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.

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.

Common errors which delay CRAC approval

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

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.

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:** It is strongly advisable to supply a study protocol.
- **Consent/Assent and Patient information sheets:** Not completely necessary to secure CRAC approval.

Completing the application form

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: Study type

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

The NIHR are keen to improve access to research for all patients and accelerate initiation and delivery of studies within Trusts. We are asked to report progress on recruitment to all clinical studies involving GOSH patients on a quarterly basis to the NIHR and you may be contacted for such information. Additionally, **if your study is a clinical trial of a medicinal product, a medical device or a study of novel intervention or randomised clinical trial to compare interventions in clinical practice**, we are required to report whether we have met a 70 day benchmark from the date of the research application received (usually the date of SSI submission) to the date the first patient has been successfully recruited to the trial. We are required to provide reasons for any delays and it is important the PI keeps in contact with the R&D office throughout study set up and post-approval. Your recruitment target and progress against it is required to be entered on the EDGE database. Please contact James Calvert (James.calvert@gosh.nhs.uk) for more details.

A7: Research Ethics

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 D: Finances

The purpose of this section is to give the Divisional Director 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. 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.