Early Phase Clinical Trial Grants – Guidance for Applicants

Purpose and Remit

This scheme provides up to £400,000 of funding to support early phase investigator-led interventional studies to evaluate new blood cancer treatments, with the aim of delivering trials which could translate into further studies to evaluate clinical efficacy. Applications are expected to be developed with the involvement of a relevant clinical trials unit.
The types of studies that the scheme supports include:

- Phase 1/Phase 2 trials to ascertain safety, side effects, best dose and preliminary efficacy of new therapies in humans or novel therapy combinations, which can include radiotherapy or novel indications for existing drugs.
- Phase 1b/2 or Phase 2 trials testing the feasibility of larger trials, and/or to explore the tolerability, biological activity and effects of the intervention.
- Studies of treatment approaches aiming to achieve equivalence of survival will be considered, if the possibility of reduced toxicity or optimisation of treatment delivery can be shown, along with the potential to substantially improve patient outcome.

This scheme will not support preclinical studies, industry-funded investigator-initiated trials, long-term follow-up, observational studies or sub-studies of larger trials, unless they meet the above remit criteria.

Eligibility

Applications must be from a tenured academic, scientist or clinician from a UK university, research institution or clinical centre, and developed with the involvement of an experienced UK Clinical Research Collaboration-registered Clinical Trials Unit (CTU). The organisation hosting the research and administering the funds for a clinical trial or study must be a UK university, research institution or CTU. The Main Applicant/Chief Investigator (CI) must have a salaried position for the full duration of the grant. Any multicentre interventional clinical trial, while remaining under the scientific control of the CI, should be managed by a UKCRC-registered CTU.

Online application system

All applications must be submitted via the Blood Cancer UK Grant Tracker grant application system. Grant Tracker is used for submission, peer review, award and monitoring of all grant applications. Please follow the instructions carefully to complete and submit an application.

Version 1.1 – March 2020

The application can be stored and edited at any time prior to submission. There is guidance on how to use Grant Tracker on our website.
The application deadline is **4:00pm on the date advertised**. No applications will be accepted after the deadline. Applicants should allow enough time for submission of their applications before the deadline to ensure all the required approvals are obtained.
For any enquiries about completing the application form or submitting your application, please contact the research team by emailing research@bloodcancer.org.uk or phoning 020 7504 2200.

Review process

Applications for this funding scheme will be reviewed by medical/scientific expert reviewers, and the Blood Cancer UK Clinical Trials Committee.
Assessment criteria used to make funding decisions will include:

- Importance and relevance of the research question(s) to people with blood cancer;
- Expected impact on clinical practice;
- Strength of trial design, including statistical design and rationale;
- Adequacy of the recruitment plan and supporting evidence;
- Appropriate patient and public involvement;
- Expertise of the study team;
- Expertise and rationale for choice of CTU, including track record of delivery, portfolio of relevant trials and anticipated recruitment rates;
- Feasibility and likelihood of successful study delivery;
- Appropriate justification of costs.

Additional criteria that the Clinical Trials Committee will consider include the capacity of the CTU, whether additional external funding has been secured or is conditional, alignment with Blood Cancer UK's priorities, and the potential to align with mechanistic studies. Applicants should state the potential research studies possible with the samples collected and stored during the trial.

All recommendations for awards made by the Clinical Trials Committee will be sent to our Board of Trustees. They then make the final decision on which applications we fund. Notification of the outcome of applications will be made after consideration of the Board of Trustees. The Trustees decision is final and non-negotiable.

Partnerships and other sources of funding

In all cases, applicants must state what support from other organisations or core infrastructure is necessary to deliver the trial and confirm whether funding is already in place or being applied for.

Should grant applications be dependent on a pharmaceutical company to provide some of the costs of the delivery of the trial, applicants should provide a letter of support from the partner confirming the support provided. This may include provision of the drug free of charge, running costs, equipment or an educational grant. The host institution accepting a grant offer must ensure that any agreements made with funding partners or contributors do not include restrictions that conflict with Blood Cancer UK's grant award terms and conditions.
It is expected that successful delivery of most trials will be dependent on other sources of funding, and normally Blood Cancer UK will not require a formal partnership with other funders. Blood Cancer UK will consider funding applications in formal partnership with other organisations, which may include funders, trusts and pharmaceutical companies, where an additional benefit of doing so can be identified. If you would like to propose this, please discuss with us and the other funder before submitting your application.

