UK Registered Clinical Trials Unit Network

# UK Registration of Clinical Trials Units

## Information Pack and Guidance Notes – Registration Renewal 2027

This document is for use by:

- CTUs seeking to renew membership

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**2027**

# Background

The UK Registered Clinical Trials Units Network aims to develop and maintain high quality capacity for specialist trial design, conduct and analysis in the UK. It is widely acknowledged that expertise in clinical trials and other well-designed studies* is vital to ensure high quality and successful, timely trial conduct and to meet regulatory and governance requirements. Such high quality expertise is therefore key to the development of research activity within the UK. The Registration Process and the UK Registered CTU Network is operated on a self-funding basis. For this reason, there is a Registration application fee of £500 inc VAT which covers the administration and International Registration Review Committee costs. For unsuccessful applications there will be no refund. A subsequent annual fee of £3500+VAT will be payable on designation as a successfully UK Registered CTU. The annual fee will be payable for each year of registration to cover the delivery of the UK Registered CTU Network Work Programme (including organisation of meetings) as agreed by the UK Registered CTU Network Executive Group

# Eligibility

Applications can be made from any CTU in the UK **responsible for *leading* the design, the *central/national* coordination and the *overall* analysis of multi-centred randomised controlled trials or other well-designed studies* using the application proforma**. CTUs with responsibility for only the local coordination of trial activity and supply of local data to a central coordinating CTU would **not** be eligible for registration. CTUs working in any disease/topic area are eligible to apply.

### Collaborative Groups

It is recognised that some clinical trials are managed by collaborative groups where all of the expertise required may not exist within the same research group. Applications from collaborative groups are eligible, and these include groupings within the same parent organisation, as well as geographically distinct collaboratives. In all cases, there will need to be clear evidence of formal arrangements and assignments of responsibilities between the groups and clarity about the roles of each group. Sufficient detail should be provided in the proforma to enable the Network's International Registration Review Committee to be confident that formal arrangements are in place for collaboration, that all key competencies are met, and that the partnership would be capable of continued success in the face of changes in key personnel. If successful, the collaborative group will be Registered, not the individual components of the collaboration.

*One must be a randomised controlled trial (RCT)

## Merged CTUs

Institutions with multiple registered clinical trials units or unregistered research groups within their organisation that have taken the decision to combine the expertise into one distinct CTU are eligible to apply.

The following scenarios provide an example of how you should apply if one or more of the units/groups merged hold registration status:

If an Existing Fully Registered CTU (lead CTU) within the parent institution merges with an unregistered research group or provisional registered CTU and the new merger takes on the identity and processes of the existing Fully Registered CTU then you must complete the Renewals proforma and provide details and clear evidence of the merger in section 11 in order to satisfy the Review Committee that all key competencies are met and the new merger is capable of continued success. If the new merger does not take the identity and processes of the Fully Registered CTU then you must apply as a new applicant.

If two or more Fully Registered CTUs within the parent institution merge and the new merger takes on the identity of one of the existing Fully Registered CTU (Lead CTU) then you must complete the Renewals proforma and provide details and clear evidence of the merger in section 11 in order to satisfy the Review Committee that all key competencies are met and the new merger is capable of continued success. If the new merger does not take the identity and processes of a Fully Registered CTU then you must apply as a new applicant using the standard form.

If the merger is between two provisional registered units you should apply as a new applicant using the standard form and provide further information in section 11.

## Provisional Registration

All provisional registered units must achieve Full registration within a 3 year timeframe. Failure to do so will result in the withdrawal of your registration status.

**Please note that if an existing Fully Registered Unit is assessed by the Registration Review Committee as no longer meeting the requirements for Full registration, that CTU will be given a period of up to 12 months to rectify all issues identified, at which point they will be subject to a further review by the Registration Review Committee, with one of the following outcomes: maintenance of full registration or loss of registration. During this period, the CTU will NOT be listed on the UK CTU website as a fully registered CTU. Instead it will be listed as Under Review.**

## How will applications be assessed?

The Registration process is coordinated by the UK Registered CTU Network Secretariat based at the University of Leeds. Applications will be reviewed with specific reference to the key competencies (Appendix 1) and evaluation criteria (Appendix 2) developed and approved by the UK Registered CTU Network Executive Group and the independent International Registration Review Committee. The key competencies and evaluation criteria form the basis by which proposals will be assessed.

