

**Guidelines for Preparing an
Application to the
Clinical Trials Advisory and Awards
Committee**

Guidelines for Application

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GA1 INTRODUCTION

GA1.1 Cancer Research UK's vision is to conquer cancer through world-class research. Cancer Research UK (CR-UK) will work alone and in partnership with others to achieve the following research objectives:

- i) **To carry out world-class research into the biology and causes of cancer**
Cancer is a highly complex disease that is still only partly understood. Only through a better understanding of the disease will the improved treatments, diagnostics and prevention strategies of the future be developed.
- ii) **To develop effective treatments and improve the quality of life for cancer patients**
Research will be carried out to accelerate cancer cure rates, aiming to translate our understanding of the disease into effective treatments. Research will also be directed at improving diagnosis of cancer, and at prolonging the life and improving the quality of life of those patients whose disease cannot be cured.
- iii) **To reduce the number of people getting cancer**
Research will be carried out into the influence of lifestyle, individual risk, environment and interventions such as vaccination on cancer, and into how people can change their behaviours to reduce their risk of the disease.

CR-UK only considers research proposals that are cancer-related and that contain a definite research aspect.

GA1.2 The types of awards available from CR-UK are listed on our website (<http://science.cancerresearchuk.org/gapp/>). Please note that CR-UK **does not** provide support for applications that fall into the following categories:

- i) *Capital grants for Buildings.* CR-UK will not accept applications for building work, other than from the director of a designated CR-UK Research Group, Department, Unit or Centre or from a CR-UK-supported Research Institute.
- ii) *Travel.* Support for travel to scientific meetings is available only for CR-UK grant holders or staff employed by CR-UK.
- iii) *Undergraduate studies.* Although undergraduate courses are not supported, a small number of Vacation Studentships are available through the Core Skills and Training Bursaries Fund. These are only available to CR-UK Programme, Fellowship or Institute funded group leaders. Direct applications from students are not accepted.
- iv) *MSc course fees.* Support is available for a limited number of MSc course bursaries in cancer relevant or transdisciplinary areas. This funding can only be obtained through the Core Skills and Training Bursaries Fund and there are restrictions on eligibility. Please see the CR-UK website for further information.
- v) *Electives for medical students* are only available on an annual basis in response to a call. Up to 2 applications are accepted per UK medical school and applications will not be accepted directly from medical students.
- vi) *Retrospective funding* of work already completed or for support while writing up work.

- GA1.3** These Guidelines are designed to help you prepare a clinical trial project grant and to explain the procedures for processing the application. Please ensure you complete your application in conjunction with these Guidelines and with our “Terms and Conditions and Administrative Guidelines for Research Grants and Awards” (hereafter Terms and Conditions), which set out the standard Terms and Conditions and Administrative Guidelines applicable to all research grants funded by CR-UK. Please note that all applicants must also comply with Cancer Research UK’s Funding Policies.

GA2 INFORMATION ABOUT THE CLINICAL TRIALS ADVISORY & AWARDS COMMITTEE (CTAAC), ELIGIBILITY AND SCHEME ADMINISTRATOR

GA2 Clinical Trials Advisory & Awards Committee (CTAAC) Project Grant funding

GA2.1 Information about CTAAC Project Grant funding and approval scheme

CTAAC considers applications for funding, or approval of investigator-led, except first in man studies. Two year grants for Phase I/II/feasibility studies are available with a funding limit of £40,000 per annum. For very large Phase II trials or Phase III trials funding is available for up to 10 years at a maximum of £100,000 per annum. Applications for extensions or renewed periods of funding are also considered by CTAAC for trials already funded by CR-UK.

Trials that are already funded by the pharmaceutical industry or other sources, such as EORTC, can apply to CTAAC for endorsement, and thereby become included on the UK Clinical Research Network (UKCRN) database of clinical trials and gain access to NHS support. Applicants should submit a full application.

Potential applicants who are unsure of the suitability of their proposal for CTAAC project grant funding should contact Miss Nicola Keat in the Clinical and Translational Operations and Funding (CTOF) Directorate for assistance (nicola.keat@cancer.org.uk).

GA2.2 CTAAC Project Grant Eligibility

Applications will be accepted from applicants in UK universities, medical schools, hospitals and some research institutions. CR-UK does not limit the number of project grants that may be held concurrently. On occasion it may be appropriate for a body of research to be divided into multiple grant applications to be considered at the same time. If you are submitting multiple applications please ensure that each proposal is complete in itself and the objectives of each project are achievable independent of the other applications.

Applicants are strongly advised to liaise with a Clinical Trials Unit (CTU) in preparing their application; trials submitted by applicants that have liaised closely with a CTU have a far higher success rate than those that do not. Information about the NCRI-Accredited Clinical Trials Units and contact details for other Trials Units in the UK can be found at: UKCRN registered <http://www.ukcrc-ctu.org.uk>.

In addition, applicants are advised to contact the Chair of the relevant NCRI Clinical Studies Group for guidance in preparing their application. Further details of the Groups' activities are available from NCRI Clinical Studies Group Senior Executive, Dr Eileen Loucaides (Tel: 020 7061 8582, Email: ncricsg@cancer.org.uk) and on the web at <http://www.ncrn.org.uk/Csg/index.asp>.

Any proposal that has any support from a pharmaceutical company must include a letter or email to this effect with the application.

In addition, please note that Cancer Research UK operates a policy on post-retirement support with which all principal applicants approaching or beyond the

normal retirement date of their host institution must comply. If you have already passed this date or if you will reach it during the period of the grant for which you are applying, please read the policy (available at http://science.cancerresearchuk.org/reps/pdfs/post_retirement.pdf) and discuss your application with the scheme administrator.

