Clinical Research Adoptions Committee (CRAC) Application

**R&D number:**

**PI and Co-applicant names**

**Project title:**

**Submission date:**

|  |
| --- |
| **Supplementary documents to be included with CRAC application checklist**  ***Please include and tick the following documents where applicable to your project.***  *Guidance and templates for protocols can be found here:* <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>  *Patient information and consent forms and guidance:* <http://www.hra-decisiontools.org.uk/consent/> |
| Protocol |
| Patient Information Sheet |
| Consent Form |
| Questionnaire |
| Other (Please specify): |

**Please refer to the CRAC Application Guidance to help with completing this form**

[**https://www.gosh.nhs.uk/our-research/our-research-infrastructure/joint-research-and-development-office-rd/clinical-research-adoptions-committee-crac/**](https://www.gosh.nhs.uk/our-research/our-research-infrastructure/joint-research-and-development-office-rd/clinical-research-adoptions-committee-crac/)

# Cover Letter

*Please provide a summary of the research using language* ***easily understood by a lay audience****. The summary should be a maximum of 2 A4 pages. Please read CRAC Guidance document for details on the content.*

**Overview:**

**Timescale:**

**Rationale:**

**Patient cohort:**

**Aims:**

**Project involves:**

**Outcomes:**

**Impact:**

**Benefits:**

**Risks:**

# CRAC Application Form

**ALL QUESTIONS MUST BE ANSWERED**

## Section A: Registration details

***R&D number*** *(if already registered):*

**A1.** **Full title of the research project** (*Q A1*):

**A2.** **Principal Investigator (PI) details** (must have a GOSH substantive or honorary contract; students cannot be PIs):

|  |  |
| --- | --- |
| Title |  |
| Full Name |  |
| Post held |  |
| Contact details (email and contact number) |  |
| Full or Honorary GOSH contract |  |
| (If ICH employee) Academic Section: |  |
| (If GOSH employee): | Brain [BI]  Heart & Lung [HL]  Operations & Images [PC]  Sight & Sound [SS]  Body, Bones & Mind [BO]  Blood, Cells & Cancer [CB]  International & Private Patients [IP]  Medicines, Therapies & Tests [SH]  Performance & Information [PI] |

**A3.** **Is this a student project?** Choose an item.

|  |
| --- |
| *If Yes, please add details below.*  Award: Choose an item. If other, please specify:  Awarding institution:  Student’s name and contact details:  Supervisor’s name and contact details:  Has supervisor reviewed and approved this application? Choose an item. |

**A4. Co-applicants** (please list all)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Title** | **Forename** | **Surname** | **Substantive employer** | **GOSH Clinical Directorate/ Department** | **ICH Academic Section** | **Position Held** | **Full/Honorary GOSH Contract** |
|  |  |  |  | Choose an item. | Choose an item. |  | Choose an item. |
|  |  |  |  | Choose an item. | Choose an item. |  | Choose an item. |
|  |  |  |  | Choose an item. | Choose an item. |  | Choose an item. |
|  |  |  |  | Choose an item. | Choose an item. |  | Choose an item. |
|  |  |  |  | Choose an item. | Choose an item. |  | Choose an item. |
|  |  |  |  | Choose an item. | Choose an item. |  | Choose an item. |
|  |  |  |  | Choose an item. | Choose an item. |  | Choose an item. |

**A5. Research project type** (please select one category from the list below):

|  |  |
| --- | --- |
|  | Clinical trial of an investigational medicinal product (CTIMP)**\*** |
|  | 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 |
|  | 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 |
|  | Other study (please specify) Click here to enter text. |
| \* Please contact [Research.Governance@gosh.nhs.uk](mailto:Research.Governance@gosh.nhs.uk) for advice as Sponsorship Committee is responsible for reviewing CTIMP studies and studies investigating Medical Devices (or both). | |

**A6. Project details**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Proposed start date: | | Proposed end date: | | Duration: |
| Will you recruit: | | GOSH patients  Non-GOSH NHS Trust 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 Directorate(s) will be responsible for these participants? | | | | |
| **Brain**  **Heart & Lung**  **Operations & Images** **Sight & Sound**  **Body, Bones & Mind**  **Blood, Cells & Cancer**  **International & Private Patients**  **Medicines, Therapies & Tests**  Additional directorates (if applicable): | | | | |
| Will you use: | New tissue  Tissue bank only. Please provide REC and R&D numbers:  Tissue from a previous study. Please provide REC and R&D numbers: | | | |
| Where will the research take place? (tick all that apply)  ICH GOSH NIHR GOSH Clinical Research Facility (please contact CRF via [crf.registration@gosh.nhs.uk](mailto:crf.registration@gosh.nhs.uk))  Other, please give details | | | | |
| Do you intend to request and analyse non-identifiable clinical data through the GOSH DRE (Digital Research Environment)? Choose an item.  If yes, please contact the team *via* [DREProjects@gosh.nhs.uk](mailto:DREProjects@gosh.nhs.uk) | | | | |
| Does this project include research on Rare Diseases? (According to the EU definition of affecting 5 in 10,000 of the general population, or fewer). Choose an item. | | | | |
| Is this project an extension of the existing study? Choose an item.  If yes, please give details. | | | | |

**A7.Regulatory approval**

Please give details of the regulatory approval status of you study:

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): Choose an item.

If ‘Other’ please specify:

**A9. Additional Information**

## Section B: Recruitment, feasibility & study groups

|  |  |  |
| --- | --- | --- |
| **Sample size/study groups** | | |
| **B1.** What is the sample size for the research? (How many participants/samples/data records do you plan to study?) | |  |
| **B2.** Please list all of you study groups and the number in each group.  *e.g. Children with leukaemia (n=20)*  *Age-matched controls (n=20)* | |  |
| **B3.** How many of these participants will be recruited at GOSH? | |  |
| **B4.** How was the sample size decided upon? (Provide enough detail to reproduce the power calculation or justification of sample size for qualitative study). | |  |
| **B5.** What is the age range of participants to be studied? | |  |
| **B6.** Please list the principal inclusion criteria *(Q A17-1)* | |  |
| **B7.** Please list the principal exclusion criteria *(Q A17-2)* | |  |
| **Feasibility** | | |
| **B8.** How many participants, 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? |  | |
| **Recruitment and informed consent** | | |
| **B9**. How will potential participants, records or samples be identified? (e.g. disease register, GP records, medical records?) Who will carry this out and what resources will be used? (*Q A27-1*) |  | |
| **B10.** Howwill potential participants be recruited?(e.g. by letter, telephone, in clinic?) |  | |
| **B11.** Who will recruit the participants and seek consent/assent? Are they qualified to do so and have they received appropriate training (GCP etc.)? |  | |
| **B12.** How will you inform the participants’ direct clinical care team of their involvement in your research study? |  | |
| **B13.** If you are recruiting participants during clinics, do you have permission ofthe **clinical lead?** |  | |

## Section C: Research Plan.

|  |
| --- |
| **C1.** Research question(s) and objectives(primary and secondary, if applicable) |
|  |
| **C2.** Scientific justification for the research  ***Max 300 words.*** *Please provide details on motivation to do the proposed research, address novelty and knowledge gaps the research intends to fill and what new knowledge and impact will the work create.* |
| Word count: |
| **C3.** Study design and methodology  ***Max 600 words.*** *Please provide details of your research methods (Q A13). What will happen to the participants and when, how often, for how long and in what order. This should be understandable to a general scientific/medical audience.* |
| Word count: |
| **C4.** What is the primary outcome measure for the study? (Q A57)  *Should normally be one outcome measure. Describe how will primary objective be met (e.g. blood pressure at the final visit). For qualitative studies, please detail primary aims of the research.* |
|  |
| **C5.** What are the secondary outcome measures? (Q A58)  *Should normally be one outcome measure. For qualitative studies, please detail secondary aims of the research.* |
|  |
| **C6.** Methods of analysis  *Please describe the methods of analysis (****detail*** *statistical or other appropriate methods, e.g. for qualitative research) 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. For qualitative studies, outline in simple terms exactly how the data from the study will be managed and analysed. For example, will it be arranged into themes?* |
|  |
| **C7.** What are the criteria for electively stopping the research prematurely? (Q A75-2) |
|  |
| **C8.** What is the potential for benefit to research participants? (Q A24) |
|  |
| **C9.** 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, and any additional services made available to participants if necessary.* |
|  |
| **C10.** In which aspects of the research process have you actively involved, or will you involve patients and/or their parents/carers, or members of the public? *(Q A14-1)*  *Give details of involvement, or if none please justify the absence of involvement.* |
|  |
| **C11.** How and where will you report/disseminate the results of the study?  *Including professionals, patients, parents/carers, etc.* |
|  |
| **C12.** Will there be a potential overlap of the proposed work with other studies. |
|  |
| **C13. Intellectual Property** |
| **C13.1** Could the research lead to the development of a new product/process or the generation of intellectual property and if so are you interested in pursuing any potential developments? If so, please provide details. *(Q A78)*  *If you are unsure and would like advice on IP, please contact the R&D Office. Conversations regarding IP development can take place following CRAC approval.* |
|  |
| **C13.2** Do you intend to use material that is, or could be, subject to third party IP or licensing? |
|  |
| **C14. Future funding**. If this project is successful, will you seek external grant funding for a larger study or further work? Choose an item. |

## Section D: Finances and Resources. *Please detail all Trust Resources which will be required for this study. This is to allow the Trust to monitor research activity*.

|  |  |
| --- | --- |
| **D1.** How will the costs associated with this research project be funded? (Possible sources of funding include Special Purpose Funds, Divisional Accounts, and studentship funds). *If your project is funded by more than one funder state the relative contribution from each funder.* | |
| If funds are at **GOSH**, please give details of the:  NHS Budget holder:  Cost Centre: | If the funds are at **ICH**, please give details of the:  ICH Budget holder:  Grant Code: |

|  |
| --- |
| **D2.** If your project involves equipment including that loaned from an external source, please state who will provide any necessary consumables and provide safety testing/maintenance/cleaning/storage. |

**D3.** Staff time (not to be paid directly from the project)

*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.*

|  |  |  |
| --- | --- | --- |
| **Full name, position, division** | **Hours/week** | **When will the work be done? (e.g. own time, permission to do so in contracted hours)** |
|  |  |  |
|  |  |  |
|  |  |  |
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|  |  |  |

**D4.** Permission from relevant manager(s) must be obtained for substantive NHS staff without protected research time undertaking research during their contracted work time. Please state who granted the permission for staff to participate.

**D5.** 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.* ***Copies of the approved costs from GOSH/ICH should be supplied with the application.***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name, FTE %** | **Employer** | **Year 1 (£)** | **Year 2 (£)** | **Year 3 (£)** | **Year 4 (£)** | **Year 5 (£)** | **Total** |
|  | Choose an item. |  |  |  |  |  |  |
|  | Choose an item. |  |  |  |  |  |  |
|  | Choose an item. |  |  |  |  |  |  |
|  | Choose an item. |  |  |  |  |  |  |
| Other costs (please list) | | | | | | |  |
| Total | | | | | | |  |

**D6.** Support department 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. Please include confirmation (e.g. email trail) from each of the services included providing acknowledgement and approval of the costs.*

|  |  |  |
| --- | --- | --- |
| **Service** | **Item** | **Cost (£)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**D7.** Justification of Resources

**D8.** Permission from Head of Service/Head of Department if unfunded

Please include details (Name, email) of the HoS/HoD

## Section E: Declarations

Please read and complete the following section. The R&D Office will obtain the necessary approvals on your behalf. 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.

**I read and agree with the above terms**

**Date and name**

**Once you have completed this application form please email it to** [**CRAC.Admin@gosh.nhs.uk**](mailto:CRAC.Admin@gosh.nhs.uk) **along with other required documents.**