibilities for Clinical Investigation of a Medical Device are governed by the EU Medical Device Regulations 2017/745 and 2017/746. For reference to current legislation please visit the HPRA website.

The Sponsor may arrange to delegate any, or all, of their trial-related functions to an individual, company, institution, or organisation. However, in all such cases, the Sponsor shall retain overall responsibility for ensuring that the conduct of the trials and the final data generated by those trials comply with all applicable legislation.

1.3.6 Host Institution:

The organisation that receives the letter of offer for the research award and is responsible for compliance with all general and specific terms and conditions of awards.

1.3.7 Letter of offer:

Means the letter issued by the funder specifying the level and duration of the award that has been accepted by the host institution by executing the acceptance certificate attached to such letter.

1.3.8 Principal Investigator (PI) - clinical trials:

Means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site. The Principal Investigator shall ensure compliance of a clinical trial at a clinical trial site with the requirements of the applicable regulations. The Principal Investigator shall assign tasks among the members of the team of investigators in a way which is not compromising the safety of subjects and the reliability and robustness of the data generated in the clinical trial at that clinical trial site.

Where UL staff hold a dual affiliation, they must decide which organisation (i.e., the HSE or the academic/other organisation) they will represent for the entire duration of the research study, and this determination must be done and confirmed in writing, set out in

³ Health Research Board. Clinical Trials and Interventions Research Governance Policy. Available from: <https://www.hrb.ie/funding/fundingschemes/before-you-apply/all-grant-policies/clinical-trials- and interventions-governance> data controllers in the context of health research as set out in the Health Research Regulations.

an agreement between the respective legal entities (i.e., HSE or the academic/other organisation) before the start of the research study. This is a vital requirement for the correct determination of controllership of data between the collaborative organisations.

1.3.9 Lead Researcher

Means the researcher leading conduct of a Health Research Study at the University of Limerick. The lead researcher may be synonymous with PI in UL sponsored Clinical Trials, or maybe a collaborating investigator in clinical trials or other Health Research sponsored by external institutes.

1.3.10 Data Controller:

A data controller is defined in the UL Data Protection Policy as 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. Obligations apply to data controllers in the context of health research as set out in the Health Research Regulations.

1.3.11 Data Processor:

A data processor is defined in the UL Data Protection Policy as the natural or legal person, public authority, agency, or other body that processes personal data on behalf of a data controller.

1.3.12 Funder:

The funder is the organisation assessing the scientific quality of the research proposed and providing funding to facilitate the conduct of the proposed study.

1.3.13 Research Site:

The research site is a facility or location (e.g., hospital) where the research is being conducted. This includes:

- the organisation or organisations where the research is taking place, and/or,
- the organisation whose service users, patients or staff are involved in the research and/or
- the organisation that provides research staff, primary data, infrastructure, or premises to facilitate the research.

When research is taking place across academic Clinical Research Facilities/Centres (CRFs/Cs) and hospitals, the associated hospital would generally be the research site.

1.3.14 Research site responsible officer:

Where studies and/or research involves an external site (e.g., HSE facility) an employee of such a site (i.e., research site responsible officer) should be involved. The level of involvement will depend on the nature of the research study and the responsibilities and requirements placed on such an employee of the site and will be set out under an agreement between the University and external site. The research site responsible officer could be a co-PI, a collaborator, a site access supervisor, or a provider of access to data. Regardless of the level of involvement, the external site will ensure that, at a minimum, the research taking place at the site is conducted in a manner that complies with the requirements of the HSE Research Governance Framework and with any relevant local

protocols, and HSE policies. The Principal Investigator must be an employee of the HSE or funded organisations if insurance is to be provided by the State Claims Agency (SCA) scheme. For all other scenarios, additional insurance and indemnity cover certificates will have to be provided.

1.3.15 Health Research Oversight Committee (HROC):

The scope of the HROC is to deliver host institutional oversight of all health research. It is also responsible for making Sponsor decisions in the case of regulated clinical trials. The HROC would review Sponsor applications and provide advice on Sponsor matters. In the case of regulated clinical trials, the HROC also reviews ongoing clinical trials and ensures that they progress as planned or any plan for deviation is appropriate. The HROC may escalate decisions relating to very high-risk studies or reports of patent harm to the institutional function responsible for managing institutional risks. **See appendix 1 for terms of reference.**

1.3.16 Health Research Reporting Officer (HRRO):

Engages with research project development and advises on the preparation of health research proposals/plans. Risk management/assessment of research projects and engagement with HROC as appropriate in the management and oversight of health research activity. The Health Research Reporting Officer is contactable via health.research@ul.ie.

