UKCRC Registration of Clinical Trials Units

PROFORMA

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) or merged units[[3]](#footnote-3) you will also need to complete Section 9. Please see Guidance Notes for further information. This form is for previously unregistered units and those applying for units moving from provisional to full registration.

Overall Summary

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

Year CTU opened/ collaborative or merged group established?

[Full / Provisional]

Are you applying for Full or Provisional Registration?

**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. |  |

If you have previously applied for registration, please use the space below to address any specific feedback you have received from the International Registration Review Committee, you can find these detailed in your feedback letter(s).

**Section 1. Details of Clinical Trials Unit Activity**

* 1. Please provide details of 3 or 5 (depending on level of registration you are applying for) multi-centre randomised controlled trials (phase II–IV) or other well designed studies (one must be a randomised controlled trial) that are **open to recruitment**, **in follow-up or in analysis** that best demonstrate your unit’s activity (Trials in set-up are accepted for Provisional registration only). Using the tables provided, please indicate for each whether your Clinical Trials Unit was/is involved in the tasks described below.

|  |  |  |
| --- | --- | --- |
| **Study 1** | |  |
| Name of study  *(Acronym & short title)* |  | |
| Name of sponsor |  | |
| Name of funding body for study |  | |
| Who was involved in the design from your unit? | Name:  Position: | |
| Is your study randomised? If so, does your unit provide randomisation for ALL study centres? | [Yes / No / In collaboration] | |
| If in collaboration, how many sites is your unit responsible for? |  | |
| What would your unit’s contribution be for the data management, data entry and central monitoring of ALL study sites? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the overall analysis of the study? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the primary publication of the study? *(Maximum 200 words)* |  | |
| Study status | [In set up / Recruitment / In follow-up / In analysis] | |
| Year opened / will open |  | |
| Year recruitment closed / will close |  | |
| Sample size |  | |
| Total number of study sites |  | |

|  |  |  |
| --- | --- | --- |
| **Study 2** | |  |
| Name of study  *(Acronym & short title)* |  | |
| Name of sponsor |  | |
| Name of funding body for study |  | |
| Who was involved in the design from your unit? | Name:  Position: | |
| Is your study randomised? If so, does your unit provide randomisation for ALL study centres? | [Yes / No / In collaboration] | |
| If in collaboration, how many sites is your unit responsible for? |  | |
| What would your unit’s contribution be for the data management, data entry and central monitoring of ALL study sites? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the overall analysis of the study? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the primary publication of the study? *(Maximum 200 words)* |  | |
| Study status | [In set up / Recruitment / In follow-up / In analysis] | |
| Year opened / will open |  | |
| Year recruitment closed / will close |  | |
| Sample size |  | |
| Total number of study sites |  | |

|  |  |  |
| --- | --- | --- |
| **Study 3** | |  |
| Name of study  *(Acronym & short title)* |  | |
| Name of sponsor |  | |
| Name of funding body for study |  | |
| Who was involved in the design from your unit? | Name:  Position: | |
| Is your study randomised? If so, does your unit provide randomisation for ALL study centres? | [Yes / No / In collaboration] | |
| If in collaboration, how many sites is your unit responsible for? |  | |
| What would your unit’s contribution be for the data management, data entry and central monitoring of ALL study sites? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the overall analysis of the study? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the primary publication of the study? *(Maximum 200 words)* |  | |
| Study status | [In set up / Recruitment / In follow-up / In analysis] | |
| Year opened / will open |  | |
| Year recruitment closed / will close |  | |
| Sample size |  | |
| Total number of study sites |  | |

|  |  |  |
| --- | --- | --- |
| **Study 4** | |  |
| Name of study  *(Acronym & short title)* |  | |
| Name of sponsor |  | |
| Name of funding body for study |  | |
| Who was involved in the design from your unit? | Name:  Position: | |
| Is your study randomised? If so, does your unit provide randomisation for ALL study centres? | [Yes / No / In collaboration] | |
| If in collaboration, how many sites is your unit responsible for? |  | |
| What would your unit’s contribution be for the data management, data entry and central monitoring of ALL study sites? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the overall analysis of the study? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the primary publication of the study? *(Maximum 200 words)* |  | |
| Study status | [In set up / Recruitment / In follow-up / In analysis] | |
| Year opened / will open |  | |
| Year recruitment closed / will close |  | |
| Sample size |  | |
| Total number of study sites |  | |

