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POLICY TITLE Approval of Research and Research Funding in Our Lady's Hospice & Care Services

AREA All areas

REFERENCE NO OLH GN 076

REVISION NO 03

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SIGNATURE Patricia Hallahan **date** 12 Oct 2017

EFFECTIVE FROM 1 March 2011

Reviewed & updated 1 Nov 2013 (01)
8 Jan 2016 (02)
12 Oct 2017 (03)

NEXT REVIEW DATE: 11 Oct 2019

Title Approval of Research and Research Funding in OLH&CS	Reference No OLH-GN 076
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Review date 11 Oct 2019	Page No Page 2 of 13

Contents

1. Policy	3
2. Scope	3
3. Definitions	4
4. Procedures	4
4.1 Submission of requests for approval	4
4.2. Research approval process	5
4.3. Research Funding	6
4.4. Conducting Research	6
4.5. Reporting Requirements	6
4.6 Publication	6
5. Personal and Organizational Rights	7
6. Evaluation and Review	7
7. References	8
Form No. 1: APPLICATION FOR RESEARCH APPROVAL	9
Form No. 2: APPLICATION FOR RESEARCH FUNDING	12

Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 3 of 13

1. Policy

Our Lady's Hospice & Care Services (OLH&CS) is committed to developing a culture and practice throughout the organisation that encourages enquiry and research at all levels in order to improve the care of patients and residents and which enhances both the quality of our education and the reputation of our organisation¹.

The purpose of this document is to detail policy and procedures governing the approval, funding and monitoring of research studies in OLH&CS.

All research conducted in OLH&CS will follow the procedures detailed here.

Research conducted here will not unduly affect the well-being of patients, residents, families, staff, volunteers, students or OLH&CS as an organisation.

All research conducted in OLH&CS requires approval from the Education & Research Committee, a sub-committee of the Board of OLH&CS.

This is not an ethics committee. Therefore, in addition to approval by the OLH&CS Education & Research Committee, clinical research requires prior ethical approval from St. Vincent's Healthcare Group Dublin, Ethics and Medical Committee or another such approved Research Ethics Committee.

2. Scope

This policy applies to all studies and data collection activities for research purposes (including clinical trials) which are carried out in OLH&CS or with patients, staff, students or volunteers of OLH&CS.

Research as defined in this policy includes:

- Clinical Research
- Non Clinical Research

It excludes clinical audit², service review and evaluation and performance management which do not require either ethical approval or approval from the Education & Research Committee and are therefore not covered in this policy.

However, if an audit may be published in future it should be defined as research and adhere to this policy.

¹ Our Lady's Hospice & Care Services Research Strategy 2015 – 2017

² Clinical Audit asks the question: Are we actually doing what we believe is the right thing, and in the right way? The term 'clinical audit' is defined as: 'a clinically led, quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and to act to improve care when standards are not met'. A Healthcare Audit Committee was established in OLH&CS in 2013 which registers proposals for audit activity and receives reports of completed audits and recommendations.

Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 4 of 13

Research conducted in other locations by staff (or others using OLH&CS resources) does not require approval by the Education & Research Committee. However information about such research must be communicated in advance to the OLH&CS Director of Education, Research and Training. Ideally this is done by cc at the time of submitting the request for approval to conduct research in the other location.

3. Definitions

- 3.1 **Research** is about obtaining new knowledge and finding out what treatments and actions are the most effective. Research tells us what we should be doing. Research studies including data collection activities, referred to in this policy are those studies that involve patients, residents, students and/or staff in activities conducted to obtain information, opinions, or attitudes through measurement means, such as clinical trials, surveys, questionnaires, interviews, interventions, tests, case studies or inventories.
- 3.2 **Clinical research** aims to advance medical knowledge by studying people, either through direct interaction or through the collection and analysis of blood, tissues, or other samples (NICHD, 2017)
- 3.3 **Non-clinical research** does not involve a particular person or group of people or use materials from humans that can be linked to a particular living person. The outcome of non-clinical research however, may impact on a person or group of persons. For example, it may include data gathered from staff opinion.
- 3.4 **Informed consent** means that prospective research participants are given as much information as might be needed to make an informed decision about whether or not they wish to participate in a study (Bryman, 2008). Consent is not a static once-off event and where patients are included, the concept of 'processual consent' (Cutcliffe and Ramcharan, 2001) may be appropriate.

It may be insufficient to take consent at the beginning of a study only. Where there are concerns over capacity and engagement (such as where patients may be cognitively impaired or in longitudinal studies), the researcher must include repeated measures to ensure fully informed consent is obtained.