2 Context

2.1 Legal and Regulatory Context

The health research covered by this policy is governed by Irish and EU legislation and must be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki⁴ and that are consistent with Good Clinical Practice (GCP)⁵. Further, the Health Research Regulations also govern certain aspects of health research practice, not limited to but including in particular data protection and privacy.

In addition, research relating to regulated clinical trials are governed by Regulation (EU) No. 536/2014 on Clinical Trials on Medicinal Products for Human Use.

This Regulation is directly implemented into Irish legislation and is directly applicable to all stakeholders referenced. However, national legislation is required to deal with matters relevant to an individual Member States. The following Statutory Instruments came into effect in Ireland on 4 February 2022:

- S.I. No. 40/2022 – European Union (Clinical Trials on Medicinal Products for Human Use) Regulations 2022, implementing the CTR, and setting out the responsibilities of each of the stakeholders, and the powers of the HPRA at national level; and
- S.I. No. 41/2022 – European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022, establishing the National Office for Research Ethics Committees ('National Office') and the National

⁴ World Medical Association (2013), *Declaration of Helsinki, ethical principles for medical research involving human subjects*. [online] Available at <https://www.wma.net/policies-post/wmadeclaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [Accessed 17.02.22]

⁵ European Medicines Agency (2016) *Guideline for good clinical practice E6 (R2)* Available at <https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice> [Accessed 17.02.22]

- Research Ethics Committees for clinical trials; -
- S.I. No 43 of 2022 – Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022, amending the Medicinal Product (Control of Manufacture), Regulations 2007 (S.I. No 539/2007).

3 Policy Statements

3.1 Principles that apply to all health research categories

3.1.1 Safety

The rights, safety and well-being of the individual prevail over the interests of science and society. For clinical trials the available non-clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the ethically approved protocol for the clinical trial.

3.1.2 Competence

All people involved in managing and conducting a research project are qualified by education, training and experience to perform their tasks under the supervision of a suitably qualified person.

3.1.3 Ethics, Research Integrity and Good Research Practice

Health research is conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with Good Clinical Practice, Research Integrity Principles, and the applicable regulatory requirements(s). Further, research activity should be undertaken in alignment with relevant University policy on data protection, records management, conflicts of interest and intellectual property among others.

3.1.4 Integrity, Quality and Transparency

Research is designed, reviewed, managed, and undertaken in a way that ensures integrity, quality and transparency.

3.1.5 Governance, Risk, Compliance and Data Management

Before health research is initiated, foreseeable risks should be weighed against the anticipated benefit for the individual subject and/or society. For clinical trials, a health research intervention should only be initiated if the anticipated benefits justify the risks.

Research which meets the definition of health research in the Health Research Regulations must have received the relevant ethics committee approvals (Faculty or HSE), the UL Health Research Oversight Committee and any other relevant body approval prior to commencement.

Where relevant, the medical care given to, and medical decisions made on behalf of, subjects will be the responsibility of a qualified clinician (physician, nurse, dentist, physiotherapist, dietician).

Further, adherence to good data management/protection principles and cognisance of

relevant University policy should be maintained from the outset of the research activity and throughout. For clinical trial-related research all governance requirements for clinical trials must be adhered to as set out in relevant grant agreements.

The Health Research Regulations govern the use of personal data for health research purposes. These regulations ensure that health research in Ireland is conducted using best practice principles of information governance in line with GDPR requirements. The regulations protect the rights of participants while at the same time promoting and facilitating the conduct of high-quality research in the public interest. Along with the submission of a researcher's Research Ethics application, it will be possible that a Data Protection Impact Assessment will be required to be completed. This should be done in line with University Data Protection policy and associated processes.

3.1.6 *Public Patient Involvement*

Where relevant and appropriate, patients, service users and the public should be involved in the design, management, conduct and dissemination of health research.

