

UKCRC Registered CTU Network International Registration Review Committee Terms of Reference

1. Remit

The role of the UKCRC Registered CTU Network's International Registration Review Committee (IRRC) is to undertake and have oversight and management of the Network's Registration process. In brief, this process assesses the expertise, experience, capability in the design conduct and analysis of trials within groups undertaking non-commercial clinical trials in the UK, with the majority of their portfolio being academic research projects. Full or provisional Registration is 'awarded' with this being recognised within the field as a marker of quality.

2. Scope of activities

- a) To work with the Network Secretariat and Executive Group to define a framework and oversee review of UKCRC CTU Registration criteria and processes.
- b) To be aware of the clinical trials environment and key national and international issues affecting clinical trials units.
- c) To report and make necessary recommendations to the UKCRC Registered CTU Network Executive Group in respect of any changes to the registration criteria or processes.
- d) To make recommendations to the UKCRC Board in respect of the eligibility of applicant CTUs.
- e) To make recommendations to the UKCRC Board in respect of the continuing satisfactory standards of fully or provisionally registered CTUs.
- f) To work with the Network Secretariat to monitor the continued maintenance of standards of registered CTUs as part of the annual registration update. This will be via the Chair and Deputy Chair, except where wider discussion is required.

3. Meetings and Communication

- a) The IRRC will usually meet twice annually either by video conference or face-to-face, however the number of meetings may vary depending on workload.

- b) The first meeting will usually take place in Q1 in order to consider any changes to the review criteria or processes for that year. This meeting is likely to last no more than two hours.
- c) The second meeting will usually take place in Q3 in order to review applications received from current and prospective registered CTUs during that year. This meeting may range from three hours to three full days depending on whether a quinquennial review of all registered CTUs is being undertaken.
- d) Additional ad hoc meetings may be undertaken as required, in agreement with IRRC members. Minor points may be agreed by correspondence, adhering to voting and quoracy terms below.
- e) A representative of the IRRC will be nominated by the Chair to attend the quarterly meetings of the Network's Executive Group and biannual Directors' meetings on behalf of the IRRC.
- f) Administrative support to the IRRC will be provided by the Network Secretariat, this includes:
 - Preparing agendas and supporting papers
 - Preparing meeting notes and information
 - Arranging meetings
 - Travel arrangements and expenses

4. Composition and Membership

- a) Committee members should be of high standing within a field relevant to the conduct of clinical trials.
- b) Membership of the IRRC will be ratified by the UKCRC Board
- c) The majority of IRRC members, including the Chair, will be appointed from outside of the CTU Network (i.e. not a member of another network body nor an employee of a member CTU) and at least one member will be from outside the U.K.
- d) of a member CTU) and at least one member will be from outside the U.K.
- e) The Network Director will attend IRRC meetings *ex-officio*.
- f) The Network Secretariat will attend all meetings in support but will not be included in official membership of the IRRC.
- g) Composition of the IRRC is detailed below:

IRRC Membership
Chair
Deputy Chair
Independent Information Systems specialist
Independent Statistics specialist
Independent Quality Assurance specialist
Patient and Public Involvement & Engagement specialist
Senior Trialist
Senior Trialist
Senior Trialist
Senior Trialist
Senior Trialist

5. Appointment

- a) Chair:
The Chair will be appointed by the UKCRC Board in consultation with the Network's Executive Group. Term of appointment will be 3 years and renewable.
- b) Deputy Chair:
A Deputy Chair will be appointed by the UKCRC Board in consultation with the Network's Executive Group. Term of appointment will be 3 years and renewable.
- c) IRRC Members:
Members will be appointed by the UKCRC Board in consultation with the Network's Executive Group. Term of appointment will be 3 years and renewable, if members would like to stand for a different position, and where experience allows they are welcome to do so.

6. Succession Planning

- a) In the event that several members wish to stand down at the same time, the process will be staggered to ensure continuity.

- b) Future members are able to attend an IRRC meeting in advance of their tenure start date to become familiar with the IRRC.
- c) It is not the expectation that the Deputy Chair will routinely evolve into the Chair position, although this is possible of course.

7. Register of Interests

A register of interests will be centrally held by the Secretariat for all members of the IRRC. Members of the IRRC are required to disclose any personal or professional interests that may cause potential conflict with their role and remit on the IRRC. The register will be updated annually and on an ad hoc basis. It is the responsibility of members to declare any potential conflicts of interest ahead of IRRC meetings. If these conflicts are felt to be significant by the Chair the member will abstain from voting or contributing to the discussion on item(s) concerned.

8. Voting and Quoracy

- a) Decisions can be taken via teleconference, in person, by phone poll, or by email vote. IRRC decisions will be made on the basis of consensus wherever possible. At the discretion of the chair, a vote will take place, with all IRRC members having an equal vote, but only if all reasonable attempts to achieve consensus have failed.
- b) A quorum of the IRRC shall be when a majority of its membership (including the Chair or Deputy Chair) is present, regardless of the method of decision-making (e.g. by teleconference, in person, phone poll, or email vote). It is the responsibility of the Chair to ensure that the Group is quorate and able to perform the business with appropriate representation.
- c) Where the Chair is unavailable, the Deputy Chair will act in that capacity.

9. Reporting Structure

- a) The IRRC reports to the UKCRC Board.
- b) Closed minutes of meetings will be taken as a summary of decisions and these will be available to the UKCRC Board if requested.

10. Review of Terms of Reference

The IRRC shall review these Terms of Reference every two years and update them as required.