



**Support and Advice Request Form**

**PLEASE SUBMIT THIS FORM AT LEAST 12 WORKING WEEKS**

**IN ADVANCE OF ANY FUNDING APPLICATION DEADLINE**

Please complete this form and return to BCTU by:

* Email: [BCTU@contacts.bham.ac.uk](mailto:BCTU@contacts.bham.ac.uk)
* Fax: 0121 415 9135/6 for attention of Natalie Ives
* Post: Natalie Ives, Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, Public Health Building, University of Birmingham, Edgbaston, Birmingham B15 2TT

**Section 1: Investigator Contact Details**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Principal Investigator** | **Other Investigator** | **Other Investigator** |
| Name |  |  |  |
| Role |  |  |  |
| Hospital/ University |  |  |  |
| Department |  |  |  |
| Telephone |  |  |  |
| Email |  |  |  |

Please add any other investigators in the ‘Other Comments’ section in the table below. We can retrieve full addresses from our database.

**University of Birmingham Principal Investigators Only**

|  |  |  |
| --- | --- | --- |
| If relevant, has a completed intention to submit form been sent to the RK&T office?  *For research council and NIHR researcher-led funding applications where the principal investigator is a UoB member of staff, an intention to submit form needs to be completed and sent to the RK&T office 12 weeks before any funding deadline. Please mark appropriate box with an X* | **Yes** | **No** |
|  |  |

**Section 2: Proposed Study**

Please provide a brief description of your study. It would be extremely useful to also supply a draft protocol, however rough and incomplete, to allow our advisors to gain an idea of the proposed study.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Stage of Study:  *Mark appropriate box or boxes with an X* | Idea |  | Funding Application |  | Submitted for Funding |  |
| Draft Protocol |  | Submitted Regulatory Approvals |  | Recruiting |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study Title (acronym): |  | | | | | | | |
| Study Type  *Mark appropriate box or boxes with an X* | RCT (please indicate trial phase) | |  | Diagnostic study |  | Monitoring/ test evaluation study | |  |
| Disease Area: |  | | | | | | | |
| Background:  *Please provide information for why the study is needed (max 250 words)* |  | | | | | | | |
| Study Design:  *Please provide information on the following:-*   * *Proposed study design* * *Treatment arms* * *Treatment schedule* * *Blinding* * *Follow-up schedule* * *Duration of follow-up* * *Outcome measures* * *Duration of study* |  | | | | | | | |
| Sample Size: |  | | | | | | | |
| Proposed Number of Centres: |  | | | | | | | |
| Location:  *Mark appropriate box with an X* | Local |  | National | |  | |  |  |
| International – Europe only |  | International – excluding USA | |  | | International – including USA |  |

**Section 3: Funding & Sponsorship**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Proposed Funder: |  | | | | | | |
| Timelines: *We ask for this form to be submitted 12 weeks in advance of any deadline* | | | | Funding application deadline | | |  |
| Proposed start date for study | | |  |
| Proposed Sponsor: |  | | | | | | |
| Has sponsorship been agreed?  *Mark appropriate box with an X* | | No |  | Yes |  | Provisional |  |

**Section 4: Level of CTU Support Requesting**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Type of Support & Advice sought - more than one can be selected:  *Mark appropriate box with an X (This will help us direct you to the member of staff most suitable to provide advice)* | Developing idea |  | Literature Searching/ Review |  | Applying for Funding |  |
| Study Design & Methodology |  | Sample Size |  | Statistical Methods |  |
| Study Management |  | Drafting Protocol & CRFs |  | Research Approval & Governance |  |
| Database System Design |  | Statistical Analysis |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Level of CTU support sought: *Mark appropriate box with an X*  *(See over page for more information)* | Consultancy Only |  | Study Management |  |  | |
| **For Study Management Support, please mark with an X all that apply** | | | | | |
| Randomisation (paper) |  | Randomisation (computer) |  | Study Management |  |
| Database System Development |  | Statistical Analysis |  | Systematic Review |  |
| Other Comments: |  | | | | | |

By requesting support and/or advice from the BCTU, you are agreeing for the following data to be held on the BCTU and Research Design Service for the West Midlands databases:

* Title of study and brief description of study objective and design
* Name and contact details of investigator and any co-investigators

**BCTU runs a Research Methods Course three times a year and we encourage all potential collaborators to attend this course.**

**Further information on this course is available on our website: www.birmingham.ac.uk/research/activity/mds/trials/bctu/research-methods-course/index.aspx/**

**We would like to send you details about our training courses in clinical trial methodology and practice, which you could pass on to colleagues if not of interest to yourself.**

|  |  |
| --- | --- |
| Please mark the box with a X if you do **not** wish to be put on our mailing list |  |

Support & Advice Service: Information

The Birmingham Clinical Trials Unit (BCTU) provides a support and advice service to prospective clinical researchers (doctors, nurses or professions allied to medicine) covering all aspects of study design, management and analysis. BCTU offer investigators help to work up their ideas or pilot studies into full-scale projects, advice on study design and methodology, advice and help with grant applications, and help with literature searches.

The Unit’s focus is on large scale late phase (III/IV) randomised controlled trials, diagnostic and test evaluation studies. Our remit is to support non-cancer research in the secondary care setting, as cancer research and primary care studies are supported by the University of Birmingham CRUK Clinical Trials Unit and Primary Care Clinical Research and Trials Unit respectively. The exception being with diagnostic and test evaluation studies where studies in cancer will be considered. BCTU are **unable** to provide advice on cohort or case-controlled studies, surveys, physiological or epidemiological studies. We also have limited experience in early phase (I/II) clinical trials.

