South Infirmary Victoria University Hospital

Policy on Health Research /Clinical Trials/Audits Requiring Access to Patient Information/Medical Records

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1. Policy Statement

Health Research/Clinical Trials/Audit

Staff of SIVUH who are involved in health research, clinical trials and audit will be guided by this policy. The SIVUH is a teaching hospital, we work closely with UCC and other third level institutions. All students of health related disciplines carrying out research or audit under SIVUH Clinical Staff will adhere to this policy. All clinical trials and health research projects must be approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals or equivalent and the SIVUH Board of Directors (where applicable). Each clinical trial and health research project is thoroughly reviewed before approval is granted. Ethical guidelines provide a standard of professional practice which is intended to embody the ideal which regulate each professional body's conduct. Ethical guidelines provide protection and contribute to safeguarding the dignity, rights, safety and well being of all actual or potential research participants (WHO 2002). Clinical audit is an essential part of clinical governance and the quality improvement process to improve patient care and outcomes.

2. Purpose

- To outline what is health research, clinical trials and audit.
- To outline the processes and permissions required before commencing health research, clinical trial or audit in SIVUH, in relation to SIVUH activities or using SIVUH data.
- To provide guidelines for SIVUH staff and students of health related disciplines on how to obtain approval for clinical trials, health research and audit in the SIVUH.

3. Scope

This policy applies to all staff in SIVUH and to anyone conducting research or audit on SIVUH activities or using SIVUH data or under supervision of SIVUH employees.

4. Legislation/Related Policies

Data Protection Act 2018
Data Protection Act (Health Research Regulations) 2018
WMA Declaration of Helsinki- Ethical Principles for Medical research involving human subjects
European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004

5. Glossary of Terms and Definitions

Health research is defined in the Health Research Regulations 2018 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

Clinical trial means any investigation in human subjects, other than a non-interventional trial, intended -

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medicinal products, or

(b) to identify any adverse reactions to one or more such investigational medicinal products, or

(c) to study absorption, distribution, metabolism and excretion of one or more such investigational medicinal products, or

(d) to discover, verify, identify or study any combination of the matters referred to at subparagraphs (a), (b), and (c), with the object of ascertaining the safety or efficacy of such products, or both

Audit is the systematic review and evaluation of current practice against research based standards with a view to improving clinical care for service users.

CREC Cork- Clinical Research Ethics Committee Cork

HPRA- Health Products Regulatory Agency

6. Roles and Responsibilities

It is the responsibility of all managers to ensure all staff are aware and comply with this policy.
It is the responsibility of all relevant employees to read and adhere to this policy.
It is the responsibility of all Principle Investigators to ensure Co-Investigators are aware of this policy.

7. Determining what is health research, clinical trial, audit

It is accepted that the distinction between research, clinical audit, service evaluation and training can be a fine one. It is for the principal investigator along with the data controller to determine whether a particular processing activity is health research or clinical audit or something else and to be able to justify that view having regard to the individual circumstances involved. Any queries in relation to determining what is research, clinical trial, clinical audit, retrospective chart review or service evaluation should be directed to dpo@sivuh.ie

8. Guideline for Health Research

Health Research must have been reviewed and approved by the CREC Cork Research Ethics Committee or equivalent as applicable prior to approval by SIVUH.

When seeking access to patient information for health research the investigator must adhere to the following, as outlined on appendix 1.

Send a copy of the CREC application and approval, including where applicable; the research proposal document, information about the main research student, the research supervisor, a copy of the consent form, information leaflet to be given to patients and the data collection sheet to the Quality & Risk Department by emailing risk.management@sivuh.ie

The documentation will be reviewed by the Data Protection Officer (DPO) to check compliance with the Data Protection Act (Health Research Regulations) 2018. The documentation will be reviewed by the Hospital insurers as applicable. Following this the proposal will be sent to the CEO's office to be added to the agenda of the next Board of Directors meeting. Documentation must be received at least one week in advance of the Board of Directors meeting to be included on the agenda. Board of Directors meet once per month, generally on the last Monday of each month.

Once a decision has been made by the Board of Directors, the applicant will receive notification in writing as to whether or not the research proposed has been approved.

A database of all research project applications in kept on the Quality Management System.

All health research must meet the requirements of the Data Protection Act (Health Research Regulations) 2018.

