**Clinical Research Adoptions Committee (CRAC) Application Form and Cover Letter**

CRAC requires all applicants to complete the CRAC application form and cover letter.

The cover letter will be used as a summary of your project, and will be sent to the parent representatives who work with the committee as an aide for them to clearly understand your project and its implications.

The letter should be a maximum of 2 sides of A4 and include:

* A brief practical overview of the project: the background, and what you intend to achieve.
* Project details: Project aims and outcomes. What will you do, and to whom?
* Impact of the work, and the benefits for GOSH patients / parents / staff
* Any risks or potentially negative effects for participants

The letter should be written in clearly understandable English without using jargon or acronyms.

**EXAMPLE:**

**Overview:** We would like to conduct a ….. study on …

**Rationale:** This is important because …

**Patient cohort:** We will specifically recruit from …

**Aims:** The primary aim of the study is to …

**Project involves:** each participantwill undergo… in addition to their routine clinical care

**Outcomes:** We will measure … on each patient; the main outcome will be the number of patients who demonstrate an increase in … over the study time period

**Impact:** If successful, this will mean that …

**Benefits:** By demonstrating that this works in this particular group, this will mean …

**Risks:** There is a risk that taking part in the study will … Please complete your letter on the next page.

The CRAC application form also requires a lay summary of the research. This summary could be more technical, and the same as will be used for your IRAS submission.

**Clinical Research Adoptions Committee (CRAC) Application Cover Letter.**

**Overview:**

**Rationale:**

**Patient cohort:**

**Aims:**

**Project involves:**

**Outcomes:**

**Impact:**

**Benefits:**

**Risks:**

**Clinical Research Adoptions Committee (CRAC) application form**

This application form is for Clinical Studies which are being conducted at GOSH that do not have any funding (own account), or where funds are not coming to the organisation. These will be considered by the Clinical Research Adoption Committee (CRAC).

Please fill in this application form and submit it to the Joint Research and Development Office by emailing CRAC.Admin@gosh.nhs.uk

Further details and submission deadlines con be found on the [GOSH website](http://www.gosh.nhs.uk/research-and-innovation/researchers/rd-office/crac/).

**PLEASE NOTE: We strongly recommend that you submit your CRAC application before applying for Health Research Authority (HTA)/ethical approval. To avoid duplication and to assist with completing IRAS forms, a number of the following questions are the same as contained in the Ethics IRAS Application Form and have the corresponding number in brackets for ease of reference and copying of text.**

**ALL QUESTIONS MUST BE ANSWERED.**

**Before you complete this application form you must ascertain ‘Is your Project Research?’**  <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/access-study-support-advice-services/>

Other activities such as clinical audit, local developments of existing research, the introduction of clinical innovations, service evaluations, patient and staff surveys and quality assurance programmes may not qualify as research even though they may use similar methods. CRAC does not need to consider service evaluations or clinical audits. These should instead be registered with the clinical audit team; please contact clinical.audit@gosh.nhs.uk.

**Section A: Registration  *R&D number*** *(if already registered)****:***

**A1.** Full title of proposed 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 & 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  | Portfolio B  |

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

Awarding Institution:

|  |
| --- |
| **A4.** Co-applicants (please list all): |
| **Title** | **Forename** | **Surname** | **Substantive employer** | **GOSH Clinical Division** | **ICH Academic Section** | **Position Held** | **Full/Honorary GOSH Contract** |
|       |       |       |       |  |  |       |  |
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| **A5.** Select a category from the list below *(Q A2)* |
| [ ]  | 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 |
| [ ]  | 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 |
| **A6.** **Project details**  |
| Proposed start date:       | Proposed end date:       | Duration:       |
| Will you recruit: | [ ]  GOSH patients[ ]  Non-GOSH 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 handle these participants?  |
|  (If GOSH employee) Clinical Division West: | Portfolio A  | Portfolio B  |
|  (If GOSH employee) Clinical Division Barrie: | Portfolio A  | Portfolio B  |
| Will you use:  | [ ]  New tissue[ ]  Tissue bank only Please provide the REC or R&D number:      [ ]  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       |
| **A7.** **Research Ethics** |
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| All Research involving NHS patients or services will require Health Research Authority (HRA) and NHS Research Ethics Committee approval. Guidance on the HRA submission process can be found here: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/. Projects involving non-NHS participants should be reviewed by a non-NHS REC (for example the 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. |
|  |

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| 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 the participants and seek consent/assent? |       |
| **B5.** If you are recruiting participants during clinics, do you have permission of the **clinical lead**?  |       |
| **Sample size/study groups** |  |
| **B6.** What is the sample size for the research? (How many participants/samples/data records do you plan to study in total?) *(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 participants will be recruited at GOSH? |       |
| **B9.** Please justify your sample size and provide a power calculation/justification |       |
| **B10.** How will you inform the participants 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 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? |       |

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| **Section C: Research Plan** |
| **C1. Lay Summary.** *Please complete this section in language comprehensible to the lay person.*Please include: Background to the disease(s) or condition to which your research relates, the aims and objectives of your project, the likely impact this research will have, and how will this research make a difference to patients at GOSH and beyond. For advice on how to write a lay summary please see the [Involve website](http://www.invo.org.uk/makeitclear/support-and-resources/). |
|        |
| **C2. Study design.** *Please summarise your design methods. (Q A13) It should be clear exactly what will happen to the research participant, how many times and in what order. (max 600 words).* |
|       |
| Word Count:      |
| **C3.** What is the primary outcome measure for the study? *(Q A57)* For qualitative studies, where no measurements will be taken, please detail the primary aims of the research. |
|       |
| **C4.** What are the secondary outcome measures? *(Q A58)* For qualitative studies, where no measurements will be taken, please detail the secondary aims of the research. |
|       |
| **C5.** What are the criteria for electively stopping the research prematurely? *(Q A75-2)*  |
|       |
| **C6.** What is the potential for benefit to research participants? *(Q A24)*  |
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| **C7.** 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.* |
|       |
| **C8. In which aspects of the research process have you actively involved, or will you involve, patients, service users,****and/or their carers, or members of the public? (Q A14-1)** *Give details of involvement, or if none please justify the absence of involvement.* |
|       |
| **C9.** Data analysis. **DO NOT LEAVE BLANK**Please describe the methods of analysis (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.  |
|       |
| **C10.** Will there be a potential overlap of the proposed work with other studies.  |
|       |
| **C11.** How do you intend to report and disseminate the results of the study, including to patients, parents/carers, professionals etc. (A51) (max 150 words) |
|       |
| **C12. Intellectual property.** *If you are unsure and would like advice on IP, please contact the R&D Office. Conversations regarding IP can take place following CRAC approval.* |
| 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? (*Q A78)* If yes, please give further details:      |

**Section D: Finances.**

**D1.** *If you are conducting an ‘own-account’ project, please complete this section. Please detail all Trust Resources which will be required for this study. This is to allow monitoring of research activity within the Trust.*

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| **D2.** How will the costs associated with this research project be funded? *(Possible sources of funding include Special Purpose Funds, Divisional Accounts, 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:       |

**D3. 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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**D4. 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 |       |

**D5. 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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| **D6.** Justification of Resources (max 150 words) |
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**Section E: Declarations**

Please 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.

**Once you have completed this application form please email it to** **CRAC.Admin@gosh.nhs.uk****, with a copy of your research protocol.**

**Peer Review**

In some circumstances peer review will be necessary. 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

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