

UK Clinical Research Collaboration (UKCRC) Registration of Clinical Trials Units

Information Pack and Guidance Notes

May 2009

1. Background

The United Kingdom Clinical Research Collaboration (UKCRC) is a partnership of organisations working to establish the UK as a world leader in clinical research, by harnessing the power of the NHS. Its aim is to re-engineer the environment in which clinical research is conducted in the UK, to benefit the public and patients by improving national health and increasing national wealth.

One component of the UKCRC's aims is to develop and maintain high quality capacity for specialist trial design, conduct and analysis in the UK. It is widely acknowledged that expertise in the design, conduct and analysis of 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 UKCRC. In 2006, the UKCRC Board approved a Registration Process for Clinical Trials Units (CTUs) responsible for centrally coordinating multi-centre clinical trials (i.e. having the overall responsibility for the design, recruitment, data management, publicity and analysis of the trial). The National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Clinical Trials Team was tasked by UKCRC to develop and manage the CTU Registration process. These are the Guidance Notes for the application process.

2. Why is a Clinical Trials Unit Registration Process needed?

The UK Clinical Research Network (UKCRN) is comprised of the four research networks across the UK funded by the UK Health Departments. The networks support and deliver high quality clinical research studies. UKCRC is keen to ensure that those organisations responsible for coordinating studies in the UKCRN Portfolio Database are integrated with the clinical research networks across the UK and their activities, and that the research community has access to sufficient high quality CTU expertise, i.e. that there is sufficient national capacity to develop and manage the increasing numbers of studies that will result from the activities of UKCRC and UKCRN. The CTU Registration Process will contribute to enabling the UKCRC to improve the quantity and quality of the available expertise, and will enable UKCRC and UKCRN to signpost researchers to high quality Clinical Trials Units with expertise in the range of clinical research being supported by the UK clinical research networks.

Registered CTUs have:

- access to and integration with UKCRC/N structures and systems

- a central role in the development of national portfolios of studies and national strategies to clinical research
- a forum to contribute to the development and implementation of national approaches, e.g. electronic remote data capture systems, patient and public involvement
- a forum to meet and discuss issues/raise problems on a national level
- the ability to respond to national needs in a coordinated way
- a forum to ensure uniformity in research governance and implementation
- a national profile as a UKCRC Registered Clinical Trials Unit
- facilitated international collaboration.

UKCRC Registered CTUs also work together to share expertise, systems and knowledge and therefore prevent duplication of effort across CTUs.

A database and website of UKCRC Registered CTUs has been established [www.ukcrc-ctu.org.uk] as a resource for investigators, researchers, and funders wishing to identify high quality CTUs with particular experience in developing, managing and analysing clinical studies in specific disease areas, or experience in specific research methodologies. This web resource is maintained and updated regularly and UKCRC Registered CTUs are asked to validate information relating to their organisation on the database prior to its publication.

3. Registration Process

a. Which CTUs are eligible to apply?

Applications can be made from any CTU in the UK responsible for *leading* the design, the *central/national* coordination (i.e. sponsor-level activity) 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 (i.e. site-level 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.

It is recognised that some clinical trials are managed by collaborative groups where 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 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.

It is also recognised that new or smaller CTUs may have relevant expertise and experience that may be worth building on for the benefit of UKCRC, but which 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 (see Section 3d below). Such CTUs should demonstrate that they have the capacity and ability to develop the full criteria over time (expected within 3 year timeframe).

Applications will also be accepted from CTUs with current Provisional Registration status which are seeking to move to Full Registration (see section 3c(i) below).

b. How will applications be assessed?

The UKCRC CTU Registration process is coordinated on behalf of UKCRC and the UK clinical research networks by the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) Clinical Trials Team.

Applications will be reviewed with specific reference to the key competencies (Appendix 1) and evaluation criteria (Appendix 2) developed and approved by a Committee of UKCRC Partners. The key competencies form the basis by which proposals will be assessed.

A UKCRC CTU Registration Committee comprising UK and international expert trialists and UKCRC representatives has been established to review the submitted proposals. A triage system will be applied and managed by the NIHR CRN CC Clinical Trials Team; any applications clearly not reaching the criteria for either Full or Provisional Registration will not be submitted to the UKCRC CTU Registration Committee.