BCTU are part of the NIHR funded Research Design Service (RDS) for the West Midlands (<http://www.rds-wm.nihr.ac.uk>). The primary aim of the RDS is to help NHS researchers, and others working in partnership with the NHS, in the West Midlands area who have a ‘good idea’ and want to turn that into a research proposal for submission to peer-reviewed funding programmes in applied health and social care.

**Please note** that any support and advice requests that come direct to BCTU will be reviewed to assess whether they can also be badged as an RDS query and if so, they will also be logged on the RDS central database.

The initial advice (which usually includes a face-to-face meeting) is offered free of charge. If the project is not likely to be co-ordinated within or associated with BCTU (see below), further limited support may be provided which depending on capacity, level of complexity and time may be provided free or is subject to a charge.

Study Management Support from BCTU

BCTU can provide support for running clinical studies such as randomisation, study co-ordination, provision of study specific database systems and/or statistical analysis. However, with NIHR funding streams now requiring that clinical trials are run through UKCRC registered trials units, BCTU has seen a large increase in requests for management support for clinical studies. Unfortunately, we **do not** have unlimited capacity to provide this support for every request. The Unit must therefore prioritise studies that fit in with the Unit’s strategic direction and speciality fields. These are reviewed annually, and currently consist of obstetrics and gynaecology, neurodegenerative diseases, renal disease, coloproctology, surgical studies, burns, trauma & critical care. This allows the Unit to consolidate expertise in particular disease areas, but retain some flexibility to be able to adapt to new developments and initiatives.

If you are requiring some level of study management support (see below), then your study will need to be reviewed by BCTU’s New Business Group to determine whether your study fits into any of the Unit’s disease portfolios and whether the Unit has the capacity to help. This group meets every fortnight. For studies where BCTU agree to provide study management support, the appropriate amount to cover the cost of this support must be included in any grant application. This information can be provided by BCTU, and must be agreed by a member of BCTU’s Management or New Business Group.

*Independent Randomisation Service*

BCTU can provide various randomisation services:-

* Paper-based telephone randomisation available Monday to Friday, 9am to 5pm.
* Basic computerised telephone randomisation available Monday to Friday, 9am to 5pm.
* Internet computerised randomisation available 24/7.

Further information on our randomisation service and related costs is available on request.

*Study Management Models (****Subject to capacity****)*

BCTU offers two levels of CTU study management support:

* *Full Study Management (preferred model)*: Where study co-ordination, randomisation, programming and statistical support is all provided by BCTU;
* *‘Hub and Spoke’*: Where the researcher manages and conducts the clinical study with the appropriate staff at their own centre, but programming and statistical support is provided by BCTU.

*Database System Design and Development Support (****Subject to capacity****)*

BCTU can provide advice on database system development and IT needs for clinical studies. We can also (subject to capacity) provide IT and database support for the study. This may include a randomisation service (see above), database system development and maintenance and/or storage of electronic data. Costs for programming support should be included in the grant application.

*Statistical Support (****Subject to capacity****)*

BCTU can also provide statistical support for studies, and costs for this service should be included in the grant application. Statistical support will generally only be provided when IT and database support for the study is also being provided by BCTU.

**FOR INTERNAL USE ONLY**

**BCTU Advisor:**

|  |  |
| --- | --- |
| Name: |  |
| Position: |  |

**RDS and Intention to Submit Form:**

|  |  |  |
| --- | --- | --- |
| Is this a RDS Query? | *If yes, please provide RDS query number.*  *If no, please check whether query can be badged as a RDS query.* |  |
| If needed, has an intention to submit form been completed and sent to the RK&T office? | |  |

**BCTU Capacity Review**

**Trial Team**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1a. Does the study fit into a current disease portfolio? | Yes |  | No |  |
| 1b. If yes, which portfolio and who should be the point of contact? | Yes |  | No |  |
| Point of contact in trial team |  | | | |
| 1c. Does the team have the capacity to help develop this study? | Yes |  | No |  |

**IT Team Support**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 2a. If BCTU IT support is being requested, what support will be required? |  | | | ***Yes (X)*** | | |
| Randomisation only | | |  | | |
| Database system | | |  | | |
| 2b. Does the IT team have the capacity to undertake this work? | Yes |  | No |  | N/A |  |
| 2c. IT staff member assigned to develop/ work on project? |  | | | | | |

**Statistics Team Support**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 3a. If BCTU statistical support is being requested, what support is being requested? |  | | | | ***Yes (X)*** | |
| Study design | | | |  | |
| Data Cleaning | | | |  | |
| Interim Analyses | | | |  | |
| Final Analysis | | | |  | |
| 3b. Does the Statistics team have the capacity to this undertake work? | Yes |  | No |  | N/A |  |
| 3c. Statistics staff member assigned to develop/ work on project? |  | | | | | |

**Systematic Review Team Support**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 4a. If systematic review support is being requested, does the Systematic Review team have the capacity to this undertake work? | Yes |  | No |  | N/A |  |
| 4b. SR staff member assigned to develop/ work on project? |  | | | | | |

**FOR COMPLETION BY MEMBER OF BCTU NEW BUSINESS GROUP:**

|  |  |
| --- | --- |
| Date of New Business Group Meeting: |  |
| Member Responsible for Informing CI of Decision |  |

**Recommendation: (Mark with X)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Agree to support |  | Agree to support, but needs revision |  | Decline to support |  |

Please provide reasons for recommendation: