Guidelines for Applicants to the LauraLynn Research Ethics Committee

Thank you for your interest in making an application to the LauraLynn Research Ethics Committee. To assist you in making this application, please read this document **before** making your final application to the Committee.

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Does my work need Research Ethics Committee approval?

Research Ethics Committee approval is required for all research undertaken under the auspices of LauraLynn, Ireland's Children's Hospice. It is **not** required for service evaluation (which may include service development and/or quality improvement) or clinical audit projects.

What's the difference between research, service evaluation and clinical audit?

RESEARCH	SERVICE EVALUATION	CLINICAL AUDIT
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them	Designed and conducted solely to define or judge current care	Designed and conducted to produce information to inform delivery of best care
Quantitative research – designed to test a hypothesis **Qualitative research** – identifies/explores themes following established methodology	Designed to answer, "What standard does this service achieve?"	Designed to answer "Does this service reach a predetermined standard?"
Addresses clearly defined questions, aims and objectives	Measures current service without reference to a standard	Measures against a standard
Quantitative research – may involve evaluating or comparing interventions, particularly new ones **Qualitative research –** usually involves studying how interventions and relationships are experienced	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care	Usually involves analysis of existing data but may include administration of interview or questionnaire	Usually involves analysis of existing data but may include administration of interview or questionnaire
Quantitative research – study design may involve allocating patients to intervention groups **Qualitative research –** uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation	No allocation to intervention: the health professional and patient have chosen intervention before audit
May involve randomisation	No randomisation	No randomisation
Normally requires Research Ethics Committee review.	Does not require Research Ethics Committee review	Does not require Research Ethics Committee review

Source: Adapted from *Defining Research,* National Research Ethics Service, National Patient Safety Agency 2009

Overview of the Research Ethics Committee Application Process

Exemptions	•All research activity must be approved by the LauraLynn Research Ethics Committee (REC) •There will be no exemptions
Security and Retention of Research Data	•The LauraLynn Research Data Storage and Retention Guidelines must be followed and referred to appropriately in the application form •Please read section "Access to LauraLynn Health Care Records" (page 5 of this booklet)
Insurance	•It is the reponsibility of the researcher to ensure that they are adequately insured and evidence of such must be included with the application form
Download Application Form	•LauraLynn accept applications on the **Standard Application Form (SAF) Adapted Version 8 July 2024** •.Form & guidelines available from www.lauralynn.ie •NOTE: Guidelines indicate that Section I should be completed first
Complete Application Form	•Refer to the SAF Guidelines as you complete the application form •All applications must be typed or completed in ink in BLOCK CAPITALS •Illegible applications will not be considered by the REC
Complete Applicant's Checklist	•Complete the Applicant's Checklist available at page 8 of these guidelines •Use this Checklist as the cover page when submitting your application form
Submit e-copy of completed application form to fwoods@lauralynn.ie	•E-copy of completed application form to be submitted at least 15 working days prior to REC meeting •Acknowledgement of safe receipt will be sent within **10** working days
Submit 1 hardcopy of completed application form to Fiona Woods at LauraLynn	•Submit 1 SIGNED hard copy of the completed application form and any other accompanying information to Fiona Woods, Education Dept, LauraLynn Ireland's Children's Hospice, Leopardstown Rowan, Dublin 18, at least 7 working days prior to REC •Acknowlegement of safe receipt will be sent within **10** working days
Research Ethics Committee Meets - attendance by applicant not necessary	•Applications will be discussed and classified as: APPROVAL GRANTED, CONTINGENT APPROVAL GRANTED (subject to satisfactory implementation of recommended changes), or REJECTED •**Approval relates only to the research as detailed in the SAF reviewed by the REC**
Outcome of Application notified in writing to applicant within 10 working days	•Issues, concerns and questions will be notified in writing to the applicant within **10** working days and a timeframe will be given during which the applicant must address the issues to the satisfaction of the REC.

Access to Health Care Records for Research Purposes

- Section E3 of the Standard Application Form relates to access to health care records.
- The Children's Sunshine Home, operating as LauraLynn, Ireland's Children's Hospice, is the legal entity that is the DATA CONTROLLER in respect of the health care records.
- If access to health care records is permitted, the records will be anonymised before being given to the researcher. The researcher is expected to cover the cost of the anonymisation process. Each request will be dealt with on a case by case basis.

