**OCTRU aims to be a full collaborator on studies which are taken onto its register: this includes contributing to study design and grant development, as well as delivery of the study. Delivery of the study typically includes senior oversight, programming, statistics, and quality assurance. For clinical trials that are to be run through one of the OCTRU groups, agreement from that the respective group should have been sought and received, prior to submitting this form to the OCTRU Central (Hub) for review.**

***Note:*** *Submission of this form once the basic concept of the study has been developed is encouraged. Compete as much of the form as possible prior to submission. It is understood that some aspects may yet to be confirmed at the point of submission.*

**GROUP**

EMR  OCTO  RRIO  SITU (General)

SITU (Ortho & Plastics)  TRAUMA

|  |  |
| --- | --- |
| 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 best 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.  If you are unsure of the categorisation, please select this box. |
| If you are proposing a clinical trial, does it involve a complex/innovative design? | Not Applicable  If applicable, please tick the most relevant design:  Umbrella  Basket  Platform  Master Protocol and associated subsidiary studies  Other, please specify: |

**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 participants (if known): |  |
| Estimated number of centres (if known): |  |
| Proposed Sponsor: |  |
| Proposed Co-applicants – (Ensure this includes senior individuals that will contribute to the development of the study design and delivery): |  |
| Proposed grant start date: |  |
| Proposed grant duration: |  |
| Other important issues to note: |  |
| Documents attached (if any): |  |

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): …………………………………………………