



Trial Governance Placement Scheme

2024

Guidance Notes

Opening Date:	08 th January 2024
Closing Date:	01 st March 2024 at 1pm
Notification of Outcome:	22 nd March 2024

Applications must be completed and submitted to the HRB-TMRN by email, hrb-tmrn@universityofgalway.ie, with the subject line "Trial Governance Placement Scheme". Applicants must read the guidance notes below in full before completing the application form. Queries relating to this Scheme can be directed to the HRB-TMRN Programme Manager at the above email address.

Key points:

- ✓ The HRB-TMRN Trial Governance Placement Scheme places Irish Researchers involved in trials (principal investigators, trial managers, statisticians, clinicians etc) or 'Mentees', virtually with experienced Trial Governance Committees internationally, to gain hands-on Trial Governance experience in a high-quality environment.
- ✓ The aim is to provide Mentees with the opportunity to observe and learn from experts in Trial Governance, across all trial governance committees.
- ✓ In addition to the placements, Mentees can avail of a €500 travel bursary to meet with placement colleagues.
- ✓ This placement scheme is open to anyone working in health or social care in Ireland, with an interest in Trial Governance at any level. Applicants must be resident of the Republic of Ireland at the time of application.

Introduction

The HRB-Trials Methodology Research Network (HRB-TMRN) is a collaborative initiative between a number of Irish and international higher education institutes and methodology centres.

Our mission is to strengthen the methodology and reporting of trials in health and social care in Ireland so that they become more relevant, accessible and influential for our community of patients and other service users, practitioners, policymakers and the public.

Our vision is to build a community that appreciates and values the importance of trials and trials methodology research in improving individuals' health outcomes and care.

The main objective of the HRB-TMRN Trial Governance Placement Scheme is to place Irish researchers involved in trials (Principal Investigators, Trial Managers, Statisticians, Clinicians etc) and Patient / Public Contributors on experienced trial governance committees for randomised trials led from the UK. This Scheme will partner with the Centre for Trials Research (CTR) at Cardiff University, Wales. The CTR is a member of the MRC-NIHR-Trials Methodology Research Partnership.

Mentees will observe a series of trial governance meetings across selected trial governance committees. Placements are virtual with the potential to travel to meet with committee members. There are no costs to the Mentees or their affiliated institution to attend governance meetings as meetings are held online [Note: A travel bursary of a maximum of €500 is available should the mentee wish to travel to meet with committee colleagues for networking purposes. This is optional part of this Scheme].

Award Details

The HRB-TMRN plans to make approximately 20 Trial Governance Placements available between 2023 and 2025. Placement duration depends on the number of committees an individual applied for, specific committee availability and duration of placement.

Background

Appropriate and functioning trial governance across all clinical trials and interventions is the cornerstone of effective and optimal trial conduct. Clinical trials funded by the Health Research Board in Ireland are subject to the HRB Clinical Trials and Interventions Research Governance Policy¹, which defines trial governance as *“the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality both nationally and internationally”*. Adhering to clinical trial

¹ <https://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/clinical-trials-and-interventions-governance/>

governance requirements safeguards participants, enhances ethical and scientific quality, mitigates risk and minimises research waste¹.

All HRB-funded trials are subject to the following¹:

- That appropriate governance arrangements be in place before a trial can begin.
- The HRB reserves the right to approve [trial governance] membership and to refuse sanction of appointments of nominated candidates, should it be determined in HRB's absolute opinion that they are inappropriate for the role.
- Formal minutes of all meetings of the governance committees must be maintained. The HRB reserve the right to obtain these minutes.

The HRB and the National Institute for Health Research (NIHR, UK) provide definitions of the various trial governance committees^{1,2}. A summary of each for this Scheme is provided below. Applicants are advised to read the full definitions before applying.

Trial Management Committee (TMC) (frequency = monthly³)

The role of the TMC is to oversee the day-to-day management and overall conduct and progress of the trial¹.

Trial Steering Committee (TSC) (frequency = once every three to six months³)

The role of the TSC is to provide oversight of the trial on behalf of the Sponsor and to ensure that the trial is conducted in accordance with the principles of GCP and relevant regulations and guidelines¹.

Independent Data Monitoring Committee (IDMC) (frequency = every three to six months³)

The role of the IDMC is to monitor data emerging from the trial, in particular in relation to safety and efficacy, and make recommendations to the TSC regarding any safety issues that should be brought to the attention of participants or recommend action to be taken including, where necessary, that the trial stop.

