Definitive Interventions and Feasibility Awards (DIFA)

2023

Levels of support available through HRB – Trials Methodology Research Network

Frequently Asked Questions

NOTE: Please read the HRB Guidance document for full call details.

Key Dates & Times

Full applications open	**01 July 2022**
Full application closing date	**13.00 15 Sept 2022**
HRB-TMRN deadline for support	**25 Aug 2022**

1. What is the HRB-TMRN?

The HRB-TMRN is a national support Network, which currently has over 3,000 members, all with an interest in the conduct of randomised trials in healthcare and trials methodology research. The Network operates across five university partners (National University of Ireland Galway, University College Cork, University College Dublin, University of Limerick and Trinity College Dublin); however, all supports are available to anyone in any institution, across both public and private sectors, on the Island of Ireland. The Network operates across four central pillars of trials methodology activity, namely; (i) Training and Education, (ii) Support, (iii) Research and Innovation and (iv) Public Engagement. The supports provided by the HRB-TMRN range from providing advice, for example signposting, up to embedding large primary methodology research work packages within trials or standalone primary trials methodology research. The Network has identified relevant expertise across a range of areas in trials methodology, and welcomes engagement from any individual, group or centre interested in advancing the methods used in trials.

2. How does the HRB-TMRN support applications for the HRB DIFA Call?

As outlined in the HRB guidance document, a specific objective of the DIFA call is to *"support conduct of trials methodology research within the context of proposed trials or feasibility studies"* and *"The scheme will also support studies within a trial (SWATs) built into the main or feasibility study to explore primary trial methodology questions".*

The HRB-TMRN can be involved in supporting your application, if your application includes at least one trials methodology research question, or uses an innovative* trial design.

*(*An innovative design is considered non-standard and aims to address the challenges of new developments and emerging trends in health care).*

The implementation of SWATs is one of the main objectives for research activity of the HRB-TMRN and we have considerable experience in the conduct of these studies.

The HRB-TMRN can assist with embedding methodology research questions as SWATs on two levels, as Co-applicant or as Collaborator. The following descriptions offer a guide as to the level of requirements and support available for both categories.

HRB-TMRN as Co-applicant

As per the HRB DIFA 2020 guidance document, a Co-applicant may receive funding for items such as running costs and personnel. An additional €20,000 (inclusive of overheads) can be requested for conducting a SWAT.

- A designated HRB-TMRN contact will be identified based on the needs of the study (clinical area will be considered where possible);
- In consultation with the Principle Investigator, a suitable SWAT work package will be written and developed by the Network member that addresses an important methodology question;
- Associated funding for the SWAT award will be managed by the HRB-TMRN SWAT lead, providing on-going assistance on the SWAT for the duration of the award and subsequent publication of findings.

Note: All the above act as a guide, and are subject to agreement between the trial team and nominated HRB-TMRN contact.

HRB-TMRN as Collaborator

The HRB-TMRN can provide a signed **Collaboration Agreement Form** or **Infrastructure Agreement Form** for applicants who meet the following criteria:

1. The application includes at least one well-developed trials methodological question or uses an innovative trial design;
2. Applicant team agree to update the HRB-TMRN of the trials methodology study progress and where this is SWAT, to register it with the Northern Ireland Hub for Trials Methodology Research Repository;

3. The applicant team agree to share the published findings of the trials methodology study with network members, through delivery of an online webinar or present the study findings at a national HRB-TMRN educational event.

4. Who can I contact to discuss specifics of my application?

You may contact the HRB-TMRN directly at hrb-tmrn@nuigalway.ie to arrange a call with the Programme Manager - Dr Sandra Galvin who will discuss the options available.

5. What initial information do I need to provide to the HRB-TMRN Programme Manager?

For applications addressing embedded trials methodology research questions:

- An abstract of the feasibility study or host trial to include the primary clinical research question and design of the proposed host trial (relevant for pilot or definitive interventions).

  OR

- The primary clinical research question of the future host trial (if feasibility study).

  AND

- The trials methodology research question(s).

For applications which address methodology research questions only (i.e. no clinical question included in the research proposal):

- The primary methodology research question(s).

6. What is the deadline for approaching the HRB-TMRN?

The closing date for expressions of interest to the HRB-TMRN is **25th August 2022.** After this date, applications cannot be considered.