

DIVISION OF RESEARCH AND INNOVATION

Joint Research and Development Office

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Revision History			
Previous version	Comments	Reviewed by	Date archived
GOSH/ICH/SOP/R&D/018	Updated finance section describing how honoraria are paid.	Valerija Karaluka	01/03/2020

1. Scope

The Clinical Research Adoptions Committee (CRAC) is an internal peer review committee that reviews and ratifies clinical research taking place at Great Ormond Street Hospital (GOSH) where the research is either supported through internal departmental resources or funded by an external body where an adequate peer-review of the project has not taken place. This may include some GOSH Children's Charity (GOSH CC) funded projects,

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industry sponsored studies, or studies funded internally (e.g. GOSH-NIHR-BRC). CRAC ratification does not equate to R&D approval / permission, nor Ethical approval / permission.

2. Purpose

This Operating Procedure describes the processes by which clinical research applications are registered with the R&D office, reviewed and approved by the CRAC.

3. Definitions/Abbreviations

Not applicable

4. Responsibilities

Duties may be delegated but the responsibility always remains with those listed.

The overall responsibility for the CRAC is with the GOSH Chief Executive Officer delegated to the Director of Clinical R&D and the Chair of CRAC. Operational management of the committee is delegated to the Committee Secretary, overseen by the Pre-Awards team in the Joint R&D Office.

The personnel responsible for the major tasks associated with the Written Procedure and their responsibilities:

4.1 CRAC Chair is responsible for:

- Overall business of the Committee and all decisions made by the Committee.

4.2 Research Grants Facilitator is responsible for:

- Duties outlined for Committee Secretary and relevant delegation of these duties to R&D Office manager and administrator. Overseeing the activities of the Administrator and ensuring the relevant procedures herein are followed.

4.3 CRAC Administrator is responsible for:

- Implementing the tasks herein which fall within the remit of the post.

5. Procedure

5.1 The CRAC Meetings

a. Meeting Schedules

The CRAC meet every month except August (11 per year) for general meetings, with additional exceptional meetings as required.

Meeting schedules will be agreed towards the end of each calendar year with the Committee's Chair and arranged by the CRAC Secretary. Meeting schedules will be published on the CRAC page of the GOSH R&I website by the CRAC Secretary, including the closing date for applications for each meeting.

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b. Agenda

The CRAC Secretary will prepare the agenda for meetings. Agendas should include the following:

- The date, time and venue of the meeting
- Minutes of the previous Committee meeting
- Matters arising from the minutes not otherwise covered by the agenda
- Applications for review by the committee stating the CRAC member who will lead discussion. Applications will be divided into Clinical Own Account applications and applications made to GOSH Children's Charity.
- Any other business
- Date, time and venue of next meeting

The CRAC Secretary should keep electronic versions of meeting agendas. A spreadsheet of all CRAC applications and information relevant to the application e.g. R&D number, meeting date, CRAC decision will be maintained by the CRAC secretary electronically.

c. Lead Reviewers

CRAC Secretary is responsible for appointing lead reviewers in consultation with the Chair of the Committee.

d. Attendance of meetings

Principal investigators are invited to attend the CRAC meeting to discuss their proposal. The CRAC Secretary will inform the PIs regarding a time to attend. In the case of student projects both the student and supervisor will be invited to attend the meeting.

e. Papers for meetings

The CRAC Secretary will compile the papers for meetings by merging all documentation into one PDF file. The PDF will be appropriately bookmarked and paginated for easy navigation.

For applications for review, documentation should be placed in the following order:

- Any letters/emails relating to CRAC review
- CRAC Application Form
- Grant Application Form (if applicable)
- Study Protocol (if applicable)
- Peer Review Forms/Evaluation Forms (if applicable)
- Any other relevant documentation

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f. Distribution of papers for meetings

The CRAC Secretary will distribute the agenda and papers no later than two weeks prior to the scheduled meeting date.

g. Quorum requirements and meeting attendance

The minimum number of committee members, including the Chair, who must be present in order for a CRAC meeting to proceed is five.

The CRAC Secretary will distribute a signature sheet during each meeting to serve as a record of attendance. Following the meeting the signature sheet is scanned and uploaded to I:\R and D\Shared Folders\CRAC into the folder of the appropriate year. The template for attendance records can be found on QPulse.