Application form

Application Details

Title: The study title should state clearly and concisely the proposed research. Any abbreviations should be spelled out in full.
Trial Acronym: Provide the trial acronym/identifier if available.
Synopsis: The synopsis should be a scientific abstract of the proposed research. This should include the hypothesis and objectives as well as brief details of the proposed methodology. Applicants should also outline the proposed outcomes and impact, and the benefits to people living with blood cancer. (200 words max.)
Trial Sponsor: Under the Medicines for Human Use (Clinical Trials) Regulations 2004, applicants must identify a sponsor (which will normally be either a University or NHS Trust), who fully understands the responsibilities and costs associated with assuming this role. Please note that Blood Cancer UK cannot act as a sponsor.
Administering Organisation: Name of the organisation responsible for administering an award.
Address: The address of the administering organisation.
Clinical Trial Unit: Name and location of the UK Clinical Research Collaboration-registered Clinical Trials Unit (CTU) involved with development of the application.
Proposed start date: Applicants should allow at least six months between the submission of the application and the proposed starting date of the research.
Proposed duration: Duration of the grant can be for up to 60 months. In exceptional circumstances, trials that require a duration of greater than five years to complete follow-up may be considered, provided that applicants can confirm that all necessary funding is in place.
Previously submitted to Blood Cancer UK? Indicate whether the application is a new submission, continuation of a current or recently closed award, or a resubmission.

Plain English Sections

Please respond to all questions that are relevant to your study and ensure all responses to questions in this section are written in plain English, using non-technical language and avoiding unexplained acronyms and/or abbreviations. Applications without satisfactory completion of the plain English sections may be returned for amendment. Further guidance on writing can be found at the National Institute for Health Research (NIHR's) INVOLVE 'make it clear' campaign website.

Application Information – Plain English

Summary: Provide a plain English summary of the proposed research and why it is needed so that people who may not be familiar with the subject can understand. If your application is funded, we may edit your summary and then use it to describe your research on our website and elsewhere. (200 words max.)

Aims of the research proposal: Briefly describe what the research is trying to find out for a non-specialist audience. (300 words max.)

Work leading up to this research proposal: Describe the background to this research proposal for a non-specialist audience. Is it a continuation of your existing research or is it a new area? (300 words max.)

How many people in the UK does the condition(s) affect each year, and what treatment options do they currently have? Provide the annual incidence or prevalence of the condition(s) in the UK and what treatments are offered to people affected by the condition(s). (200 words max.)

Benefits of the research: What difference could this research make to people affected by blood cancer? If successful, when will the benefits be likely to reach patients? (200 words max.)

Next Steps: If the research is successful, what are the next steps? What further research will be needed? (200 words max.)

Patient recruitment plans and the patient pathway

In this section you will be asked to provide details of your patient recruitment plans for a non-specialist audience, including a description of the benefits and risks, plus information about what people who agree to take part in the study can expect in terms of clinic appointments, treatment schedules and follow-up.

Who can take part in the research and how will they be recruited? Include a brief outline of the process for seeking informed consent for people taking part in the study.

How many people do you need for this research, and do you think there will be any challenges in finding people willing to take part? Provide the total number of people needed for each group of patients receiving a specific treatment. Briefly outline the possible challenges in recruiting the required number of people to take part in the research, and how these challenges could be addressed.

What will taking part in the research involve? Provide a plain English summary of the patient pathway from the time people are recruited, to the time at which participation

ends. Include a brief description of the types of test and number of check-ups and follow-up appointments. (500 words max.)
What are the benefits of taking part in this research? Describe the benefits to study participants.
What are the potential risks and side effects for people taking part? Describe the potential risks to study participants and the side effects they might experience.
What patient information materials will be provided? We encourage you to attach relevant draft or final versions of patient information and consent documents, if they are available at the time of submission.
How will you keep people (both participants and the wider public) informed about research progress and the final results? Describe how progress updates and information about the research results will be provided to study participants and other interested parties. (300 words max.)

