UCD Research and Innovation

HRB Definitive Interventions and Feasibility Awards 2020 Pre – UCD Guidance Notes

These guidance notes are designed to help UCD applicants prepare a pre-proposal for submission to the HRB Defined Interventions and Feasibility Awards (DIFA) 2020 call. These notes must be read in conjunction with the DIFA Guidelines (only pages 1-25 at this stage). Please also be sure to read the DIFA FAQs.
This note contains information on:

- The scope and purpose of the call.
- UCD's internal deadlines and submission process.
- Contact details for UCD Research Office and Research Finance Office support.
- Hints and Tips for completing proposal sections.
- Reviewer feedback from previous DIFA calls.

Supplementary guidance will be provided by UCD Research to those applicants invited to full proposal.

Please Note:

Some key changes to note for DIFA 2020:

- Increased budget cap for individual studies (DIs): up to €1.2m where justified
- Additional resources if including a Study Within A Trial (SWAT), additional €20,000 budget allowance
- Co-Lead Applicant option, to allow more Health and Care Practitioners to take a leadership role
- Applicant Team: more Co-applicants allowed, to a combined total of 15 Co-applicants and Collaborators
- Mandatory engagement with lead Host Institution to undertake a risk assessment review of all Full Applications
- International studies: further justification needed, limits to per patient costs outside of Ireland
- Please consult the detailed Pre-application Guidance notes and FAQ document on the website for full details. If you have further queries on the DIFA scheme, please don't hesitate to contact me.

1. Scope and Purpose of the call

The DIFA scheme supports research that addresses questions of direct relevance to the improvement of patient care, health of the public and health services and that has strong potential to have immediate use for decision makers in everyday clinical practice or policy.

This year the call will operate via a 2-stage process with an open call for Pre-Applications followed by invitation of selected applicants to submit a Full Application.

The types of studies funded;

1. **Definitive interventions** of any appropriate design, including randomised controlled trials and non-randomized trials, designed to assess the efficacy, effectiveness, cost and broad impact of a therapy or intervention
2. **Stand-alone feasibility studies** conducted in preparation for a future definitive intervention. The sole intention behind the funding of these studies is to establish a pipeline for definitive interventions. Clear progression criteria to a substantive study are required. It is not possible to apply for a feasibility study,

including a pilot study, and the associated definitive intervention trial at the same time

The awards will support research proposals up to a maximum value of **€1,200,000** (where justified, and inclusive of overheads) with duration of typically 2-4 years (but not beyond 60 months). The earliest start date is February/March 2019. HRB expects that feasibility studies for Randomised Control Trials (RCTs) will have a significantly lower budget of below €380,000.

STUDIES WITHIN A TRIAL (SWATS)

Please Note: HRB are increasingly interested in seeing SWATs included in their applications, especially DIFA. Including one may increase the competitivity of your application and improve your chances of being funded. This is partly why they have funded the **Trials Methodology Research Network (HRB TMRN)** at NIUG.

To ascertain whether or not your project may involve a SWAT, please use the HRBA Decision Tree provided via the UCD Portal alongside this support document. Please also contact Dr Sebastian Vencken at the **UCD Clinical Research Centre (CRC)** for more information. Additional funds (€20,000) are available under this call for SWATs (see pages 4, 6 of Guidelines). For more information on SWAT (and DIFA) supports, please see 'Access to a Clinical Research Infrastructure' section of this document.

2. UCD Contacts & Procedures

UCD Research Office Contact

Any queries on the call may be directed to Dr Paul Huddie via proposalsupport@ucd.ie,(ext. 4059) at UCD Research.

Budget

At pre-proposal stage applicants are required to provide a detailed budget (personnel, running costs, equipment costs, dissemination costs and overhead contribution) and brief justification (1000 words) of the costs and duration associated with the project.

Please ensure you have your full budget checked and approved by Aidan McElwaine (aidan.mcelwaine@ucd.ie), Ext 4021, in the UCD Research.

With regards to your project's Intellectual Property (see Section 3.17 'IP Considerations' of Guidelines), please contact your Knowledge/Technology Transfer Officer – Dr Ena Walsh – at NovaUCD.

Clinical Research Centre support

For clinical trial advice please contact Dr Peter Doran, (peter.doran@ucd.ie, phone 716 4582), Centre Director of the UCD Clinical Research Centre (CRC).

Feedback

If you would like feedback on your draft proposal, please email a draft (as complete as possible) of the proposal to Dr Paul Huddie via proposalsupport@ucd.ie once it is ready, but at least a week before deadline.

GEMS application system

When you start the application on the HRB GEMS website there is a button to click notify the UCD

School Dean. You should notify as soon as possible. "Dean of Research" refers to UCD Research on the system, so this notification will come to UCD Research office.

