UKCRC Registered Clinical Trials Units

UKCRC Registration of Clinical Trials Units

Information Pack and Guidance Notes 2023

This guidance is for use by:

- New applicants
- CTUs seeking transfer from provisional to full status

UK Clinical Research Collaboration

igniting our potential

Information Pack and Guidance Notes

Summer 2023

Background

The UKCRC 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 UKCRC 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 Review Panel costs. For unsuccessful applications there will be no refund. A subsequent annual fee of £3000+VAT will be payable on designation as a successfully UKCRC Registered CTU. The annual fee will be payable for each year of registration to cover the delivery of the UKCRC Registered CTU Network Work Programme (including meeting organisation) as agreed by the UKCRC Registered CTU Network Executive Group (For information about the Work Programme visit www.ukcrc-ctu.org.uk).

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 (phase II-IV) 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 host 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 UKCRC CTU 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

Host 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 host 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 9 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 host 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 9 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 9.

Provisional Registration

It is also recognised that new or smaller CTUs may be working towards having relevant expertise and experience that may be worth building on, but which currently falls short of the full complement of infrastructure, resources, and experience required for Registration. It is hoped that rather than lose such expertise and commitment, these CTUs could either collaborate with another unit to fulfil the totality of requirements for UKCRC CTU Registration or apply for Provisional Registration. Such CTUs should demonstrate that they have the capacity and ability to develop the full criteria within a 3 year timeframe.

How will applications be assessed?

The Registration process is coordinated by the UKCRC 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 UKCRC Registered CTU Network Executive Group and the 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 listed SOPs within the timeframe could affect your registration application.**
- **We will continue to operate a no right of appeal rule.**

A UKCRC International CTU 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 clearly not reaching the criteria for either Full or Provisional Registration will not be submitted to the Registration Committee.

The Registration Committee meeting will take place in autumn 2023. Decisions are ratified by the UKCRC Board and detailed feedback will be provided on all applications.

For a detailed list of 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 UKCRC Partners 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 (phase II-IV) 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 host institution.

<u>Please note</u> that CTUs applying for Full Registration may be awarded Provisional Registration if they do not meet the criteria for Full Registration but do meet the criteria for Provisional Registration. CTUs applying for Full Registration which do not meet the criteria for Full or Provisional Registration will not be registered.

All existing Fully Registered Units that the Committee recommends no longer meet the requirements for Full registration will be given a period of up to 12 months to rectify any issues identified at which point they will be subject to a further review by the Review Committee, with one of the following outcomes: maintenance of full registration or loss of registration.

Applying for Provisional Registration

It is recognised that new CTUs may be developing relevant expertise and experience that may be worth building on, but which fall short of the full complement of infrastructure, resources, and experience required for Full Registration status.

Evaluation criteria have been developed for CTUs that do not meet the criteria for Full Registration status, but that are working towards possessing sufficient expertise and experience to enable Full Registration. These CTUs may be granted Provisional Registration.

Only CTUs that can provide clear evidence of the competencies for Provisional Registration will be given Provisional Registration status. It is expected that units granted provisional registration demonstrate that they have the capacity and ability to develop the full criteria within a 3 year timeframe, failure to do so will result in the withdrawal of your registration.

General Notes

Please note that the standards set by the UKCRC 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 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 UKCRC 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 UKCRC Registered CTUs and be involved in the UKCRC strategy towards trials.

Guidance Notes for Completing the Proforma

One proforma should be completed for each CTU submitting a proposal.

Existing Registered units must complete the Renewals form. All new applicants should apply using the standard proforma. For new applicants the same proforma is to be completed regardless of whether Full or Provisional Registration is being applied for.

When completing the proforma, please type all responses, using the format and tables provided. Areas which require free text will expand to accommodate your answer. 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 and also whether you are applying for Full or Provisional Registration. Note that applicants may be awarded Provisional Registration even if they submit an application for Full Registration if they meet the criteria for Provisional Registration but not for Full Registration.

We also request the following information:

- The summary of trials within your organisations portfolio
- Details on how your organisation has responded to previous feedback received from the UKCRC International CTU Registration Review Committee, this includes applicants who have previously held UKCRC Registration or have previously applied but were unsuccessful in achieving registration. 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.

Sections of the proforma

Section 1 requests information about the roles of the CTU/ Collaboration or Merged Group and your current and recent clinical research activity and related publications.

- The Sponsor is an individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.
- Please send a full paper pdf copy of 3 recent significant peer reviewed publications of recent existing/closed studies with details of the author contributions for Full registration or 1 if applying for provisional registration as Appendix 1. Please include a summary for EACH publication of name(s) of CTU staff on the publications listed and outline their role on the trial. Publications must be from separate clinical trials or other well-designed studies that best demonstrate your unit's activity and should be ordered chronologically with the most recent first. Published protocols from different studies do qualify for inclusion. For Full registration one publication must be a final analysis of a randomised controlled trial (RCT).

- Questions 1.3 – 1.5 focus on your organisational strategies. You must demonstrate you have a clear vision and operational plans in place to deal with future challenges.
- Questions 1.6 – 1.7 look at how you embed Patient and Public Involvement and Engagement (PPIE) in your unit's operational and research activities.

