Instructions for Completing Clinical Adjunct Research Authorisation Form

For all research studies involving University of Limerick(UL), the Vice President Research (VPR) provides final approval for the University's involvement in the research, and is the authorised legal signatory for any agreements relating to the research as per the Signing Authority Policy.
The procedure below outlines the steps required to seek approval for HSE investigator studies having UL as the host institution. This procedure applies where a HSE investigator wishes to submit a grant application to a funder, or where they are asked to join a study/trial for which they need an academic host institution. This procedure does not apply to studies where UL is the sponsor of a regulated clinical trial, in which instance the clinical research policy for UL sponsored regulated clinical trials applies.

Note: This procedure is only intended for investigators for whom UL will act as host institution. The HSE Lead Investigator in this case is the individual who leads UL's research activities under the study. For multi-partner studies, this may be separate from the overall lead investigator for the study as that individual may be affiliated to another institution.

Procedure:

1. The procedure is initiated when the VPR Office is contacted to advise them of the planned study and the Investigator(s) involved.
2. The VPR Office checks if the HSE investigator has an adjunct appointment at UL. For those without an adjunct appointment, the HSE investigator/UL initiates application for an adjunct appointment in parallel with the steps below.
3. The HSE lead investigator completes and signs the attached Clinical Adjunct Research Authorisation Form, and requests each Co-Investigator to complete and sign the relevant sections of the form.
4. The Clinical Adjunct Research Authorisation Form, accompanied by the proposal or study description, and the budget breakdown, are sent to the VPR Office.
5. The VPR Office will request review and sign-off from the various approvers listed on the form:
    a. Head of Department
    b. Clinician Member of UL Staff (relevant Clinician will be identified by the VPR Office)
    c. Finance Office
    d. VPR Office
6. Once the Clinical Adjunct Research Authorisation Form is fully completed and signed, the proposal can be submitted, or the contracts/agreements can be signed if their terms are acceptable
7. Prior to the research commencing, UL assigns a suitable resource to act as an interface between the HSE investigator and the various UL functions. These functions will include:
    e. HR: This resource will be responsible for recruitment or assignment of existing resources and for the personnel management of staff hired. This responsibility would not include directing the research activities of these staff, which would remain with the HSE investigator.
    f. Finance: This resource will be responsible for interfacing with the UL Finance Office on the management of project accounts, budgets, cost claims, etc, and would act under the direction of the HSE investigator in this regard, in compliance with UL policies and procedures.
8. Reporting requirements will take into account funders' requirements and will adhere to relevant governance requirements, and will be advised to the HSE investigator on a case by case basis
9. In all cases, the clinical activities will remain under the direction of the HSE investigator

UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

Office of the Vice President Research

Office Use Only
Reference Number

CLINICAL ADJUNCT RESEARCH AUTHORISATION FORM

INSTRUCTIONS

This form is required for all research projects/studies with HSE-based investigators requiring UL to act as host institution. This applies to investigators applying for funding, and to investigators joining a new or existing project. This does not apply to studies requiring UL to be a sponsor (see separate UL Clinical Research Policy for sponsored studies, available on request).

Lead Investigators should complete Sections 1, 2 and 3, and request any Co-Investigators to complete Sections 4 and 5.

Once Section 1-5 are complete, the forms **accompanied by the proposal or study description, including detailed budget**, should be sent to rss@ul.ie for approval. Please allow sufficient time for signatories to review documentation and sign prior to funder and project deadlines.

PROJECT & INVESTIGATOR(S)

Section 1: Project Details

Funder:

Funding Programme:

Project Title:

Project Acronym: Submission Date:

Section 2: Lead HSE Invstigator Details

Name of Investigator:

Contact Email: Contact Phone:

Primary Employer: e.g. UHL

UL Affiliation Title: e.g. UL Adjunct Clinical Lecturer

UL Department: UL Research Institute:

UL and UL Affiliated Co-Investigators:

A Co-Investigator is accountable for a portion of the research programme, and may receive research funding from the award. Separate sections 4 and 5 should be added to this form for each UL and UL Affiliated (e.g. Adjunct) Co-Investigator.