All applications to the Health Research Consent Declaration Committee must be reviewed by the Data Protection Officer before submission. Any queries should be emailed to dpo@sivuh.ie.

All research and published items e.g. conferences, peer review papers etc. must be submitted to the CEO's office on request for inclusion in the SIVUH Annual Report.

9. Guideline for Clinical Trials

Before a medicinal product can be authorised for use, it must go through the clinical trials process to ensure that it is safe and effective and also that the quality of the product is sufficient.

The HPRA is responsible for the assessment of clinical trials with medicinal products conducted in Ireland.

Clinical trials begin with small studies in a controlled population of volunteers or patients and, as data are gathered, expand to large scale studies in patients. These large scale studies will often investigate the new product and the currently used treatment to see how these two compare. As information is obtained, larger numbers of patients are exposed to the new product and safety data can be collected showing the safety of the product in the intended patient population. Information on the quality of the product and its non-clinical safety will have been obtained before the clinical trial program commences.

Legislation

Clinical trials in Ireland are currently governed by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004.

A new Clinical Trials Regulation (EU) No 536/2014 was adopted on 16 April 2014, and implementation is planned to take place in 2021. When implemented, Directive 2001/20/EC and associated laws will be repealed.

The key features of the new Regulation are

- Identical rules for conducting clinical trials throughout the EU.
- Increase in the efficiency in approval process for clinical trials.
- Single submission & approval of multinational clinical trial applications through an EU 'Clinical Trial portal and database'.
- A harmonised procedure for assessment by member states, divided in two parts:
- Strictly defined deadlines for assessment.
- Involvement of the ethics committees in the assessment procedure

According to Regulation 10 of the Regulations, a trial may only be started or conducted in Ireland if:

- an ethics committee has issued a favourable opinion;
- HPRA has granted an authorisation;
- a sponsor, or legal representative of the sponsor, is established within the European Economic Area

Making an Application for a Clinical Trial at SIVUH

All relevant documentation as outlined below must be sent to the Quality & Risk Department by emailing risk.management@sivuh.ie as per appendix 1

- Research proposal
- Clinical Supervisor details
- Cork Regional Ethics Committee (CREC) application and approval (or equivalent) (if applicable)
- Data Collection Methodology
- Confirmation of liability insurance
- Copy of consent forms
- Copy of Information leaflet for patients
- HRPA authorisation

The documentation once reviewed by DPO and the Hospital Insurers will be sent to the CEO's office to be added to the agenda of the next Board of Directors meeting. Documentation must be received at least one week in advance of the Board of Directors meeting to be included on the agenda. Board of Directors meet once per month, generally on the last Monday of each month.

Once a decision has been made by the Board of Directors, the applicant will receive notification in writing as to whether or not the Clinical Trial proposed has been approved. If approved the Drugs & Therapeutics Committee, SIVUH will be notified.

10. Guideline for Clinical Audits

Clinical Audit is a cyclical process which can be outlined in five stages:

1. Planning for audit
2. Standard/criteria selection
3. Measuring performance
4. Making improvements
5. Sustaining improvements

Each stage of the clinical audit cycle must be undertaken to ensure that an audit is systematic and successful. Key steps include; involving stakeholders, determining the audit topic and planning the delivery of audit fieldwork.

For a clinical audit to be delivered effectively, all staff should be appropriately trained and briefed with regard to their role. All team members must have:

- A basic understanding of clinical audit.
- An understanding of and commitment to the plans and objectives of the audit.
- An understanding of what is expected of the audit team – this needs to be clarified at the outset and may be expressed in a terms of reference document.

For all audits requiring access to patient data, the process outlined in Appendix 2 must be followed.

All clinical audits must be notified to the Quality and Risk Department in advance. These audits are reviewed by the DPO to ensure they are in keeping with the Data Protection Act (Health Research Regulations) 2018.

Medical or other students conducting audits as part of their course work, must submit an Audit Application Form as in Appendix 3.

10. Guideline for Retrospective Chart Reviews

Retrospective Chart Review Studies: The current position agreed by the Department of Health with the Data Protection Commissioner pending the making of a formal amendment which is expected in 2020 follows:

The requirement for explicit consent in the Health Research Regulations will not apply in relation to a retrospective chart review study to be carried out by a controller and approved by a research ethics committee where the REC states in its approval that the required assessment carried out by the controller of the data protection implications of the processing of the personal data being processed in the research does not indicate a high risk to the rights and freedoms of data subjects.

