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| **New Trial/ Research Proposal Form**  **For consideration at the Surrey Clinical Trials Unit (CTU)** |

**Completion and submission of this form will enable a new trial proposal to be considered for conduct at the Surrey CTU. This minimal information allows a quick decision from the CTU as to whether the CTU is able to support the proposal. It is essential that the proposal is submitted at the earliest opportunity (ideally 3 months before a submission deadline).**

The intention of this part of the Trials Review Group process is to ensure that:

* Each new trial proposal is reviewed by the CTU Trials Review Group (TRG) as soon as possible
* Investigators are provided with the best possible service
* Trials can be costed in a timely fashion
* The CTU maintains a comprehensive and balanced trial portfolio

If the applicant requires the trial to be sponsored by the University of Surrey please indicate in the form below so that this can be considered simultaneously.

**Review Process**

Please complete the form below and return it to the CTU Email: [ctu@surrey.ac.uk](mailto:ctu@surrey.ac.uk)

Proposals should be kept brief – Please limit to4 pages if possible

Please use 10 point font. Boxes will expand as necessary when typing.

1. On receipt the completed form will be allocated the next available TRG submission no
2. The applicant will be notified of the number and given an estimated response date

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| --- | --- | --- | --- | --- | --- |
| **Proposed Trial/ Study Title:** | | | | **Disease Area:** | |
| **CI Name:**  CI on Previous Surrey CTU trial?  Y  N | | | | **CI Institution:** | |
| **CTU Contact:** | | | | **CI Email or Phone No:** | |
| **Status of Proposed Research:** | Anticipated funding or approval submission date:  Anticipated Funding Committee/Body name: | | | | |
| Discussed with CSG/ sub-group or other specialist group?  Y  N  Name of group: | | | | |
| **Type of Trial/Research:** | First in Human  Phase 1 | | Phase II (rand)  Phase II (non-rand)  Phase III | | Other Research  Type: |
| **Co-investigators:** |  | | | | |
| **Brief Summary of Background & Justification for Trial** Include how this proposal fits in with previous or ongoing trials in this area. |  | | | | |
| **Trial Design**  Main inclusion/exclusion criteria.  Summary of treatment(s). Identify control arm & justify choice of experimental arm/s.  For complex designs please attach separate trial flowchart/ diagram. |  | | | | |
| Feasibility of Trial and Potential ImpactInclude how trial results will be used & population size i.e. how many patients p.a. would be eligible for the trial |  | | | | |
| Potential Major Issuese.g. with trial design, feasibility, drug supply etc |  | | | | |
| Primary End-point:(if known) |  | | | | |
| Sample Size (approx) |  | **UK sites only?**  or UK and international sites?  **No. expected UK sites:** | | | |
|  | | **If international:** which countries (+no. of sites)?  What is rationale for inclusion of this/these countries? | | | |
| **IMP(s) involved?**  Y  N  **ATMP(s) involved?**  Y  N  **Medical device(s)?**  Y  N  **CE mark?**  Y  N Supplier(s) involved?  Y  N If yes, name(s):  Funding?  Y  N | | **Products involved:**   |  |  |  | | --- | --- | --- | | Name: | Licensing status: | Free/ discounted? | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | | | |
| **What support would you like from the CTU?** | |  | | | |
| **Who is the expected sponsor** | |  | | | |
| **If you would like the sponsor to be the University of Surrey, have you had any contact with RIGO so far regarding this study?** | | Y  N | | | |
| **If University of Surrey is to sponsor, have you had any contact with other university departments, such as finance, legal and contracts, and if so who are your contacts?** | | Y  N | | | |
| **If sponsor is RSCH, have you had any contact with R&D so far regarding this study?** | |  | | | |
| **What is the bid submission date** | |  | | | |
| **If the bid is successful, please confirm anticipated start and end dates of trial** | | Start Date       End Date | | | |

**DO NOT EXCEED 4 pages**