In addition to the key competencies and evaluation criteria the following rules apply:

- **We will use all publicly available information.**
- **We will consider information contained in any historical registration applications that you may have provided to us during previous registration calls to inform our decision.**
- **We will undertake a random audit of SOPs at short notice for close review. Failure to supply any of the requested SOPs within the timeframe could affect your registration application.**
- **We will continue to operate a no right of appeal rule.**

An independent International Registration Review Committee comprising UK and international expert trialists has been established to review the submitted proposals. A triage system will be applied and managed by the Network Secretariat; any applications that are incomplete or submitted late will not be submitted to the Registration Review Committee.

The Registration Review Committee meeting will take place in 2027.

For a detailed list of the International Registration Review Committee members please visit our website: www.ukcrc-ctu.org.uk. Please note that Review Committee meetings will be observed by key partners, details are also listed on our website.

## Applying for Full Registration

It is essential that the CTUs that receive Full Registration have sufficient expertise and long-term viability to provide the UK with a national, stable critical mass of expert staff and the infrastructure to support successful, timely and high quality completion of clinical research studies. Registered CTUs must have sufficient capacity in terms of staffing, time and expertise to assure the successful management of clinical trials or other well designed studies, even in unexpected/unplanned circumstances (for example, personnel changes or trial problems). Only CTUs that can provide clear evidence of the essential competencies will be given Full Registration status. In order to obtain Full Registration status, CTUs must demonstrate:

- A track record and experience of coordinating multi-centre randomised controlled trials or other well-designed studies
- Presence of a core team of expert staff to develop studies
- Presence of robust quality assurance systems and processes to meet appropriate regulations and legislation (e.g. the principles of Good Clinical Practice, UK Policy Framework for Health and Social Care Research, the Data Protection Act and any other UK regulations and legislation relating to Clinical Trials).
- Evidence of longer-term viability of capacity for trials coordination and the development/maintenance of a trials portfolio, including core funding or evidence of a rolling programme of grants, with evidence of commitment from the parent institution.

## General Notes

Please note that the standards set by the UK CTU Registration Process are high, and demonstrable evidence that a CTU fulfils all of the criteria described above is considered essential. CTUs should **not** apply for renewal of Registration unless they are able to demonstrate all of the competencies using the evaluation criteria set. Any application that does not meet the essential criteria will not be forwarded to the UK CTU Registration Committee for consideration.

**Applications must be submitted in full before the closing date. Late submissions will not be accepted under any circumstances. Please note that incomplete applications will be rejected and not reviewed.**

Note that the CTU Registration Process is **not** a research funding scheme. It will identify CTUs possessing core competencies that wish to join the network of UK Registered CTUs and be involved in the UK strategy towards trials.

## Guidance Notes for Completing the Proforma

All relevant sections of the proforma must be completed before submission of the application.

## Cover page of the proforma

The cover page requests information about the CTU making the application, together with contact details and the year that the CTU opened (or collaborative/merger established for collaborative or merged group applications). The cover page should also be used to indicate whether a collaborative or merged group application is being made.

## Sections of the proforma

**Section 1** requests information about your current and recent clinical research activity and related publications including:

- A summary of trials within your organisations portfolio.
- Details on how your organisation has responded to previous feedback received from the UK International CTU Registration Review Committee. Feedback can be found on detailed letters from the Registration Committee. Please contact the Secretariat if you require copies of any correspondence. Please note it is the applicant's responsibility to ensure all feedback is addressed.
- Questions 1.3 – 1.9 focus on your organisational strategies. You must demonstrate you have a clear vision and operational plans in place to deal with future challenges.

**Section 2** focuses on staff in the CTU, including details about staff funded to work on clinical trials and other well-designed studies through 'core' infrastructure grants, retained funds or overhead recovery and through specific research grants.