3.1.7 *Study protocol*

The design and procedure of the research are clearly described and justified in a research proposal or protocol (for clinical trials), where applicable conforming to a standard template and /or specified contents. The research is conducted in compliance with institutionally approved protocols which shall be set out and agreed under the relevant research agreement between the University and third part(y/ies). Such a protocol would describe the objective(s), design, methodology, statistical considerations, and organisation of relevant research. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

For clinical trial-related research the protocol means a document that describes the objectives, design, methodology, statistical considerations, and organisation of a clinical trial. The term 'protocol' encompasses successive versions of the protocol and protocol modifications are recorded.

3.1.8 *Legality*

The researchers and Sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research as appropriate, in support of ensuring the rigour and transparency of UL health research.

3.1.9 *Information about the Research*

Information about clinical research projects (other than those for educational purposes) is made publicly available before they start where possible (unless a deferral is agreed by or on behalf of the relevant research ethics committee). Clinical trial-related research is usually made available on a clinical trials repository such as clinicaltrials.gov in line with the requirements of the grant agreement.

3.1.10 *Accessible findings*

Research findings should be managed and disseminated in a manner which adheres to FAIR data principles; data should be findable, accessible, interoperable, and reusable. Research findings should be made available in a timely manner, in compliance with any

applicable regulatory standards, i.e., legal requirements or expectations of regulators and funders. In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, should be made available to those who participated.

3.1.11 Choice and consent

Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' consent is required, it is voluntary, informed, explicit and granular. Where consent is refused or withdrawn, this is done without reprisal. In all cases, participation in research activity will be governed by the stipulations of the Health Research Regulations.

3.1.12 Insurance and Indemnity

Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project. Researchers should ensure that they have engaged with the University's resources on insurance and indemnity in the planning and implementation of their research activity as appropriate.

3.1.13 Compliance

Along with 3.1.8 above, compliance with this policy and associated processes/guidance will serve to support the rigour, transparency, and quality of UL Health Research as well as facilitating the monitoring and oversight of said research.

However, in situations in which compliance with this policy is found to have been breached, sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual, or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

3.1.14 Justified Intervention

Where relevant (normally clinical trial-related research only) the intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research).

3.1.15 Ongoing Provision of Treatment

The research proposal or protocol and the participant information sheet explain the special arrangements, if any, after the research intervention period has ended (e.g., continuing or changing the treatment, care or other services that were introduced for the purposes of the research).

3.1.16 Integrity of the Treatment and/or Intervention Record

All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the

confidentiality of records of the participants remains protected. Relevant data protection and records management governance principles and policies should be adhered to in this regard, as elsewhere in this policy.

3.1.17 Duty of Care

The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care professional retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment, care or other services. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.

4 Related Procedures for Health Research

The policy identifies clear lines of organisational, institutional, and individual responsibilities and accountability to protect staff and research participants, enhance ethical and scientific quality and promote good standards of practice for health research. Approval for the undertaking of health research at UL (including as Sponsor in the case of Regulated Clinical Trials and unregulated) is a multi-step process with final approval dependent on completion of all steps as detailed below.

4.1 Pre Award (funded)

All researchers must register their intended research in RPAS (Research Project Approval System). As part of this registration, the PI/Lead Researcher shall document (via checkbox) if the intended research is Health Research.

On a weekly basis, the HRRO shall download a report from RPAS and screen for newly registered intended 'Health Research'. Where such research has been identified, it shall be noted and reviewed by the HRRO. Evidence of reviews shall be stored on the Health Research Teams Site (<https://ulcampus.sharepoint.com/sites/ULHealth.Research>). The HRRO shall communicate any (e.g. ethics, DPIA, HROC etc.) and communicate any pre-identified risks associated with the project. The HRRO shall support the funding officer and PI during the pre-award stage as required. Once successful notification of funding is achieved, the PI shall immediately engage in the Health Research Oversight and Governance Pathway as per step 4.3 of this policy.

4.2 Pre-approval (unfunded)

Where members of the University community engage in unfunded health research (including FYP and Masters projects. Researchers shall ensure they have departmental approval to proceed with the intended research. The Lead Researcher shall then engage in the Health Research Oversight and Governance Pathway as per step 4.3 of this policy.

4.3 Health Research Oversight and Governance Pathway (see figure 1 for pathway diagram. For the purpose of this pathway, the terms PI and Lead Researcher are synonymous).