Assessment Criteria

Please note for proposals that incorporate separate (although integrated) trials for sub-sets of patient populations you must submit clear and separate outline proposals for each component of the study, including trial design and statistics, in order to allow each trial to be reviewed as stand-alone proposals. NIHR funding dictates that all trials are subject to national, competitive peer review, therefore the committee must be given the opportunity to review and question (and if appropriate) reject separate components. This type of outline proposal should be submitted with a cover letter, which includes justification for integrating the various components of the study, including that of cost effectiveness.

The Committee recognises the advantages of submitting a single full proposal both in terms of cost effectiveness to the Charity, but also in negotiating the necessary legislative requirements. Therefore, if you are successful at the outline stage the Committee will provide clear guidance on which components of the trials should be incorporated within a single full proposal.

GA 2.3 Scheme Administrator

The scheme administrator for CTAAC Project grant funding is:

Miss Nicola Keat

Research Officer (Clinical Trials),
Clinical and Translational Operation and
Funding,
Cancer Research UK,
61 Lincoln's Inn Fields,
London,
WC2A 3PX

T: 020 7438 5392
F: 020 7438 5450
E: nicola.keat@cancer.org.uk

GA3 COMPLETING THE APPLICATION FORM

You should complete one of the following forms:

1. **Outline Proposal Form** – for a new, investigator-led late phase clinical trial that is requesting funding. The office will obtain international peer review from a standing panel of reviewers and the Committee will refer to this in its decision-making. The Committee will decide one of the following outcomes: (1) decline, (2) request a revised outline or (3) request a full application.
2. **Full Proposal Form** – for a trial invited following an outline application, or for a study that has funding from another source that is seeking endorsement from CTAAC, or a study that is already open internationally.
3. **Extension Form** – for a renewed period of funding for late phase trials already funded by CR UK: you must contact the office before submitting an extension form.
4. **Feasibility Study Application Form** – for a new, investigator-led phase I/II/feasibility study that is requesting funding or seeking endorsement (i.e. has funding from another source).

The following guidance relates to the completion of the **Full** Proposal Form for CTAAC. All other forms are based on the full proposal form; please use the notes given on the forms themselves. Please do not hesitate to contact Miss Nicola Keat if you have any queries.

There is a checklist on the front of each form that summarises the documentation required when submitting an application for funding; you should refer to this when starting to write your proposal and check the boxes once the application is complete.

Applications must be printed and not hand-written and should be submitted in both paper and electronic form (see guidelines section GA5.1). Please take time to read the notes below and ensure that the appropriate sections of the form and any necessary supplementary forms have been completed.

The following supplementary forms may be required:

- Microarray initiative form – form CR-UK MIF:
http://science.cancerresearchuk.org/reps/worddocs/apps_mif.doc
- Career Ambitions Form – form CR-UK CAF:
http://science.cancerresearchuk.org/reps/worddocs/apps_caf.doc
- Additional Co-investigator CV – form CR-UK CICV:
http://science.cancerresearchuk.org/reps/worddocs/apps_cicv.doc
- Additional Named Research Staff CV – form CR-UK NRSCV:
http://science.cancerresearchuk.org/reps/worddocs/apps_nrscv.doc
- Programme-Associated Clinical Research Training Fellowship Application Form – form CR-UK PACRTF:
http://science.cancerresearchuk.org/reps/worddocs/apps_pacrtf.doc

Use the link below to access the CTAAC Committee homepage, then follow the links on the right hand side of the page to download the application form templates for Full, Extension, Outline and Feasibility study applications.

<http://science.cancerresearchuk.org/gapp/clinicaltrialsfund/cta/>

Checklist and Undertakings Form

Please complete the checklist on the first page of the application form and the Undertakings (Application) form (section 10 of the application form) once all other sections of the form have been filled in. Please ensure that printed and signed copies are returned with your application to Miss Nicola Keat. Please allow sufficient time when writing your application for the undertakings section to be completed by all parties. These can be completed on separate sheets if necessary, but must be original signatures.

Publication on the internet

The checklist asks for your permission for some sections of your application to be published on the internet if the application is successful. To increase the awareness of CR-UK-funded research and to stimulate interactions between CR-UK scientists, CR-UK maintains a Directory of Research, which is published on its web site. Periodically these publishable details are submitted to the National Cancer Research Institute (NCRI) accompanied, in confidence, by outline financial data relating to the application. The NCRI provides publishable information to the web-based International Cancer Research Portfolio. It is a condition of award that the host institution and Lead Investigator (i.e. grantee) consent to the use and disclosure of this information in this way.

Please note that the application forms allow you to prevent the publication of confidential information contained in your research abstract and, if you wish, your professional contact details.

Section 1 – Application Summary

1.1 - Research Project Title and Acronym

The title should accurately reflect the content of the proposal but must not be longer than 185 letters (including spaces). Applications received with longer titles will be shortened. Please provide an acronym for ease of reference.

1.2 – Applicant Details

Along with full name and title, the Department and Host Institution at which the applicant is based are also required.

1.3 - Co-Investigators

Here a simple summary of the names of all Co-Investigators working on the trial is required. Their CVs are to be included in a subsequent section of the application.

1.4 - Collaborators

To be entered as a summary of those names entered into the table in section 4.1.

1.5 – Study Duration

The full duration of the project should be noted in months.

1.6 - Proposed start date

The proposed start date of a new grant must be the first day of any given month. Where possible Cancer Research UK will comply with requests for a specific start date for an award but adequate time must be allowed for the necessary review and award procedures to be completed. Generally the proposed start date should be within 4 to 12 months of the submission date.