The UKCRC CTU Registration Committee meeting will take place in the final quarter of 2009. **Applicants (or their designee) will not be required to attend this meeting however they should be available to respond to any requests for further clarification in relation to their applications from 25 September through to 14 October, 2009.**

Full feedback on all applications will be provided.

c. 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 UKCRN portfolio 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, the NHS Research Governance Framework, the Data Protection Act and the UK regulations that implement the EU Directive for 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.

Please note 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.

(i) Existing Provisionally Registered CTUs

Existing Provisionally Registered CTUs seeking to move to Full Registration will be required to complete an abridged application consisting of:

- Sections of the application form relating to the areas that were identified by the CTU Registration Committee as requiring further development and refinement in 2007.

and/or

- In the case of units that applied for Provisional Registration in 2007, sections of the application form where the competency requirements differ between Full and Provisional Registration will also be required.

All existing Provisionally Registered CTUs applying for Full Registration status will be required to provide a declaration confirming that, for sections where no additional information is required over and above that provided in 2007, there have been no significant changes to the original information submitted.

All existing Provisionally Registered CTUs seeking to apply for Full Registration must contact the NIHR CRN CC Clinical Trials Team to discuss their applications prior to completing the proforma (see section 6).

d. Applying for Provisional Registration

It is recognised that new CTUs may be developing relevant expertise and experience that may be worth building on for the UKCRC, but which falls 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 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.

e. Registration of Specific Research Experience

All CTU Registration applicants (i.e. Full and Provisional) will also have the opportunity to register specific experience in any or all of the following areas:

- Disease/topic specific experience (CTUs will be asked to specify their particular disease/topic experience)
- Types of study conducted (e.g. Investigational Medicinal Product (IMP) trials, medical device trials)
- Methodological research area (e.g. systematic reviews, statistical methods, health economics, primary care, prevention, screening, early phase trials, complex interventions)

This information will be listed on the UKCRC Registered CTU website (<http://www.ukcrc-ctu.org.uk>) for CTUs awarded UKCRC Registration.

Please note that this information will not be assessed by the UKCRC CTU Registration Committee. However, the Committee may refer to this information where it is considered pertinent to the assessment of other Registration competencies.

f. Best Practice Principles

UKCRC Registered CTUs will be expected to collaborate within the framework of the UKCRC and applicants should therefore be committed to working towards the aims and objectives of the UKCRC and the UK clinical research networks, and to collaborating on the various initiatives being developed. CTUs wishing to be registered must agree to the following principles:

- A commitment to working with the UK clinical research networks to support clinical research, e.g. contribution to national CTU committees and working groups
- A commitment to providing study information and monthly accrual data to the UKCRN Portfolio Database for UKCRN Portfolio studies
- An organisational commitment to patient/public involvement
- A organisational commitment to follow the principles of GCP for all trials.

g. 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.

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/UKCRN's strategy towards trials.

4. Guidance Notes for Completing the Proforma

One proforma should be completed for each CTU submitting a proposal. The same proforma is to be completed regardless of whether Full or Provisional Registration is being applied for, and regardless of whether applicants are currently a non-registered CTU or an existing Provisionally Registered CTU.

The proforma has been developed as a PDF form which can be downloaded from the UKCRC Registered CTU website at <http://www.ukcrc-ctu.org.uk> or requested from Lyndsey Tuck, NIHR CRN CC at lyndsey.a.tuck@nihr.ac.uk.

Applicants will require access to Adobe Reader software in order to complete their application. The PDF proforma is not compatible with some earlier versions of Adobe Reader and Adobe Acrobat Software. Functionality has been confirmed with Adobe Reader version 8.0 and above. It is strongly recommended that you download the latest version of Adobe Reader Software which can be downloaded without charge from Adobe at <http://getadobe.com/uk/reader>. Please note, depending on your permissions, this software may need to be installed by your IT Administrator.

Please contact Lyndsey Tuck, NIHR CRN CC at lyndsey.a.tuck@nihr.ac.uk, if you experience any difficulties using the proforma.

General notes on completing the proforma

When completing the proforma, please type all responses, using the format and tables provided. Fields to be completed can be highlighted by selecting the "highlight fields" button located at the top right hand side above the page view. Highlighted areas on the electronic proforma require an answer – either free text or an answer from a drop down menu. 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 established for collaborative applications). The cover page should also be used to indicate whether a collaborative application is being made and also whether the CTU is 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.

