Appendix 1 OLHC&S Research Approval Form*

*(**NB – form must be typed, not handwritten**)

Name of research study	
Sponsor of research study	
Name of Chief Investigator (CI)	
Email address of CI	
Name of OLHC&S Co-Investigator	
Email address of OLHC&S Co-Investigator	

Site of research:

Harold's Cross	Palliative Care Unit	Y/N
	Gerontology Unit	Y/N
	Rheumatology Unit	Y/N
Blackrock Hospice		Y/N
Wicklow Hospice		Y/N

Research participants:

Patients	Y/N
Carers	Y/N
Staff	Y/N

If staff, which group of staff_____

Number of participants to be recruited at OLHC&S	
Proposed start date at OLHC&S	
Proposed end date at OLHC&S	

Who will be identifying potential participants?	
Who will be consenting/recruiting participants?	

***To be returned to the Academic Secretary of the Academic Department of Palliative Medicine at OLH&CS: adpm@olh.ie / adunne@olh.ie**

Does the study involve use of additional resources* (at OLHC&S)?	Y/N
If yes, please give details	

*(Resources include staff time).

Is the study funded?	Y/N
If yes, please give details	

Please include copies of the following documentation (with version number/date written):

1.	Protocol	Y/N
2.	Participant Information Sheet	Y/N
3.	Participant Consent Form	Y/N
4.	Clinical Record Form/Research Study Questionnaire	Y/N
5.	Ethical Committee approval confirmation.	Y/N
6.	Other relevant approvals	Y/N

Incomplete submissions will not be reviewed.

I confirm that the information in this form is accurate, and will inform OLHC&S of any changes to the study methodology/documentation.

I confirm that I will abide by any conditions imposed as part of the OLHC&S approval process

In confirm that I will keep the Academic Department of Palliative Medicine updated on the progress of the study, and provide them with electronic copies of all journal articles arising from the study.

_____ _____

Signature Date

_____

Name

Appendix 2 OLH&CS Data Protection Confirmation Form

Researcher Name(s):	
Title of Research:	

1. Governance

Ethical approval has been obtained	Yes No N/A
Details of any controller, in addition to OLH&CS, are included	Yes No N/A
Details of any processor involved are included	Yes No N/A
Data Processing Agreements are in place with any processors	Yes No N/A
Details of any person(s) providing funding is included	Yes No N/A
Details of who it is intended to share any personal data collected (including where it has been pseudonymised or anonymised) and has the purpose of such sharing.	Yes No N/A
Data protection training in law and practice has been completed by OLH&CS staff involved	Yes No N/A

2. Processes and Procedures

Data protection implications assessment has been completed	Yes No
If high risk indicated, a data protection impact assessment has been conducted	Yes No N/A
Measures to demonstrate data minimisation compliance in place	Yes No
Controls in place to limit access to personal data	Yes No
Controls to log whether/by whom personal data have been accessed	Yes No
Measures to protect the security of personal data in place	Yes No
Arrangements to anonymise, archive or destroy personal data on completion	Yes No
Technical/organisational measures to ensure processing carried out in accordance with the GDPR, together with processes for testing the effectiveness in place	Yes No
Arrangements to ensure personal data is processed transparently	Yes No
Explicit consent has been obtained from data subject in advance	Yes No
The consent form contains details of the rights and freedoms of the data subject in compliance with data protection regulations	Yes No

_____ _____

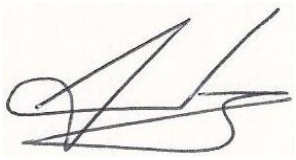
Signature Date

I confirm that the information provided here is true and accurate to the best of my knowledge. I confirm that I have read and agree to adhere to the policy in relation to Approval of Research and Research Funding in OLH&CS (ref OLH-GN 076 dated 01 May 2021).

I confirm that I have read and agree to adhere to the policy in relation to Data Projection (Ref OLH-GN 038) and I will ensure that my research is complaint with Data Protection Regulations.

_____ _____

Signature Date

POLICY TITLE	**Our Lady's Hospice and Care Services (OLH&CS) Research Approval Process**
AREA:	All clinical areas
REFERENCE NO:	OLH GN 076
AUTHOR:	Professor Andrew Davies (Professor of Palliative Medicine)
SIGNATURE:	 Date: 10/05/2021
CO-SIGNATORY:	Professor Michael Connolly (Professor of Clinical Nursing)  Date: 10/05/2021
APPROVED BY:	Education & Research Committee, Our Lady's Hospice, Harold's Cross.
EFFECTIVE FROM:	10/05/2021
NEXT REVIEW DATE:	10/05/2022

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Appendix 1 OLH&CS Research Approval Form
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1. Policy

OLH&CS is committed to promoting evidence-based care, and facilitating multi-professional clinical research within its services.

