Title Clinical Adjunct Research Authorisation Process

1.0 Introduction

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.

2.0 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

3.0 Records

In accordance with the UL Records Management & Retention Policy the following Records are held:

1. Authorised proposals are logged by RSS and copies of the proposal authorisations forms and proposals are stored
2. Contracts relating to grant awards are stored by TTO

4.0 Review

This process is reviewed in accordance with the Self-Assessment Process, and any necessary changes will be documented in a new revision of this process.

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