All existing Provisionally Registered CTUs applying for Full Registration status will be required to complete the declaration for provisional units as Appendix 1. Both an electronic and signed scanned copy should be submitted with your application.

Sections 1-5 of the proforma

Sections 1-5 are mandatory for all applicants with the possible exception of existing Provisionally Registered applicants¹.

¹ In some cases, this will not apply to existing Provisionally Registered CTUs applying for full registration where completion of only certain sections of the proforma is required. This will be determined on a case by case basis as described in section 3c(i) of the guidance. Existing Provisionally Registered applicants should contact Lyndsey Tuck (NIHR CRN CC) on +44 (0)113 3430412 / lyndsey.a.tuck@nihr.ac.uk or Jacqueline Mathews (NIHR CRN CC) on +44 (0)207 670 4649 / jacqueline.n.mathews@nihr.ac.uk, for confirmation of sections to be completed.

Section 1 requests information about the roles of the CTU and the CTU's current and recent clinical research activity and related publications.

The categories for disease/topic areas in Table 1.1 are based on the health research classification codes developed through the UKCRC in the UK Health Research Analysis, plus the NIHR Clinical Research Topic Networks (e.g. Medicines for Children). These categories should be used where possible. If your CTU works on any other disease/topic which cannot be assigned to any of the categories provided, then please provide details of the disease/topic as indicated in Table 1.1.

Please list up to 5 significant publications from the last five years relating to separate clinical trials or other well-designed studies, that best demonstrate your unit's clinical trials activity. At least one publication should relate to the primary analysis of a study. If your CTU has only one publication related to your clinical trials activity, other evidence must be provided as Appendix 2 that demonstrates high quality trial conduct, (e.g. your most recent report to funders for one trial or an MHRA Inspection report). Published protocols do not qualify for inclusion.

Section 1 also requests information about external clinical collaborations/groups (e.g. groups or collaborations specialising in a particular disease/health area), as well as methodological/specialist groups external to the CTU, which the CTU works with (e.g. groups or collaborations specialising in health economics, quality of life etc.).

Section 2 focuses on staffing and infrastructure 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.

Applicants are required to provide an organisational chart of the staff within their CTU. Please refer to job titles rather than staff names, ensure posts which are currently vacant are included. This chart should be included as Appendix 3 and should provide details of practical working arrangements, including managerial accountability and geographical location for staff located outside your main premises.

All applicants must submit a statement of support, at the level of Dean or Pro-Vice Chancellor, from their host organisation as Appendix 4.

Section 2 also requests details of senior clinical input at a strategic level. This relates to senior clinical representation at board level (e.g. CTU Steering Committee; executive management group) within the CTU that allows input into the direction, policies and strategy of the unit (e.g. development of the units research portfolio).

This section also requests details about the stability of staffing in the CTU and provision of staff training, education and development.

Section 3 requests details about the CTU's information systems, in terms of data management systems, the systems in place to ensure robust and secure information systems, and access to a secure randomisation system (if applicable).

Section 4 concentrates on the CTU's 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 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 NHS Research Governance Framework, the Data Protection Act, the UK Regulations that implement the EU Directive for Clinical Trials (if applicable)).

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.

Please note that the NIHR CRN CC is currently working with existing Registered CTUs to develop template SOPs in the following areas: Deviations, misconduct and serious breaches of GCP and/or the Protocol; Urgent safety measures; Sponsorship; Contracts/agreements and indemnity; Data protection and confidentiality; and Document control. Completed templates will be made available to all Registered CTUs.

Section 5 relates to archiving of trial data.

Section 6-9 of the proforma

Sections 6-9 are mandatory for all applicants with the possible exception of existing Provisionally Registered applicants¹.

Section 6 is an open section for the provision of any additional information that you wish to provide in support of your application. If your CTU has had an MHRA inspection, you may wish to include details of the findings in Section 6 of the proforma.

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 relates to the commitment of applicants to the best practice principles described in 3f of the guidance notes.

Section 9 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.

Section 10 of the proforma

Section 10 is an optional section which offers applicants the opportunity to register specific experience in the following areas:

- Disease/health research area experience. Complete section 10.1.

¹ In some cases, this will not apply to existing Provisionally Registered CTUs applying for full registration where completion of only certain sections of the proforma is required. This will be determined on a case by case basis as described in section 3c(i) of the guidance. Existing Provisionally Registered applicants should contact Lyndsey Tuck (NIHR CRN CC) on +44 (0)113 3430412 / lyndsey.a.tuck@nihr.ac.uk or Jacqueline Mathews (NIHR CRN CC) on +44 (0)207 670 4649 / jacqueline.n.mathews@nihr.ac.uk, for confirmation of sections to be completed.

