

UK Renal Trials Network

Terms of reference

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1. Composition

The UKRTN will be composed of a General Committee and an Operational Subcommittee. The General Committee (GC) will be responsible for scientific evaluation and input into trial proposals and general functions of the UKRTN. The Operational Subcommittee (OSC) will be responsible for administrative matters and will oversee the processing of submissions and delivery of outputs.

The UKRTN forms part of the UK Kidney Research Consortium (UKKRC). The chair of the UKRTN will attend UKRTN meetings as representative of the UKRTN.

2. General Committee Membership

The UKRTN GC will consist of the following

1. Chairperson
2. Deputy chair
3. At least 2 trials statisticians
4. At least 1 health economist
5. The national renal CRN portfolio lead
6. A representative from the UK Renal Registry
7. A member with expertise of patient reported outcomes (PROMs)
8. A member with experience of and expertise in qualitative research
9. Two patient expert members (with at least a professional scientific background)
10. At least one specialist trials nurse member
11. At least one member with experience in trial management and coordination

The UKRTN GC should include at least 4 scientists with expertise in randomised trials and prospective studies (not limited to nephrology).

The UKRTN is likely to have a minimum of 16 members as outlined above, and given that the UKRTN meets more regularly than other groups supported by the UKKRC, there are cost and operational considerations to any expansion of the UKRTN membership. Given the purpose of the UKRTN, recognised expertise in the design, conduct, analysis and reporting of clinical trials is a fundamental requirement for membership. Membership is therefore not open to all, and should be limited to 30 members.

New members may be appointed through one of two routes.

1. Where existing UKRTN members identify a specific need for expertise not available among existing members, the UKRTN may approach and nominate and invite clinical trials professionals to become members of the UKRTN. The decision to invite a new member should be taken by the UKRTN, supported by majority vote.
2. Where vacancies arise, these will be listed on the UKRTN web pages. Individuals who consider themselves suitably qualified to serve on the UKRTN and wish to apply will be required to complete an expression of interest form available for download from the UKRTN web pages or by contacting the UKRTN chair or deputy chair. Applications will be considered at the first subsequent UKRTN meeting, and members will determine by majority vote whom to appoint.

For applicants to be appointed as UKRTN members, the following conditions must be satisfied:

- a. The expertise brought by the applicant must not already exist within UKRTN membership
- b. The UKRTN membership must agree (by majority vote) that the new member will add value to the UKRTN and that their inclusion is justified.

2.1. Chairperson

A suitably qualified chairperson would be elected by the UKRTN GC, and would serve a term of 3 years. The chair would be elected by majority vote. Chairpersons may be elected for one additional consecutive 3-year term to serve a maximum of 6 consecutive years.

Ideally, the deputy chair should succeed the chair to allow continuity. In the event that the deputy chair is unable to take up the position of chair, candidates for the position of chair should have prior operational experience of the UKRTN wherever possible.

Chairpersons of UKCRC Clinical Study Groups (CSGs), and the National Renal CRN Portfolio lead, would not be eligible for the position of UKRTN chairperson during their respective tenures.

2.2. Deputy chair

A deputy chairperson will be elected by the UKRTN GC by majority vote, and will serve a term of 3 years. A deputy chairperson may be re-elected for one additional consecutive 3-year period to serve a maximum of 6 consecutive years. The person elected to deputy chair should, in principle, be willing to succeed the chair.

The deputy chair will assume the role of chair

- in the absence of the chairperson
- In the event that trial proposals are considered by the UKRTN GC of which the chair is not independent, the deputy chair will assume the role of chair.

In the event that proposals come before the UKRTN GC of which neither the chair nor deputy chair is independent, discussions will be chaired by the National CRN Portfolio lead.

3. Operational Subcommittee Membership

The operational subcommittee will consist of the chair, deputy chair and at least 3 other members. The OSC will be appointed by the UKRTN GC by consensus.

4. UKRTN role and terms of reference

4.1. General

The UKRTN will meet approximately 3 times per year. The UKRTN will

1. Establish and maintain links with other international trial networks including AKTN and CNTN, and ISN-ACT, in order to facilitate the delivery of definitive global outcomes trials.

2. Encourage the proposal and development of research ideas and encourage prospective investigators to submit proposals for consideration
3. Encourage submission of trial proposals for discussion by UKRTN early in their development
4. Provide opportunity for proposers to attend round table discussion with the UKRTN at 4-monthly intervals
5. Provide guidance and advice and, where necessary, design input for the development of trial protocols
6. Provide peer review
7. Provide research design advice, notably for applications arising outside England where the NIHR Research Design Service is not accessible to investigators
8. Provide endorsement of trial proposals under conditions defined below.
9. Identify situations where conflicting proposals emerge, and promote and facilitate unification of competing proposals where possible.
10. Maintain a website with information about the UKRTN.
11. Assume an advocacy role, establishing communication with key funders including NIHR and lobbying for funded calls to address key knowledge gaps
12. Address areas of uncertainty regarding trials methodology and produce and publish reports or reviews as appropriate.

4.2. Endorsement of Trial Proposals

Investigators seeking endorsement from the UKRTN may submit their trial proposal using the UKRTN proforma or, where a protocol has been developed or detailed grant application has been prepared, such documentation may be submitted for the UKRTN's consideration.

In order to allow sufficient time for review, proposals must be received by the UKRTN at least 6 weeks before the outcome of such a review is required. The UKRTN cannot provide letters of endorsement for proposals received less than 6 weeks from the date that such letters are required.

