UKCRC Registration of Clinical Trials Units

PROFORMA FOR RENEWAL OF REGISTRATION

One form should be completed for each Clinical Trials Unit[[1]](#footnote-1). If this is an application from a collaborative group[[2]](#footnote-2), merged units[[3]](#footnote-3) or CTUs with multiple units within their host institution you will also need to complete Section 9. Please see Guidance Notes for further information.

Overall Summary

|  |
| --- |
| Name of Clinical Trials Unit:  |
|  |
| **OR** Name of Collaborative: |
|  |
| **OR** Name of Merged Group: |
|  |
| Contact details for Head of Clinical Trials Unit / Lead party in collaborative group  |
| Name |  |
| Address |  |
| Email |  |

Year Clinical Trials Unit opened / collaborative group established?

**Section 1. CTU Overview**

1.1 **Summary of Portfolio**

|  |  |
| --- | --- |
| Number of studies in set up?  |  |
| Number of studies in recruitment?  |  |
| Number of studies in follow-up? |  |
| Number of studies in analysis?  |  |
| Number of peer reviewed publications published in the last 5 years? |  |
| In relation to the number of peer reviewed publications published in the last 5 years, please indicate how many individual studies this represents. |  |

1.2 Please use the space below to detail how your CTU has addressed any specific feedback you have previously received from the International Registration Review Committee, you can find these detailed in your Registration Letter(s).

1.3 Please provide a brief overview of your Clinical Trials Units Research strategy over the next 5 years below (Maximum 500 words)

1.4 Please provide a brief overview of your Clinical Trials Units operational strategy over the next 5 years (In particular how you ensure your Statistics, Information Systems and Quality Assurance are fit for purpose) and how you are prepared for changes to UK legislation and governance requirements. (Maximum 500 words)

1.5 Please describe your Clinical Trials Unit strategy to ensure adequate and stable infrastructure and senior leadership (including succession planning below). (Maximum 500 words)

1.6 Please describe how your CTU is working towards the National UK Standards for Public Involvement when designing/delivering PPI&E. Provide examples of PPI&E work where possible, and reflect on areas for improvement. *(Maximum 500 words)*

**Section 2. Staff Structure**

**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) and label this as Appendix 1.For these staff, please specify where they are located if not within the CTU and how they report into the senior management structure of your CTU. (Maximum 300 words)

**2.2** For these staff please indicate whether they are funded independently of specific research grants and indicate the source of their funding.

**2.3** Please provide a detailed organisation chart of your CTU as Appendix 2. Organograms must be at trials unit level and no higher, do not include information of how the trials unit sits within your host institution and include all named senior staff and vacant posts. For collaboratives, merged units and units with multiple units within their host organisation see Section 9. For senior staff not located within the CTU indicate how they link into the CTU structure.

**Section 3. Host Institution**

**3.1** Please supply a statement of support from your host organisation(s) at the level of Dean or Pro-Vice Chancellor or Chief Executive (as applicable) as Appendix 3. Collaborative applications should include this statement from each host organisation which is involved. If your host organisation(s) hosts multiple CTUs they must provide a clear rationale for supporting the registration application of multiple Clinical Trials Units, and must 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. Quality Assurance**

It is important that the UKCRC Clinical Trials Units Registration Committee understands the systems and processes that your Clinical Trials Unit has in place/in development to meet appropriate regulations and legislation (e.g. the principles of Good Clinical Practice (GCP), 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 t).

**4.1** The list of essential SOPs sets out the minimum areas in which Clinical Trials Units should have documented procedures in place. With regard to each of the listed topics, please provide the title(s) of your unit's corresponding procedure including current version number and dates. You must provide your equivalent SOP title to each of the listed SOP Content titles or explain why you do not require an SOP in a specific area. Please ensure you clarify which SOP covers the areas required.

***NOTE: The International Review Committee reserves the right to request copies of the SOPs listed below at short notice. Failure to supply the requested SOP(s) within the timeframe could affect your registration application.***