1.7 – Proposed Research Cost for first years requested from CR-UK

1.8 Total research costs requested from CR-UK

Please provide details of the total contribution of funds requested from CR-UK.

1.9 – Trial Sponsor

Please provide the name of the proposed trial sponsor for the trial being submitted to CTAAC. Please complete the EUCTD box or the Research Governance framework sponsor box as appropriate. Please visit the Clinical Trials Tool Kit web site (<http://www.ct-toolkit.ac.uk/>) for an overview of the clinical trials process in the UK and for practical help when trying to meet the requirements of the UK Medicines for Human Use (Clinical Trials) regulations 2004. These regulations implement the EU Clinical Trials Directive in the UK.

1.10 - Trials Unit Contact(s)

Please enter details of the trials unit contact(s) for the trial(s) and the location at which the Trials Unit Contact(s) can be reached.

Section 2 – Research Proposal Outline

2.1 - Research Goals

If your application is successful this statement will be published on the CR-UK website and in other web-based directories of research. For this reason you should not include information that you do not wish to be made public such as commercially sensitive data.

2.2 - Research Abstract

If your application is successful then your abstract will be published on the CR-UK website and other web-based directories of research. For this reason you should avoid the unnecessary inclusion of commercially sensitive or confidential information in your abstract. However please be aware that the primary purpose of your application abstract is to aid the peer review process and that it may, for example, be used by potential reviewers to judge whether or not they should take the time to review your application. You should not therefore exclude any information that you feel would reduce the clarity of the abstract for expert

reviewers. If you have indicated that your abstract should not be published, then unless your application is highly confidential you will be required to submit a publishable abstract at a later date. Please note that unless you specify otherwise, your abstract will be deemed publishable.

Please do not exceed 10 sides of A4 in total for sections 2.3 to 2.4 (font 12 point), excluding appendices (e.g. references or summary flow diagram of trial design). For outline applications the limit is 6 pages in total for section 2.3-2.5 and for feasibility studies the limit is 10 pages for section 2.3 and 2.4.

2.3 - The Need for a Study

Please answer each question in turn to provide an overall scientific justification for your proposal. Please use the notes under each question to guide you in how to answer these questions.

2.4 – Study Design and Delivery

Please provide sufficient detail on the trial design to facilitate the review of the proposal by external expert reviewers. Please use the notes under each question to guide you.

2.5 – Sample Size and Statistical Design

Please complete in line with the guidance notes included in the application.

2.6 NCRI CSG Involvement

Please indicate the degree of Clinical Study Group involvement in design and development of the study.

2.7 Study Management

Please provide details of all those involved in conducting the trial, as requested under each question. Where appropriate please provide summary details from section 2.11 on the team responsible for trial. Please note, this section should not include the details of any collaborators, TSC members etc.

2.8 – Study Governance

Please answer each question in turn to provide detail of the proposed governing bodies necessitated by CR-UK. In addition, please indicate plans for future data sharing with patients who enter onto the trial.

2.9 - Additional Study Information

Please answers as directed by the notes included in the application.

2.10 – Participating Centres

Please complete in line with the guidance notes provided in the application.

2.11 – Study Development and Trial Management Group.

Please provide the details of involved in developing and running the trial, excluding collaborators.

Section 3 - Financial details

Overheads

CR-UK does not pay overheads on research awards. Awards are provided on the understanding that the host institution will meet overhead costs. Overhead costs include lighting, heating, central support staff salaries, costs of equipment maintenance (unless the equipment has been purchased by CR-UK), telephones, photocopying, postage etc. (except in special cases where the volume of paperwork and mailings are considerable, e.g. epidemiological or behavioural studies), use of library facilities and general laboratory equipment. Cancer Research UK will consider requests for a contribution to the maintenance costs of the equipment, purchased through a Cancer Research UK award. Where institutions operate a policy of access charges to equipment, Cancer Research UK

will consider payment of an access charge in lieu of consideration of maintenance costs. However, having paid for the equipment, in whole or in part, Cancer Research UK will not pay for access under full economic costing. If you are in any doubt as to what might constitute an overhead, please contact Miss Nicola Keat before submitting your application.

3.1 - Financial details - staff

Grant applications may not include salaries for clinical staff or research nurses (apart from in exceptional circumstance). Funding is intended to provide support for trial co-ordinators, data managers, statisticians, IT or administrative posts.

If it is anticipated that staffing requirements will change during the grant the financial implications of this should be summarised in section 3.8. If a staff member will only be required for the first year of the grant, please note this next to their surname on the form. If additional staff members are required in subsequent years of the grant, please do not include the salary in section 3.1 of the application form – this section is for year 1 of the grant only.

All staff details must be agreed with the personnel office of the institution where the worker will be employed. Contact your personnel or administrative representative for full details on up-to-date salaries, London weighting, other supplements and the percentage to be used for calculating oncosts (superannuation and National Insurance contributions).

Many institutions operate nationally agreed pay models but increasingly local models are being developed. CR-UK will provide salary costs within a recognised pay model, but must be advised of the applicable pay model in the grant application. Where a local pay model is to be applied a copy of the appropriate scale(s) must be sent to CR-UK with the application.

Please note that the anticipated staff costs should be entered for the first year of the grant only. If the grant is awarded, CR-UK will take salary increments, merit awards etc. into consideration when issuing Grant Award Letters for the first year only. For any subsequent instalments, a single, fixed indexation rate will be applied with the exception of fellowship and studentship salaries.

