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| **PART A: Trial details (completed by trial office)** | | | | |
| **Trial title: Nailbed INJury Analysis trial (NINJA)** | | | | |
| **Date trial open to recruitment** | Start 09Jul2018 | **Recruitment duration** | | End 31Dec2019 |
| **Trial funding basis / source(s)** | National Institute for Health Research – Research for Patient Benefit | | | |
| **Trial NIHR Adoption status** | Yes | | | |
| **Proposed trial agreement type** | Standard template: unmdified mNCA | | | |
| **Trial Co-ordination** | Amy Jones (Trial Manager) ninja@ndorms.ox.ac.uk | | | |
|  | | | | |
| **PART B: Site details (to be completed by Site)** | | | | |
| **Site** |  | | | |
| **Principal Investigator**  (should be a consultant) |  | | Attach CV with details of GCP training / research experience | |
| **Tel. No. / Email** |  | | | |
| **Main contact for site setup** |  | | Job title / role | |
| **Tel. No. / Email** |  | | | |
| **Main contact for trial (e.g. RN)** |  | | Job title / role | |
| **Tel. No. / Email** |  | | | |
| **Full postal address** |  | | | |

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| **Patient Recruitment** | | | |
| **How many paediatric patients (<16years old) with a nail bed injury requiring surgery are seen by your site every month?** | | | |
| **What is your expected recruitment rate for this trial (based on the numbers above and the protocol selection criteria)?** | | | |
| **Per month:** | **Per year:** | | |
| **Does this trial compete with any existing or planned trials at this site? If so, how will the effects on recruitment be mitigated?** | | | |
| **How will patients be identified and recruited? i.e. by who and where (e.g. Day Surgery Unit / A&E / Hand Clinic / Minor Injuries Unit / Other)** | | | |
| **Are patients referred from other sites / hospitals / trusts? (if yes please specify)** | | | |
| **Will any trial related procedures take place at other sites / hospitals / trusts / patient home? (if yes please specify)** | | | |
| **Will patients be discharged from the site prior to the end of trial follow up? (If yes please specify)** | | | |
| **Does participation in this trial have the necessary local support from colleagues / peer groups and equipoise etc.?** | | | |
| **Staffing and Experience** | | | |
| **Please summarise the PI and site’s research experience relevant to conducting this trial:** | | | |
| **What research staff do you expect to be assigned to the trial?** | | | |
| **Are your research staff GCP trained?** **Can they provide a research CV and evidence of recent GCP training on request?** | | | |
| **Specified protocol requirements** | | | |
| **Can the site meet the following requirements** | | **Yes** | **No (specify/discuss options)** More space on page 3 |
| IIs local research support available? | |  |  |
| Are there Paediatric specialist departments and services? | |  |  |
| Can randomisation take place during preoperative care? | |  |  |
| Do patients have a routine clinical follow up between 7-10 days? | |  |  |
| Do patients attend any other follow up appointments? (Please specify) | |  |  |
| Will participants be seen by an appropriate NINJA team member during follow up visits? | |  |  |
| Is there reasonable WiFi access for mobile devices? | |  |  |
| **Monitoring** | | **Yes** | **No (specify/discuss options)** |
| **Are facilities adequate for on-site monitoring?** | |  |  |
| **Will all source documents be made available for monitoring?** | |  |  |
| **Is there easy access to site computers/internet for data entry and monitoring purposes?** | |  |  |

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| **Local contracting and approvals** | | |
| **Give details of any internal trial approval process (e.g. internal review for prioritisation) needed to proceed.** | |  |
| **Estimated timeline (days) from receipt of core submission documents to site R&D permission?** | |  |
| **Projected time to complete trial contract negotiations from receipt of the initial draft?** | |  |
| **Any other relevant information or feasibility issues?** Please let us know if you have any concerns about your sites ability to deliver the protocol or to meet recruitment/ set up and other targets. | | |
| **Other relevant information:** | | |
| **Part B completed by:** | | |
| **Print name / Sign** |  | |
| **Role** |  | |
| **Date** |  | |
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| **PART C: For office use only** | |
| **Issues identified which may impact on site’s ability to deliver the trial according to the protocol, required recruitment rate or set-up within required timelines:** | |
| **Mitigating or follow up actions and timelines**: | |
| **Any known site compliance / performance issues in other trials?** | |
| **Any general training / experience issues or local protocol specific training requirements?** | |
| **Recommendation / Outcome**  Feasible – Proceed to set-upFeasible – Reserve Not Feasible Site declined trial | |
| **Sign off** | |
| **Print name / Sign** |  |
| **Role** |  |
| **Date** |  |
|  |  |

**NINJA POINTS SYSTEM FOR PUBLICATION AUTHORSHIP**

To ensure fairness and encourage engagement and participation in the trial, “points” will be awarded for involvement and conduct of particular parts of the trial. Points are tracked centrally by completion of CRFs.

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| --- | --- |
| **Event** | **Points** |
| Setup | 5 |
| Recruitment | 1 |
| Randomisation/Operation | 1 |
| Follow up | 1 |
| SAE review | Automatic authorship |
| Photo panel | Automatic authorship – for application |

A minimum of 10 points is needed overall at each site.

Authorship points:

**8 points and above –certificate and PubMed searchable author**

**5-8 points – certificate and acknowledgement**

Points can travel with clinicians as they go on rotation to different NINJA sites

For a PI to be recognised as an author, they need to ensure they fulfil the following:

* Overall leadership of trial
* Support trainees and the whole trial process
* Ensure completion of F/U
* Timely responses to emails
* Recruit to target
* Ensure screening data is maintained