Access to Service Users for Research Purposes

- The researcher will be expected to sign a confidentiality agreement with LauraLynn before any contact with potential research participants is made.
- For the purposes of research at LauraLynn, Ireland's Children's Hospice, the researcher is **NOT** permitted to directly contact potential research participants.
- If the Research Ethics Committee grants approval for the research to take place, a member of LauraLynn staff will make contact with potential research participants to determine if they are interested in participating in the research. If the individual is interested, the member of staff will send them an information pack (see below) about the research along with the researcher's contact details. In this event, the researcher will have provided **Fiona Woods**, with an information pack about their research that has pre-paid postage and also has a stamped-addressed envelope for any returns.
- If the potential research participant decides to participate in the research, they will contact the researcher directly.
- LauraLynn WILL NOT follow up on any information packs sent out on behalf of the researcher.
- AT NO POINT will LauraLynn give the researcher the personal contact details of potential research participants.

Access to LauraLynn Staff for Research Purposes

- Staff at LauraLynn are frequently identified as potential research participants within the area of children's palliative care and intellectual disability services. Given that several parties may be interested in circulating questionnaires to staff at the same time, the timing of the questionnaire circulation will be determined by LauraLynn.

Data Storage and Retention Guidelines

(Source: Adapted from http://www.ucd.ie/t4cms/REC%20Guidelines%20-%20Data%20Storage%20and%20Retention%20260410.pdf accessed October 2016)

Content of Research Data

Research data comprises all recorded descriptive, numerical or visual material collected and used in the conduct of research, irrespective of medium. It may include physical and electronic records, digital images, microfilm, microfiche, audiotape, videotape and photographs. Research data may be augmented by objects, specimens and samples.

LauraLynn owns all data generated by research projects conducted by or under its auspices, regardless of funding source, unless stipulated otherwise by funding agreement.

Responsibility for the management of research data

The Principal Investigator is the custodian of the research data and is responsible for its management, including security, storage and retention. The Principal Investigator is also responsible for informing research participants of their obligations in relation to the data.

Security of research data – access

The Principal Investigator must determine and control access rights to research data. It is particularly important that access rights to personal data are strictly confined only to those who have been granted access. As well as ethical considerations, the privacy rights conferred by the Data Protection Acts 1988 and 2003 prohibit the processing of personal data without prior consent and, in the case of certain types of sensitive data, without the explicit written prior consent of the data subject. For the purpose of the Acts, processing includes storing, retrieving, accessing and retaining personal data. However, personal data collected anonymously, or data that have been de-identified to the extent that the data subject can never again be identified from the data, do not come within the terms of the Acts.

Security of research data – storage

Once access rights have been established, data storage arrangements must also reflect the sensitivity of the data. Appropriate levels of storage security must therefore be established by the Principal Investigator and maintained by research participants. These will include strict protocols for the protection from unauthorised access of all physical and electronic locations where data are stored.

Retention of research data

The Principal Investigator must determine and make arrangements for the retention of data for appropriate periods following the conclusion of the project. Retention periods can vary depending on the research disciplines, research purpose and type of data involved. They should therefore be determined on a project by project basis, taking into consideration any existing documented legal obligations governing retention periods, conditions imposed by research sponsors and the need to allow sufficient time for reference. Once the period of retention has expired, research data must be disposed of or deleted securely and confidentially in a manner appropriate to its format.

Guidelines for Conducting Research amongst Vulnerable Persons

Information that may be helpful in dealing with the issues arising during the conduct of research amongst vulnerable persons is as follows:

- National Consent Policy
- The National Disability Authority www.nda.ie
- National Disability Authority Ethical Guidance for People with Disabilities http://nda.ie/nda-files/Ethical-Guidance-for-Research-with-People-with-Disabilities.pdf
- www.hse.ie

(Please note this list is not exhaustive)

Applicant's Checklist (Mandatory)

(Source: Adapted from St Francis Hospice 2013 Application Checklist)

(Please use this form as the cover sheet for your application to the LauraLynn Research Ethics Committee; each member of the REC will receive a copy of the application form and all relevant accompanying information)

APPLICANT NAME:			
TITLE OF RESEARCH PROJECT:			
NAME/ADDRESS FOR CORRESPONDENCE:			
APPLICATION CONTENT	**YES**	**NO**	**N/A**
***Please submit all forms by email and then one hard copy**			
Email Application Form (Hard copies x 1 signed original)			
Principal Investigator Research CV - (Hard copy x 1)			
Supervisor Researcher CV if Principal Investigator is Student (Hard copy x 1)			
Research Subject Consent Form (Hard copy x 1)			
Advertisement for Research Subjects (Hard copy x 1)			
GP/Consultant information sheet or letter (Hard copy x 1)			
Draft letter of invitation to research subjects (Hard copy x 1)			
Information sheet for research participants (Hard copy x 1)			
Proposed Questionnaire (Hard copy x 1)			
Evidence of insurance indemnity (Hard copy x 1)			
ANY ADDITIONAL INFORMATION – provide details:			