- i) *Last name/First name*: If the name of a worker is not known at the time of application, then enter “to be appointed”.
- ii) *Most recent qualification*: Include the highest degree or qualification obtained.
- iii) *Years of past CR-UK support*: The total number of years during which the worker has been paid from CR-UK (including Cancer Research Campaign or Imperial Cancer Research Fund) funding should be noted.
- iv) *CR-UK Job category*: Please identify one of the following codes for each of the proposed posts which best describes the work of that staff member:
 - **TC** Trial Coordinator
 - **DMC** Data manager & computing roles
 - **STAT** Statistician
 - **NURSE** Nursing staff
 - **OMP** Other Professional Allied to Medicine—e.g. psychologists, radiologists
 - **ADMIN** Clerical & administration role
 - **STU** Student
 - **OTHER** Staff members that cannot be classified by these descriptors
- v) *Pay grade*: The grade quoted should be that at which an appointment is required e.g. RA1A, Research Associate (Cambridge), Technician D, Scientific Officer, Nurse etc.
- vi) *Pay scale*: This should be described as ‘University’, ‘MRC’, ‘Whitley Council’, etc.
- vii) *Scale point*: Enter the number of the scale point at which an appointment is required.
- viii) *Full time equivalent (%)*: If a worker is to be employed part-time, the appropriate percentage must be included.
- ix) *First incremental date*: If a worker has an existing salary increment date e.g. from the university or previous grant support, the incremental date should be entered.

- x) **Basic Salary:** The first basic salary (100% fte) which will be paid at the scale point indicated should be entered. Please contact CR-UK for current PhD stipend rates. Do not enter composite salary costs, *i.e.* estimating pay awards or incremental increases. The figures should be taken from the scale operating at the time of application and should not include provision for anticipated pay awards.
- xi) **Location allowance:** London weighting, or other location allowances.
- xii) **Additional allowances:** Any additional allowances entered in the application form must be explained and fully justified in the covering letter.
- xiii) **Type of Merit award/Supplement:** Indicate the title of any merit award or salary supplement entitlement.
- xiv) **Value of Merit awards or supplements:** Enter the costs of any described merit awards, supplements included. Please note that CR-UK does not meet the cost of NHS merit awards.
- xv) **Studentship fees:** Standard University consolidated fees for post-graduate students, plus college fees for students undertaking research at the Universities of Oxford and Cambridge, will be met.
- xvi) **Oncosts used (%)/Value of oncosts:** Employer's oncosts, *i.e.* superannuation and National Insurance contributions, must be included for all staff except PhD students. Please note that the employer's pension contribution must be no higher than the rate used by the USS or NHS schemes.

3.2 - Staff Salary Sub-Total (For Year 1 Only)

Calculate the total salary cost to CR-UK for year 1 only.

3.3 - Financial administration contact details

Basic contact information should be provided for the staffing administrator responsible for supplying the salary costing information. This will enable faster processing of any staffing issues should an award be made.

3.4 - Running expenses

Detailed running expenses **for the first year only** should be included here. This will form the basis for allocation of running expenses in subsequent years of the grant. If the level of running expenses required will vary in subsequent years of the grant, please summarise these changes in costs in section 3.8 and provide further details and an explanation in the covering letter.

A detailed breakdown of the running costs is required for the purposes of reviewing the application and considering the justification for the running expenses. The level of running expenses provided to successful applicants will be assessed by CTAAC in light of expenses normally required for similar work.

Running expenses may include contributions to the use of central facilities or charges for use of specialised equipment where these are required for the research project. Maintenance costs for equipment purchased through a CR-UK grant are permissible while the equipment is being used for approved CR-UK work. Requests for travel expenses to attend meetings should not form part of the grant application, although the cost of travel that forms an integral part of the proposed study (such as travel between collaborating centres or reimbursement of trial-participant expenses) can be included under 'Travel related to research proposal'. If there is underspend on the award this may be used to pay for costs of attendance and travel (standard class only) to conferences related to the research. Please refer to Section 7.7 of the Terms and Conditions for further information.

3.5 - Total Running Expenses

Please calculate the total running expenses for year one only.

3.6 - Equipment

CR-UK assumes a basic level of equipment provision by the host institution and applications should be limited to items required specifically for the research proposed.

3.8 - Projected costs

If you are applying for more than one year's funding, please provide approximate total costs under the given headings. Except when the grantee is informed otherwise, awards will be provided on the following basis: After Cancer Research UK has established the level of award for the first instalment (or for awards existing as at February 2009, the 2009/10 instalment) a single, fixed indexation rate will be applied to all subsequent instalments of the award for both salaries and running expenses, with the exception of fellowship and studentship salaries. The indexation rate set will apply for the remaining duration of the award. Once the award value has been set no additional money will be available for any increases to salaries or running expenses (unless changes in the level of award in subsequent years were approved at time of funding). Please refer to section 7.7 of the Terms and Conditions.

Please ensure that you discuss any planned increases in costs with Miss Nicola Keat before submitting your application to ensure eligibility for funding. If present, all such increases must be fully justified in the research proposal.

NHS Support Costs for Randomised Controlled Trials

If your proposal is to undertake a randomised controlled trial in any form you should break-down projected costings using the following format within your research proposal:

Y r	Research Costs requested from CR-UK				Excess Treatment Costs to the NHS (see question 3.9)				Service Support Costs to the NHS (see question 3.10)			
	Staff	Running Expenses	Equipment	Total	For Control Arm of Study (if not standard of care)	For Experimental Arm of Study (1)	For Experimental Arm of Study (2)	Total	For Control Arm of Study (if not standard of care)	For Experimental Arm of Study (1)	For Experimental Arm of Study (2)	Total

For a definition of such costs, please refer to the NHS Guideline for Researchers for Non-Commercial Externally funded R & D (HSG(97)32). This is available from the Department of Health Website (www.dh.gov.uk) by following these links: >> "Research and Development" >> "Research and Development A to Z" >> "National NHS R+D funding" >> "Attributing revenue costs of externally funded non-commercial research in the NHS (ARCO)".

