**GROUP**

EMR [ ]  OCTO [ ]  RRIO [ ]  SITU (General) [ ]

SITU (Ortho & Plastics) [ ]  TRAUMA [ ]  OTHER [ ]  (Please state):………….…………………………….

|  |  |
| --- | --- |
| Chief Investigator: |  |
| Contact email:Contact telephone: |  |
| Trial title: |  |
| Proposed acronym (if applicable): |  |
| Funder and call being responded to (if applicable): |  |
| Funding deadline: |  |
| Research question: |  |
| Brief summary of clinical problem |  |
| Brief Summary of importance / relevance of Research question |  |
| Please select which one of these categories describes your research (as per IRAS definitions): | Clinical trial of an investigational medicinal product (IMP).[ ]  Clinical investigation or other study of a medical device.[ ]  Combined trial of an IMP and an investigational medical device.[ ]  Other clinical trial to study a novel intervention or randomised clinical trial to  compare interventions in clinical practice.[ ]  Basic science study involving procedures with human participants.[ ]  Study administering questionnaires/interviews for quantitative analysis, or  using mixed quantitative/qualitative methodology. [ ]  Study involving qualitative methods only.[ ]  Study limited to working with human tissue samples (or other human  biological samples) and data (specific project only).[ ]  Study limited to working with data (specific project only).[ ]  Research tissue bank.[ ]  Research database.[ ]  If your research does not fit into any of the above, please select this box. |
| Does your trial involve a complex innovative design? | [ ]  Not ApplicableIf applicable, please tick the most relevant design: [ ]  Umbrella[ ]  Basket[ ]  Platform[ ]  Master Protocol and associated Submodules |

**Please describe your project in terms of PICOS below:**

|  |  |
| --- | --- |
| **P – Patient group:** |  |
| **I – Intervention(s)** ***If intervention involves an IMP please indicate if it is a licensed drug within the EU*** |  |
| **C – Control/Comparator** |  |
| **O – Outcomes and follow-up period*****(do outcomes match any relevant core outcome set?)*** |  |
| **S – Study/Statistical Design (e.g. randomised controlled trial, pilot study)** |  |

**PPIE**

|  |  |
| --- | --- |
| **How have patients/service users, carers and the public have been involved in developing this proposal.** For example* Defining the research question to be addressed and important outcomes
* The acceptability of the trial intervention and its timing
* The design/ schedule of the protocol (esp patient flow/ patient journey/ methods of data collection)
* If PPI not yet involved, how do you plan to involve them?
 |  |

|  |  |
| --- | --- |
| Estimated number of subjects (if known): |  |
| Estimated number of centres (if known): |  |
| Proposed Sponsor: |  |
| Proposed Co-applicants: |  |
| Proposed grant start date: |  |
| Proposed grant duration: |  |
| Other important issues to note: |  |
| Documents attached (if any): |  |

**SERVICES REQUESTED**

Please describe who is providing the below services – or tick if you would like OCTRU to quote for providing these. **Please note OCTRU routinely provides statistics and programming for any trials it collaborates on.**

|  |  |  |
| --- | --- | --- |
| Statistics: | Would you like OCTRU to provide this? [ ]  YES [ ]  NO If yes, please tick whether you wish to have an embedded statistician in the trial, **or** senior oversight only: Embedded statistician [ ]  Senior oversight ONLY [ ]   | If No was selected, please enter details of who will be performing this service: |
| Randomisation:(excluding programming) | Would you like OCTRU to provide this? [ ]  YES [ ]  NO  | If No was selected, please enter details of who will be performing this service: |
| Programming:(including databases) | Would you like OCTRU to provide this? [ ]  YES [ ]  NO  | If No was selected, please enter details of who will be performing this service: |

Form completed by:

Name: Date:

**Please note completion of this form does not mean that the trial will be accepted onto the OCTRU Trials Register – this is a 'Request to Collaborate' Form.**

**Please email this form to** **octrutrialshub@ndorms.ox.ac.uk** **and after the form has been validated it will be reviewed.**

**OCTRU HUB USE ONLY:**

OCTRU ID: …………………………………..

Date form confirmed as valid: ………………………………………………………….

What review is needed for this application: Full [ ]  Post submission adoption [ ]  Post funding adoption [ ]

Date submitted electronically to OCTRU New Business Committee: …………………………………………………….

Date discussed by OCTRU New Business Committee: …………………………………………………….

Outcome of review: ……………………………………………………………..

Comments to feedback: …………………………………………………………………………………………………………………………………………..

Date of outcome emailed to form originator: …………………………………………………

Date of outcome emailed to host unit (If applicable): …………………………………………………