CRAC Application form guidance

Please read this document carefully before completing the CRAC application form.

1. Is your project Research?

Before you complete this application form you must ascertain 'Is your Project Research?' using the following tool: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/access-study-support-advice-services/

Decision table:
http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf

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.

CTIMP studies and studies investigating medical devices are considered by the Sponsorship committee and are therefore outside the scope of CRAC. Please contact Governance team for advice on research.governance@gosh.nhs.uk

2. 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. Please make sure that the language used is accessible for general audience.

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

- A brief overview of the project: background, need and importance of the study, 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 …

Timescale: Duration of research and duration of involvement for participants

Rationale: This is important because …

Patient cohort: We will specifically recruit from …

Aims: The primary aim of the study is to …

Project involves: each participant will 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 …

3. CRAC Application form

This application form is for "own account" clinical research studies conducted at GOSH (i.e. projects that did not attract external funding or funded by an external body where an adequate peer review of the project proposal has not taken place). Please note, **GOSH NHS Trust will not indemnify or act as sponsor for own account research that has not been peer reviewed**.

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

Further details and submission deadlines can be found on the GOSH website.

PLEASE NOTE: We strongly recommend that you submit your CRAC application before applying for Health Research Authority (HRA)/ethical approval. To avoid duplication and to assist with completing IRAS forms, a number of 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.

Completing the application form

Section A

A2: Principal Investigator

The PI will take responsibility for the study and its conduct until completion. The PI must be a member of GOSH staff or honorary staff. If the application is for a Student project the student's supervisor should be PI. If the study is being conducted by a group who are not based at GOSH a local PI must be identified.

A5: Research project type

If you are unsure which study type to choose please visit the HRA Website for further information.

Please note, CTIMP studies and studies investigating medical devices are outside the scope of CRAC committee and are reviewed by the Sponsorship panel. Please contact Research.Governance@gosh.nhs.uk for further details.

A7: Regulatory approval

You need to apply for HRA and HCRW Approval if your project meets all of the following criteria:

- The lead NHS R&D Office is in England or Wales
- It is a project-based study type, except "research tissue banks" and "research databases".
- NHS premises and/or NHS patients and/or NHS staff in England and/or Wales are participating in the project

All Research involving NHS patients or services will require Health Research Authority (HRA) approval. This will include NRES and MHRA as appropriate. 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.

We strongly advise applicants to complete the CRAC process before beginning an Ethics application. Once CRAC approval has been granted the Research Management and Governance team can support you with your Ethics application.

To find out if your study requires Ethics use the HRA decision tool.

A8: Sponsorship

- GOSH based clinical projects: GOSH will act as Sponsor as long as the PI is a substantive member of GOSH staff or has a GOSH clinical honorary contract.
- Student projects: The Institution awarding the academic qualification will act as Sponsor.

If you are based at GOSH but the work is taking place elsewhere and you would like GOSH to act as the Sponsor you must contact Research.Governance@gosh.nhs.uk to discuss GOSH Sponsorship of your study.

Section C: Research Plan

Please make sure that you make it clear where in your study planned activities are part of the proposed research study and where these are part of standard clinical care.

Section D: Finances

The purpose of this section is to give the Chief of Service and Finance an idea of the impact of the research project on Divisional Resources. Many costs may be negligible as staff participating in research projects will be doing so during their own time, protected research time or samples will be taken as part of normal clinical care with excess material being used for research.

Each application will be scrutinised for cost implications, it is the applicant's responsibility to detail any costs and resources directly attributable to research (equipment, staff etc.) that are to be used in the project.

The use of Departmental funds, or Special Purpose funds must be detailed in Section D, the applicant is responsible for obtaining the budget holders permission for the use of any funds.

Peer Review

In many 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

If you require assistance completing the form, or have any questions regarding the CRAC process please contact CRAC.Admin@gosh.nhs.uk in the first instance.

4. CRAC Frequently Asked Questions/Common Errors

Is your Project Research?

Before you complete the CRAC application form you must ascertain that your project is classified as Research. The HRA decision tool can help you http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/. If you are still unsure, please send a brief outline of your study to CRAC.Admin@gosh.nhs.uk and we can advise you.

Common errors to avoid delay in CRAC approval

Poorly written applications: Applications which lack detail often require resubmission.

Please make sure to include as much relevant detail as possible for the reviewer to understand what the study involves, e.g. specific activities, any procedures that patients will undergo as part of this research and make it clear where this is part of research study.

Inconsistencies: Variations in information, this can be inconsistencies throughout the application or differences between information in the study protocol and application form i.e. numbers per group, cohort age groups etc.

Statistics: No power calculation or justification for patient numbers, no statistical analysis plan (a list of statistical tests is not sufficient), inappropriate statistical methods. Please note a statistician sits on the Committee and will review your statistical plan.

Supporting documents not provided:

- **Questionnaire:** If a questionnaire is being used the applicant must supply the questionnaire for CRAC review.
- **Study Protocol:** Please provide a study protocol (please do not copy/paste Cover Letter and make it into a protocol). Guidance on protocol formats can be found on e.g.
    - HRA website: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/
- **Consent/Assent and Patient information sheets:** Provide a draft as part of your application to make sure that sufficient information is given to the patient about the study and get feedback from e.g. lay members about how accessible information is.