The above applies only where the retrospective chart review study is carried out on behalf of the controller by-

(a) a health practitioner employed by the controller or a person studying to be a health practitioner who is under the direction and control of the controller, or(b) an employee of the controller (other than a health practitioner in subparagraph (a)) who, in the course of his or her duties for the controller, would ordinarily have access to the personal data of individual held by the controller that was obtained for the provision of health care to those individuals.

Where the controller intends to carry out a retrospective chart review study, the arrangements by the controller to ensure that personal data are processed in a transparent manner must include appropriate notices and posters on display in public areas of the data controller's organisation stating that-

(a) personal data collected by the controller for the provision of health care to an individual may be used but not disclosed to another person by the controller for the study,
(b) any findings from a study that are published shall not identify an individual whose personal data was used in the study, and
(c) a study will be reviewed and approved by a research ethics committee prior to commencement of the study.

A 'retrospective chart review study' means a health research study carried out by a controller on personal data for the purposes of health research that has already been obtained by that controller for the purposes of the provision of health care to an individual by the controller.

10.1 Retrospective Chart Reviews carried out for research purposes

As per appendix 1, for a retrospective chart review carried out for research purposes the following documentation must be sent to the Quality & Risk Department by emailing risk.management@sivuh.ie

- Research proposal
- Clinical Supervisor details
- Cork Regional Ethics Committee (CREC) application and approval (or equivalent) (if applicable)
- Data Collection Methodology

10.2 Retrospective chart reviews that are undertaken for the purposes of clinical audit or service evaluation or training

Retrospective chart reviews that are undertaken for the purposes of a) clinical audit, b) service evaluation or c) training do not fall under the remit of the Health Research Regulations 2018.

Retrospective chart reviews carried out for the purposes of clinical audit must be notified to the Quality & Risk Management Department. All Medical and other students carrying out retrospective chart reviews as an audit must submit the Audit Application form as per Appendix 3.

11. Implementation Plan

The sequence of events for this procedure is as follows:

- Communicate and make the SOP available to relevant SIVUH personnel
- Monitor, review and adjust as necessary