Step 1: For all health research which falls under the Health Research Regulations, and the categories listed in 1.1, the PI must prepare a First Contact Questionnaire which incorporates a risk checks, data protection and insurance checks and submit to the Health Research Reporting Officer (health.research@ul.ie). *Note: contact the Health Research Reporting Officer for the latest version of the First Contact Questionnaire or access through SharePoint (<https://forms.office.com/e/FqfJDULfXT>).*

Step 2: Once all the appropriate detail has been provided to the Health Research Reporting Officer (HRRO) by the PI through the completion of the First Contact Questionnaire, the HRRO will review the application for completeness (finance/insurance/identification of Clinical Research support required/data sharing agreement in place/in progress if required) and conduct a classification-based risk assessment. The study will be classified as minor, moderate, or serious or extreme risk, in line with current UL Risk Management governance documents. All studies in which fall under the definition of medicinal product or medical device clinical trial will be considered at least serious risk by default.

Step 3: Studies categorised as low risk will be directed to proceed to ethics approval and regulatory approval (where applicable).

Research ethics approval shall be governed by appropriate institutional governance documents and National Office for Research Ethics Committees; in most cases (see 4.3) research ethics approval will be sought from and approved by HSE-affiliated Research Ethics Committees.

Step 4: Studies categorised as medium or high risk will be submitted by the PI to the Health Research Oversight Committee via the HRRO for evaluation. In cases where a funding application for a relevant study requires the signature of the Vice President for Research before submission, permission to proceed to research ethics application stage⁶ must be obtained from the HROC first. *See appendix 1 for terms of reference of Health Research Oversight Committee.*

Step 5: The Health Research Oversight Committee will review the application and take a decision to Sponsor and deliver institutional oversight of the research. The Committee will determine whether the study is denied, approved or further information is required.

Approval denied: such decisions may be appealed by the PI per the process described below.

Approval granted: the PI may progress to the relevant ethics committee(s) and progress regulatory approvals (as required).

Further information: the committee may seek additional information for the application to be further assessed by the committee for a final decision.

For all applications, the advice and decision of the Committee will be documented, and a report issued to the PI to enable them to process to the next step.

⁶ In exceptional circumstances and only with permission from the HRRO, the researcher may apply for ethics in parallel to the HROC process.

Appeals Process

In cases where an application is denied, a PI may appeal the decision of the HROC in writing to the Vice President for Research (VPR), within ten (10) working days of being notified of the decision to deny. The VPR will acknowledge receipt of the appeal, where practicable, within five (5) working days of receipt. The VPR will consider the documented decision of the Committee and the grounds stated by the applicant on which the appeal is based and will have access to all relevant material related to the application in question. Following their consideration, the VPR will issue a report to the HROC and PI making one of two possible directions: The appeal should not be upheld, and the original decision of the HROC should stand, or; the HROC should reconsider the application considering the stated grounds of the PI as submitted in the appeal. The VPR's report shall be issued, where practicable, within twenty (20) working days of receipt of appeal from the PI.

It should be noted that the HROC is empowered to deny approval to such applications after the VPR's review or request further information from the PI. Following such subsequent adjudication, the decision of the HROC is final.

Step 6: Studies categorised as moderate or serious risk and in receipt of Oversight Committee approval proceed to ethics approval and relevant regulatory approval (where applicable).

Step 7: As appropriate, evidence of research ethics approval, full risk management plan, insurance cover, regulatory approvals (where applicable), clinical trial agreement (where applicable), data sharing agreement are then submitted to the Health Research Reporting Officer.

Step 8: HRRO reviews all paperwork and when satisfied that the necessary evidence has been supplied will submit their review together with the relevant paperwork including the Clinical Trial Agreement (where applicable) to the Oversight Committee.

Step 9: Oversight committee will confirm study approval. In the case of serious-risk studies, the Committee will appoint a Quality Manager to the study. In case of clinical trials, this shall be the Quality and Regulatory Affairs Officer located within the CRSU, for all other research a person of suitable expertise will be assigned.

Step 10: PI progresses to Hospital/CHO governance approval (where relevant) and submits the confirmation of study approval of the Oversight Committee.

Step 11: For high-risk studies, the appointed Quality Manager will review study documentation and conduct a site visit (if applicable), the PI will subsequently be issued approval to begin recruitment. For clinical trials conducted within the CRSU, approval for recruitment will be completed via the study 'green lighting' process.

Step 12: The Quality Manager identified in Step 9 will conduct monitoring reviews on a 6-monthly basis and issue their report to the Oversight Committee.

