The NPEU CTU welcomes requests for collaborations on trials. We deliver on all aspects of clinical trials including trial design, trial management, randomisation, trial programming, statistical analyses, health economics analyses and dissemination. Typically our work is on late phase, multicentre, randomised controlled trials but we welcome requests to collaborate on other types of studies within the perinatal field.

Please complete the form as fully as possible and email it to ctu@npeu.ox.ac.uk

Please note that if the application is received within 2 months of the funder deadline, we may not be able to support the project*.*

# Research proposal

|  |  |
| --- | --- |
| **Name of enquirer:** | Click to add name |
| **Position:** | Click to add position |
| **Organisation:** | Click to add organisation |
| **Email:** | Click to add email |
| **Telephone:** | Click to add telephone |
| **Chief Investigator** ***(if different from above)*:** | Click to add Chief Investigator |
| **Position:** | Click to add position |
| **Organisation:** | Click to add organisation |
| **Other collaborators and their expertise identified (e.g. PPI):** | Click to add other collaborators |
| **Working research title** |
| Click to add working research title |
| **What is the problem being addressed?** |
| Click to add what is the problem being addressed |
| **Why is this research important in terms of improving health and/or wellbeing of a population of interest?** |
| Click to add importance of research |
| **Review of existing evidence/how does the existing literature support this proposal?** |
| Click to add review of existing evidence |
| **Study design (e.g. RCT, pilot study, blinded etc.)** |
| Click to add study design |

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| --- |
| **If a Randomised Controlled Trial (RCT) please describe your research question in terms of PICO (Population, Intervention, Control, Outcomes)** |
| **Population group:** | Click to add population group |
| **Intervention:** | Click to add intervention |
| **Control:** | Click to add control |
| **Primary outcome(s) and follow up period:** | Click to add primary outcome(s) |
| **Aims and objectives** |
| Click to add aims and objectives |
| **Sample size (estimated or actual):** | Click to add sample size (if known) |
| **Sample size assumptions:** | Click to add sample size assumptions (if known) |
| **Setting:** | Click to add setting |
| **Anticipated number of sites:** | Click to add anticipated number of sites |
| **Number of sites: identified:** | **UK:** | Click to add number of UK sites |
| **International:** | Click to add number of international sites |
| **Is sponsorship agreed?** | Choose an option. |
| **If yes, name of Sponsor:** | Click to add name of sponsor |

# Funding status

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of funder identified** | **Funding status** | **Deadline for new submissions** | **Type of application** | **Date of award** | **Estimated grant total** |
| Click to add name of funder | Choose an option. | Click to add deadline for new submissions | Choose an option. | Click to add date of award | Click to add estimated grant total |
| Click to add name of funder | Choose an option. | Click to add deadline for new submissions | Choose an option. | Click to add date of award | Click to add estimated grant total |
| Click to add name of funder | Choose an option. | Click to add deadline for new submissions | Choose an option. | Click to add date of award | Click to add estimated grant total |
| Click to add name of funder | Choose an option. | Click to add deadline for new submissions | Choose an option. | Click to add date of award | Click to add estimated grant total |
| **If any applications have been unsuccessful, please briefly outline funder’s feedback** |
| Click to add outline of funder’s feedback |
| **Is the study eligible for the NIHR portfolio?** | Choose an option. |
| **Has contact been made with an NIHR CRN Speciality Group or similar?** | Choose an option. |
| **If yes, please indicate the name of the group** |
| Click to add name of group |
| **Has contact been made with a Comprehensive Local Research Network (CLRN)?** | Choose an option. |
| **If yes, please indicate the name of the group** |
| Click to add name of group |
| **Have you engaged with a Research Design Service (RDS)?** | Choose an option. |
| **If yes, please indicate which RDS** |
| Click to add which RDS |
| **Have you previously approached a CTU regarding this study?** | Choose an option. |
| **If yes, what was the outcome?** |
| Click to add outcome |

# Patient and Public Involvement (PPI)

|  |  |
| --- | --- |
| **Have you engaged with any PPI groups?** | Choose an option. |
| **If yes, please enter details** |
| Click to enter details |

# CTU input required

|  |
| --- |
| **CTU input required (please tick all the apply)** |

|  |  |
| --- | --- |
| [ ]  **Study/trial design** | [ ]  **Statistical/methodological input** |
| [ ]  **Statistical analysis** | [ ]  **CRF design** |
| [ ]  **IMP management**  | [ ]  **IMP procurement** |
| [ ]  **Statistical reports for DMC** | [ ]  **Regulatory and ethics submissions** |
| [ ]  **Costing** | [ ]  **Data management** |
| [ ]  **Grant application writing** | [ ]  **Information technology (database build, remote data capture etc.)** |
| [ ]  **Trial management** | [ ]  **Health Economics** |
| [ ]  **Trial monitoring** | [ ]  **Access to other methodologist**Click to add details |
| [ ]  **Randomisation** | [ ]  **Equality, Diversity and Inclusion (EDI) coordination** |
| [ ]  **Pharmacovigilance** | [ ]  **Parent, Patient, Public Involvement & Engagement (PPPI&E) coordination** |
| [ ]  **Other** Click to add details |

Once complete, please return (preferably by email) to ctu@npeu.ox.ac.uk

For information or queries please call 01865 289700 and ask for the CTU.