|  |  |  |
| --- | --- | --- |
| **Study 5** | |  |
| Name of study  *(Acronym & short title)* |  | |
| Name of sponsor |  | |
| Name of funding body for study |  | |
| Who was involved in the design from your unit? | Name:  Position: | |
| Is your study randomised? If so, does your unit provide randomisation for ALL study centres? | [Yes / No / In collaboration] | |
| If in collaboration, how many sites is your unit responsible for? |  | |
| What would your unit’s contribution be for the data management, data entry and central monitoring of ALL study sites? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the overall analysis of the study? *(Maximum 200 words)* |  | |
| What would your unit’s contribution be to the primary publication of the study? *(Maximum 200 words)* |  | |
| Study status | [In set up / Recruitment / In follow-up / In analysis] | |
| Year opened / will open |  | |
| Year recruitment closed / will close |  | |
| Sample size |  | |
| Total number of study sites |  | |

**Publications**

* 1. Please provide a full paper pdf copy of 3 significant peer-reviewed publications of recent existing/closed studies with author contributions for Full registration or 1 for Provisional registration as Appendix 1. Publications 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 the publications should be primary or secondary analyses of recent/existing clinical trials. However, 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).

**Strategy**

* 1. Please provide a brief overview of your Clinical Trials Units Research strategy over the next 5 years below (*Maximum 500 words*)
  2. Please provide a brief overview of your Clinical Trials Unit’s 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)
  3. Please describe how your Clinical Trials Unit ensures adequate and stable infrastructure and senior leadership e.g. succession planning below (Maximum 500 words)
  4. Please summarise your approach to PPI&E and describe how that approach is integrated into your research strategy, operational strategy, infrastructure, senior leadership, and publication activities (e.g. publishing on PPI& work both directly and integrated into overall study publications). Please include information any SOPs or policy, guidance or strategy documents covering your PPI&E activities.
  5. 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**

* 1. Please provide details of the number of each type of staff (WTE) funded by specific research grants and the number of each type of staff (WTE) funded independently of specific research grants indicating their source of funding in the table below. (Please only refer to staff who have some or all of their time dedicated to the central coordination of clinical trials e.g. if your unit is also involved in meta-analyses or audit or clinical work, please do not include the staff who work on such studies unless they also work on clinical trials. If so, please only include the proportion of WTE that they spend on clinical trials).

***Example:*** *A CTU has 3 full time statisticians: Statistician 1: 50% of time is grant funded and 50% core funded; all time is dedicated to CTU activity. Statistician 2: 30% of time is grant funded and 70% core funded; all grant funded time is spent on CTU activity plus 1 day per week of core funded time. Statistician 3: 100% of time is grant funded; all time is dedicated to CTU activity.*

|  |  |  |
| --- | --- | --- |
| *Staff* | *Funded by specific  research grants*  *Number of staff (WTE)* | *Funded independently  of specific research grants*  *Number of staff (WTE)* |
| Statisticians | (Explanation: 1.8 = Statistician 1 provides 0.5 FTE Statistician 2 provides 0.3 FTE Statistician 3 provides 1.0 FTE) | (Explanation: 0.7 = Statistician 1 provides 0.5 FTE Statistician 2 provides 0.2 FTE) |

| **Staff** | **Funded by specific  research grants**  *Number of staff (WTE)* | **Funded independently of specific research grants**  *Number of staff (WTE)* | **Located within your unit?**  [Yes / No] |
| --- | --- | --- | --- |
| Director of Clinical Trials Unit |  |  |  |
| Clinicians |  |  |  |
| Clinical Epidemiologists |  |  |  |
| Senior Statisticians |  |  |  |
| Junior Statisticians |  |  |  |
| Trial Managers/ Coordinators\*  *(or equivalent)\** |  |  |  |
| Data Managers  *(or equivalent)\** |  |  |  |
| Quality Assurance staff |  |  |  |
| Computing staff |  |  |  |
| IT Systems staff |  |  |  |
| Secretarial staff |  |  |  |
| Other, specify… |  |  |  |
| Other, specify… |  |  |  |