- The UKRTN will provide endorsement for funding applications where such applications have been previously reviewed by the UKRTN.
- The UKRTN will be under no obligation to endorse trial proposals where methodological, design or feasibility issues raised by UKRTN review have not been satisfactorily addressed.
- UKRTN reserves the right to refuse endorsement of trial proposals that have not been submitted to UKRTN for review prior to a request for endorsement.
- Endorsement will only be provided after discussion at a UKRTN meeting, where the decision to endorse rests on majority vote.
- It is recognised that circumstances may arise that require endorsement to support funding applications where timelines do not allow discussion at a scheduled UKRTN GC meeting. In this setting, endorsement may be agreed after ad hoc discussion by UKRTN members that include, as minimum, the UKRTN OSC, with any other members that are able to contribute to such discussions. Where decisions to provide endorsement are taken outside scheduled meetings of the UKRTN GC, such discussions will be minuted and minutes tabled at the next UKRTN GC meeting.

Criteria for endorsement:

Proposals must satisfy three criteria in order for the UKRTN to provide endorsement:

1. Design – trials must have robust design. It is within the remit of the UKRTN to identify design shortcomings, and where such shortcomings exist, the UKRTN reserves the right to decline endorsement. It is however envisaged that feedback from the UKRTN would result in resubmission of amended designs, at which point endorsement may be offered.
2. Feasibility – It is the remit of the UKRTN to consider the feasibility of trial proposals. If a proposal is not considered feasible, the UKRTN reserves the right to decline endorsement. It is however envisaged that UKRTN feedback may result in amended design, allowing a reassessment of feasibility and possible subsequent endorsement.
3. Research Priority – The UKRTN may comment on whether proposals represent a research priority. Whilst it is recognized that it is not within the remit of the UKRTN to set research priorities, the UKRTN will consider how proposals relate to existing or other emerging projects and, particularly where proposals compete with other high priority programmes or trials for enrolment, the UKRTN reserves the right to decline endorsement.

Feedback to applicants

The UKRTN will provide written feedback to proposers within 4 weeks following the UKRTN meeting at which proposals have been discussed. Feedback will be provided by the lead reviewer on behalf of the UKRTN and may take the form of an email from lead reviewer to proposer.

Written endorsement may be provided. Where endorsement is provided, this will be explicitly stated.

If the UKRTN is unable to endorse a proposal, the reasons for non-endorsement will be provided in writing, including a description of the UKRTN's assessment of the endorsement criteria listed above, and the conditions under which resubmission may be considered.

The decision of the UKRTN concerning endorsement is taken by majority vote, and is therefore final.

4.3. Databases

The UKRTN will seek to maintain the following databases:

1. Suitable persons to serve on Trial Steering Committees and Data Monitoring Committees
2. Current active or funded trials in the UK and their chief investigators
3. Trials-active research sites in the UK
4. Maintain an online searchable database of proposals under development and those already funded that had been considered *a priori* by UKRTN. Under exceptional circumstances, for example where confidentiality agreements are in place, the UKRTN will agree to withhold proposals from listing.

4.4. Education

The UKRTN will promote education of clinicians, researchers, patients and the public on the design and conduct of clinical trials, and will

1. Make available resources that would provide tips on how to design and develop trials (a top-tip list)
2. Publish such information on the UKRTN website
3. Provide or contribute to training days or courses at relevant meetings or conferences
4. Invite young nephrologists to participate as non-voting members on the UKRTN.

4.5. PatientView

The UKRTN will facilitate the posting of information about relevant trials to patients' pages via PatientView.

Proposals for text to be placed on PatientView must be submitted to UKRTN via a submission proforma available via the UKRTN chair or members of the operational subcommittee. Prerequisites for approval include 1) that trials must be on the National portfolio, and 2) ethical approval for the proposed text must be in place and provided to the UKRTN at the time of submission.

The UKRTN will make a recommendation to the PatientView team, but the final decision to publish trial information will rest with PatientView.

5. Submission of Trial Proposals

Prospective investigators may submit a proposal for consideration by the UKRTN. This may be in the form of a trial protocol, or by completion of the submission form made available either through the UKRTN web pages or obtained from the UKRTN chair.

6. Relationship with the UKKRC

The UKRTN forms part of, and is supported by, the UKKRC. However, UKRTN will maintain operational independence, recognising that trial proposals are likely to arise from other groups within the UKKRC (for example, CSGs or KRUK).

7. Conflicts of Interest

The majority of UKRTN members are clinical trialists or specialist academic researchers. It is recognized that proposals submitted for UKRTN consideration may conflict or compete with proposals being prepared by UKRTN members.

In order to maintain impartiality and confidentiality of the UKRTN, the following rules and procedures apply.

1. When proposals are received for consideration, UKRTN members will not receive any documentation pertaining to such proposals prior to providing a conflict of interest statement. Only members declaring no conflict of interest will receive materials for consideration. Members declaring a conflict or submitting no declaration will not be sent materials. The conflict statements submitted in relation to each proposal will be collated, and will be presented at UKRTN meetings where such proposals are to be tabled. Conflicted members will be asked to leave the room when projects upon which they are conflicted are discussed.
2. Some UKRTN members represent specialist fields and may have involvement with multiple competing bids. One example is the UKRR representative. Under such circumstances the relevant UKRTN member may be permitted to be present during discussions of such projects providing that all conflicts are declared. Members thus conflicted or involved with bids under consideration may not vote on the decision to endorse such projects.

Funding body reviews

Given the nature of the UKRTN membership, it is very likely that nephrology trial proposals submitted to funding bodies will be sent to UKRTN members to review. In this setting, UKRTN members may have previously reviewed such proposals as part of their UKRTN role.

It is the view of the UKRTN that this situation does not present a barrier to reviewing such proposals for funding bodies, but that UKRTN reviewers should declare their involvement with the UKRTN and the fact that the relevant project had previously been reviewed by them.