| **SOP Content** | **Title(s) of your unit’s equivalent/related SOP(s)** | **Current Version***(I.e. draft, 1, 2 etc.)* | **Date** | **Revision Due Date** |
| --- | --- | --- | --- | --- |
| **Quality Management Systems** |  |  |  |  |
| **Quality Management Systems** * **Description of internal audit and quality checks**
* **Vendor selection (e.g. central laboratory) N.B this is only as it pertains to Q.A**
 |  |  |  |  |
| **Non Conformance** * Non-Conformance- definition
* How non-conformance is captured and documented
* Corrective and Preventative action plan to address non-Conformance
 |  |  |  |  |
| **SOP on SOPs** * **SOP template/description of standard structure and content**
* **Responsibility for sign-off**
* **Document control**
* **Review process**
* **Circulation and dissemination**
* **Relevant regulatory references**
 |  |  |  |  |
| **Training** * **Development, maintenance, and management of training plans and training records**
 |  |  |  |  |
| **All Trials**  |  |  |  |  |
| **Sponsorship, Contracts/ agreements and indemnity** * **Arrangements for financial disclosure**
* **Responsibilities at CTU (if applicable)**
* **Registration for sponsorship/ communication between CTU and Sponsor**
* **Negotiating, issuing & amending contracts/agreements**
* **Implementation of trial agreements with sites**
 |  |  |  |  |
| **Protocol development*** **Protocol template/Definition of content**
* **Responsibility for sign-off**
* **Protocol amendments**
* **Review**
 |  |  |  |  |
| **Statistics** * **Responsibility for sign off of documentation**
* **Analysis plan, including interim analysis**
* **Statistical reports**
* **Sample size calculations**
* **Outcome data reports**
* **Statistical Quality Assurance**
* **Manipulation of data after export**
* **Archiving key statistical analyses files**
 |  |  |  |  |
| **Ethical approvals** * **Submission**
* **Responsibility for sign-off of submission**
* **Submitting substantial amendments**
* **Maintaining approval**
* **Trial Registration**
 |  |  |  |  |
| **Regulatory approvals** * **Submission**
* **Responsibility for sign-off of submission**
* **Submitting substantial amendments**
* **Maintaining approval**
 |  |  |  |  |
| **Site Set-up*** **Site feasibility**
* **Site suitability assessment**
* **Site initiation/training**

**Site activation** |  |  |  |  |
| **Patient Information** * **Development of patient information, including Patient Information Sheet, Patient Consent Form, GP letter and any other documentation**
* **Communication at the end of a trial to patients**
* **Implementation and dissemination (including approvals required)**
* **Process for managing revisions and document control**
 |  |  |  |  |
| **Registration/Randomisation (if run randomised trials)*** **Details of processes used by CTU e.g. web-based, phone-based**
* **Procedures involved including:**
* **Confirmation of treatment allocation/ unique patient identifier for trial)**
* **Unblinding**
* **Procedures for emergency randomisation in event of system failure**
 |  |  |  |  |
| **Data management*** **Data handling processes**
* **Data transfer processes**
* **Data security**
* **CRF development & completion**
* **Data quality and returns**
 |  |  |  |  |
| **Data sharing** * **Roles and Responsibility**
* **Request process**
* **Review of request**
* **Decision making process**
* **Preparation of data pack**
* **Data Use agreement**
* **Providing access/transfer**
* **Transparency**
 |  |  |  |  |
| **Monitoring and Independent Oversight*** **Development of monitoring plans (central & site)**
* **Procedures for site & central monitoring**
* **Internal & independent oversight arrangements**
 |  |  |  |  |
| **Trial Master File/Site Files (Investigator & Pharmacy)*** **Detail of contents**
* **Responsibilities and procedures for maintenance**
 |  |  |  |  |
| **IT/database** * **Hardware management**
* **System and data security**
* **User management and access control**
* **System procurement and / or development**
* **System validation**
* **Database development**
* **Database validation**
* **Database change management**
* **Business continuity & disaster recovery**
* **Archiving**
* **Software Management**
* **User training and support**
* **Where ‘system’ refers to underlying and / or cross-trial software systems and ‘database’ refers to trial-specific databases.**
 |  |  |  |  |
| **Trial closure** * **Site closure**
* **Notification of end of trial to regulators**
* **Procedures for closing trial early**
 |  |  |  |  |
| **End of trial reporting and publication*** **Dissemination of findings – investigators, patients, public and regulators**
 |  |  |  |  |
| **Archiving** * **Policy and procedure for data storage**
* **Security**
* **Process for access**
 |  |  |  |  |
| **Deviations, Misconduct and serious breaches of GCP and/or the Protocol** * **Definition of circumstances**
* **Policy for addressing**
* **Notification to key stakeholders, e.g. regulators, Sponsor, employers**
 |  |  |  |  |
| **Data protection and confidentiality*** **Security measures to be taken**
* **Processes for dealing with breaches**
* **Defining sensitive data**
 |  |  |  |  |
| **Document control*** **Version control**
* **Distribution control**
* **Archiving**
 |  |  |  |  |
| **\* Trials supplies (e.g. drug supply, devices, equipment etc)*** **Trial supply management, including storage, accountability, distribution, recall procedures, labelling and incident reporting**
 |  |  |  |  |
| **Safety reporting/ Pharmacovigilance** * **Expedited reporting**
* **Annual safety reporting (DSUR)**
* **Definition of reporting responsibilities**
 |  |  |  |  |
| **Urgent safety measures** * **Definition of circumstances**
* **Procedures for notifying investigators, Sponsor, regulators,**
* **TSC & DMC**
* **Immediate measures to be taken**
 |  |  |  |  |

