**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 Applicable  If 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**](mailto: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): …………………………………………………