Potential participants must never be under pressure to participate in research activities.

4. Procedures

4.1 Submission of requests for approval

Research in OLH&CS must align with the strategy of OLH&CS.

Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 5 of 13

All research conducted at OLH&CS requires 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 complete the Application for Research Approval (Form No 1) in full.

Supporting documentation (e.g. copies of survey forms, observation checklists, information and consent forms and evidence of ethical approval) must accompany the application. Failure to provide these or to fully complete the application form will result in the application being returned unprocessed to the applicant.

Applications must be concise and pages must be numbered.

Applications can be submitted at any time. Applications received by the last day of the month will be sent to the committee for review in the first week of the following month.

The researcher should submit the application & supporting documentation to the CEO's office in softcopy. Please send to ppierce@olh.ie and include the word 'Research' with your name in the email subject line. One signed hard copy should also be sent to the CEO's office (for attention Pat Pierce).

4.2. Research approval process

All applications are reviewed by the Education & Research Committee with appropriate members appointed by the Board of OLH&CS.

Following review, applications may be

- Approved.
- Approved subject to certain conditions and / or receipt of further information.
- Not approved.

The decision of the Chair of the Education & Research Committee is informed by the comments and recommendations of the members of the Education & Research Committee and is communicated to the Researcher by the CEO's office.

Such approval is provisional until ethical approval and management agreement (if required and outstanding) is secured and communicated to the CEO's office.

The CEO's office will notify the researcher in writing of the committee's decision. Details of any conditions which apply and/or feedback will be provided within 20 working days of the start of the month following receipt of the application.

Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 6 of 13

4.3. Research Funding

The Board of OLH&CS encourages staff to carry out research through the provision of facilities and research grants. The maximum grant per project or per study to any individual or group is €10,000. Applications for funding may be submitted at the same time as the Application for Research Approval. Individuals who wish to access funding from OLH&CS must complete the Application for Research Funding (Form No 2).

If research approval has already been granted, the application for funding may be submitted later. In this case, the research approval application and approval letters should be attached.

Applications for funding are considered by a sub-committee of the Education & Research Committee which includes at least the Chairperson of the Education & Research Committee who is a Board member of OLH&CS as well as the CEO and the Director of Education, Research and Training.

4.4. Conducting Research

Individuals undertaking research in OLH&CS 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 as described; 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.

The Education & Research Committee maintains records of research proposals, decisions and reports.

4.5. Reporting Requirements

The researcher must submit a final report on the research to the CEO's office by the first anniversary of the research approval. If the research is not completed by this time, further annual reports must be submitted until the final report is provided. The researcher must submit one copy of the final research report to the CEO's office (email to ppierce@olh.ie). The report should display a disclaimer that *'the work and opinions are those of the author and do not represent the views of Our Lady's Hospice & Care Services'*.

4.6 Publication

The Education & Research Committee encourages widespread dissemination of research findings. Publication may include articles in journals and magazines as well as verbal presentations and posters. OLH&CS must be acknowledged in all publications of

Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 7 of 13

research findings³. When making a submission for possible publication (oral, written or poster), the researcher must provide the librarian with a copy of the abstract.

If the topic of the proposed publication is outside that detailed in the research proposal or subsequent reports, the Education and Research Committee must be informed prior to publication.

After publication, the researcher must provide the OLH&CS librarian with a copy of the published work. This may be used as information, teaching and/or as a learning resource.

5. Personal and Organizational Rights

- Participation in research studies by patients, students, staff and volunteers of OLH&CS is voluntary and participants may withdraw at any time during the study.
- Informed consent is required from each participant.
- Anonymity of each participant must be preserved.
- Researchers are obliged to be aware of and 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 Intranet (Policy GN - 038).
- Confidentiality of all patient, family, student and volunteer information must be secured and protected at all times.

6. Evaluation and Review

This policy will be reviewed on or before the scheduled review date. Any comments or suggestions to improve this policy may be sent at any time to the authors or to the Director of Education, Research and Training.

³ If there is a reason OLH&CS is not acknowledged (for example to protect anonymity of participants) this must be agreed in advance with the OLH&CS Director of Education, Research & Training.

Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 8 of 13

7. References

Bryman, A. (2008) *Social Research Methods*, Oxford: Oxford University Press.

Byrne, M. (2015) *How to conduct research for service improvement: a guidebook for health and social care professionals*, 2nd edition, Tullamore: Health Service Executive.

Cutcliffe P and Ramcharan JR (2001), Judging the ethics of qualitative research: considering the 'ethics as process' model. *Health and Social Care in the Community*, 9(6), 358 – 366.