12. Revision and Audit

Every three years and as necessary

13. Appendices

1. Flowchart for Research and Clinical Trials
2. Audit Flowchart
3. Audit Application Form

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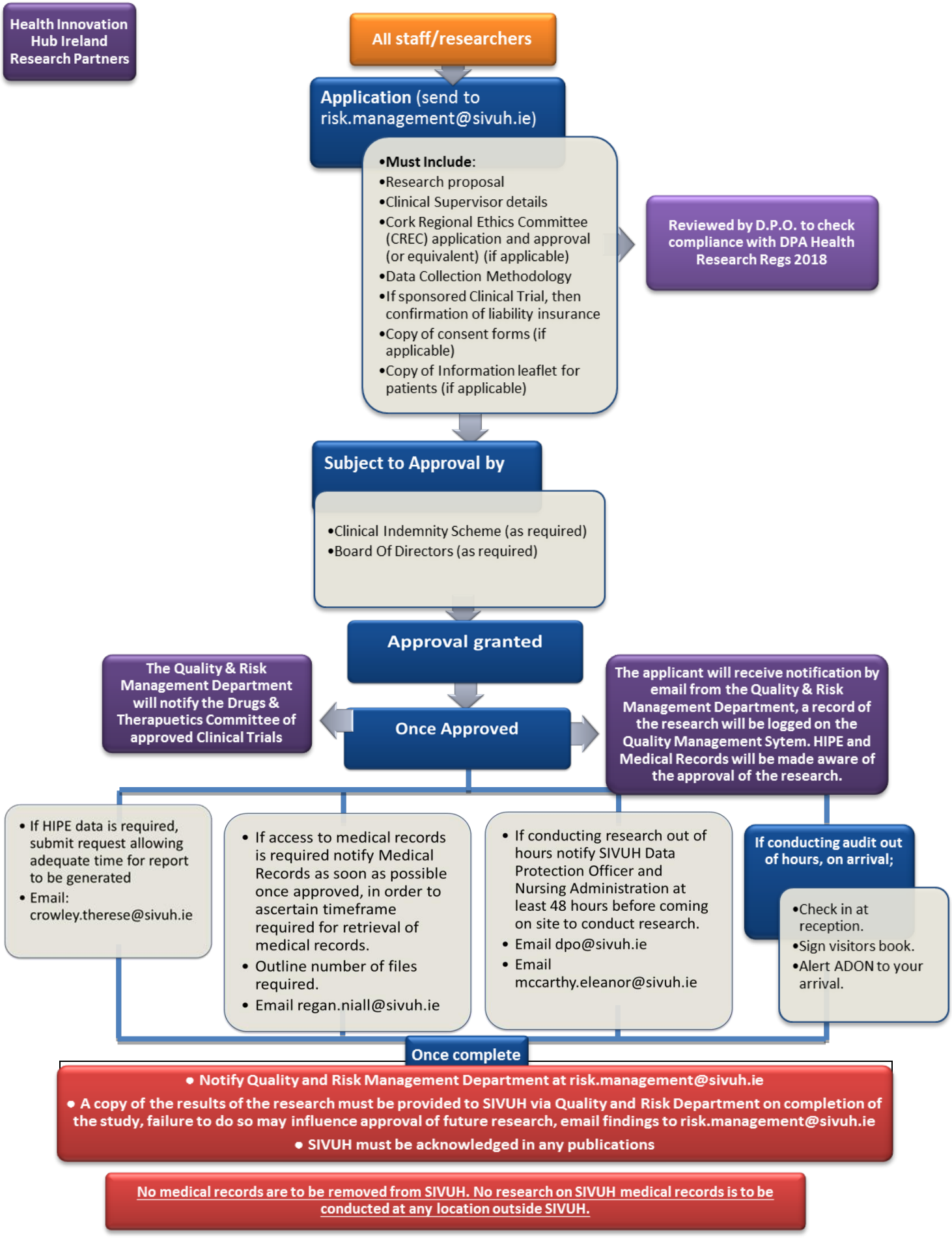
Appendix 1: Flowchart for Research Studies and Clinical Trials requiring access to Patient Information



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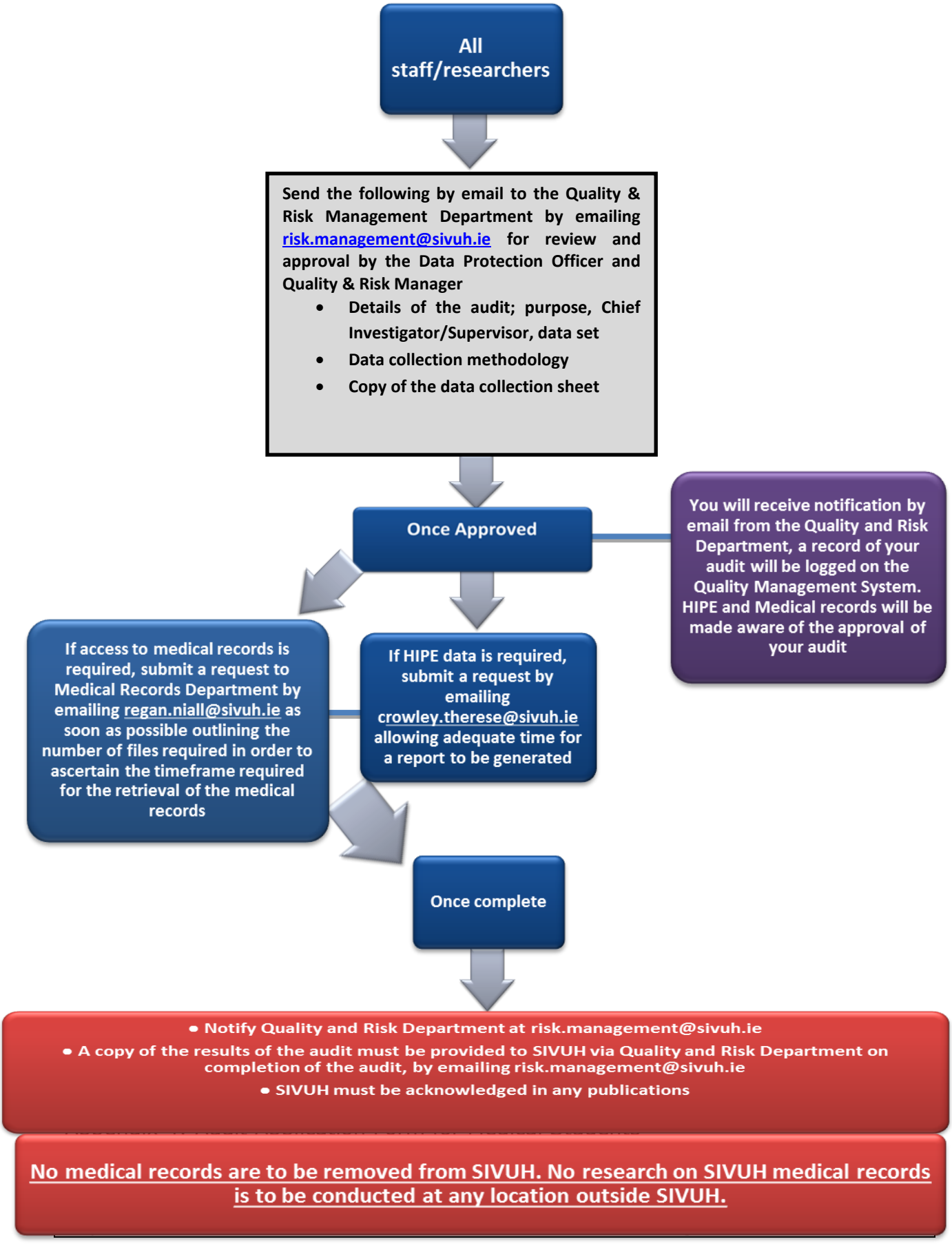
Appendix 2: Audits requiring access to Patient Information



