UKCRC Registered Clinical Trials Units

UKCRC Registered CTU Network – CTU Chief Investigator Advisory Groups' Terms of Reference

UK Clinical Research Collaboration

igniting our potential

CTU Chief Investigator Advisory Groups' Terms of Reference

Prepared by the UKCRC Registered Trials Units Network Chief Investigator Network Group (CING)

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Contents

1. Abbreviations

CI – Chief Investigator

CING – Chief Investigator Network Group

CTU – Clinical Trials Unit

UKCRC – UK Clinical Research Collaboration

2. Executive summary

Many clinical trials units (CTUs) have advisory and oversight groups, with varying compositions of members internal to a CTU's host organisation, or external to it. One type of CTU advisory group can represent chief investigators (CIs) of clinical trials to provide strategic advice for the CTU and to consider the collaboration between CTUs and chief investigators. These CI advisory groups may range from experienced to early-mid career CIs (e.g. clinical academics or methodologists) who are representative of their community and uphold the value of a collaborative and interdisciplinary team science approach to the delivery of clinical trials. These CI advisory group members would recognise the contributions of all members of the CTU, support a positive and inclusive research culture, value diverse perspectives, and exhibit team working skills and interdisciplinary competencies.

In May 2023, a survey of 53 Network CTU Directors about CTU oversight and collaborative working with CIs yielded 41 responses and revealed variation in the existence of advisory groups representing CIs, which were referred to as 'clinical advisory groups' at the time: 11 (27%) CTUs had such a group, seven (17%) had clinical representation within a broader advisory group, 23 (56%) did not have a clinical advisory group, and neither clinical CTU leadership nor a clinical advisory group existed at four (10%) of the responding CTUs.

Since the UKCRC Network of registered CTUs published a Framework for clinical director role descriptions in June 2025, accompanied by a selection of role descriptions for the different clinical director models, there have been requests for examples of the Terms of Reference for CTUs' clinical advisory groups.

Therefore, in July 2025, Directors of CTUs in the UKCRC Network were approached for the Terms of Reference of any clinical advisory/oversight groups for CTUs, or divisions within CTUs, with the intention of creating a resource for the benefit of CTUs in the Network that are thinking about establishing or formalising arrangements for a group of CIs to support the CTU and its collaboration with CIs. Two CTUs provided relevant documents, which are appended for other CTUs' reference.

Finally, the Chief Investigator Network Group (CING) wished to recognise the diversity of CIs who contribute to these advisory groups that represent CIs, some of whom are not 'clinical'. Therefore, we prefer to name these groups "Chief Investigator Advisory Groups".

Rustam Al-Shahi Salman, UKCRC CTU Network clinical director

6 October 2025

Clinical Advisory Group Terms of Reference

Purpose and scope:

The Swansea Trials Unit (STU) Clinical Advisory Group (CAG) supports, reviews and improves the interaction between STU and chief investigators of clinical research, in order to design, develop and deliver clinical trials that support the Swansea University Faculty of Medicine, Health and Life Science Continuing Excellence: Strategy for Growth 2023-2026.

Terms of Reference Document

Remit

- Represent the experience and aims of chief investigators leading locally sponsored clinical research.
- Engage with clinicians who at all stages of their research career, promoting and disseminating information regarding the role of STU and its services.
- Offer coaching and peer support for new chief investigators of clinical research throughout the trial, from the initial funding application through to the write up of final reports and publication of papers.
- Identify educational resources and opportunities that benefit chief investigators in their conduct of clinical trials.
- Assist the STU Research Development Team with pre-submission internal peer review of funding applications for clinical trials led by chief investigators.
- Co-design a programme of educational and team-building activities (virtual and face to face workshops) involving STU staff and chief investigators and other clinical academics, in order to optimise mutual knowledge and understanding of the activities of chief investigators and STU staff, and celebrate / showcase success.

Members

The STU CAG currently consists of nine members including the Chair. These members are experienced clinical academic chief investigators of clinical research, representative of the diversity of their community in Swansea, with a track record of successful collaboration with STU in the delivery of clinical research. Members can also be early-career clinical academics, representing first-time chief investigators of clinical research.

Stakeholders

The key stakeholders are the chief investigators leading clinical research in Swansea, STU, SBUHB and other local Health Boards, the Faculty of Medicine, Health and Life Sciences, WAST.

Organisation of meetings

The clinical director convenes bi-annual meetings of the STU CAG. The frequency of any additional meetings will be determined by requirements. Administrative support will be provided by the STU admin team.