* 1. If you have staff listed in Table 2.1 but who are located outside your main Unit/Collaborative, please provide details of reporting structures. For collaborative or merged groups see additional Section 9.

\* 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.

- IT Systems Staff – Responsibilities can include development of randomisation systems, trial and data management systems.

**Other Staff Information:**

* 1. Please submit a one-page CV of your CTU Director, and depending on whether you are applying for Provisional or Full registration, one or two of your most experienced Statisticians, one or two of your most experienced Trial/Project Managers, one or two of your most senior IS leads (i.e. those who fulfil an IT function as below), the person responsible for the QA function, and the person who leads your PPI&E activities. Please label these as Appendix 2. For these staff, please specify where they are located if not within the CTU. Please ensure that these key staff meet the criteria listed in the guidance notes document.
  2. For these staff please indicate whether they are funded independently of specific research grants or describe the nature of their contracts.
  3. Please 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 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. Infrastructure**

* 1. Please supply a statement of support from your host organisation(s) at the level of Dean, Pro-Vice Chancellor or Chief Executive (as applicable) 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).
  1. Please provide details of any existing registered (fully or provisionally registered) Clinical Trials Units within your host organisation or any units within your organisation that are applying at this time:

|  |  |
| --- | --- |
| **Name of Unit** | **Registration Status** |
|  |  |
|  |  |
|  |  |
|  |  |

* 1. Describe how your Clinical Trials Unit would assure successful management of on-going trials, even in unexpected/unplanned circumstances (for example, personnel changes or trial problems? (Maximum 300 words)
  2. Please explain how your Clinical Trials Unit ensures adequate and stable infrastructure and senior staff, as well as long term continuity of core disciplines for example, give details of staffing levels for the last 5 years (Maximum 300 words)
  3. Does your Clinical Trials Unit have senior clinical input at a strategic level? Please state how this is achieved (Maximum 300 words)

**If there are multiple units within your host institution please complete the following questions:**

* 1. Please briefly explain the reasons and justification for multiple clinical trials units within your host institution? (Maximum 300 words)
  2. 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)

**Section 4. Quality Assurance**

It is important that the UKCRC CTU International Registration Review 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).

Please summarise your systems and processes for the following tasks briefly, but as thoroughly as necessary to provide us with sufficient information to understand the systems and processes in place/in development.