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 2.2 – 2.4: Applicants are required to demonstrate that they 'employ' or have access to the following staff:
  - For Full Registration: at least two senior Statisticians (one with at least 5 years' experience); for Provisional Registration: At least one statistician with at least three years' relevant experience, and with evidence of access to senior statistical support,
  - For Full Registration: two Senior Trial Managers (one with at least 5 years' relevant experience); For Provisional Registration: at least one trial/project manager with at least three years' relevant experience
  - An appropriate level of experienced IT/IS personnel support. For internally hosted systems this would usually be a minimum of 2 persons, Where the IS/IT provision is entirely managed by the host 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, at least one IT staff member must have minimum three years relevant experience; for Provisional Registration at least one IT staff member must have a minimum one year's relevant experience.
  - 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 Provisional Registration: A named PPI&E lead (this can be as a part of their job role) with at least one year's relevant experience,

  It is preferable if all the above core positions are funded independently of specific project grants.
- Question 2.3 also requires applicants to submit one page CVs of your CTU Director (Or lead named Director in your collaborative or merged group) and a one page CV for each of your key staff in the roles above and submit these with your application as Appendix 2. Please ensure that relevant dates of education and employment are included in these CVs.
- Definition of roles:
  - Trial Manager/Coordinator – responsibilities include development of new trials, grant applications; management and oversight of adherence to quality standards; provision of continued expertise in trial management; management of long-term

follow-up of trials beyond primary analysis; conduct of other research activities; training, staff management and development.

- Data Manager - Responsibilities include provision of expertise in the design of tools for data collection, data quality and reporting in preparation for analysis. Typically assists the Trial Manager or IS depending upon the structures of the CTU. NB: Some units combine Trial Manager/Coordinator and Data Management roles. If this is the case for your CTU please respond under Trial Managers/Coordinators only.
- IS – Responsibilities can include development of randomisation systems, trial and data management systems.
- QA lead – Responsibilities include oversight of Quality Management System at the CTU, assuring the quality of trials / studies carried out at the CTU , and ensure that trials / studies are carried out in compliance with local SOPs and national legislation

- Question 2.5 requires you to provide a detailed organisation chart of your CTU as Appendix 3. Organograms must be at trials unit level and no higher. The names of senior staff should be included as well as all those referred to at 2.3. Please also indicate all vacant posts within the trials unit. Do not include information of how the trials unit sits within your host institution. For collaborative groups and merged units see Section 9. For senior staff not located within the CTU indicate how they link into the CTU structure.

Section 3 focuses on CTU Infrastructure. This section also requests details about the stability of staffing in the CTU and asks applicants to describe the level of senior clinical input at a strategic level.

- Question 3.1 requires all applicants to submit a statement of support, at the level of Dean, Pro-Vice Chancellor, or Chief Executive (as applicable) from their host organisation and submit this as Appendix 4. Collaborative applications should include this statement from each host organisation which is involved. If your host organisation(s) already hosts a UKCRC 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).

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 UKCRC CTU 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 the CTU's information systems, in terms of data management systems, and the systems in place to ensure robust and secure information systems.

Section 6 requests details about the level of statistical involvement throughout the trial, and about access to a secure randomisation system (if applicable).

Section 7 inquires about the extent/scope of your CTU's availability to collaborate with researchers (i.e. whether or not the CTU is willing and able to collaborate on trials with Chief Investigators outside your geographical area).

Section 8 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 5.

Section 9 is required **only for applications from collaborative groups or merged CTUs for which it is mandatory**. This section should be used by CTUs comprised of collaborating groups or merged units to provide information on the roles of each group in the collaboration and how the groups work together. Evidence should be provided to satisfy the UKCRC CTU 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	Please provide the full paper pdf of up to 3 recent significant peer reviewed publications with details of author contributions as Appendix 1.

2	One-page CVs of staff in key roles i.e. CTU Director, up to two Statisticians, up to two Trial Managers, up to two IS Leads, the person leading the QA function, and the PPI&E lead.
3	Detailed organisation chart
4	Statement of Support from Host Organisation(s)
5	Signed, scanned copy of the signature page

Confidentiality

All information provided to the UKCRC CTU Registration Review Committee will be treated as confidential. In the event that UKCRC Registration is awarded, some information provided may be made available in the public domain (e.g. via the UKCRC 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

UKCRC Clinical Trials Unit Registration status will normally apply for five years for Fully Registered units and 3 years for those awarded provisional status. A review of all UKCRC 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 provide this update could result in the withdrawal of your registration.

Fees

The Registration process and the UKCRC 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 Review Panel costs. For unsuccessful applications there will be no refund.

Fees are payable online to make a payment please follow the instructions on the following link: https://store.leeds.ac.uk/product-catalogue/faculty-of-medicine-health/faculty-of-medicine-health-fomh/2023-ukcrc-registered-ctu-network-registration-application-fee

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 of 12:00 noon on Monday 6th November 2023.

A subsequent annual registration maintenance fee of £3000 + VAT will be payable on designation as a successfully UKCRC Registered CTU. This annual fee will be payable for each year of registration and will cover the delivery of the UKCRC Registered CTU Work Programme.

Further information

For further information about the UKCRC 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 is 12:00 noon on Monday 6th November 2023.

The completed application form and appendices, and scanned signature pages should be emailed to regctus@leeds.ac.uk. Please mark the email: 'UKCRC 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 and supporting documents are not required.

The UKCRC CTU Registration Committee meeting will take place in autumn 2023.