There will be no formal requirement for members to attend all meetings, but failure to attend three consecutive meetings will result in a discussion regarding membership of the CAG.

The admin support will circulate the necessary agenda and meeting documents five days prior to the meeting and minutes within 10 days of the meeting. The minutes will be approved at the next meeting.

Meetings will be held virtually.

Any CAG minutes and outputs will be shared with the STU Director.

Governance

The STU CAG will be chaired by the STU co-deputy director (clinical); other members can chair if required. The STU CAG chair will report to the STU Director, with whom they will meet annually.

Terms of office

Membership will be reviewed every three years, with no minimum term agreed.

Review of terms of reference

These TOR will be reviewed annually in March and updated as required. Each new iteration will be saved separately and labelled with the date of the review.

THE UNIVERSITY of EDINBURGH

ECTU Edinburgh Clinical Trials Unit

Edinburgh Clinical Trials Unit (ECTU) Clinical Advisory Group (CAG) Terms of Reference

Purpose and scope

The ECTU Clinical Advisory Group supports, reviews and improves the interaction between ECTU and chief investigators of clinical trials in Edinburgh, in order to design, develop and deliver clinical trials that support The University of Edinburgh's Clinical Trials Strategy.*

Remit

- Represent the experience and aims of chief investigators leading locally sponsored clinical trials in Edinburgh.
- Offer coaching and peer support for new chief investigators of locally sponsored clinical trials in Edinburgh throughout the trial, from funding application (as a co-applicant) to publication (as a co-author).
- Identify educational resources that benefit these chief investigators in their conduct of clinical trials.
- Review the scope and content of local educational activities about clinical trials (e.g. MSc in Clinical Trials and the Edinburgh Clinical Trials Management Course).
- Assist the ECTU Research Development Team with pre-submission internal peer review of funding applications for clinical trials led by chief investigators in Edinburgh.
- Co-design a programme of educational and team-building activities involving ECTU staff and chief investigators and other clinical academics involved in locally sponsored clinical trials in Edinburgh, in order to celebrate success and optimise mutual knowledge and understanding of the activities of chief investigators and ECTU staff.
- Raise awareness and promote the clinical trials strategy.
- Assist ECTU with its review of delivery and prioritisation of the clinical trials strategy.

Membership

There are between 5-10 members, including the ECTU clinical director. They are experienced clinical academic chief investigators of clinical trials, representative of the diversity of their community in Edinburgh, with a track record of successful collaboration with ECTU in the delivery of clinical trials. One early-career clinical academic represents first-time chief investigators of clinical trials. Usher Institute Affiliate status will be sought for the members.

Stakeholders

The key stakeholders are chief investigators leading clinical trials in Edinburgh, ECTU, ACCORD, and the College of Medicine and Veterinary Medicine.

* https://www.ed.ac.uk/usher/edinburgh-clinical-trials/clinical-trials-strategy

Organisation of meetings

The clinical director convenes bi-annual meetings of the ECTU CAG, with catering funded by ECTU. The frequency of any extraordinary meetings will be determined by requirements, and the date of the next meeting will be discussed at the end of each meeting.

Administrative support for scheduling, agenda, minutes and associated actions is provided by the ECTU Research Administrator.

While there is no formal requirement for all members to attend each meeting, attendance will be monitored and failure to attend two consecutive meetings will result in a review of the term of office.

The Research Administrator will circulate an agenda and papers by email at least five working days in advance. Attendees are expected to familiarise themselves with meeting papers sufficiently far in advance so as not to delay meeting proceedings.

The Research Administrator will circulate actions and minutes by email within ten working days of the meeting, and approved at the next meeting.

Meetings will take place virtually or in person. In-person meetings will include an option to join virtually.

ECTU CAG minutes and outputs are shared with the ECTU director and chief operating officer.

Governance

The ECTU CAG is chaired by the ECTU clinical director; other members may deputise for the chair if required.

ECTU CAG reports to the ECTU clinical director, with whom they shall meet annually, accompanied by the ECTU chief operating officer. For the purpose of this annual review, ECTU CAG receives formal reports from the team leads in ECTU.

Term of office

Membership will be reviewed every three years, and renewed subject to the mutual satisfaction of ECTU and the ECTU CAG member. No minimum term has been agreed.

Review of terms of reference

These Terms of Reference will be reviewed annually in November, and updated as required. Each new iteration will be saved separately and labelled with the date of review.