In the event that this application is approved by the Research Ethics Committee, I confirm that I will adhere to the following conditions:	**Please tick**
• I will fully acknowledge the role of LauraLynn, Ireland's Children's Hospice, in facilitating this research in any written papers, posters and/or conference presentations	
• Any publication of the findings will a) include LauraLynn as a contributor and b) incorporate the logo where possible (a jpeg file will be provided upon request)	
• I will forward a copy of my findings and/or any publications/research posters to the LauraLynn Library upon completion, to be made available to all staff	
• I will permit my findings and/or any publications to be made available to the general public on the www.lauralynn.ie website upon completion	
• Upon completion I agree to present my findings at a mutually convenient time to members of LauraLynn staff who have an interest in my work	
• I will inform Fiona Woods, LauraLynn, of the names of individuals originating from LauraLynn who are asked to and who agree to participate in my research (where such names are identified) as soon as my data gathering is complete. I understand that this is essential in order to ensure that such individuals are protected from over-exposure to research activity	
Signature: Date:	

Declaration: Signatory Page (Mandatory)

(Source: Adapted from HSE North East Area Research Ethics Committee Signatory Page, 2014)

Name of Committee: LauraLynn Research Ethics Committee

Title of Study:

DECLARATION OF PRINCIPAL INVESTIGATOR:

I confirm that the information provided in this application is correct, that I am not aware of any other ethical issue not addressed within this form and that I understand the obligations to and the rights of participants (particularly concerning their safety and welfare, the obligation to provide information sufficient to give informed consent, the obligation to respect confidentiality and all the obligations as set out in the **Declaration of Helsinki** governing the conduct of research involving human participants and/or other relevant guidelines (please refer to your Head of Department/School)

Name: **(BLOCK CAPITALS)**			
SCHOOL/DEPARTMENT			
COURSE OF STUDY **(if appropriate)**		**YEAR**	
SIGNATURE:		**DATE**	

DECLARATION OF RESEARCH SUPERVISOR:

Student applicants are required to have their Academic Research Supervisor complete this section. Applications from students that have not completed this section will not be accepted.

Name of Academic Supervisor: **(Block Capitals)**	
Position:	

As the Student's supervisor:

1. I accept responsibility for the ethical conduct of this project †
2. I have read the application and am familiar with its contents †
3. I have discussed this application with the above named applicant
4. I can confirm that this research has an educational value †

(Please note all boxes must be ticked. Incomplete applications will be returned)

Signature of Academic Supervisor:	
Date:	

Information post-Committee decision

Access Process	•If approval is granted, access to clients/caregivers/ family members/staff/volunteers will be facilitated by members of LauraLynn staff. •Direct contact with clients/caregivers/family members/staff/ volunteers by the researcher is strictly prohibited
Annual Report Submission	•It is a requirement of approval that a written progress report is provided each year to the REC, and this will be circulated to the REC members
Request for Amendment or Extension	•Permission to amend or extend an approved study is at the discretion of the Chair of the Research Ethics Committee. •Depending on the nature of the request, some amendments may require a full review by the Research Committee •Requests to amend or extend must be made in writing using the Amendment/Extention form at page 16 of these guidelines •In the event that the amendment/extension is due to an adverse event, an Adverse Event Form must also be submitted (page 18)
Presentation of Findings	•We may invite the researcher to present their findings to interested parties at LauraLynn upon completion of their study •We ask that a copy of your findings is included in our Library collection and highlighted on www.lauralynn.ie
Committee Decision	•The decision of the Research Ethics Committee is final. •Resubmissions are welcome.
Revocation/Suspension of Approvals	•The LauraLynn REC reserves its right to revoke, suspend, modify or reconsider an approval at any point in time without prior notice to the applicant and with immediate effect
Resubmission Guidelines	•In the event of a resubmission, the original application form must be used with all amendments made in ***bold italics and underlined***

Study Completion Report

For a Word version of this form, please contact fwoods@lauralynn.ie
(Source: Adapted from www.ucd.ie/researchethics/apply/end_of_study/ accessed October 2013)

Name (s) of Principal Investigator/ Applicant:		
University/Institution		
Supervisor Name *(if applicable)*		
Title of study:		
Date Ethics Approval Granted:		**Date Research Commenced:**
Date of Completion:		**Academic Qualification Granted/to be Granted:**
Please confirm that all data stored in connection with this study has been destroyed	**Yes** ☐ **No** ☐ ***If No**, please confirm that the data will be destroyed at the end of the period which was indicated in the original application and state:* *(a) whose responsibility it will be to destroy the data and* *(b) how that person will inform the LauraLynn Research Ethics Committee that this has taken place. (i.e. correspondence at the time the data is destroyed)*	

Were there any unexpected adverse events during your study? Please provide details including a copy of the Adverse Events Report submitted if applicable.	
How many participants were involved in your study? **Please provide details of any problems encountered during the recruitment process.**	
Please provide details of any publications related to this research that are currently in preparation, completed or pending publication.	