The purpose of this document is to detail policy and procedure governing the approval of research studies within OLH&CS.

No research can be undertaken within OLH&CS unless there is prior ethical committee approval and approval from the OLH&CS Education & Research Committee.

Researchers should ensure that any other required approvals are also in place prior to the start of the study.

2. Scope

This policy applies to all research studies undertaken within OLH&CS, but does not apply to service evaluations or audits.

Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service.

Audit usually involves a quality improvement cycle that measures care against predetermined standards (benchmarking), takes specific actions to improve care and monitors ongoing sustained improvements to quality against agreed standards or benchmarks.

Research involves the attempt to extend the available knowledge by means of a systematically defensible process of enquiry.

Table 1 shows the main differences between service evaluation, audit and research. The following link provides a tool for determining whether or not a project constitutes a research project.

http://www.hra-decisiontools.org.uk/research/index.html

Table 1 Key criteria to consider when deciding whether your project is service evaluation, audit or research

	Service Evaluation	**Audit**	**Research**
Overall aim (intent)	To judge the quality of the current service	To measure clinical practice against a standard	To generate new knowledge/add to the body of knowledge
Initiated by	Service providers	Service providers	Researchers
Involves a new treatment	No	No	Sometimes
Randomisation	No	No	Sometimes
Allocates patients to treatment groups	No	No	Sometimes

3. Procedures

3.1 Submission process

Research in OLH&CS must align with the strategy, mission and vision of OLH&CS.

All research conducted at OLH&CS requires prior approval from the Education & Research Committee (a sub-committee of the Board of OLH&CS).

Individuals who wish to conduct research in OLH&CS must fully complete the OLH&CS Research Approval Form (Appendix A), and the Data Protection Compliance Form (Appendix B).

Supporting documentation (study protocol, participant information sheet, participant consent form, clinical record form/research study questionnaire, Ethical Committee approval, and other relevant approvals) must accompany the application. Incomplete applications will not be processed.

The researcher should submit the application & supporting documentation to the Academic Secretary in the Academic Department of Palliative Medicine (adpm@olh.ie).

3.2 Approval process

All applications are reviewed by the OLH&CS Education and Research Sub-Committee, which includes the CEO, the Director of Nursing, the Professor of Palliative Medicine and the Professor of Nursing.

Following review, applications may be

- Approved
- Approved subject to certain conditions
- Not approved

The decision of the Sub-Committee will be relayed to the researcher within two weeks of the relevant meeting. The Sub-Committee are unable to enter into further discussion about the decision, and approval for a study start is only valid for a period of six months. Studies which do not start within six months of approval will need to be re-assessed by the Sub-Committee.

3.3 Conducting Research

Individuals undertaking research in OLH&CS must have appropriate training (including GDPR training), and must conduct themselves professionally at all times. Failure to do so will be sufficient cause for termination of the study.

Research proposals approved by the Education & research Committee allows the researcher to proceed only with the research outlined; it is not an endorsement and does not compel any patient or staff member of OLH&CS to participate in the study.

Any proposed adjustments or amendments to the original research proposal must be approved by the Education & Research Committee before being implemented.

External researchers wishing to carry out research in OLH&CS will be required to have an appropriate internal co-applicant. If required, co-applicants can be sourced via the Professor of Palliative Medicine or Professor of Clinical Nursing.

3.4 Reporting Requirements

The researcher must submit an annual report to the Academic Department of Palliative Medicine, and a final report within three months of the end of the study. Failure to do so will be sufficient cause for termination of the study. These should be sent to the Academic Secretary of the Academic Department of Palliative Medicine at OLH&CS**:** adpm@olh.ie

3.5 Publication

OLH&CS should be acknowledged in all publications and it should be clear whether or not OLH&CS were the sponsors of the study. The researcher is expected to inform the Academic Department of Palliative Medicine of all outputs relating to the study (i.e. research presentations, journal articles), and

must provide an electronic copy of all journal articles. These should be sent to the Academic Secretary of the Academic Department of Palliative Medicine at OLH&CS**:** adpm@olh.ie

4. Personal and Organizational Rights

- Participation in research studies by patients, students, staff and volunteers of OLH&CS is voluntary.
- Informed consent is required from each participant.
- Anonymity of each participant must be preserved.
- Researchers must adhere to the Data Protection Policy of OLH&CS. The policy is available to access from the CEO's office or the OLH&CS Portal (Policy GN-038).

5. Evaluation and Review

This policy will be reviewed on or before the schedules review date. Any comments or suggestions to improve this policy may be sent at any time to the author or to the Academic Secretary of the Academic Department of Palliative Medicine.