**GOSH BRC Call for Applications for Advanced Treatments for Malformation and Tissue Damage Theme Support Grants**

The NIHR Great Ormond Street Biomedical Research Centre is pleased to announce this new funding opportunity. The theme for [Advanced Treatments for Malformation and Tissue Damage](http://www.gosh.nhs.uk/research-and-innovation/nihr-great-ormond-street-brc/about-us/our-research-themes/2017-2022-great-ormond-street-brc) aims to pioneer advanced treatments and develop new devices to provide therapeutic options for children with congenital malformations and tissue damage.

This funding call will support projects starting on 1st April 2019 for up to 24 months. Funding of up to £50K per project is available including staff costs (excluding PI time) and consumables. The funding limit for consumables is £10K per application and the total amount available for purchasing of equipment shall not exceed £5K per item.

Applications must be registered and costed through the normal process. Completed [registration forms](https://www.gosh.nhs.uk/file/27821/download) must be emailed to [research.registration@gosh.nhs.uk](mailto:research.registration@gosh.nhs.uk) **at least 15 working days** before the deadline.

Application forms containing approved costs should be submitted to Dauda Bappa (**BRC@gosh.nhs.uk**) together with a copy of the Investigator's CV (2 pages max) **by 5pm 23rd November 2018**.

**Section A: Registration  *R&D number*** *(Office use only)****:***

**A1.** Full title of proposed project:

**A2.** Principal Investigator (PI) details (students cannot be PIs):

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| Title |  | |
| Full name |  | |
| Post held |  | |
| Contact details (email & contact number) |  | |
| Full or Honorary GOSH contract |  | |
| (If ICH employee) Academic Section |  | |
| (If GOSH employee) Clinical Division West: | Portfolio A | Portfolio B |
| (If GOSH employee) Clinical Division Barrie: | Portfolio A/C | Portfolio B |

**A3.** Is this a student Project? Which award? If other please specify:

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| **A4.** Co-applicants (please list all): | | | | | | | | | |
| **Title** | | **Forename** | **Surname** | **Substantive employer** | **GOSH Clinical Division** | **ICH Academic Section** | **Position Held** | **Full or Honorary GOSH Contract** | |
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| **A5.** Select a category from the list below | | | | | | | | |
|  | Clinical trial of an investigational medicinal product | | | | | | | |
|  | Clinical investigation or other study of a medical device | | | | | | | |
|  | Combined trial of an investigational medicinal product and an investigational medical device | | | | | | | |
|  | Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice | | | | | | | |
|  | Study to work with human tissue samples (or other human biological samples) and data (specific project only) | | | | | | | |
|  | Other laboratory study | | | | | | | |

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| **A6.** **Project details** | | | | |
| Proposed start date: | Proposed end date: | | Duration: | |
| Will you recruit new participants:  Yes  No | GOSH patients  NHS patients  GOSH staff | | Non-NHS participants  (e.g. relatives, volunteers, international private patients, other NHS staff)  Other give details | |
| If GOSH patients, or staff, are involved which Clinical Division will be involved? | | | | |
| (If GOSH employee) Clinical Division West: | | Portfolio A | | Portfolio B |
| (If GOSH employee) Clinical Division Barrie: | | Portfolio A | | Portfolio B |
| Will you use human tissue or patient data:  Yes  No | Tissue bank only  New tissue  Tissue from a previous study. Please provide the REC or R&D number: | | | |
| Where is the research being undertaken? (tick all that apply)  ICH GOSH  Somer’s Clinical Research Facility Other, give details | | | | |

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| **A7.** **Research Ethics** |
| |  | | --- | | All Research involving NHS patients or services will require Health Research Authority (HRA) Research Ethics Committee approval HRA application form: (<http://www.hra.nhs.uk/research-community/applying-for-approvals/>). Projects involving non-NHS participants should be reviewed by a non-NHS REC (UCL Ethics committee <http://ethics.grad.ucl.ac.uk/>).  The majority of applications to the CRAC will occur prior to Research Ethics Committee submission. In some cases, REC approval will have already been obtained. | |  | |
| Please give details of your studies ethical status:  N/A  Pending  To be submitted  Re-submitted  Refused  REC Approved REC No:       Please send a copy of your Favourable REC approval along with you application form. |
| **A8. Sponsorship and Indemnity** |
| Lead Sponsor (this will normally be GOSH NHS Foundation Trust or ICH-UCL):  If ‘Other’ please specify: |

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| **Section B: Recruitment, feasibility & study groups** *(please ignore this section if your study is solely lab based)* | |
| **B1.** How will participants, records or samples be identified? |  |
| **B2.** Who will identify potential participants, records or samples to be used in your study? |  |
| **B3.** How will potential participants be recruited? e.g. by letter, telephone, in person at a clinic. |  |
| **B4.** Who will recruit subjects and take consent/assent? |  |
| **B5.** If you are recruiting subjects during clinics, do you have permission of the **clinical lead**? |  |
| **Sample size/study groups** |  |
| **B6.** How many subjects, in total, will participate in your study? *(Q A59)* |  |
| **B7.** Please list all of your study groups and the number you plan to study in each group.  *e.g. Children with leukaemia (n=20)*  *Age-matched controls (n=20)* |  |
| **B8.** How many of these subjects will be recruited at GOSH? |  |
| **B9.** Please justify your sample size and provide a power calculation |  |
| **B10.** How will you inform the patients direct clinical care team of their involvement in your research study? |  |
| **B11.** What is the age range of participants to be studied? |  |
| **B12.** Please list the principal inclusion criteria (Q A17-1) |  |
| **B13.** Please list the principal exclusion criteria (Q A17-2) |  |
| **Feasibility** |  |
| **B14.** How many patients, who fit the inclusion criteria stated, have you identified or, do you/will you see per clinical session?  How many clinics are held per week/month in which potential participants can be recruited? |  |

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| **Section C: Research Plan** |
| **C1. Lay Abstract**  Please describe the research in simple terms in a way that could be published to a general audience (in no more than 300 words). If awarded, this may be made publicly available and applicants are responsible for ensuring that the content is suitable for publication. |
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| **C2. Project Summary.** *Please complete this section in language comprehensible to a research active clinician who may not have a background in the subject area.*  Please include: (i) Background to the disease(s) or condition to which your research relates, (ii) the aims and objectives of your project, (iii) plan of investigation, (iv) the likely impact this research will have, and how will this research make a difference to patients at GOSH and beyond. *Please provide up to 10 key references* |
|  |
| **C3. Study design.** *Please summarise your design methods in language comprehensible to a research active clinician who may not have a background in the subject area. It should be clear exactly what will happen to the research participant, how many times and in what order. Please provide up to 10 key references (max 600 words).* |
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| Word Count: |
| **C4.** What is the primary outcome measure for the study? *(Q A57)*. |
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| **C5.** What are the secondary outcome measures? *(Q A58)*. |
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| **C6.** What are the criteria for electively stopping the research prematurely? *(Q A75-2)* |
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| **C7.** What is the potential for benefit to research participants? *(Q A24)* |
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| **C8.** What are the potential risks and burdens for research participants and how will you minimise them? (*Q A22) For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.* |
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| **C9.** Statistical analysis. **DO NOT LEAVE BLANK**  Please describe the methods of analysis (statistical or other appropriate methods) by which the data will be evaluated to meet the study objectives (Q A62). For statistical methods, outline what specific data will be analysed by each method. |
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| **C10.** Will there be a potential overlap of the proposed work with other studies. |
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| **C11.** How do you intend to report and disseminate the results of the study (A51) (max 150 words) |
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| **C12.** Please explain how this funding will help to secure longer term funding to support the project and/or the core activity of the Advanced Treatments for Malformation and Tissue Damage Theme. |
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| **C13.** Please describe how this funding will help support national and international partnerships with other academic and non-academic groups. |
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| **C14.** Describe the likelihood of this research producing patentable results? |
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**Section D: Finances.**

**D1. Staff time (not to be paid directly from the project)**

In this section please give details of staff time involvement in your research project (either directly conducting the research or as a supervisor). This may not have a direct cost implication to the project, as staff may have protected time in their contracts for research. However, the time spent on research must be monitored to assess the impact of research on Trust resources.

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| **Name, Grade** | **Hours/week** |
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**D2. COSTINGS REQUESTED**

**Please note:**

* **This funding call makes available up to £50K per project including staff costs and consumables.**
* **The funding limit for consumables is £10k per application.**
* **The total amount available for purchasing of equipment shall not exceed £5K per item.**

**Staff Costs (if paid directly from the project)**

If a member of staff will be employed to work on this project, please fill in this section.

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| **Name, FTE %** | **Employer** | **Year 1 (£)** | **Year 2 (£)** | **Year 3 (£)** | **Year 3 (£)** | **Year 3 (£)** | **Total** |
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| Other costs (please list) | | | | | | |  |
| Total | | | | | | |  |

**D3. Service Support Costs**

This section should include details of treatment costs which are additional to routine as a result of the research study, for example additional pharmacy costs, radiology costs, additional blood tests or additional hospital stay.

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| **Item** | **Cost (£)** |
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| **D5. Laboratory and Equipment Costs**   |  |  | | --- | --- | | **Item** | **Cost (£)** | |  |  | |  |  | |  |  | |  |  | |  |  | | | | |
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| **D4.** Justification of Resources (max 150 words) | | | |
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**Section E: Declarations and Signatures**

In order for your application to be accepted you are required to gain approval from the relevant stakeholders within your department and/or institution. These approvals are required to ensure that the applicants agree to support the proposed project, and that the research activity can be accommodated by the department where the work will be performed. These approvals can be supplied as an e-signature or a ‘wet ink’ signature. If the Principal Investigator is also a Section Head we will obtain approval from the Deputy Director of Research.

**By submitting this application form to CRAC you, as the Principal Investigator, are agreeing to the following terms and conditions:**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the principles of the Research Governance Framework, and, if relevant, the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Human Tissue Act 2004.
3. I undertake to conduct this research in accordance with the relevant Good Clinical Practice guidelines.
4. I take responsibility for ensuring that all staff involved in this research hold appropriate contracts of employment for the duration of the research, and are familiar with the Research Governance Framework, GOSH/ICH Data Protection Policies and all other relevant policies and guidelines.
5. If the research is approved, I undertake to adhere to the study protocol, and to request approval from the R&D Office and the Research Ethics Committee within local timelines for any subsequent amendments to the protocol.
6. I undertake not to conduct any research which does not comply with any conditions requested by GOSH/ICH.
7. I undertake to complete any interim and/or final reports as requested by the R&D Office, Study Sponsor and the Research Ethics Committee and understand that continuation of permission to conduct this research within the organisation is dependent upon the satisfactory completion of such reports.
8. I undertake to maintain a project file for this research in accordance with the GOSH/ICH policies and Good Clinical Practice Guidelines.
9. I take responsibility for ensuring that all adverse events are handled within the GOSH/ICH policies for reporting and handling of adverse events.
10. In the case of randomised controlled trials, I agree to register the study with the International Standard Randomised Controlled Trial Number Register (ISCRTN)
11. I understand and agree that the study files and documents and research records and data may be subjected to inspection by the R&D Office, the sponsor or an independent body for audit and monitoring purposes.
12. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in this research are aware of their responsibilities to disclose conflicts of interest.
13. I understand that information about this research, and about me as a researcher, will be held by the R&D Office and on the R&D database. The information will be managed according to the principles established in the Data Protection Act 1998.

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| I can confirm that the information given on this form is complete and correct, that all co-applicants mentioned on this form have seen a copy of this application and that I shall be actively engaged in this project and responsible for its overall management.  Signed: ……………………………………………………………………………………………………………………. Date: …………………………………..  **(Lead applicant)**  Signed: ………………………………………………………………………………………………………………….... Date: …………………………………..  **(Co-applicant)**  Signed: ………………………………………………………………………………………………………………..….. Date: …………………………………..  **(Co-applicant)** |
| I can confirm that I have read this application and that, if funded, the work will be accommodated in this department / institution and that the applicants for whom we are responsible may undertake and support this work.  Signed: ……………………………………………………………………………………………………………………. Date: …………………………………..  **(Representative of the institution hosting the research e.g. clinical general manager, unit/department head)** |

**Peer Review**

Please suggest 2 independent reviewers who are able to scientifically review your study proposal. Reviewers must be of lecturer status or above working in fields that are relevant to the research proposal.

They cannot be:

* Co-applicants
* Current collaborators
* Immediate colleagues

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| --- | --- | --- | --- | --- |
|  | **Name** | **Institution/Department** | **Post** | **E-mail address** |
| **Reviewer 1** |  |  |  |  |
| **Reviewer 2** |  |  |  |  |