Applicants also have a duty to inform the lead service providers of the possible NHS support implications of proposed research projects at the earliest opportunity and must also indicate within the research proposal that the relevant provider(s) have been notified. In addition, all applicants should contact Trudi Simmons of the Department of Health to discuss the excess treatment and service costs associated with the trial (E-mail: trudi.simmons@dh.gsi.gov.uk, 020 7972 4895). Discussions with the Regional Director of R&D in parallel with CR-UK may also be needed. Access to service support costs to the NHS is guaranteed for studies on the UKCRN portfolio.

3.9 – NHS Excess Treatment Costs

In addition to the figures provided for the table in section 3.8, using the guidance notes included below the question, please provide a detailed breakdown of the excess treatment cost implications for the NHS should the service in question be continued following this trial's closure.

3.10 – NHS Service Support Costs

Please complete as above

3.11 – Cancer Research Network Support

Please indicate whether support from any of the listed Cancer Research Networks is required, and if so please specify which one and detail the staff time you plan to request.

3.12 – Industry Support

In the event that either an educational grant or free drug provision will be used in this study please provide the details as requested.

3.13 - Commercial outputs

CR-UK, as a UK medical research charity, is obliged to ensure that the fruits of CR-UK-funded research are used and disseminated so that the understanding, diagnosis and treatment of cancer is maximised for the benefit of the cancer patient and the general population. Please refer to section 9 of the Terms and Conditions for details of how CR-UK meets these obligations through its wholly owned subsidiary Cancer Research Technology Limited (CRT).

To contact Cancer Research Technology please visit the CRT website at <http://www.cancertechnology.co.uk>, email enquiries@cancertechnology.com, or phone 020 7269 3640.

Section 4 - Additional Research Information

4.1 - Collaborations

A Collaborator is an individual who is named in the application and has agreed to supply research materials, specific expertise or access to patients, but will not be involved in the day to day running of the project.

Written confirmation from your collaborator should be included with your application in the form of an original signed letter that states their willingness to participate in the project. If these letters are delayed then they should be sent to the office separately, noting your application reference number, which will be given to you when your application is acknowledged.

4.2 - Animal studies

Please provide the details requested that are standard across all CRUK forms

4.3 - Human studies

Clinical studies represent a very sensitive area where the consequences of mismanagement could result in harm to patients and, for CR-UK, litigation and/or adverse publicity. Please see guidelines section GA4.2.4 for details of the ethical approval details that should be submitted as part of your application.

4.4 – Specific Technologies

Please clarify the use of specific technologies and resources as part of this trial. In the event that a CR-UK Microarray facility will be accessed, please access the appropriate request form at: http://science.cancerresearchuk.org/reps/worddocs/apps_mif.doc

4.5 - Other Cancer Research UK Support

Do you or any of the co-investigators on this application already hold CR-UK funding or support?

If the principal investigator or any co-investigators already hold CR-UK awards, please list them in the first box. For each award you should list the grant reference, Chief Investigator, title, duration, level of support and type of award. All grant reference numbers should be in the format C#### / A#### (where '####' is equal to a numerical value).

A statement should then also be given that explains how the new application fits in with any of the identified existing CR-UK support. Applications that overlap significantly with existing grants are unlikely to be supported. In the event that an overlap is identified between current and proposed work, the office may contact you for clarification.

4. 6- Awards from Other Organisations

Details should be given of any other awards from other research organisations currently awaiting decision or already held by both yourself and any co-investigators.

Has a similar application been submitted to other organisations for consideration?

An application will not be accepted that is essentially the same as one currently under consideration for funding by another CR-UK committee or any other funding body. The only exception to this policy is for applications for personal fellowships. CR-UK may

share pertinent information about your application with other funding bodies to ensure that you have not made a parallel application.

CR-UK welcomes applications proposing joint support for research with other funding bodies, but all such proposals **MUST** be discussed with CR-UK staff prior to submission.

Section 5 - Applicant Details

5.1 – Applicant

CR-UK requires a single person to be listed as the primary contact regarding any proposals and this person should be identified as the Applicant. It is realised that the work involved in a research proposal is often split between several people and when completing a proposal form a chance is given to fully specify the different roles of individuals in the application. In exceptional circumstances where there is genuinely joint leadership of a research group or project this can be recognised (see 7.1 – Co-investigator), but in all cases a single Applicant must be nominated, see below.

ROLE IN APPLICATION	DESCRIPTION
Chief Investigator (Clinical)	<p>This role is only applicable for Clinical Trial applications.</p> <p>As defined under the EU Directive the clinician who will sign the CTA should also be used for the lead clinician for trials not falling under the EU Directive e.g. radiotherapy.</p>

5.2 - Contact details

Please note the full address of the host department and institution where the grant will be held and administered. If a project is to be based at two or more institutions, one institution must be designated as the host institution. If support is awarded the grant will be paid to a single institution that will be responsible for transfer of funds to the other centres and will administer the grant. In some cases CR-UK may consider support for a collaborating overseas institution but applicants are advised to consult Miss Nicola Keat, before submission, to discuss the proposal.

5.3 - Alternative contact details

If you are applying for a grant to be held at a host institution other than the one at which you currently work, please enter your current contact details in this section. You can also use this section to enter your direct contact details if you *do not* wish these to be published on our website. Please enter departmental telephone and email details in section 5.2.