Institutional endorsement of proposals

For compliance check and institutional submission, please submit your proposal through the HRB GEMS system 2 working days before HRB deadline i.e. **18 December 2019**. At that point the budget and all required letters of support must be finalised/checked/signed.

3. Things to consider as you prepare a proposal

Budget

It is important when drafting your budget that you think about the allocation of budget among the different partner sites. This budget breakdown, while not required as part of the application, will be required for the set-up of the project if funded and it smooths the grant award process if this is factored into the initial preparation of the budget.

Trial Sponsor

It needs to be clear who is acting as Sponsor for the Clinical Trial, and where are they located, especially if there are separate sponsors within the EU and outside the EU. If the project is funded, agreements will need to be set up between UCD and the Sponsor, and also between UCD and the individual sites (exceptions being SVUH and the Mater).

4. Completing the proposal sections

Abstract (350 words)

Your abstract should comprise the following:

- 1-2 sentences outlining the topic that your research addresses
- 1 sentence describing the aim and hypothesis of your project. What is the key research question?
- Highlight the gap(s) in current knowledge and state how your proposed research aims to fill the knowledge gap(s)
- 2-3 sentences describing how you are going to go about carrying out this project – methodology.
- 1-2 sentences describing the intended or expected outputs of your proposed research project.

Project Description (1500 words total)

Relevance and Rationale for Proposed Research

- State the principal research question being asked.
- What is the rationale for the study?
- Why is this intervention needed? What problem is being addressed? Justify the necessity for the research, both in terms of timeliness and relevance to health of patients/public/health system especially in an Irish context.
- Will the results be generalizable beyond the research setting of the study in a way that will maximise the impact of the results?

Overall aim

- Clearly state the overall aim of the project.
- Explain how your proposed research is within remit of the DIFA call.

Objectives and Deliverables

- Suggest listing a minimum of 3 research **objectives** clearly which will contribute to achieving the overall aim. Objectives should be SMART (specific, measurable, achievable, realistic and time-bound).
- For each objective list a subset of **deliverables** which will be used to monitor progress throughout the lifetime of the award if successful.

Brief Overview of Research Design and Methodological Approach

- Summarise the proposed research plan. Include details of the general experimental approaches, study designs and techniques that will be used.

- Outline clearly the methodology / project design by dividing the work up into Work Packages. Ensure that you also include a separate Work Package on Project Management. Detail the interactions between individual sub-projects.
- Detail the Study design – rationale for sampling strategy, justification of sample size and power calculation, details on the design chosen and the intervention, the methods of data collection, measures, instruments and techniques of analysis for quantitative and qualitative designs, outcomes measures, cost effectiveness and data analysis/management plans as appropriate. Seek advice and input from an experienced research design and statistics expert. See CSTAR for assistance in this section.
- The UCD Library has prepared a comprehensive website dedicated to Research Data Management, including checklists and plans, which can be accessed here: http://libguides.ucd.ie/data

Impact Statement (250 words)

- Provide an overview of the likely impact from the proposed research on patients, public and/or healthcare system and articulate the pathway by which the research will achieve this.
- By "Impact" HRB means the direct contribution to improvements/benefits to patient care, health of the public and health services from this research in the short to medium term (1-5 years after the end of award).
- UCD Research has produced Supports and Resources to help you to write your Impact section, including an Impact Planning Canvas, Short online tutorial and Impact planning guide, along with many case studies of Impact from previous research projects
- The HRB evaluation team tracks and collates the wide variety of outputs and outcomes that arise from its funded research over time, and uses this information to evaluate the benefits and impact of its investment in health research against the HRBs strategic objectives and mission. These impacts are listed under five broad categories, with indicators listed under each category. Full details here.

Public and Patient Involvement in the research project (250 words)

- Where appropriate, include details of where individual members of the public or patients and public advocate groups have been actively involved in the preparation and/or design of this proposal.
- If you feel that this is not applicable to your proposal, you must explain why. It is not sufficient to leave this section blank.
- UCD was recently awarded a PPI Ignite award by the HRB to support PPI activity across the university. This award is led by Prof Thilo Kroll, School of Nursing, Midwifery and Health Systems and is currently in its mobilisation phase. The UCD PPI award will fundamentally embed PPI in health-related research, education and training, professional practice and administration in UCDs institutional structures and procedures.

Project Budget & Details of Research Team

- provide a summary and brief justification of the costs and duration.
- provide an outline of the role of all applicants and collaborators.