- Study Types (e.g. Investigational Medicinal Product (IMP) trials, Medical devices trials). Complete question 10.2.
- Methodological research areas (e.g. systematic reviews, statistical methods, health economics, primary care, prevention, screening, early phase trials, complex interventions). Complete question 10.3.

The information provided in section 10 will be listed on the UKCRC Registered CTU website (<http://www.ukcrc-ctu.org.uk>) for CTUs awarded UKCRC Registration.

Please note that the information provided under section 10 will not be assessed by the UKCRC CTU Registration Committee. However, the Committee may refer to this information where it is considered pertinent to the assessment of other Registration competencies.

Section 11 of the proforma

Section 11 is required only for applications from collaborative groups for which it is mandatory.

This section should be used by CTUs comprised of collaborating groups 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 Committee that formal arrangements are in place for collaboration, that all key competencies are met by the collaboration, 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	Reference	Description
1	Cover Sheet	Provisional Unit Declaration For units with current provisional registration only
2	Section 1, Q1.3	Other evidence of high quality trial conduct e.g. most recent report to funders, MHRA inspection report. Required if your CTU has only one publication relating to your clinical trials activity.
3	Section 2, Q.2.4	Current Organisational Chart
4	Section 2, Q.2.6	Statement of Support from Host Organisation

Confidentiality

All information provided to the UKCRC CTU Registration 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.

5. Review of Registration Status

UKCRC Clinical Trials Unit Registration status will apply for three years (Full and Provisional). A review of all UKCRC Registered Clinical Trials Units will be carried out every three 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 will be able to apply for Full Registration status at the review. The paperwork for the review will be kept to a minimum.

6. Further information

For further information about the UKCRC CTU Registration Process, please contact Lyndsey Tuck (NIHR CRN CC) on +44 (0)113 3430412 / lyndsey.a.tuck@nihr.ac.uk or Jacqueline Mathews (NIHR CRN CC) on +44 (0)207 670 4649 / jacqueline.n.mathews@nihr.ac.uk.

7. Submission of Proposals

The deadline for submission of proposals is Friday 7 August 2009.

One hard copy of the completed application including appendices should be returned to Lyndsey Tuck, NIHR CRN CC Clinical Trials Team, Fairbairn House, 71-75 Clarendon Road, Leeds, LS2 9PH and marked UKCRC CTU Registration Application.

In addition, the completed application form and appendices, and scanned signature pages should be emailed to crncc.ctus@nihr.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.

The UKCRC CTU Registration Committee meeting will take place in the final quarter of 2009. **Applicants (or their designee) will not be required to attend this meeting however they should be available to respond to any requests for further clarification in relation to their applications from 25 September through to 14 October, 2009.**

Appendix 1. Key Competencies for UKCRC Registered Clinical Trials Units

The following competencies should exist in Clinical Trials Units (CTUs)¹, responsible for the design, conduct and analysis of trials and other well-designed studies (referred to collectively in this document as studies). Clinical Trials Units in this context are defined as a single unit or as a collaborative group (i.e. it is not necessary for all of the expertise required to exist in the same geographical location) fulfilling or working towards all key competencies. New Clinical Trials Units, or epidemiology units extending their activities into clinical trials, should demonstrate that they have the capacity and ability to develop these competencies.

1. Key Competencies

Expertise, Continuity and Stability

- Knowledge, experience and a track record of coordinating multi-centre clinical research studies from design and initiation to publication in peer reviewed journals, with good multi-disciplinary working relationships with investigators, clinicians, academics and experts from other specialties.
- An established multi-disciplinary team of experienced staff including statisticians, trial/project managers and IT staff with clinical input at the strategic as well as the project level. Collaborative groups will need to explain/define how the multi-disciplinary team will be established, managed and monitored and in addition, to set out a formal approach to reviewing the individual core disciplines being provided from a different location, prior to the start of any project, to ensure quality from the outset.
- Capability and experience of identifying the need for and sourcing of the necessary expertise for component studies to clinical studies and/or associated research (e.g. systematic reviews, psychosocial issues, patient assessed outcomes, qualitative research, health economics, pharmacogenomics, pharmacokinetics etc).
- Resources to provide adequate and stable infrastructure and senior staff as well as an ability to ensure continuity of the core disciplines.
- Adequate infrastructure to support trials activity with a documented commitment to the Clinical Trials Unit from the host institution.
- Systems and processes in place for continuing professional development, including Good Clinical Practice (GCP) training for all relevant staff.