Section 6 – Curriculum Vitae - Applicant

An up-to-date CV and recent publication list for the applicant must be provided. Please note that only the information requested on the Form is required; separate CVs or extensive publication lists will be returned to the applicant for amendment, which may result in a delay in processing your application.

6.1 Name of applicant

Applicants applying for their own salary on a project grant must complete supplementary form CR-UK CAF providing additional career details. Please ensure that you list the source of funding for your post. For source of funding, please enter the funding body and the type of support, e.g. Senior Clinical Fellowship, University Chair etc. If you are not applying for personal support as part of this application, your position must be secure for the duration of the proposed award period.

6.2 Qualifications

Enter the date of award, the title (e.g. PhD, Biochemistry) and the awarding body (e.g. University of Manchester, UK) of up to 6 qualifications. Please list your most recent qualification first.

6.3 Current post

Please ensure that you list your current position and full job title.

6.4 Previous positions held

Please list all previous positions held, with your job title, location and the name of the group leader you worked for where the position involved a research component.

6.5 Publications

Please provide the number of your peer-reviewed publications broken down into the number of first author, last author and total publications, and then list your publications during the last 5 years *that are of relevance to the application*. If you have an extensive publication record, then a selection of publications should be chosen for inclusion on the form. The list should not exceed one page and longer publication lists will be truncated after the first page. Please note publications in the following format, underlining the name of the investigator: e.g. Andrews A, Brown B & Charles C (1999) Title of paper Nature **217**, 199-201.

6.6 Disclosure of Potential Competing Interests

Please read the descriptions of potential Conflicts of Interest and check the appropriate box, providing additional information as necessary.

Section 7 – Co-investigator Details

7.1 - Co-investigator

A Co-investigator is a researcher who will provide significant intellectual input into the research and will be responsible for the day to day running of some aspects of the work. CR-UK recognises the significance of co-investigator status by naming co-investigators on Grant Award Letters and by requiring co-investigators to sign the Undertakings Form accepting the Terms and Conditions under which CR-UK awards are made.

The application form lists a number of categories of co-investigator that define the relationship to the Chief Investigator in more detail.

- i) *Standard co-investigator*: This category is appropriate for most co-investigators who have significant input into a research project as outlined above, but do not have any other specific leadership role. For applications to CTAAC, this can include the Lead Investigator of a trial if the main applicant is a Lead Investigator.
- ii) *Joint Principal Investigator*: There are rare circumstances in which a research project may require joint leadership. CR-UK wishes to recognise this arrangement where it exists, but sees this as exceptional. In all such cases a single *Applicant* must still be identified. If you feel that Joint PI status is appropriate for your application please consult Miss Nicola Keat to discuss this further.
- iii) *Main PhD Supervisor*: In most cases, it is anticipated that students associated with an application will be supervised by the Principal applicant. Where this is not the case, the main Supervisor should complete a co-investigator form.
- iv) *Laboratory Supervisor/Day to Day Supervisor*: If a student's main Supervisor has more than 3 other PhD students under their supervision, or where the main supervisor is not able to spend sufficient time with the student on a day to day basis, a separate Laboratory Supervisor should be identified and should complete this form.
- v) *Post-Doctoral Advisor*: Applicants for certain Fellowships are required to identify a post-doctoral Advisor. This category is for use in these situations only.

Section 8 – Curriculum Vitae - Co-investigator/Co-applicant

An up-to-date CV and recent publication list must be provided for any co-investigators or co-applicants (for each additional co-investigator, please complete supplementary form CR-UK CICV available at http://science.cancerresearchuk.org/reps/worddocs/apps_cicv.doc). Please note that only the information requested on the Form is required; separate CVs or extensive publication lists will be returned to the applicant for amendment, which may result in a delay in processing your application.

8.2 Qualifications**8.3 Current post****8.4 Previous positions held****8.5 Publications**

Please refer to the guidance notes for sections 6.2 to 6.5 for information on how to fill out these sections.

Section 9 – Curriculum Vitae - Named Research Staff

An up-to-date CV and recent publication list must be provided for any senior (post-doctoral or clinical) staff to be appointed, if these are known at the time of the application.

For each member of staff, please complete supplementary form CR-UK NRSCV available at http://science.cancerresearchuk.org/reps/worddocs/apps_nrscv.doc. Please note that only the information requested on the Form is required; separate CVs or extensive publication lists will be returned to the applicant for amendment, which may result in a delay in processing your application.

9.2 Qualifications**9.3 Current post****9.4 Previous positions held****9.5 Publications**

Please refer to the guidance notes for sections 6.2 to 6.5 for information on how to fill out these sections.

Section 10 – Undertakings

This form must be signed by the applicant and co-investigators, Head(s) of Department and the appropriate administrative authority for the host institution. These individuals must have taken note of CR-UK's Terms and Conditions and Administrative Guidelines for Research Grants and Awards (<http://science.cancerresearchuk.org/gapp/terms/>).

If a small grant, project or programme is to be based at two or more institutions, one institution must be designated as the host institution, but each institution must complete a separate Undertakings form as part of the application. Additional Undertakings (application) forms are available at (http://science.cancerresearchuk.org/reps/pdfs/uf_award.pdf)

Section 11 – Peer Review

For CTAAC applications for funding, at the outline stage applicants are asked to nominate up to 5 reviewers and supply as much contact information for each reviewer. If you are submitting a trial to CTAAC for endorsement/approval, or for any reason you have not submitted your application as an outline, please complete this section in the Full Proposal Form. You are also welcome to provide additional referees to those already provided if you wish to do so. See guidelines section GA7 for details of how CR-UK uses peer review to inform its funding decisions.