Number of Co-Investigators:

Section 3: Lead Investigator Declarations

Declarations and Undertakings

As Lead Investigator of this project/study on behalf of UL:

- I declare the information submitted within the proposal is true, complete and accurate
- I declare that the proposal is in conformity with the eligibility requirements set by the funder
- I declare that no conflict of interest exists in relation to my involvement in the project
- I commit to comply with relevant compliance and governance requirements (funder and host institution)
- I commit to comply with all legislation and regulations relating to the protection of personal data including the Data Protection Acts, 1988 - 2018, the General Data Protection Regulation 2016/679 and all other statutory instruments, industry guidelines or codes of practice
- I commit to take responsibility for the project, including direction of the clinical activities and of any personnel employed by UL for the purposes of conducting the project
- I commit that the project will be undertaken within the agreed budget
- I commit to furnish UL with confirmation of relevant ethics approval to include confirmation of approval of any conditions therein and confirmation of HSE indemnity prior to commencing the project
- I confirm that I have the agreement of my employer in relation to the project/study
- I authorise submission of the proposal to the funder and acceptance of the project award by the University of Limerick

Signature of Lead Investigator: Date:

Sections 4 and 5 should be completed for UL and UL Affiliated Co-Investigators.
Please copy additional sections 4 and 5 for each additional Co-Investigator, as required.

Section 4: Co-Invstigator Details

Name of Co-Investigator:			
Primary Employer:			
UL Affiliation Title:			
UL Department:		UL Research Institute:	

Note:
A Co-Investigator has accountability for a portion of the research programme, and may be in receipt of research funding from the award. Separate sections 4 and 5 should be added to this form for each UL and UL Affiliated (e.g. Adjunct) Co-Investigator.

Section 5: Co-Investigator Declarations

Declarations and Undertakings

As Co-Investigator of this project/study:

- I declare the information submitted within the proposal is true, complete and accurate to the best of my knowledge
- I declare that the proposal is in conformity with the eligibility requirements set by the funder
- I declare that research to be undertaken has not already been funded from another source
- I commit to comply with the relevant compliance and governance requirements (funder and host institution)
- I commit to comply with all legislation and regulations relating to the protection of personal data including the Data Protection Acts, 1988 - 2018, the General Data Protection Regulation 2016/679 and all other statutory instruments, industry guidelines or codes of practice
- I commit to take responsibility for the project, including direction of the clinical activities and of any personnel employed by UL for the purposes of conducting the project
- I confirm that I have the agreement of my employer in relation to the project/study

Signature of Co-Investigator:		Date:	

APPROVALS

Department Approval

As Head of Department, I authorise submission of this proposal to the funder and acceptance of the award

Name of Head of Department:

Signature of Head of Department:

Date:

Clinician Approval

I have reviewed the Clinical aspects of this study and I approve University of Limerick to act as host institution for this research

Name:

UL Clinician Signature: (Member of UL Staff)

Date:

Finance Approval

Research Finance Signature:

Date:

Research Finance – Office Use Only

Budget Breakdown	UL Budget	Total Project Budget (if known)
Direct costs (cash)		
Overheads		
Total Budget		
UL cost-share commitment		
UL in-kind commitment		
Industry cash contribution		
Industry in-kind contribution		

Comments:

VPR Office Approval

VPR Office Signature:

Date:

VPR Office – Office Use Only

Comments:

☐ CRD ☐ PTN ☐ IND

Revision & Approval Log

Rev No.	Date	Revised By:	List of Revisions	Approved Sign & Date
0	01/04/2020	PS	New Document	PS, 01/04/2020
1	18/06/2020	PS	Edit to ethics section	PS, 18/06/2020