Patient and Public Involvement

Complete this section to explain how patient and public involvement has informed and/or influenced the development of your application, and how patients and/or members of the public will be involved in the research. The term involvement refers to an active partnership between patients, members of the public and researchers in the research process.
Please note that PPI does not refer to the recruitment of patients or members of the public as participants in the trial or study.
For additional guidance about involving patients or members of the public in research, many resources are available for researchers:

- INVOLVE – Briefing notes for researchers: public involvement in NHS, public health and social care research. (INVOLVE is a national advisory body funded by the NIHR to support public involvement in NHS, public health and social care research).
- INVOLVE – Briefing note: Why involve members of the public in research?
- People in Research – a resource to help members of the public find opportunities to get involved in research and for research organisations/researchers to advertise involvement opportunities.
- Cancer Research UK Patient involvement toolkit for researchers

Describe how you have involved, or plan to involve, people affected by blood cancer in your research: Briefly describe any involvement activities already completed and if, or how they influenced development of the research proposal. Outline your plans for research involvement during the research.
Involvement activities might include, for example:
• participation in the choice of research topics – helping to ensure that the research is a valuable and respectful use of people's time and the results are likely to be useful to patients/the public;

• advising on the process of informed consent – making it easier for prospective participants to understand the research and potential risks;
• checking that the practical arrangements for participants are appropriate and not overly burdensome, thereby improving the patient experience;
• assisting in oversight and management of the research (e.g. serving on a Trial Steering Committee);
• improving the communication of findings to people taking part and the wider public (e.g. helping in the drafting of a plain English summary of findings).

Training and support to those actively involved in your research: Describe any training and support you have, or will, offer to people involved in your research. Refer to the INVOLVE guidelines for developing training and support for public involvement in research.
Expenses and payment: Provide details of any reimbursement of expenses and/or involvement payments you have, or will, offer to people involved in your research. For further
guidance, refer to the NIHR INVOLVE policy on payments and expenses for members of the public.
If there are no plans for active research involvement, please explain why: If you have not involved people affected by blood cancer in your research to date and/or have no future plans to do so, please explain why research involvement is not considered to be appropriate or feasible.

Scientific/Technical Sections

Research Proposal and Rationale

What is the problem being addressed? Provide a clear explanation of the health problem to be addressed. (300 words max.)
What are the key research questions, aims and objectives? Summarise the research question/key aims and objectives. As a guide, include the aim (broad question) of your proposed research, a sentence describing the primary outcome measure and a list of the clinical objectives.
Need for trial: Explain why this research is needed now. Please put your research into the context of current practice, other recent or ongoing research. Is there a gap that this research aims to address? (300wordsmax.)
Quality of life issues addressed by the trial: Provide a brief description of any quality of life issues that could be addressed by this research.
Economic issues addressed by the trial: Provide a brief description of any economic issues that could be addressed by this research.
Importance of the trial to the research community: Explain how this study will advance the research field. (250wordsmax.)
Related trials: How will the trial differ from, or complement, any relevant planned, ongoing or recently completed trials elsewhere in the UK or internationally?

How will the results of the trial be used? What is the potential significance of the results? How might the study impact on clinical practice? On completion of the study what would be the next trial to be undertaken?
Do you intend to collect any biological samples from patients as part of the trial? If yes, what samples will be collected and what would be the research questions. Do

you intend to apply to Blood Cancer UK or another funder for additional funding to support laboratory studies using trial samples?

References

A maximum of 2 A4 pages of key references related to your application can be uploaded as an attachment.

Trial Design and Delivery

Trial design: Describe and justify the choice of clinical trial design, including planned trial interventions (experimental and control) and duration of treatment. If the study is randomised, what are the proposed practical arrangements for allocating participants to trial groups?
Investigational Medicinal Products: If any investigational medical products are to be used, provide details, including relevant information about availability, manufacture, quality and consistency.
Target population: Provide details of the proposed target population groups, e.g., gender, age range. Include key inclusion/exclusion criteria and any relevant details about how that population will be identified for recruitment.
Trial outcome measures and endpoints: Outline the outcome measures and endpoints and how these will be assessed.
Frequency and duration of follow up: Outline the planned frequency and duration of follow-up for trial participants. Describe any anticipated problems with non-compliance and/or loss to follow-up and how these problems could be addressed.
Early stopping rules: As appropriate, describe stopping rules for (i) efficacy (ii) toxicity (iii) futility.
Risks to the safety of patients taking part in the research: Describe any risks to the safety of patients taking part in the research and explain how the level of risk will be assessed.
Sample size and statistical analysis: Describe and justify the sample sizes and proposed statistical analyses. Include the number of samples for each analysis, the associated level of statistical power, and potential limitations or bias (1000 words max.).
Recruitment strategy: Outline and justify the patient recruitment strategy for the trial. (1000 words max.) It is important to provide substantive evidence of feasibility to support your application and pilot work to establish numbers of available patients.
Patient recruitment graph – Upload a graph showing projected patient recruitment numbers for the duration of the trial.