Section 12 – Research classification

If successful, outline details of your award will be published on CR-UK and other national and international research web sites.

Use of keywords will ensure your work is highlighted when people search for research in your field. Applications without keywords will not be accepted.

12.3 – Type of Research

The Common Scientific Outline (CSO) is a classification system used by UK and US funding bodies to help lay the framework for better coordination among cancer research organisations by making it easier to compare public, private, national, and international

cancer research efforts. For example, the International Cancer Research Portfolio (<http://www.cancerportfolio.org/>) is organised around the CSO categories and details of CR-UK funded awards are automatically uploaded to this database.

If you need further definitions of the categories of research, please refer to the Common Scientific Outline at <http://www.cancerportfolio.org/cso.jsp>

GA4 THE RESEARCH PROPOSAL

GA4.1 Format

A research protocol is not required as part of the application. Please simply use the relevant proposal forms provided. The proposal should be printed on A4 paper and text should be single line spaced in a font size no smaller than Arial point 11 in black.

GA4.2 Supporting documents

GA4.2.1 Photographs and colour figures

Only where completely unavoidable, should photographs or colour figures that cannot be photocopied successfully in black and white be submitted. If these are present (e.g. histological sections, some gels, colour graphs), **ten copies** of the figures should be submitted with the application. All pictures and figures must be on A4 paper: please do not send loose or unmounted photographs. If possible, colour images or photographs should be presented on separate pages and not included in the body of the text. If requested CR-UK will make every effort to return some of the photographs to you but this cannot be guaranteed.

Where possible, electronic copies of images should be submitted. Images should be inserted into a word document and a figure legend attached; the document should also contain the applicant's full name and the date in the header or footer.

GA4.2.2 Supporting letters

Please include signed original copies of any supporting letters.

GA4.2.3 Preprints and unpublished papers

Preprints and reprints are not required for an application and **should not be sent** unless the data or the methodology is directly applicable to the proposal and has not been published previously by the applicant. For this purpose preprint refers exclusively to papers which have been refereed and accepted for publication. Details of the journal and publication date are required. If publications are submitted with an application, a single copy should be appended.

Non-peer reviewed papers should not be submitted with an application and any such papers sent will not be forwarded to referees. Research that has not been accepted for publication should not be cited in the reference list (e.g. 'manuscript in preparation', 'submitted for publication' etc.).

GA4.2.4 Ethics Committee approval (for studies involving patients)

In all studies involving patients, patient tissue or patient information the necessary ethics approval must be applied for. It is the responsibility of the applicant and the host institution to ensure compliance with all legal requirements and ethics approval.

GA4.2.5 Ethics approval (for studies involving animals)

A Local Animal Research Ethics Committee must approve research proposals involving the use of animals and the appropriate documentation should be submitted with the application. Where ethical approval can only be considered

after funding is approved, the final outcome of the approval process must be submitted as soon as it is known.

It is the responsibility of the host institution to ensure that all ethical and legal requirements and Home Office regulations are met.

GA4.2.6 Extension Applications (for applications for Project Extensions)

CR-UK grantees who wish to apply for a further period of funding to follow on from their current project grant should prepare an extension application form. This applies whether the application is a logical progression of the existing work or just for continuation of the existing project.

GA5 SUBMISSION OF THE APPLICATION

GA5.1 Paper Copies

Please submit 1 top copy of the application form and all supplementary forms and supporting documents. This must be double sided, unbound and of a quality suitable for photocopying. The pages of the proposal must be in the requested order, with supplementary forms attached at the end. Supporting documents should be placed at the end.

At the full proposal stage please submit 9 further copies of sections 1 – 9 of the proposal form (removing sections 10-13) and all supplementary forms. These edited sets should include copies of collaborators supporting letters and may be double sided and stapled, but should form 9 collated documents. These are the papers that will be sent for external peer review immediately after the closing date for submission.

Bound copies should not be submitted. Failure to submit the required number of copies in the correct format may delay the processing of your application.

GA5.2 Electronic Copies

The main application form and all supplementary forms should be submitted by email. Electronic submission of applications is required in addition to postal submission and your application will not be considered formally submitted until the office receives both the electronic and hard copies.

GA5.3 Submission

Please email your application to the address shown on the front page of the application form and post paper copies to Miss Nicola Keat at the following address:

Clinical and Translational Operations and Funding,
Cancer Research UK,
61 Lincoln's Inn Fields,
London,
WC2A 3PX.

Dates of deadlines for receipt of grant applications are listed under the respective funding Committees on CR-UK's website at:

<http://science.cancerresearchuk.org/gapp/clinicaltrialsfund/cta/>

CR-UK takes no responsibility for deadlines missed due to consultation of sources other than the correct CR-UK funding Committee's webpage for deadline dates.

GA6 RECEIPT AND PROCESSING OF APPLICATIONS

GA6.1 Numbers of applications considered at meetings

For most committees, it is necessary to limit the number of applications considered at any one committee meeting. Applications will be processed in the order they are received. If the quota is reached, **subsequent applications will be deferred to the next committee meeting**. If an application cannot be processed immediately, because it is incomplete or for any other reason, it is very likely that consideration of the application will be deferred.

Applications for project grant funding to CTAAC are not usually subject to these restrictions.

GA6.2 Acknowledgement of applications

Receipt of the application will be acknowledged in writing (email, fax or letter) within 2 weeks of the closing date for submission.

GA6.3 Deferral of applications

CR-UK reserves the right to defer consideration of applications without prior reference to the applicant and accepts no responsibility for the consequences of any delay in considering an application.