Step 13: The PI, in consultation with the individual identified in step 9, will conduct the close-out review of the study and issue their report to the Oversight Committee. The PI will submit their completion report to the relevant ethics committee.

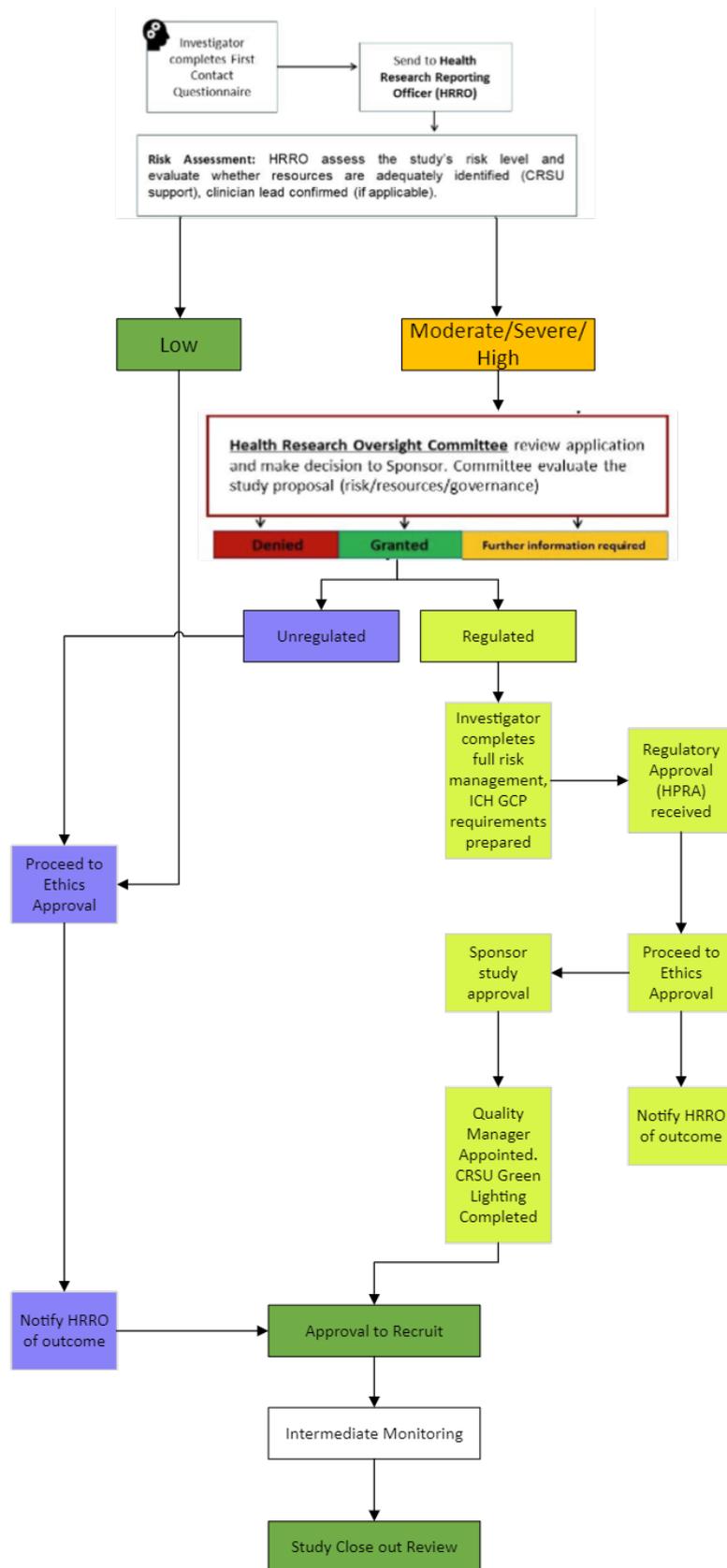
4.4 Collaboration Arrangements

In the case of collaborative research with an external organisation (e.g., a hospital, community care or voluntary agency), an employee of the external research site (i.e., the research site responsible officer) should be involved in the research study. Where a UL employee is a joint appointment with the research site, they must decide which organisations they will represent for the entire duration of the study and that determination is confirmed in writing to the HROC and the research site before the study commences. Any such activity (such as access to patients, patient data and materials) requires that a written agreement is entered into between the hospital and UL including a data sharing agreement before the research commences. Hospital employees with no contractual relationship with the academic institution and leading research under the auspices or in the name of the academic institution should be in possession of a research affiliation (e.g., adjunct role) or other contract issued by the academic institution and agreed by the investigator and the employer hospital. They must also work with a named UL PI to fulfil a similar role for UL as the external research site responsible officer.