* 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: We reserve 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/ Other document content** | **Title(s) of your unit’s equivalent/related SOP(s) )/ or other document(s)** | **Current Version**  *(I.e. draft, 1, 2 etc.)* ***and effective date*** | **Revision Due Date** |
| --- | --- | --- | --- |
| **Quality Management Systems** |  |  |  |
| **Quality Management Systems**   * Overview/Description of QMS (*This may be in a quality manual, a diagram or other document)* * Internal audit and quality checks * Vendor selection/qualification process (e.g. central laboratory) N.B this is only as it pertains to QA not financial/procurement audit. * Risk Assessment Process(es) |  |  |  |
| **SOPs creation, update etc**   * SOP template/description of standard structure and content * Review update, and approval processes * Circulation and dissemination, Training * Relevant regulatory references * Obsolescence of SOPs |  |  |  |
| **Induction (new staff) and Training (ongoing- all staff)**   * Development, maintenance, and management of induction/training plans and training records * Training Matrix / specifications on what training is needed for each role. * Job description for each role.   \**Training process/ documentation may be covered under HR processes nor necessarily in CTU SOPs* |  |  |  |
| **Dealing with Non-Conformance (serious breaches of GCP or Protocol, Systems errors etc)**   * Definitions, responsibilities, actions – Corrective and Preventative Action (CAPA) * Escalation of serious breaches * Notification to appropriate stakeholders, Sponsor, REC, Regulators   **Note:** *Non-conformance in this context does not include minor protocol deviations which are dealt with within each study.* |  |  |  |
| **Good documentation practices**   * Version control * Corrections and updates (ALCOAC) * Document distribution and tracking * Archiving |  |  |  |
| **Change Control**  **●** Defines what changes need to be controlled (e.g. new staff member, new system, new legislation**)**  **●** How are changes noted and controlled?  ● Review and follow up of actions taken to control the change |  |  |  |
| **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 |  |  |  |
| **Business Continuity:**   * Disaster Planning * Staff Changes |  |  |  |
| **Protocol development**   * Protocol template/Definition of content * Review and approval, signoff. * Protocol amendments * Review |  |  |  |
| **Patient Information**   * Development of patient facing information, including Patient Information Sheet, Patient Consent Form, GP letter and any other documentation * Communication of findings at the end of a trial to patients * Implementation and dissemination (including approvals required) * Process for managing revisions and document control * Amendments to Patient facing documents review and approval |  |  |  |
| **Ethical approvals**   * Preparation of Submission dossier * Responsibility for sign-off of submission * Submitting substantial amendments * Maintaining approval * Trial Registration |  |  |  |
| **Regulatory approvals (where relevant to type of trial).**   * Preparation of Submission dossier * Responsibility for sign-off of submission * Submitting substantial amendments * Maintaining approval |  |  |  |
| **Site Set-up**   * Site feasibility * Site suitability assessment * Site initiation/training * Site activation |  |  |  |
| **Statistics**   * Responsibility for sign off of documentation * Development of Statistical 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 * Revision and amendments |  |  |  |
| **Registration/Randomisation  (if running randomised trials) and Unblinding**   * Details of processes used by CTU e.g. web-based, phone-based * Procedures involved including: * Confirmation of treatment allocation/ unique patient identifier for trial) * Procedures for emergency randomisation in event of system failure * Unblinding for Medical Reasons * Unblinding for SUSAR reporting (where PI can remain blinded) |  |  |  |
| **Data management**   * Data collection and checking (QC) processes * Data queries and resolutions * Data transfer (import and export) processes * Data security * CRF or eCRF development validation and user testing & completion * Data quality and returns * Software management (changes, updates and validations) * Data backup plan and process * Archiving of electronic or paper CRFs/data   Note: *database’ refers to trial-specific databases. ‘System’ refers to underlying and / or cross-trial software systems IT see Systems below* |  |  |  |
| **Data sharing**   * Roles and Responsibility * Request * Review of request * Review and decision making process * Data Use agreement * Providing access/transfer * Transparency |  |  |  |
| **Monitoring and Oversight**   * Development review and approval of trial monitoring plan. * Procedures for site &/or central data monitoring * Review and follow up of monitoring reports/findings * Appropriate escalation of major issues identified. |  |  |  |
| **Trial Master File Investigator Site File (ISF) & Pharmacy**   * File set up and maintenance * Index of contents * Procedures and responsibilities for file set up and maintenance * File archiving at end of trial |  |  |  |
| **IT Systems**   * Hardware management * System and data security * User management and access control * System procurement and / or development * System validation * Business continuity & disaster recovery * Software Management * User training and support * Note ‘system’ refers to underlying and / or cross-trial software systems and ‘database’ refers to trial-specific databases see data management above. |  |  |  |
| **Data protection and confidentiality (GDPR)**   * Defining personal/sensitive data * Security measures for handling and storing personal data// sensitive data. * Dealing with Data breaches including appropriate escalation and reporting |  |  |  |
| **Trial closure**   * Site closure and (where relevant) final monitoring visit * Notification of end of trial to regulators and REC * Procedures for closing trial early |  |  |  |
| **End of trial reporting and publication**   * Dissemination of findings to stakeholders including investigators, patients, public REC and regulators * Upload of results to trial registry * Archiving   + Data storage, security, and access   + Archiving of ISF and TMF |  |  |  |
| **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/Device Vigilance**   * Individual safety reports * 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 |  |  |  |