GA6.4 Processing of applications

If there is a problem with the application or any of the required attachments are missing the application may be returned to you, in which case consideration of the application may be deferred to a later meeting. If certain documents are not available at the time of submission it is strongly recommended that you indicate when these will be available and forwarded to CR-UK. No grant will be awarded until all the required conditions have been met and the necessary documentation received and approved by CR-UK.

GA7 REVIEW PROCEDURES**GA7.1 Peer Review**

CR-UK is rigorous in the application of peer review in the assessment of its research. All applications will be reviewed by experts in the field. In-house expertise, represented by the membership of the funding Committee is supplemented by written assessments by external peer reviewers. These reports will be made available to the applicant to provide the applicant with an opportunity to respond to the comments – the applicants response will be circulated or tabled for the Committee to take account of during its deliberations (see Section GA10 - Feedback).

Applications for funding are accepted on the understanding that CR-UK will select appropriate peer reviewers to review the proposal without reference to the applicant. External referees' reports will be taken into account when considering applications but other factors relating to CR-UK's portfolio and priorities will also influence the committee's decisions. In all cases the committee's decisions are final.

GA7.2 Scoring system

CR-UK uses five main rating categories, which are, in descending order: Outstanding, Forefront, Competitive, Good and Not Competitive. The Outstanding rating is reserved for truly exceptional applications. Applications rated as Good or above are potentially fundable, although in most cases the funding cut-off will fall in a higher category. The Not Competitive rating is given to applications which, for whatever reason, are not recommended for funding.

A sixth rating category, Preliminary, is reserved for applications which are considered to be unfundable in their current form but that may be fundable with

further work and this rating may be used by a funding Committee if it wishes to consider a reapplication.

The Funding Committees may associate a numerical score with the rating categories so that all the proposals can be ranked to establish a funding cut-off. Numerical scores, if used, are for use **within the Committees only**.

GA7.3 **Funding cut-off**

CR-UK funding Committees are not always able to fund all of the 'Competitive' rated proposals that they receive. In this circumstance, 'Competitive' rated applications that fall below but close to the funding cut-off may be carried forward to the next meeting at the sole discretion of the Committee. The application will not normally be discussed or re-scored at the second meeting and no revision of the proposal or additional justification for support can be considered unless specifically requested by the Committee. If the score remains below the funding cut-off at the second meeting the application will not be considered further.

GA7.4 **CTAAC project grant approval steps**

Project grant applications to CTAAC are usually considered in a two-stage process, with the first step being the submission of an outline proposal. If the Committee decides to shortlist an application following its consideration of the outline, the next stage is the submission of a full proposal. The exceptions to this are applications to CTAAC for endorsement (no funding required), and feasibility studies.

GA8 **CONFIDENTIALITY**

CR-UK requests its peer reviewers to consider all applications in confidence but if an applicant has any concerns regarding commercial confidentiality of the data or proposals this should be indicated clearly in a covering letter. If necessary CR-UK will contact the applicant to discuss any steps that need to be taken to preserve the confidentiality of the application.

GA9 **NOTIFICATION OF OUTCOME**

Applicants who submit proposals to CTAAC will be informed if their proposal has been shortlisted (for outline applications) or funded (for full applications, extensions or feasibility studies) as soon as possible after the meeting, usually within a few days. A full feedback letter will be forwarded to applicants once the Chair has provided approval, usually within 2 weeks of the meeting.

A formal Grant Award Letter (GAL) detailing the level of the award will only be issued once any concerns raised by the Committee have been addressed, and once confirmation of the Trial Sponsor has been received in the case of new trials.

GA10 **FEEDBACK**

GA10.1 CR-UK always aims to provide feedback on applications. Please note that if an application was not considered to be fundable, or the external referees' comments were not submitted with the intention of them being seen by the applicant, it may not be possible to provide feedback.

GA10.2 Applicants are asked to note that feedback on an application or the application process will only be provided by CR-UK's Clinical and Translational Operations

and Funding Directorate. Members of CR-UK Funding Committees adhere to the Code of Practice for Funding Committees, which exists to ensure the protection of applicants, Committee members and external reviewers and to ensure the impartiality of the review process. Committee members cannot discuss Committee decisions with applicants and applicants must not approach Committee members directly. The peer review process is of the highest importance and CR-UK reserves the right not to consider applications from individuals who compromise its integrity.

GA11 REVISION / RESUBMISSION OF AN APPLICATION

CR-UK will only accept resubmission of a revised proposal if this is recommended by a Committee and this will only happen in exceptional circumstances.

GA12 AWARD OF A RESEARCH GRANT

- GA12.1 Once an application for financial support has been approved a grant will only be awarded when CR-UK is satisfied that all the necessary conditions have been met.
- GA12.2 Before any grant can be awarded CR-UK may require that a satisfactory arrangement between the host institution and Cancer Research Technology (CRT) is in place concerning intellectual property and commercial exploitation of CR-UK-funded research. Technology transfer agreements are already in place with the majority of relevant institutions but if an agreement does not exist, or the parties cannot reach agreement, award of the grant will be delayed until this issue is resolved to the satisfaction of both the host institution and CR-UK.

GA13 TERMS AND CONDITIONS FOR RESEARCH GRANTS

Please ensure that you read the Terms and Conditions and Administrative Guidelines for Research Grants and Awards. The Terms and Conditions, Cancer Research UK Funding Policies, any additional special terms and conditions specified by Cancer Research UK on any grant awarded and the Grant Award Letter (GAL) together set out the Terms and Conditions on which the grant is awarded by Cancer Research UK.

Clinical and Translational Operations and Funding Directorate
Cancer Research UK
61 Lincoln's Inn fields
London
WC2A 3PX

Tel: 020 7438 5391
www.cancerresearchuk.org