What are the proposed participating centres? For each participating centre, provide the centre name, location, lead investigator, estimated number of eligible patients per year, expected annual and total patient recruitment per year.
Track record of Clinical Trial Unit (CTU): Provide details of the CTU team involved with your study. Justify the choice of CTU and study team in terms of expertise, capacity and track record of trial delivery. (1000 words max.) Details of CTU trial delivery track record can be presented in table format and uploaded as an attachment if preferred (1 A4 page max).
Additional Supporting Information: A maximum of 2 A4 pages of additional information can be provided in support of the research proposal. Additional information can include graphs, figures, tables and essential unpublished data relevant to your application.
Gantt Chart: Please upload a Gantt chart outlining the proposed timeline and key milestones for study set up and delivery. As a minimum, include Health Research Authority (HRA) submission, first site open, first patient recruited, all sites open, completion of recruitment, follow-up, data analysis, end of study and archiving.
Input from the National Cancer Research Institute: Provide details of any input to the proposed study from the relevant NCRI Group(s). (300 words max.) We strongly recommend approaching the relevant group(s) for their comments on the proposal before submission. The groups typically meet twice a year, so you will need to approach them in advance of submitting a grant application to Blood Cancer UK. Once your research proposal has been discussed formally by the relevant NCRI Group, please request a letter of support from the Chair, which should be uploaded with your application. Blood Cancer UK will accept letters of support from the Chairs of sub-groups of the NCRI Haematological Oncology Group and the NCRI Lymphoma Group. Where the Chair of a subgroup is also the Chief Investigator, then a letter of support will be required from the Chair of the parent group.

Finance and Costs

Our expectation is that the budget requested from Blood Cancer UK for an Early Phase Clinical Trial Grant will not exceed a total of £400,000.
The following **directly incurred research costs** can be requested in your grant application:
Salary costs for staff working on the grant: Costs for full or part-time staff to be employed on the grant on a fixed-term contract can be requested. Eligible CTU costs can include funding for posts required for delivery of the study but are not part of the core CTU infrastructure, unless there is strong justification. Salary costs may be used to fund salary, the employer's national insurance contribution, and an employer's pension contribution which will not be higher than the rate used by the University Superannuation Scheme (USS) or NHS pension scheme. Organisation salary scales must also be provided with your application for all the posts requested.
Within the online application form, insert the relevant salary figures where prompted in the salary budget table: basic salary, NI, Superannuation, London allowance (if applicable) and inflation.

Grant Tracker will add these costs up and insert a total figure. Please show the percentage figure used for the inflation addition and for the FTE in the relevant boxes. If your costing tool automatically adds inflation to the basic salary amount then add 0 to the inflation box, but please show the percentage figure used in your calculations in the relevant box.

Equipment: We assume that there is a basic level of equipment provision by the host institution. Applicants can include small item(s) of essential equipment (costing less than £25,000 in total) which are needed for the proposed research.

Items of equipment greater than £5,000 must include a written estimate of cost. Written confirmation is also required if an item of equipment is to be co-funded by the host institution. The equipment must not be disposed of during the period of the grant without Blood Cancer UK's prior written approval.

Blood Cancer UK does not provide funds for computers and/or software unless essential to the proposed research. A justification must be provided if computers and/or software are costed. The cost for a computer must not exceed £700. The cost for specific software must also be included.

Access charges for use of specialist equipment can be applied for. A breakdown must be provided.

Recurrent costs: Research consumables directly attributable to the study, including the costs of data collection and analysis and other activities undertaken specifically to answer the research questions (see AcoRD guidance Annex A for eligible research costs, which include MHRA fees, HRA assessment, sending samples for storage and biobanking to a central laboratory). Costs for travel to conferences and patient involvement can also be requested, as detailed below.

Travel: Travel for conferences to present research outputs directly from the award is an allowable cost for the staff member(s) employed on the grant. Costs include standard travel, accommodation and conference fees. The maximum allowance is £750 per year (pro rata). For example, for a five-year award, the maximum allowance would be £3,750 and can be spread over the grant years. Travel costs for conferences must be a separate budget line in the recurrent costs section. Blood Cancer UK grant holders are expected to acknowledge Blood Cancer UK in all presentations and/or posters. In order to access the travel budget, grant holders must inform Blood Cancer UK prior to attending the conference and provide a copy of the accepted abstract.