Host Institution Infrastructure and Support (200 words)

The following documents may be of assistance in describing UCD and its Infrastructure and Support Units:

- UCD Description – A general description of UCD, also including UCD's track record in obtaining research funding
- UCD Facilities – describes the facilities in UCD that are available to you to assist in the execution of your project, such as the Conference and Events Centre, Créche, Applied Language Laboratory etc.
- Major Research Programmes – details the Major and Multidisciplinary Research Institutes and Centres that are located in UCD. You should include details of any that are relevant to your research project. This will highlight to the evaluators that there is a critical mass of researchers already located within UCD in your research area, that your proposed research project will be located within one of these Centres and will benefit from the knowledge and experience already available here. It also details the laboratory equipment that is available in UCD. If you need to use existing equipment for your research, it is important that you clearly specify that this

equipment is available here for your use.

- See the UCD Research Support Units details the many Institutional support units that are available in UCD to assist with the implementation and management of the grant. This section should include details of the support units and how they will be able to assist with the management of your research project. UCD Research and Innovation - set up a specific Research Account for the Award and Intellectual Property protection and exploitation; UCD Library - supports in the provision of metrics / bibliometrics, data management plans, open access compliance; Research Finance Office - financial administration, preparation of Cost Statements and management of audits; UCD Legal – legal support; UCD Human Resources - employment of Research Staff, assistance with obtaining Visas; UCD Office of Research Ethics
– Ethical approval; CSTAR – provision of statistical support; Research IT Services – IT resources and supports; UCD Clinical Research Centre (CRC).

Access to a Clinical Research Infrastructure (200 words)

Provide specific details where you have accessed or plan to access the support/services of a Clinical Research Facility/Centre, Clinical Trials Unit, Imaging Centre or Research Network at study design and/or implementation phase.

This is very important, as very specific supports can be offered at UCD via the **UCD Clinical Research Centre (CRC).**

- For queries on DIFA grant writing, please contact Professor Peter Doran, (peter.doran@ucd.ie, phone 716 4582), Centre Director.
- For queries about SWATs (which we encourage all applicants to try and include, as appropriate), please contact Dr Sebastian Vencken, (venckens@ucd.ie)
- Additional dedicated personnel at CRC can also advise you on Data Management, Patient Recruitment and Patient Literature, and Adherence to funder rules and national regulations.

Please also consult and keep in mind for the full application the support offered by HRB-Trials Methodology Research Network (HRB-TMRN). Sebastian Vencken can tell you more about it.

Assessment

The Pre-application assessment will focus on:

1. Case for the study
   - Important research question
   - Evidence supports the need for this study
2. Potential for impact of the study
   - Likely to impact on patients, public and/or healthcare system
3. Research team and environment
   - Appropriate skill mix and experience
   - Appropriate supports, infrastructures and research environment

These aspects will form the assessment criteria for pre-applications and will have equal weight. *While applications will not be scored on "Appropriate methodology", or "Feasibility", Panel members will provide feedback for applicants to consider if invited to submit Full Applications.*

Peer Reviewer feedback from previous calls

Below is a summary of main feedback points from previous calls. They are divided in strengths and weaknesses.

Strengths

- Reviewers like to see detail on the study design, consideration of placebo effects and how patients are enrolled.
- Clarity of the research question.
- Need to provide robust evidence for the potential of a clinically relevant outcome and rationale for targeting patients.
- Proposed study shows trends toward improvement with the intervention for a compelling problem.
- The intervention is low cost and low risk.
- Project proposes therapeutic method that could be rapidly deployed in hospitals worldwide after data dissemination and education.
- International collaboration is viewed favourably.
- Provide supporting literature and current evidence regarding the challenges facing individuals including citing a number of systematic reviews and using available data where available.
- Interdisciplinary teams are a strength.
- Sound inclusion and exclusion criteria.
- Potential risks are described in the study plan as well as risk management.
- The planned process evaluation is an important part of the study and could potentially provide very rich qualitative data to understand the implementation requirement.
- Inclusion of adequate literature support to study design.

Weaknesses

- Concern as to whether the site will have enough for patient recruitment.
- The lack of a comparison group with which to test the intervention.
- Not explaining fully, the rationale for chosen sample size.
- Data management and analysis - not adequately describing any mixed method approaches.
- Not fully describing how the intervention will be implemented.
- Not fully describing collaborators' expertise and how they contribute to the project.
- Sound protocols proposed but plans for follow-up after the treatment was missing.
- Gaps in the literature review presented.
- Not addressing difficulties and risks associated with the project e.g. recruitment challenges, ability to consent, follow-up post intervention.
- No clear engagement of patients or stakeholders.
- Unintentional introduction of bias in the study through participant recruitment.
- A PPI (Patient Public Involvement) co-applicant would strengthen the proposal.
- The sample size of the main trial is not explicit.
- Randomisation procedures not being robust enough.