Norwich Clinical Trials Unit

**Collaboration Request Proforma**

We welcome requests for collaboration, particularly from local investigators.

Please contact us for any new trials you are planning, **at least 3 months** before the application deadline by completing this **Collaboration Request Proforma**.

Please complete it with as much detail as you have. If you are at a very early stage of trial development and details are unknown, leave the section blank.

Alternatively, guidance for completing this form can be found in the “NCTU Overview document”, available on our website: [www.uea.ac.uk/norwichctu](http://www.uea.ac.uk/norwichctu).

Once completed, please email this form to NorwichCTU@uea.ac.uk. A member of the CTU will contact you to discuss your proposal and the next steps that you will need to take.

|  |  |
| --- | --- |
| **Trial Title** |  |
| **Investigator** |  |
| **Position** |  |
| **Organisation** |  |
| **Email** |  |
| **Telephone** |  |
| **Expected submission date** |  |
| **Funding stream** | e.g. EME, RfPB, HTA, CRUK, NIHR Fellowship (please specify which) etc. |

|  |
| --- |
| **1. Background to clinical problem (including demographic/frequency of condition/problem):**  |
|  |
| **2. Brief summary of importance/relevance**  |
| **2a. to NHS priorities:** |
|  |
| **2b. to UEA/NRP or NNUH priorities:** |
|  |
| **3. Is Patient and Public Involvement planned? YES/NO** |
|  If yes, describe level of Patient and Public involvement thus far:  |
| **4. Have you performed a literature Review? YES/NO** |
| Please provide a maximum of 5 key references (ideally as pdfs) for the proposed area of research (Please attach copies of any publications which are currently accepted for publication or in press).  |
| **5. Are you planning a single centre pilot or feasibility study YES/NO** |
|  If Yes, explain how this will lead to a main study |
| **6. Please describe your project in terms of PICOS (Patient, Intervention, Control, Outcomes and Study/Statistical design):** |
| **P - Patient Group:** |
| **I - Intervention(s):** |
| **C - Control:** |
| **O - Outcomes and follow up period:**  |
| **S - Study/Statistical design (e.g. randomised controlled trial, case control study, pilot study):** |
| **7. For trial development and sample size calculations, you will need to provide:****• An estimate of your primary study outcome measure for the control group (for example response rate expected without the new intervention)****• Also think about a clinically significant difference you would want to observe between groups for the study to be convincing (e.g be worthwhile for funders and patients, change practise)** |
| **7a. Please provide an estimate of your primary study outcome measure for the control group (for example response rate expected without the new intervention)** |
| Please provide sources/justification for these estimates from pilot work/literature: |
| **7b. Sample size (not required, but helpful if already performed or estimated):** |
|  |
| **8. Anticipated number of sites:** |
|  |
| **9. Number of sites already identified as willing to participate:** |
| 1. UK:
2. International (if applicable):
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| **10. Have you made contact with a research network or national speciality group(s)? YES/NO** |
|  If yes, name of research network or national speciality group: |
| **11. Have you previously approached a CTU regarding this study? YES/NO** |
|  If yes, what was the outcome? |
| **12. Has the project been submitted for funding in the past? YES/NO** |
| If yes, please provide details of feedback obtained from the funder: |
| **13. Briefly describe the clinical trials experience of the CI and the current trial team:** |
|  |
| **14. Is any translational research being planned? YES/NO** |
|  |
| **15. Details and status of interventions:** |
|  |
| **16. Have you spoken to your Local Research Design Service? YES/NO** |
| If Yes, please could you let us know the name of the RDS advisor you are working with |
| **17. CTU collaboration required (please tick all that are required):** ***NOTE: CTU can only act as your official Clinical Trials Unit provided it has oversight of the main trial activities*** |
|  Protocol developmentStudy/trial designStatistical designStatistical analysis Interim statistical reports for DMCStudy Coordination (to include study and participating site set-up, preparation of all essential study documents, regulatory and ethics submissions, preparation of annual reports etc)Study monitoringRandomisationPharmacovigilanceStudy specific procedures development Some IMP management (including sourcing and re-ordering)CRF designDatabase build and maintenance, remote data captureData management (including data cleaning processes)Health EconomicsAccess to other methodologist, please specifyRegulatory Oversight (for CTIMPs only)Management of TSC/DMCSpecimen/tissue management Other, please specify |

Please email your completed form to **NorwichCTU@uea.ac.uk**