* 1. Please state which member(s) of the Clinical Trials Unit is responsible for writing and reviewing your Clinical Trials Unit’s SOPs (Maximum 300 words)

* 1. Please explain how staff are trained in implementing SOPs in your Clinical Trials Unit (Maximum 300 words)
  2. Please explain how adherence to SOPs is monitored in your Clinical Trials Unit (Maximum 300 words)
  3. Please explain your approach to taking into account new legislation and/or risk adaptive approaches.
  4. Ensuring data quality, please summarise your systems for:

1. Monitoring receipt of data from participating sites, edit checks of data, generation of queries and receipt of response to those queries. Include information about procedures for ensuring retention of original and updated data) (*Maximum 300 words*)
2. Ensuring patient confidentiality (*Maximum 300 words*)
3. Adverse event reporting (*Maximum 300 words*)
   1. Please explain who undertakes risk assessment for your clinical trials and explain how this guides monitoring of the whole study process including central committees such as Trial Steering Committees, Data Monitoring Committees (if appropriate). (Maximum 300 words)
   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**

* 1. Please provide a summary of the IT systems currently used to collect *clinical trial data* within your Clinical Trials Unit, using the table below. Use one line for each system, and for each please indicate:

1. the *type* (**C** = commercial, **S** = open-source, **L** = locally developed, **T** = other),
2. the *name and version* (for commercial and open-source systems), e.g. ‘Macro V4’, or ‘OpenClinica 3.4.1’
3. the *physical location* of the system’s servers (**U** = in the trials unit itself, **P** = in a parent organisation’s IT facilities (e.g. a university IT department), **X** = externally hosted, e.g. by the system vendor, and **T** = Other),
4. The approximate *percentage of your current trials* where that system is used,
5. the approximate *percentage of eRDC* (electronic remote data capture) used for data collection within that system,
6. the *‘back end’ database system* used to store the data (e.g. SQL server, PostgreSQL, Oracle).

N.B. Only clinical database management systems should be listed. Trial administration and treatment allocation systems should not be included.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type**  **C / S / L / T** | **Name, version**  **(if commercial or open source)** | **Location**  **U / P /**  **X / T** | **%**  **current trials** | **%**  **EDC used** | **Back-end data store** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

* 1. Please add explanation of any ‘other’ classifications used above. You can also use this section to provide further description of your present systems, if you feel they have not been accurately summarised by the table entries. (Maximum 500 words)
  2. If there are any planned future changes in the pattern of system usage by your unit, please describe them below, with an indication of the approximate timeline for those changes. (Maximum 500 words)
  3. If you have a **locally developed** clinical database system, please describe below. **If not, go to question 5.5**

1. What technologies were used to construct it (e.g. ASP.Net, LAMP stack, Ruby on rails etc.) *(Maximum 500 words).*
2. How the audit functionality (tracking changes to individual data items) is supported *(Maximum 500 words).*
3. How many staff are involved in developing, maintaining, documenting, and testing the system. *(Maximum 500 words)*
   1. Please outline how backups (including long term) are carried out, when, by whom, and how they are stored, for each of the systems listed in 5.1. (maximum 500 words)
   2. Please summarise how security is maintained for each of the systems listed in 5.1. This does not refer to differential access within systems, but to the physical, firewall, encryption and other measures that are used to block unauthorised access to data from outside the unit. (Maximum 500 words)
   3. Please provide a description of your validation processes that you employ for a) software you develop internally and b) software that you purchase or license to support your Clinical Trials Unit efforts, excluding operating and networking systems (Maximum 500 words)." (Maximum 500 words) 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.