Risk Assessment Group (frequency = ad hoc as needed³)

The RAG is responsible for facilitating the development of a systematic, prioritised, risk-based approach to the quality management of trials. It steers the delivery of high-quality risk management processes across a suite of trials.

There is an absence of structured training in trial governance to Irish trialists. This scheme helps address this need.

² <https://www.nihr.ac.uk/documents/research-governance-guidelines/12154>

³ Approximate frequency, subject to change based on specific trials.

Who should apply

Mentees may be in full-or part-time employment and can be clinicians or clinician-academic trainees, researchers, patient / public contributors, academics and/or postgraduate students currently residing in the Republic of Ireland and with a work/study remit relevant to clinical trials and interventions.

Placements will be offered to those individuals that can best justify the benefit of placement and the potential for impact. Previous experience is not a requirement, however, attendance on Independent Data Monitoring Committees (IDMCs) will be restricted to those with a clearly articulated need for this training. Members of the public / patients who envisage a role in trial governance are welcome to apply.

Placement Process

Selection and identification of trial governance committees and Mentees

- The HRB-TMRN will work with the Centre for Trials Research at Cardiff University to maintain a register of trials that welcome Mentees to attend trial governance meetings as an observer only.
- Mentees will identify their requirements and apply to be matched with a suitable trial(s) through the HRB-TMRN application process. Clinical topic focus will be considered a secondary factor when matching to a trial.
- Mentees can select and prioritise their interest across different trial governance committees.

Benefits for Mentees

It is expected that Mentees will gain the following benefits from their participation in the Trial Governance Scheme:

- Practical, hands-on experience on how trial governance committees operate and function.
- €500 bursary to support optional travel for networking purposes.
- Networking and collaboration opportunities with international experts.

Financial contributions

- Mentees are **NOT** paid by HRB-TMRN or by the Centre for Trials Research at Cardiff University and will likely join meetings remotely.
- There is access to an optional bursary (held centrally by HRB-TMRN) for receipted travel and expenses up to a value of €500 available to each Mentee to support travel to the host centre or trial site for networking purposes.
- HRB-TMRN will financially contribute to the Centre for Trials Research at Cardiff University to support the learning for each Mentee hosted.

Expectations

Trial Committees are expected to:

- Facilitate Mentee observational access to a pre-agreed number of governance meetings to the Mentee, providing timely dates and times of meetings and online access links.
- Recognise that the Mentee is in a learning capacity.
- Facilitate post meeting debriefs where needed with an appointed mentor.

Mentees are expected to:

- Attend meetings as invited, capacity as an observer only, without disrupting normal business activities of the meeting.
- Request clarity of any terms or acronyms used in meetings with their appointed mentor.
- Comply fully with the terms of the engagement agreement signed at the beginning of the placement, including the confidential nature of all meetings and associated materials (signing of an engagement agreement and non-disclosure agreement required).
- Review *the patient and public involvement in trial governance* video resource (as provided) ahead of starting any placement.

Application Process

1. **HRB-TMRN Placement Application Form** - Complete the application form and **sign**.
2. **Curriculum Vitae** – 2-page (maximum) CV in **PDF**.
3. Submit the Application and CV as a single PDF attachment to hrb-tmrn@universityofgalway.ie by **March 01st 2024 at 1pm.** Please include “Trial Governance Placement Scheme” in the email subject line.

Applicants are advised to **read carefully** these Guidance notes, which outline the conditions of the Placements before completing an application.

Deadline for Applicants

The deadline for submission of complete applications is **March 01st 2024, at 1pm.** Queries relating to this application can be sent to hrb-tmrn@universityofgalway.ie. All documentation must be submitted by email by the deadline listed.

Peer Review Process

Applications will be screened internally for eligibility and then matched based on requirements and available suitable trials at that time. Where demand exceeds the placements available, applications will be ranked according to greatest need (i.e., current requirements to fulfil trial governance roles) and greatest potential

impact as outlined in the application form. Where a candidate has specific needs for a trial type or clinical area, there may be a wait time for suitable trials to become available.

Assessment Criteria

Reviewers will review the applicant's application form and CV and score the application based on the following criteria:

- Evidence of applicant's interest in and need for training in trial governance.
- Evidence of the applicant's planning regarding impacts of trial governance placement on research interests, career trajectory and addressing trial governance needs.
- Track record of the applicant as demonstrated by their work on trial governance committees or future requirements to do so as part of their current role.

Feedback and Impact Assessment

Mentees will be requested to feedback on their experience of this Scheme to the HRB-TMRN to improve the quality of the Scheme. Mentees will also be asked to share any relevant impacts associated with this training, which may become evident after the placement has been completed.