NICHHD (2017) The National Institute of Child Health and Development, USA.
Available at: <http://www.nichd.nih.gov/health/clinicalresearch>, [Accessed on 12 September 2017].

Our Lady's Hospice & Care Services, (2017) *Research Strategy 2015 – 2017* available on OLH&CS intranet.

Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 9 of 13

Form No. 1: APPLICATION FOR RESEARCH APPROVAL

1. Title of Research Proposal

2. Person submitting this application

Name	
Position	
Qualifications	
Address	
Phone/s	
email	

3. Principal Investigator (PI) if different to No 2 above

Name	
Position	
Qualifications	
Address	
Phone/s	
email	

4. Area of Research (please tick)

Palliative Care	<input type="checkbox"/>	Rheumatology	<input type="checkbox"/>	Gerontology	<input type="checkbox"/>
Other (specify)					

5. Type of Research (please tick)

Clinical	<input type="checkbox"/>	Non-Clinical	<input type="checkbox"/>
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6. Has approval been received from a Research Ethics Committee? Yes ☐ No ☐

Details

7. Name and Position of Supervisor/s

Academic	
Clinical	
Other	

8. Name and role of others involved in this research (if any)

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9. Previous research experience of Principal Investigator & others involved. (Presentations, abstracts, papers etc.)

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Title Approval of Research and Research Funding in OLH&CS	Reference No	OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision	No 03
Approved by Director of Education, Research & Training	Effective from	1 Mar 2011
Review date 11 Oct 2019	Page No	Page 10 of 13

10. Proposed duration of research

Start date	End date
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11. Will the project lead to an educational award (tick) Yes ☐ No ☐

If yes, name award	
Academic institution	
Expected date of graduation	
Name of graduand	

12. Principal research question or hypothesis to be tested

13.1. Summary of research proposal (Brief description of background to project, rationale, primary and secondary aims etc. Max 200 words).

13.2 References (Up to 5 max)

i	
ii	
iii	
iv	
v	

14. Is this a piece of original research? Yes ☐ No ☐

details

15. Describe the population and/or sample to be studies

details

Sample (e.g. patients, staff, students)	Number	Description (e.g. location, age)

16. Data collection methods to be used (administration of instruments and timelines – include a copy of questionnaires, surveys, interview protocols etc.)

Sample (e.g. patients, staff, students)	Instrument / type of data	Time required (days, weeks etc.)	Timeline From To

17. Describe the statistical or other analysis techniques to be used (200 words).

Title Approval of Research and Research Funding in OLH&CS	Reference No OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision No 03
Approved by Director of Education, Research & Training	Effective from 1 Mar 2011
Review date 11 Oct 2019	Page No Page 11 of 13

18. In what form/s and to whom will the findings be reported. Indicate if and where it is intended to publish the findings.

19. What resources are required to conduct the research and what are the proposed or approved sources of funding?

20. Name and number of any documents attached to this application

- 1.
- 2.

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 Our Lady's Hospice & Care Services (Ref OLH-GN 076 dated 12 Oct 2017).

Applicant Signature	Date

Title Approval of Research and Research Funding in OLH&CS	Reference No OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision No 03
Approved by Director of Education, Research & Training	Effective from 1 Mar 2011
Review date 11 Oct 2019	Page No Page 12 of 13

Form No. 2: APPLICATION FOR RESEARCH FUNDING

1. Person submitting this application

Name	
Position	
Qualifications	
Address	
Phone/s	
email	

2. Title of Research Proposal

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3. Principal Investigator (PI) if different to above

Name	
Position	
Qualifications	
Address	
Phone/s	
email	

4. Is Application for Research Approval Attached

Yes ☐

No ☐

If approval has been obtained from the OLH&CS Education and Research Committee date of approval.

5. Budget summary (attach a detailed breakdown)

Item	Amount of funding being sought from OLH&CS	Amount of funding (€) being sought from other sources	Total (Column 2 plus Column 3)
Staff			
Equipment			
Materials			
Other			
Total			

6. Relevance of proposal to OLH&CS (max 300 words)

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I confirm that the information provided here is true and accurate to the best of my knowledge.

Title Approval of Research and Research Funding in OLH&CS	Reference No OLH-GN 076
Author/s Librarian & Nurse Tutor	Revision No 03
Approved by Director of Education, Research & Training	Effective from 1 Mar 2011
Review date 11 Oct 2019	Page No Page 13 of 13

I confirm that I have read and agree to adhere to the policy in relation to Approval of Research in Our Lady's Hospice & Care Services (Ref OLH-GN 076 up-dated 12 Oct 2017).

Applicant Signature	Date