The CRAC Secretary will maintain yearly spreadsheets of attendance. This should be saved into the appropriate year folder in QPulse.

h. Student Projects/ Short term projects

Typically student projects require no Trust resources, and last less than 6 months in duration. Additionally, some pilot studies submitted to CRAC last < 6 months and have no impact on Trust resources. These projects, where judged appropriate by the Chair, will be processed by an expedited route. The application with accompanying material (study protocol, questionnaires, information sheets, consent forms) will be sent to two members of the CRAC committee for review or, in the case of qualitative studies will be sent to at least 2 members of a panel with expertise in qualitative methods. Reviewers will feed back to the Chair outside of committee meetings. A project deemed satisfactory will then be approved by Chair's Action. The PI/Student will receive feedback. A project deemed unsatisfactory will receive feedback from the reviewing panel and asked to resubmit. If appropriate, resubmissions will be reviewed at a CRAC meeting. Only projects that the qualitative panel cannot adequately review will be sent to external reviewers. The qualitative panel volunteers will receive correspondence confirming the scope of the task and laying out likely numbers of projects per year.

i. Honoraria

Full Members of the CRAC are entitled to receive an honorarium payment of £1000, provided that they attend all scheduled meetings in a calendar year. If a member attends fewer than the total number, the member will receive a payment pro-rata to the number of meetings attended. For those sharing a post, the honorarium will be divided between the two individuals; again payment will be pro-rata to the number of meetings attended.

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After the last meeting in the calendar year the CRAC Secretary will calculate for each member the number of meetings they have attended and the honorarium payable. CRAC Secretary will discuss appropriate methods of payment with GISH R&D Finance team.

Associate members of CRAC (Lay members, R&D staff, Finance staff, co-opted attendees etc.) will not be eligible for the honorarium payments, although Lay Members will be able to claim for appropriate expenses for meeting attendance.

j. Membership

For details of CRAC membership refer to the CRAC Terms of Reference on QPulse.

The CRAC Secretary is responsible for publishing and maintaining up to date details of CRAC membership on the CRAC page of the GOSH R&I website.

k. Co-opted members

The CRAC may co-opt members at any meeting for the purposes of that meeting.

l. Declarations of Interest

Members are expected to comply with the current GOSH Declarations of Interest, Gifts and Hospitality Policy, and to have made any required disclosures and declarations under that policy. Members will declare to the Committee any conflicts of interest they have in relation to an application. Declarations may be made orally at the meeting, or in writing in advance of the meeting when invited to review an application in which they have a conflict, or upon receipt of meeting papers. In the case of a declared interest, the Committee will collectively consider whether or not it is appropriate for the member concerned to take any part in the review process.

The Committee has the following options:

1. The member should leave the meeting room and take no part in the discussion or the scoring of the application (if applicable).
2. The member may remain in the meeting room in order to provide any relevant information requested by other members but may not comment or score the application (if applicable).
3. The member may remain in the meeting room and take a full part in the review and scoring (if applicable).

If members leave the meeting room for any items due to a conflict of interest, this should be recorded in the minutes by the CRAC Secretary.

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m. Responsibilities of the CRAC Secretary

Overall responsibility lies with Research Grants Facilitator, but certain duties may be delegated to the R&D Office Manager/Administrator.

- (i) Publishing the schedule, submission requirements and deadlines for documents to be considered at CRAC meetings
- (ii) Updating the internet pages for the CRAC
- (iii) Requesting peer reviews on behalf of the Chair of the Committee
- (iv) Preparing the agenda, collating and preparing the meeting papers, and ensuring they are appropriately bookmarked.
- (v) Inviting Principal Investigators to attend the meeting
- (vi) Distributing the agenda and papers to members
- (vii) Inviting members to sit on the Committee or attend meetings as co-opted members.
- (viii) Preparing the venue (room bookings, refreshments, technical equipment)
- (ix) Recording apologies for absence prior to the meeting
- (x) Recording attendance of members at meetings
- (xi) Advising the meeting as necessary on compliance with standard operating procedures
- (xii) Making written records of the meeting
- (xiii) Preparing the minutes of the meeting for review and approval at the following meeting
- (xiv) Notifying applicants of decisions taken at the meeting and taking other follow-up action as necessary.

n. Minutes

The minutes of the meeting will be prepared by the CRAC Secretary. It is not mandatory for the minutes to be approved formally by the Chair before letters are issued to applicants giving the Committee's decision, though it is good practice for the Secretary to check the drafting of technical or sensitive issues with the Chair and/or any other relevant members if in doubt.

In relation to applications for review, the minutes will contain the following:

- (i) Any members who were not present in the room either through early absence or due to a declared conflict of interest.
- (ii) A summary of the main concerns or comments from the Committee.

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(iii) The decision of the Committee regarding approval

(iv) The score given (if applicable)

The minutes should be presented as the outcome of collective discussion, and not attribute particular statements to individual members.

The minutes should be submitted to the following CRAC meeting for ratification as a true record. Any necessary revisions should be incorporated in the final version of the minutes. The final version should be signed and dated by the Chair. The signed minutes should be filed by the CRAC Secretary in the relevant file and electronic copies kept.

5.2 Applications for review by the CRAC

a. Submission guidelines

An electronic application form and study protocol (and any other relevant documentation) must be submitted to the CRAC Secretary by emailing CRAC.admin@gosh.nhs.uk in order to be considered by the Committee.