- Question 2.1 – 2.2: Applicants are required to demonstrate that they 'employ' or have access to the following staff funded independently of specific research grants:
  - at least two senior Statisticians (one with at least 5 years' experience for Full registration)
  - two Senior Trial Managers (one with at least 5 years' relevant experience for Full Registration) and
- an appropriate level of IT/IS persons, one with at least with three years' experience. For internally hosted systems an appropriate level would usually be a minimum of 2 persons, Where the IS/IT provision is entirely managed by the parent institution or an external provider CTUs should demonstrate that the support they receive is equivalent to that expected of a CTU where the IS/IT provision is provided internally.
- For Full Registration: a named person who is responsible for overseeing the QA function (this can be as a part of their job role) with at least three years' relevant experience. For Provisional Registration: a named person who is responsible for overseeing the QA function (this can be as a part of their job role) with at least one year's relevant experience.
- For Full Registration: A named PPI&E lead (this can be as a part of their job role) with at least three years' relevant experience,
- For Full Registration: A named Research Inclusion lead (this can be as a part of their job role) with at least three years' relevant experience.

- It is preferable if all the above core positions are funded independently of specific project grants.
- Question 2.1 Please provide us with one page CVs for your CTU Director, your two most experienced Statisticians, two Trial/Project Managers and one or two IS staff members (as appropriate), QA lead, PPI&E lead and Research inclusion lead and label this as Appendix 1. Please ensure that relevant dates of education and employment are included in these CVs.
- Question 2.3 requires you to provide a detailed organisation chart of your CTU as Appendix 2. Organograms must include all named key senior staff and any vacant posts. For collaborative groups and merged units see Section 11. For senior staff not located within the CTU indicate how they link into the CTU structure.

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**Section 3** focuses on CTU Infrastructure. This section requires all applicants to submit a statement of support, at the level of Dean or Pro-Vice Chancellor or Chief Executive (as applicable), from their parent organisation and submit this as Appendix 3. Collaborative applications should include this statement from each parent organisation which is involved. If your parent organisation(s) already includes a UK Registered Clinical Trials Unit or are supporting another application, they should provide a clear rationale for supporting the registration application of additional Clinical Trials Units, and include details of processes already in place, or in planning, for the following:

- Optimising support and resources for multiple Registered Clinical Trials Units and sharing of best practice across the organisation (e.g. in relation to staff training and development, how resources will be shared)
- Strategic oversight of core infrastructure support (e.g. database system development; QA resources).

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**Section 4** focuses on your systems and processes in place to meet appropriate regulations and legislation.

- Please ensure that sufficient detail is provided to demonstrate that research governance standards are thorough and high. Evidence should be provided to satisfy the International Registration Review Committee that the CTU has high quality systems and processes in place to meet appropriate regulations and legislation (e.g. the principles of Good Clinical Practice, the UK Policy Framework for Health and Social Care Research, the Data Protection Act, and any other UK regulations and legislation relating to Clinical Trials
- Please include details of your CTU's Standard Operating Procedures (SOPs), including version numbers (please indicate if in draft) and dates, in Table 4.1. It should be noted, that the core SOPs specified in the application are not intended as an exhaustive list, but represent the essential areas in which CTUs are expected to have documented procedures in place as a minimum. It is acknowledged that some units may be in the process of improving their systems, Table 4.1 also asks you to demonstrate that your CTU has appropriate systems in place to monitor and review SOPs through the inclusion of a scheduled revision date.

**Please note that we reserve the right to request copies of any SOPs listed at short notice. Failure to supply the requested SOP(s) within the timeframe could affect your registration application.**

**Section 5** requests details about changes to the CTU's information systems, in terms of data management systems, the systems in place to ensure robust and secure information systems.

**Section 6** requests details about the level of statistical involvement throughout the trial,

**Section 7** asks for information about your systems and processes for secure randomisation.

**Section 8** requests details about your recent publications. As a separate appendix (Appendix 4) please provide a full paper copy of 3 significant peer-reviewed publications of recent existing/closed studies. Publications must fall within your most recent period of registration and must be from separate clinical trials or well-designed studies that best demonstrate your unit's activity. Please include a summary for EACH publication of name(s) of CTU staff involved (both named authors and others with significant contribution) and outline their role on the trial. The publications should be ordered chronologically with the most recent first. Published protocols from different studies do qualify for inclusion. Two publications must be a final analysis of a randomised controlled trial (RCT).