Patient Involvement costs: For patient involvement representatives sitting on steering groups or advisory boards specifically relating to the funded research, reasonable travel and subsistence costs, as well as fees or honoraria can be requested where applicable and fully justified.

Fees or honoraria should be no greater than:

- £150 per day (where more than 4 hours is contributed);
- £75 per half day (where between 2-4 hours is contributed);
- £50 for up to 2 hours, or

- where the patient involvement representative is sitting on a committee which includes other professional experts who are offered an honorarium, an amount equal to the honorarium offered to those other professional experts.

Please refer to the NIHR INVOLVE policy on payments and expenses for members of the public for guidance.

Ineligible Costs

- Costs relating to staff recruitment and relocation costs;
- Apprenticeship levy;
- PhD student tuition fees;
- Personal license fees;
- Funding to provide maintenance and/or insurance of equipment;
- Office stationery costs unless required for the project and justified accordingly,
- Indemnity insurance;
- Training courses.

We will **not** fund directly allocated costs or indirect costs, including:

- Directly-allocated costs – shared costs, based on estimates and do not represent actual costs on a project-by-project basis, such as: o Investigators: the time spent by the Principal Investigator, Co-Applicants and Co-Investigators
    - Estates
    - o Shared resources, such as administrative and clerical staff and equipment

- Indirect costs – necessary for underpinning research but cannot be allocated to individual projects, and cover computing and information support, central services, general maintenance and other infrastructure costs.

Publications: Publication costs are not eligible to be included as a cost in your application. Blood Cancer UK is a partner in the Charities Open Access Fund (COAF) and open access costs (article processing charges) should be applied for from the COAF university block grant. If the university is not an eligible institution or has used the block grant, grant holders can request from Blood Cancer UK that grant underspend is used to cover the cost.
Justification for resources requested: Applicants must justify all aspects of funding requested for each budget heading (i.e. staff, recurrent costs, equipment, patient involvement). For staff costs requested, it is important to outline their responsibilities and how their role relates to the objectives and timelines of the research study.

NHS Costs

Details of NHS Costs: Outline the NHS cost implications for this trial and provide a summary of the estimated costs and your plans for seeking support for any Excess Treatment Costs.

Confirm that you are in the process of completing a 'Schedule of Events Cost Attribution Tool (SoECAT)' form as per the guidance below. (1000 words max.) **A completed SoECAT form signed by an AcoRD specialist, must be sent to the Blood Cancer UK Research Team (research@bloodcancer.org.uk), no later than one month before your application is reviewed by the Clinical Trials Committee.**

Guidance on NHS costs

The costs of non-commercial research are met by different funders depending on the type of cost. Guidance from the DoH and Social Care for the Attribution of Costs for Research and Development(AcoRD)sets out the principles for determining who pays for the different costs. Please refer to this guidance before completing the finance and costs section of your application to Blood Cancer UK.

As Blood Cancer UK is a member of the Association of Medical Research Charities (AMRC),Blood Cancer UK will **only** fund the costs for activities attributed to the **Research Part A Costs** category, in line with the Department of Health (DoH) AcoRD GUIDELINES .

The following costs should **NOT** be included in the budget requested from Blood Cancer UK in your application:

- Research Part B Costs (the NHS pays these costs where the funder is an AMRC Member);
- Service Support Costs;
- Treatment Costs;
- Excess Treatment Costs (ETCs).

NHS Service Support Costs should be funded via the Clinical Research Networks. NHS Treatment Costs, including any ETCs/Savings, will be met by the NHS through normal patient care commissioning arrangements. Further background information and links to resources are provided below:

Excess Treatment Costs (ETCs)

ETCs occur when treatment costs (the patient care costs) in a research study are greater than in routine care. For example, a patient taking part in research maybe given a new drug to see how it performs in comparison with the standard drug given to the non-research patients. If the cost of the new drug being tested in the study is more than the one usually prescribed, then it is an 'excess treatment cost', as it would not occur in standard care. For non-commercial research studies, these costs are the responsibility of the NHS.