Any other Comments:	
Signature of Applicant: **Date:**	
Signature of Supervisor *(if applicable)* **Date:**	

Please submit this report by email to fwoods@lauralynn.ie
OR by post to
Fiona Woods, Education Department at
LauraLynn, Ireland's Children's Hospice
Leopardstown Road
Dublin 18

Amendment/Extension Request Form

For a Word version of this form, please contact fwoods@lauralynn.ie
(Source: Adapted from www.ucd.ie/researchethics/apply/amendments_extensions/ (accessed October 2016)

To make an amendment to/request an extension for an approved study please complete this form and submit it, along with a covering letter, to the Chair of the LauraLynn Research Ethics Committee.

Please note:

- Only straightforward cases will be dealt with by the Chair and notified to the Committee at its next meeting
- A case is straightforward if it refers to issues to do with timing of research, increases in sample size, or where the procedure remains the same and where there is no threat to consent, confidentiality and anonymity of participants, or no increased risk over and above that identified in the original application
- All other cases not satisfying these conditions will be tabled and reviewed by the Committee in the normal way
- The Committee will review all cases where an adverse event has been reported
- Multiple requests for amendments/extensions will alert a review of the current policy

Name (s) of Principal Investigator/ Applicant:		
University/Institution		
Supervisor Name *(if applicable)*		
Title of study:		
Date Ethics Approval Granted:		**Date Research Commenced:**
Estimated Date of Completion:		**Academic Qualification Granted/to be Granted:**

Do you wish to amend your approved study? If so, please provide details of the proposed amendments

Do you wish to extend the approval for your study? If so, please provide details of how long you require and the justification for the extra time.	
Were there any unexpected adverse events during your study? Please provide brief details *but note you will need to submit an Unexpected Adverse Events Report with this form.*	
Any other Comments:	
Signature of Applicant: **Date:**	
Signature of Principal Investigator *(if Applicant is not the P.I.):* **Date:**	
Signature of Supervisor *(if applicable):* **Date:**	

Please ensure that you submit this Form by email to fwoods@lauralynn.ie,
LauraLynn, Ireland's Children's Hospice
Leopardstown Road
Dublin 18

Adverse Events Report Form

For a Word version of this form, please contact fwoods@lauralynn.ie
(Source: Adapted from www.ucd.ie/researchethics/information_for_researchers/adverse_events/accessed October 2016)

If you wish to report any unexpected adverse event which has occurred during your research you will need to complete this form and submit with a covering letter to the Chair of the LauraLynn Research Ethics Committee

What do we mean by Unexpected Adverse Event? : Any adverse event or outcome experienced by any participants (subjects or researchers), which exceeds the risk participants were informed of prior to consent or during debriefing.

Name (s) of Principal Investigator/ Applicant:		
University/Institution		
Supervisor Name *(if applicable)*		
Title of study:		
Date Ethics Approval Granted:		**Date Research Commenced:**
Estimated Date of Completion:		**Academic Qualification Granted/to be Granted:**

Were there any unexpected adverse events during your study? Please provide details.

In light of the Unexpected Adverse Events listed above do you wish to amend your approved study? If so, please complete and submit an Amendment /Extension Form	
Any other Comments:	
Signature of Applicant: **Date:**	
Signature of Supervisor (if applicable)**:** **Date:**	

Please ensure that you submit this Form by email to fwoods@lauralynn.ie,
LauraLynn, Ireland's Children's Hospice
Leopardstown Road
Dublin 18

Additional Resources Available

The following resources may be useful:

- **National Consent Policy**. Further information available at: 20240524_HSE_Consent_Policy_2022_v1.2.pdf

- **Office of the Data Protection Commissioner**. Further information available at: https://www.dataprotection.ie/

- **NMBI** promotes high standards of professional education, training and practice and professional conduct among nurses and midwives thus ensuring the protection of the public.
- **Bord Altranais agus Cnáimhseachais na hÉireann (the Nursing & Midwifery Board of Ireland)** NMBI - Nursing and Midwifery Board of Ireland home

- **CORU**: protects the public by promoting high standards of professional conduct and professional education, training and competence through statutory registration of Health and Social Care Professionals https://www.coru.ie/

- **The Irish Qualitative Data Archive (IQDA)**: is a central access point for qualitative social science data generated in or about Ireland. The archive frames the parameters and standards for archiving qualitative data within the Irish research community.

- **National Intellectual Disability Database:** http://www.hrb.ie/health-information-in-house-research/disability/nidd/

- **Health Research Board:** www.hrb.ie