4.2 Please explain whether and if so, how you risk assess each trial or study, describe how often you undertake risk assessments and include details of how you implement risk adapted procedures? (Maximum 300 words)

**Section 5. Information Systems**

**5.1** Since your last Registration Review, have there been any changes to the IT systems supporting data collection and /or treatment allocation? This could include major upgrades as well as changes in the systems used, changes in system location and changes in the staff supporting these systems. Please tick all that apply:

* Confirm the IT Staff supporting the systems you have in place. Let us know if there have been any changes since your last full registration review.

*Please describe these changes below. (Maximum 500 words)*

* Confirm the Database Management Systems you have in place. Let us know if there have been any changes since your last full registration review.

*Please describe these changes below. (Maximum 500 words)*

* Confirm the server management (e.g. backups, security) you have in place. Let us know if there have been any changes since your last full registration review.

*Please describe these changes below. (Maximum 500 words)*

* Confirm the treatment allocation Systems you have in place. Let us know if there have been any changes since your last full registration review.

*Please describe these changes below. (Maximum 500 words)*

**5.2**  Please confirm whether there have been any substantive changes to your validation processes described in your last submission. If yes, please provide details and confirm that the changes would not adversely impact the quality of your validation processes, for *trial specific* database systems and treatment allocation systems.

The description should outline how and by whom the trial specific systems are specified, and then how, when and by whom they are checked against that specification.

N.B. Details of the validation of the underlying systems (e.g. the clinical database management system itself) are not required. (Maximum 500 words)

**Section 6. Publications**

**6. 1** 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 other well-designed studies that best demonstrate your unit's activity. Please include a summary for EACH publication of name(s) of CTU staff on the publications listed and outline their role on the trial. The publications should be ordered chronologically (most recent first). Ideally, all 3 should be primary or secondary analyses of recent/existing clinical trials. However, published protocols from different studies do qualify for inclusion. One publication must be a final analysis of a randomised controlled trial (RCT).

**Section 7. Contribution to Network Activity**

**7.1** Since your last Registration Review please describe the contributions you have made to Network activity (including and not restricted to attendance at meetings and contributions to sub group activity). (Maximum 300 words)

**Section 8. Signatures**

I confirm that the information I have provided is an accurate representation of the systems, processes and resources in place at this Clinical Trials Units.

**Contributing to Network activities is an essential important part of Network functioning. If CTUs do not wish to be involved with any knowledge sharing activities and events such as annual meetings and webinars etc then they can choose not to pay for this component. All registered clinical trials units are asked to support all activities which include but are not limited to attendance at national meetings, membership and/or contribution to sub group activities, responding to information and feedback requests in a timely manner and providing senior input to the strategic direction of the activities of the Network.**

I agree that if registered, our CTU will actively contribute to Network activities.

|  |
| --- |
| Head of Clinical Trials Unit or Lead party in the collaborative applying for Registration: |
| Name | Signature | Date |
|  |  |  |

**This page should be printed, signed, scanned, and submitted with your application and labelled as Appendix 5.**

**THIS COMPLETES THE INFORMATION REQUIRED FOR UKCRC CLINICAL TRIALS UNIT REGISTRATION, EXCEPT FOR COLLABORATIVE, MERGED UNITS OR CTUS WITH MULTIPLE UNITS WITHIN THEIR HOST INSTITUTION APPLICATIONS FOR WHICH SECTION 9 MUST ALSO BE COMPLETED (THIS CAN BE FOUND ON THE NEXT PAGE).**

**Once completed, please check that you have:**

* You have completed all applicable questions.
* If required check you have submitted one page CVs of the Trials Unit Director and up to 2 of your most experienced Statisticians, up to 2 of your most experienced Trial/Project Managers and up to two of your most senior IS leads and label this as Appendix 1.
* You have included Appendix 2, a detailed organisation chart.
* You have included Appendix 3 (i.e. statement of support from your host institution(s) - refer to question 3.1). For Collaborative Groups check you have obtained a joint letter of support from collaborator(s) (and host if institution is different).
* You have submitted the full pdf and detailed information of up to 3 significant publications as Appendix 4.
* You have included Appendix 5, a signed, scanned copy of the signature page in section 8.