The CRAC secretary will forward the application(s) to appropriate staff in the R&D Pre Awards team for registration and generation of an R&D reference number, according to the current guidelines as set out by the Senior Research Project Manager. After registration, applications will undergo preliminary triage for completeness by the Research Grants Facilitator. If sections of the form about statistics, sponsor and NHS resources are incomplete, the form will be returned to the applicant for completion.

Once registered, applications will be sent by the CRAC secretary for approval to the GOSH Divisional Director, ICH Head of section (if relevant) and the relevant Finance offices.

All documents associated with an application including approval emails should be uploaded onto ReDa into the relevant folder.

If a project has been peer reviewed evidence of the peer review should be provided. If this is not the case the appropriateness of the peer reviewers cited in the application will be scrutinised by the Chair and the application will be sent for peer review.

Projects from external students require at least one peer review from the student's educational institution.

b. Before meetings

CRAC Secretary will follow process outlined in section 5.1 to prepare paper packs with applications for CRAC review. Agenda and papers will be sent out to

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the committee at least 2 weeks before the meeting. Full details can be found in CRAC Terms of Reference on QPulse.

c. At meetings

CRAC applications should be presented by the lead reviewer and assessed by the whole Committee. After the lead reviewer has presented the project the Principal Investigator will be invited to join the meeting. For student projects both the student and supervisors are able to attend.

d. After meetings

The CRAC Secretary is responsible for providing feedback to applicants within two weeks of the meeting.

The CRAC Secretary will draft a letter using the appropriate templates filed in QPulse. Letters will include anonymised peer reviews and committee feedback composed by the Chair of the Committee.

All letters, responses and resubmissions will be approved by the Chair prior to sending to the applicant, and will be uploaded onto the ReDa database into the appropriate folder.

e. Approval

Once an application has CRAC approval the following fields must be updated in Reda:

- CRAC Approval Date – insert date
- Status – change to Governance Review
- Events – Select: File passed to Governance

An email must be sent to Research.Governance@gosh.nhs.uk listing all the studies that have CRAC approval (R&D number, study title & PI name).

f. Conditional Approval

Where an application has gained conditional approval, the CRAC Secretary will write to the PI stating the conditions which must be met for approval, this may include information from the committee or anonymised peer reviewers that the Chair considers useful to the applicant. R&D Research Governance will be included in communication to ensure that conditions outlined are met before obtaining R&D approvals for the study.

5.3 Applications for Internal GOSH Children’s Charity Funding

a. Use of Special Purpose funds

Research to be funded via the GOSHCC departmentally held or discretionary funds (i.e. Special Purpose Funds) will be reviewed by CRAC up to £100,000.

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The nature of CRAC engagement will depend on the nature of the funding request.

CRAC will not review requests for Special Purpose Funds costing over £100,000. In such cases, the administration will be undertaken by GOSHCC. There will be a requirement for any such projects to be registered with R&I via the R&D registration form.

b. Existing Projects registered with R&I

Where a PI seeks to use Special Purpose Funds for an existing project where there will be no new work over and above the existing project specification / protocol that has already had all necessary approvals (HRA, R&D approval, ethical approval etc.) AND the cost is less than £25,000, such requests may be approved by Chairs action (e.g. employment of a temporary fellow to work on a project, doing work towards existing approved project objectives). The PI should provide a document outlining the proposed work, and attach the application for the existing project, the approvals, and any existing peer reviews. The CRAC Secretary will send all details to R&D for registration and review by Governance.

Applications for use of Special Purpose Funds for existing projects costing £25,000 - £100,000, a CRAC form will be completed and committee scrutiny required. The CRAC secretary will process such applications as per all other CRAC applications.

Where a PI seeks to use Special Purpose Funds for **new** work on an **existing** project, a CRAC form will be completed regardless of the cost of the work. The proposal will be reviewed, and undergo full committee scrutiny. The CRAC secretary will process such applications as per all other CRAC applications.

c. New Projects

For new projects where the cost is <£100,000 from discretionary funds, a CRAC form will be completed by the PI. The CRAC secretary will process the application as per all other CRAC applications and external review and full committee scrutiny is required.

5.4 GOSHCC Commissioned Research

If the project costs <£100,000, a CRAC form will be completed by the PI. The CRAC secretary will process the application as per all other CRAC applications and the proposal will undergo external review (as appropriate) and full committee scrutiny. The submission should include supporting information such as any existing peer review, information sheets, consent forms or questionnaires. CRAC will not review commissioned projects costing over £100,000, where the administration will be undertaken by GOSHCC. There will be a requirement for any such projects to be registered with R&I via the generic R&D registration form.

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6. Related Documents

- CRAC Committee: Terms of Reference
- CRAC template for attendance records
- CRAC Letter templates
- CRAC Application Form.

7. References

Not Applicable

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