**Section 6. Robust Statistical Input**

* 1. What is your policy/procedure for statistical involvement in trial design? (Maximum 300 words)
  2. What is your policy/procedure for statistical involvement in the development of randomisation processes? (Maximum 300 words)
  3. What is your policy/procedure for statistical involvement in the development of protocols and CRFs? (Maximum 300 words)
  4. What is your policy/procedure for statistical involvement in data management and trial monitoring? (Maximum 300 words)
  5. What is your policy/procedure for statistical involvement in the analysis of trials? (Maximum 300 words)
  6. Describe your systems and processes for the management of secure randomisation and unbiased treatment allocation including details of how these systems are accessed by Statisticians and Methodologists. Please include details on the methods, workflows, storage and access measures that are in place to ensure:
* Correct generation of allocation sequences, according to trial specific specifications.
* Concealment of the allocation sequence, until allocation occurs
* Blinding, if and when appropriate (Maximum 500 words)

**Section 7. Extent/level of availability**

* 1. Please state whether your Clinical Trials Unit role is available locally (i.e. your Unit only collaborates on trials with Chief Investigators within your geographical area), or whether it is available nationally and/or internationally? (i.e. your Unit is willing and able to collaborate on trials with Chief Investigators outside your geographical area).

[Locally / Nationally / Internationally]

**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 important aspect of registration. 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 gain by fully supporting all activities which include but are not limited to attendance at national meetings, membership and/or contribution to subgroup 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 if registered, that our CTU will actively contribute to Network activities.

|  |  |  |
| --- | --- | --- |
| Head of Clinical Trials Unit or Lead party in the collaborative or merged CTU 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 OR MERGED UNITS 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
* Submitted the full pdf and collaboration information of up to 3 significant publications as Appendix 1.
* Submitted one-page CVs of the Trial 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 2
* Included Appendix 3, a detailed organisation chart.
* Included Appendix 4 (i.e. a statement of support from your host institution(s) (refer to question 3.1)). For collaborative units You have obtained a joint letter of support from collaborator(s) (and host if institution is different)
* Included Appendix 5 a signed, scanned copy of the signature page in section 8.
* You have paid the application fee.

**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](mailto:regctus@leeds.ac.uk) and ensure that all Appendices are attached to your email.

**Section 9. Applications from Collaborative Groups, or Merged CTUs ONLY**

This section is ONLY for applications from a collaborative group or merged CTUs.

**For Collaborative Groups:**

* 1. Please provide details of all parties in the collaborative group in the table below

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

* 1. Please provide a detailed organisation chart of your collaborative group as Appendix 3. 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 collaborative group. Organograms must include high level information on the oversight of the parties within the collaborative group.
  2. Please briefly explain why an application from a collaborative group is being submitted and how the collaboration occurs? (Maximum 500 words)
  3. Please describe how you have integrated the work, systems, and personnel of all groups within the collaboration? (Maximum 300 words)
  4. 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 System provision *(Maximum 300 words)*
   1. Please explain how you maintain the integration? (Maximum 300 words)
   2. Please describe how you coordinate, support, monitor, and evaluate PPI across all parties in order to avoid duplication and maximise resources. (Maximum 300 words)

* 1. Please provide details of the formal arrangements in place for collaboration between the Clinical Trials Units in this collaborative group (Maximum 300 words)
  2. Please explain how the collaborative group would be capable of continued success in the face of changes in key personnel (Maximum 500 words)

**For Merged CTUs:**

* 1. Please provide details of all parties in the new merger in the table below

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

* 1. Please provide a detailed organisation chart of the merged units as Appendix 3. 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 merged CTU. Organograms must include detailed information on the new merged structure at a local level and how this sits within your host institution.
  2. Please briefly explain the reasons for merging the clinical trials units and details of when the merger took place? (*Maximum 500 words*)
  3. Please describe how you have integrated the work, systems, and personnel of the CTUs within the merger? (Maximum 300 words)
  4. 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)*
   1. Please explain how your CTU will maintain all aspects of the integration as noted above? (Maximum 300 words)
   2. Please provide details of the formal arrangements in place for collaboration between the Clinical Trials Units in this merger. (Maximum 300 words)
   3. Please explain how the merged group would be capable of continued success in the face of changes in key personnel (Maximum 500 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)