Quality

- Systems and processes in place to ensure that staff work to appropriate guidelines and standards.
- Systems and processes in place to meet appropriate regulations and legislation (e.g. the principles of GCP, the NHS Research Governance Framework, the Data

¹ The term Clinical Trials Unit has been used in this document but experience of *leading* the design, the *central/national* coordination (i.e. sponsor-level activity) and the *overall* analysis of other clinical research studies, especially large multi-centre epidemiological studies as well as Randomised Controlled Trials will be taken into consideration

Protection Act, the UK Regulations that implement the EU Directive for Clinical Trials).

- Systems and processes in place for risk assessment to guide appropriate monitoring of the whole study process, centrally and at clinical sites.
- Systems and processes in place to archive study data at the end of a study and to retrieve it subsequently.

Information Systems

- Robust and secure information systems.
- Access to a secure randomisation system, as appropriate.

Best practice principles

Applicants will be required to sign up to the following four principles:

- A commitment to working with the UK clinical research networks to support clinical research, e.g. contribution to national CTU committees and working groups
- A commitment to providing study information and monthly accrual data to the UKCRN Portfolio Database for UKCRN portfolio studies
- An organisational commitment to patient/public involvement.
- A organisational commitment to follow the principles of GCP for all trials.

Appendix 2. Evaluation Criteria for UKCRC Registration of Clinical Trials Units

* Denotes essential evaluation criteria that must be met to enable UKCRC Registration of Clinical Trials Units

Expertise, Continuity and Stability

Competency	Evaluation Criteria for Full Registration	Evaluation Criteria for Provisional Registration
<p>Knowledge, experience and a track record of coordinating multi-centre clinical research studies from design and initiation to publication in peer reviewed journals, with good multi-disciplinary working relationships with investigators, clinicians, academics and experts from other specialities.</p>	<p>* At least five open/in follow-up multi-centre randomised controlled trials (RCTs) or other well-designed studies, of which at least one has been funded by open national competition with full peer-review.</p> <p>* Evidence of being involved in the design, conduct and analysis of most of the unit's studies.</p> <p>* At least one trial publication from the Clinical Trials Unit (CTU) of an existing/closed study. If only one publication is available from the CTU, additional evidence of high quality trial conduct is also required e.g. reports to funders, MHRA inspection report.</p> <p>Evidence of having worked with at least one external clinical collaboration.</p>	<p>* Between one and four multi-centre RCTs or other well-designed studies, at least one of which must be an open multi-centre RCT or well-designed study.</p> <p>* Evidence of being involved in the design, conduct and analysis of most of the unit's studies.</p> <p>Have not worked with external clinical collaborations but willing to do so.</p>

Competency	Evaluation Criteria for Full Registration	Evaluation Criteria for Provisional Registration
<p>An established multi-disciplinary team of experienced staff including statisticians, trial/project managers and IT staff with clinical input at the strategic as well as the project level.</p>	<p>* At least one statistician with at least five years' relevant experience, at least one trial/project manager with at least three years' relevant experience and at least one IT/IS person, ideally all core funded.</p> <p>*Evidence of clinical input at strategic level (need senior clinical input either as member of CTU or member of CTU advisory/executive committee).</p> <p>*Collaborative groups will need to explain/define how the multi-disciplinary team will be established, managed and monitored and set out a formal approach to reviewing the individual core disciplines being provided from a different location, prior to the start of any project, to ensure quality from the outset.</p> <p>* Evidence of appropriate governance (as shown by a formal organisational chart of the staff in the CTU).</p>	<p>* At least one statistician with at least three years' relevant experience, evidence of access to senior statistical support, at least one trial/project manager with at least three years' relevant experience and at least one IT/IS person, ideally all core funded.</p> <p>*Evidence of clinical input at strategic level (need senior clinical input either as member of CTU or member of CTU advisory/executive committee).</p> <p>*Collaborative groups will need to explain/define how the multi-disciplinary team will be established, managed and monitored and set out a formal approach to reviewing the individual core disciplines being provided from a different location, prior to the start of any project, to ensure quality from the outset.</p> <p>* Evidence of appropriate governance (as shown by a formal organisational chart of the staff in the CTU).</p>