4.5 Ethics Approval (including for Multi-Site Studies)

All health research must have the necessary ethical approval in place before the research commences. Such approval will be sought from the relevant Faculty REC, relevant Health Service Executive (HSE)-affiliated Research Ethics Committee, or National Research Ethics Committee as appropriate. In situations where research activity is being undertaken across multiple sites (e.g., across separate hospitals, HEIs, etc.) then ethical approval as obtained should be demonstrated to each separate institutional research ethics governance body per relevant institutional policy. The National Office for Research Ethics Committees was established in 2020 and is currently implementing a roadmap of transition to a national system of research ethics review for health research including or regulated remits including clinical trials of medicinal products and clinical investigations of medical devices. PIs should familiarise themselves with this national office and the emerging national research ethics committees (NRECs).

Figure 1 University of Limerick Health Research Oversight and Governance Pathway



4.5.1 **Monitoring and Review**

Review process: In the case of funded research, monitoring reviews may be mandated by the terms of the funding. In this instance, it is recommended that the Quality and Regulatory Affairs Officer is included in these reviews in order to ensure connectivity to the Sponsor oversight committee.

Regulated and non-regulated Clinical trials: Review reports for regulated health research should include updates on the overall study recruitment status, safety reports, protocol amendments, major protocol deviations as managed per previous stipulations in this policy, updates on changes to site personnel, risk assessment status and adherence to financial target and any other information required by the funder.

Close-out review: involves but is not limited to, PI submission of final report to Oversight Committee(s) via the Health Research Reporting Officer, PI submits close-out review to Ethics Committee(s) and update clinicaltrials.gov registry (where applicable).

5 **Related Documents**

Including but not limited to:

- University of Limerick Code of Conduct for Employees
- University of Limerick Data Protection Policy
- University of Limerick Research Integrity Policy
- University of Limerick Procedure for Managing Allegations of Misconduct in Research
- Corporate Enabling of Clinical Research Report, Clinical Research Development Initiative
- Health Research Oversight Committee terms of reference
- Clinical Research Procedure for UL Sponsored Clinical Trials
- University of Limerick Guidelines on Insurance Cover for Research

6 **Document Control**

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Appendix 1 Health Research Oversight Committee (HROC) Terms of reference

Health Research oversight on behalf of the University of Limerick will be undertaken by the Health Research Oversight Committee (HROC). The HROC will report to the University Research Committee (URC) chaired by the VPR.

Remit:

The Committee will support the Signatory Official (Vice President Research), to take host institution/Sponsor decisions in the case of Regulated Clinical Trials and deliver institutional oversight of clinical research.

The Committee will review ongoing health research on behalf of the Host Institution and ensure that the studies progress as planned or any plan for deviation is appropriate.

Membership:

- The Director, Health Research Institute (Chair);
- Director of Research Support Services (or alternate as nominated by the Director RSS)
- Manager of the Clinical Research Support Unit
- Two members drawn from the employees of University of Limerick and/or University Hospitals Limerick who are engaged in, or who have experience undertaking health research; nominated by Vice President Research.
- Risk Management Officer
- Research Contracts Solicitor
- Corporate Secretary or nominee.
- University Insurance Administrator.
- Research Governance Officer.
- Health Research Reporting Officer (*ex officio*)

Administrative support of the committee will be provided by the Health Research Institute. Further external expertise may be sought by the committee when necessary.

Conduct of Business:

The Committee will meet at least four times per year for strategic and/or policy development purposes but will establish an approval schedule for considering applications on a monthly basis, to support research activity and practice. Approvals of such applications will be granted electronically where necessary, through communication by the Chair to the committee membership. The Chair will be empowered to call extraordinary meetings outside of the established schedule as appropriate. The formal meeting schedule for each year will be established on an annual basis.

Quorum:

A formal meeting of the committee quorate when at least a third of the membership, including the Chair, are present.

Conflict of Interest:

All members of the committee shall be required to declare any conflict of interest in relation to research presented for review.