**Next steps:**

* Please save your application form and include the name of your Clinical Trials Unit in the file name.
* Please send your form by email to regctus@leeds.ac.uk and ensure that all Appendices are attached to your email.

**Section 9. Applications from Collaborative Groups, Merged CTUs or CTUs with multiple units within their host institution ONLY**

This section is ONLY for applications from a collaborative OR merged CTU groups OR CTUs with multiple trails units within their host institution.

**For Collaborative Groups:**

# 9.1 Please provide details of all parties in the collaborative group in the table below

|  |  |
| --- | --- |
| **Names of parties in the collaborative group** | **Address** |
|  |  |
|  |  |
|  |  |

9.2 Please provide a detailed organisation chart of your collaborative group as Appendix 2. Organograms must include high level information on the oversight of the parties within the collaborative group.

9.3Please briefly explain why an application from a collaborative group is being submitted and how the collaboration occurs? (Maximum 500 words)

* 1. Please describe how you have integrated the work, systems and personnel of all groups within the collaboration? (Maximum 300 words)
	2. Please explain which party in the collaborative group will have responsibility for the following tasks and how standards are maintained in the following areas:
1. Statistics (design, monitoring and analysis) (Maximum 300 words)
2. Data management/data entry/central monitoring (Maximum 300 words)
3. Database provision (Maximum 300 words)
4. Quality Management Systems provision (Maximum 300 words)

9.6 Please explain how you maintain the integration? (Maximum 300 words)

**For Merged CTUs:**

# 9.1 Please provide details of all parties in the new merger in the table below

|  |  |
| --- | --- |
| **Names of the CTUs in the Merger** | **Address** |
|  |  |
|  |  |
|  |  |

9.2 Please provide a detailed organisation chart of the merged units as Appendix 2. Organograms must include detailed information on the new merged structure at a local level and how this sits within your host institution.

9.3 Please briefly explain the reasons for merging the clinical trials units and details of when the merger took place? (Maximum 500 words)

* 1. Please describe how you have integrated the work, systems and personnel of the CTUs within the merger? (Maximum 300 words)
	2. Please explain how your merged CTU will ensure how standards are maintained in the following areas:
1. Statistics (design, monitoring and analysis) (Maximum 300 words)
2. Data management/data entry/central monitoring (Maximum 300 words)
3. Database provision (Maximum 300 words)
4. Quality Management Systems provision (Maximum 300 words)

9.6 Please explain how your CTU will maintain all aspects of the integration as noted above? (Maximum 300 words)

**For CTUs with multiple units within their host institution:**

# 9.1 Please provide details of all CTUs within your host institution in the table below.

|  |
| --- |
| **Names of the CTUs within your Host Institution** |
|  |
|  |
|  |

9.2 Please provide a detailed organisation chart of your clinical trials unit as Appendix 2. Organograms must include high level information on the oversight of the multiple CTUs within your host institution.

9.3Please briefly explain the reasons and justification for multiple clinical trials units within your host institution? (Maximum 300 words)

9.4 Please explain how your host institution optimises support and resources for multiple 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. (Maximum 300 words)

**THIS CONCLUDES THE APPLICATION FORM**

1. To be eligible for registration, a Clinical Trials Unit must be responsible for leading the design, the central/national coordination and the overall analysis of multi-centred randomised controlled trials (phase II-IV) and other well designed studies (one must be a randomised controlled trial). A Clinical Trials Unit must have core competencies of statistics, IT support, access to randomization capability, trial project management and data quality control systems. Units which primarily enter patients in clinical trials and have responsibility only for the local coordination of trial activity and supply of local data to a central coordinating unit, are not eligible for registration, nor are R&D departments which provide oversight to clinical trials activities within a Health Board/ NHS Trust. [↑](#footnote-ref-1)
2. It is recognised that some clinical trials are managed by collaborative groups where all the expertise required may not exist within the same research group. Where expertise is through distinct groupings within the same host organisation or through geographically distinct organisations, applications should be submitted as a collaborative group. [↑](#footnote-ref-2)
3. Where host institutions with multiple registered trials units or unregistered research groups within the organisation have taken the decision to combine the expertise into one distinct CTU, applications should be submitted as a merged CTU. [↑](#footnote-ref-3)