Competency	Evaluation Criteria for Full Registration	Evaluation Criteria for Provisional Registration
<p>Capability and experience of identifying the need for and sourcing of the necessary expertise for component studies to clinical studies and/or associated research.</p>	<p>Evidence of existing collaboration(s) with specialist group(s).e.g. health economics, primary care, prevention, screening, translational research, early phase trials, complex interventions.</p>	<p>Same as Full Registration.</p>
<p>Resources to provide adequate and stable infrastructure and senior staff as well as an ability to ensure continuity of the core disciplines.</p> <p>Adequate infrastructure, to support trials activity with a documented commitment to the Clinical Trials Unit from the host institution.</p>	<p>* Evidence of core funding or of a rolling programme of grants. Evidence of commitment from the host institution.</p> <p>* Evidence of capacity in terms of staffing, time and expertise to manage unexpected/unplanned circumstances (e.g. personnel changes or trial problems).</p>	<p>* Evidence of commitment from the host institution.</p>
<p>Systems and processes in place for continuing professional development, including Good Clinical Practice (GCP) training for all relevant staff.</p>	<p>* Evidence of a functional process for staff training, including GCP training for all relevant staff.</p>	<p>* Same as Full Registration.</p>

Quality

Competency	Evaluation Criteria for Full Registration	Evaluation Criteria for Provisional Registration
Systems and processes in place to ensure that staff work to appropriate guidelines and standards.	* Need to see list of Standard Operating Procedures (SOPs) with version numbers and dates. Need to have SOPs in areas identified by the UKCRC-Registered CTUs (see page 5). Need to show evidence of how it is ensured that staff follow SOPs and who is responsible for managing SOPs.	* SOPs could be in development, but need to see planned list. Need to have SOPs in areas identified by the UKCRC-Registered CTUs (see page 5). Need to show evidence of how it is ensured that staff follow SOPs and who is responsible for managing SOPs.
Systems and processes in place to meet appropriate regulations and legislation (e.g. the principles of GCP, the NHS Research Governance Framework, the Data Protection Act and the UK Regulations that implement the EU Directive for Clinical Trials).	* Evidence of systems for ensuring data quality, audit trails of data and data queries, ensuring patient confidentiality, adverse event reporting (pharmacovigilance for clinical trials of Investigational Medicinal Products (IMPs)), informed consent processes. Expect most studies to have Data Monitoring Committees (DMCs) and Trial Steering Committees (TSCs). Must show evidence of adherence to the principles of GCP.	* Same as Full Registration.
Systems and processes in place for risk assessment to guide appropriate monitoring of the whole study process centrally and at clinical sites.	Evidence of a functional system for risk assessment.	System could be in development, but need to be assured adequate.

Competency	Evaluation Criteria for Full Registration	Evaluation Criteria for Provisional Registration
Systems and processes in place to archive study data at the end of a study and to retrieve it subsequently.	* Evidence of a system for this.	* System could be in development, but need to be assured adequate.

Information Systems

Competency	Evaluation criteria for Full Registration	Evaluation Criteria for Provisional Registration
Robust and secure information systems.	* Evidence of an appropriate data management system. Evidence of a satisfactory validation process and infrastructure components for this system.	* Same as Full Registration.
Access to a secure randomisation system, as appropriate.	* Evidence of access to a randomisation system, if run RCTs and need to specify system used.	* System could be in development, but need to be assured adequate or else that access is available to a secure randomisation system.

Essential areas to be covered by SOPs:

1. SOP on SOPs
2. Protocol development
3. Monitoring
4. Trial Master File/Site File (Investigator & Pharmacy)
5. Regulatory approvals
6. Trial Initiation and site set up
7. Data management
8. Trials supplies
9. Safety Reporting/Pharmacovigilance (if IMPs)

10. Quality Management Systems
11. Patient Information
12. Training
13. Registration/Randomisation (if run randomised trials)
14. Statistics
15. IT/database
16. Trial closure
17. End of trial reporting
18. Archiving

Recommended areas to be covered by SOPs:

19. Deviations, Misconduct and serious breaches of GCP and/or the Protocol
20. Urgent safety measures
21. Sponsorship, contracts/agreements and indemnity
22. Data protection and confidentiality
23. Document control