SIVUH Audit Proposal Form for Medical Students/Healthcare Students

Please complete section 1 in full (where a question is not applicable please insert n/a). Forward to completed form to Data Protection Officer by email to dpo@sivuh.ie Uncompleted forms will be returned. Please allow at least one week for review by DPO. You will be notified by email if the audit is approved or if additional information is required.

Section 1

A. Study and Investigators Details

Chief Investigator:

Contact details:

Study Name/Title:

Study Sites:

Co-Investigator Details:

Study Description:

Details of the Purpose of the Study:

Details of the Procedures to which humans will be subjected:

Potential benefits to subjects and/or society:

Potential risks to subjects and precautions taken to minimise risk:

Alternative procedures, if any, available to subjects:

2. Information on Patients/Participants/Audit

What is the total number of Patients/Participants to be studied?

How will the subjects be chosen (inclusion/exclusion criteria)?

How many charts will be reviewed if any?

Please tick additional reasons (if any) for carrying out this audit:

Patient centeredness	☐	Professional development	☐
High volume activity	☐	Service improvement	☐
High risk activity	☐	Re-audit	☐
High cost activity	☐	Risk management	☐
Policy/guideline recommendation	☐	Specify if: Local ☐ National ☐	

Other, please state:

This audit must satisfy all of the following:

- It should aim to improve patient care.
- It should be multidisciplinary where possible.
- It should have support within your department, including a willingness to implement changes.

The audit must meet the requirements of Data Protection legislation- Data Protection Act 2018, Data Protection Health Research Regulations 2018 and General Data Protection Regulations 2018.

By submitting this proposal you are committing to handling all personal and special category data processed for this audit in line with data protection requirements.

Have all the potential stakeholders been identified? Yes ☐ No ☐

List relevant stakeholders by name	*Are these stakeholders aware of this audit?*
	Yes ☐ No ☐
	Yes ☐ No ☐
	Yes ☐ No ☐
	Yes ☐ No ☐

Has a literature search been undertaken?	Yes ☐ No ☐
Length of time to audit and target completion date:	
I confirm that all data collection/storage will comply with **SIVUH** ICT/Data Protection policies:	Yes ☐

Section 2

Quality & Risk Department Review

Received by		Date	
Reviewed by Quality & Risk Manager		Date	
Reviewed by Data Protection Officer		Date	
Added to Quality Management System		Date	
Audit No			
Sent to AON/CIS if necessary		Date	
Notification of Approval to Audit Lead		Date	