**Section 9** enquires about your units' contribution to Network activity in relation to achieving its work programme. Applicants are asked to describe their organisational contribution during their most recent period of registration including and not restricted to attendance at meetings/conferences and membership and contribution to groups' activity.

**Section 10** requires the signature of the Director/Head of the CTU applying for CTU Registration. This page should be printed, signed, scanned, and submitted with your application as Appendix 6.

**Section 11** is required **only for applications from collaborative groups, merged CTUs or CTUs with multiple units within their parent institution for which it is mandatory**. This section should be used by CTUs comprised of collaborating groups, merged units or CTUs with multiple units within their parent institution to provide information on the roles of each group and how the groups work together. Evidence should be provided to satisfy the International Registration Review Committee that formal arrangements are in place for collaboration/merger, that all key competencies are met by the collaboration/merger, and that the partnership would be capable of continued success in the face of changes in key personnel. Further guidance can be found within individual sections of the proforma.

## Appendices

All appendices should be submitted as separate documents.

| Appendix | Description |
|---|---|
| 1 | One page CVs of staff in key roles i.e. CTU Director, up to two Statisticians, up to two Trial Managers and up to two IS Leads, QA lead, PPI&E lead and named research inclusion lead |
| 2 | Detailed organisation chart |

| | |
|---|---|
| 3 | Statement of Support from Parent Organisation(s) |
| 4 | Please provide the full paper pdf of up to 3 recent significant peer reviewed publications with details of contributions. |
| 5 | Any supporting analogous quality assurance assessments or certifications (not mandatory) |
| 6 | Signed, scanned copy of the signature page |

## Confidentiality

All information provided to the UK CTU Registration Review Committee will be treated as confidential. In the event that UK Registration is awarded, some information provided may be made available in the public domain (e.g. via the UK Registered CTU website: www.ukcrc-ctu.org.uk). Registered CTUs will be contacted and asked to validate information prior to its release.

## Review of Registration Status

UK Clinical Trials Unit Registration status will normally apply for six years for Fully Registered units and 3 years for those awarded provisional status. A review of all UK Registered Clinical Trials Units will be carried out every five years, to ensure that Clinical Trials Units still possess the required competencies to allow them to retain their Registration status. Clinical Trials Units with Provisional Registration status must apply for Full Registration status at the 3 year review. There is an expectation that units granted provisional registration demonstrate that they have the capacity and ability to develop the full criteria within a 3 year timeframe.

**An annual registration update in the form of a self-assessment review will be expected for all Registered Units. The paperwork for the annual review will be kept to a minimum. This is mandatory to maintain your Registration, failure to do so could result in the withdrawal of your registration.**

## Fees

The Registration process and the UK Registered CTU Network will be operated on a self-funding basis. For this reason, there will be a Registration application fee of £500 which covers the administration and International Registration Review Committee costs. For unsuccessful applications there will be no refund.

**Please note that applications which have been submitted without the correct fee will not be considered. Payment (in full) should be received before the application deadline**

**A subsequent annual fee of £3500+VAT will be payable on designation as a successfully UK Registered CTU. The annual fee will be payable for each year of registration, the annual fee will cover the delivery of the UK Registered CTU Work Programme.**

## Further information

For further information about the UK CTU Registration Process, please contact Helen Evans, Network Programme Manager at regctus@leeds.ac.uk or 0113 343 9132.

## Submission of Proposals

**The deadline for submission of proposals will be announced in due course**

**The completed application form and appendices, and scanned signature pages should be emailed to regctus@leeds.ac.uk. Please mark the email: 'UK CTU Registration Application' and include the name of your Clinical Trials Unit in the name of the form and email subject heading.**

**Hard copies of the proforma or supporting documents are not required.**

**The UK CTU Registration Committee meeting will take place in autumn 2027.**