NHS England, with the NIHR and HRA, want to improve the management of these costs and thereby, through a more rapid, consistent and standardised approach, cut delays, maximise patient recruitment and make administration simpler than previously. In line with that, NHS England has implemented a new national ETC process. The ETC process is managed by the NIHR Local Clinical Research Networks (LCRNs), on behalf of their local Clinical

Commissioning Groups (CCGs), and in collaboration with NHS England's Specialised Commissioning function. This will create a single point of access for all proposals for which ETCs may be applicable and is designed to make the process simpler for researchers to navigate. As part of this process, researchers will be required to complete a SoECAT form for clinical research. To ensure HRA approval and NIHR portfolio adoption, a completed SoECAT form must first be approved and signed by an AcoRD specialist – for further details see the next section.
See the NIHR guidance on ETCs for further information about ETCs and the way they are paid. For queries and assistance with ETC payments, please contact the NIHR's helpdesk: (etc.helpdesk@nihr.ac.uk).

Schedule of Events Costs Attribution Template (SoECAT)

Researchers applying for clinical research grants need to complete a SoECAT to be eligible for the NIHR Clinical Research Network portfolio and to access the appropriate funding support for the study.
The SoECAT is a spreadsheet tool that helps to keep track and calculates the different activities and costs associated with clinical research in a standardised way. Please follow the NIHR SoECAT guidance and ensure you have downloaded the correct version of the SoECAT tool .
You must submit a completed SoECAT form with your Blood Cancer UK grant application:

- if you are applying for funding for clinical research;
- if you will carry out your research in England;
- if your research requires HRA approval;
- if your research will use NHS England resources;
- even if your clinical research does not involve ETCs.

NIHR AcoRD specialists work with researchers, R&D support and/or CTUs, to confirm that the attribution of costs is accurate before submission to the HRA and funding bodies. They can also signpost to resources and training to understand the principles of AcoRD, provide tailored advice, help to resolve queries and validate the attribution of costs.
Please note that the AcoRD specialists cannot be held accountable for any delays for late submissions to funding bodies. If you need support from an AcoRD specialist in your region on how to correctly identify and attribute relevant activities, please contact your LCRN representative at early stage in the development of your application. Other sources of assistance and support are the NIHR Early Contact and Engagement team or the NIHR Study Support Helpdesk supportmystudy@nihr.ac.uk .

Support from other sources

Support from other sources: Confirm whether funding and/or support from other organisations is required to deliver the trial. Provide details and confirm if funding and/or support is already in place or being applied for.

Letter(s) of support from industry partner(s): If your application includes any collaboration with an industry partner (for example the provision of free drug, equipment, or of an educational grant), we strongly recommend that you provide a letter demonstrating support for the proposed study, and confirming any contribution made.

Main applicant

The main applicant is the Chief Investigator (CI) for the research proposal. The CI has overall responsibility for the delivery and reporting of the grant. The CI should be a tenured academic, scientist or clinician at an eligible institution. Applicants who hold time-limited posts should state the duration of the appointment. The CI must ensure that the terms and conditions of the award are met. For new Blood Cancer UK Grant Tracker users, details on how to register are here.
The pre-populated details are those we have stored for you. Please ensure that they are accurate. To amend them, save and close the application and visit the 'Manage My Details' section.

Main applicant's CV

The pre-populated details are those we have stored for you. Please ensure that they are accurate. To amend them, save and close the application and visit the 'Manage My Details' section.

Grants

In the last five years, please list all the grants awarded to the Main Applicant/CI that were not awarded by Blood Cancer UK and grants that were awarded by Blood Cancer UK.

Co-applicants

A co-applicant is an investigator who will contribute equal time and intellectual input to the project as the Main Applicant, and who will have equal status on the grant.
Add details of all co-applicants who will be involved with the project. You will be able to select individuals who already have a Grant Tracker account with us. Individuals who do not have an account with us will be asked to register and will be sent details via an automated email.

Co-investigator

A co-investigator is an investigator who will provide significant intellectual input, as well as overseeing some aspects of the experimental work.
If the co-investigator you are adding is also going to be paid from the grant, then please tick the 'staff member' box. This will automatically add their name(s) into the staff section on the finance pages.

Collaborators

A collaborator is an investigator who may provide reagents, advice or access to research materials, but won't be directly involved in the day-to-day work. A letter of support, stating

their involvement and commitment to the project, must be attached where indicated. This page will display all of the collaborators added for this grant.
Please note, collaborators added on this page will be provided with details on how to access the system to view the application PDF. They will not however have access to edit the application form.

Governance and Monitoring

Ethical Approval: Ethical approval must be sought from the appropriate NHS research ethics committees and other regulatory committees as required, for all Blood Cancer UK-funded research involving human participants, biological samples or personal data. Please state when the application will be submitted to the appropriate ethics committees for approval. Ethical approval must be obtained prior to the start of a successful grant and Blood Cancer UK notified of approval. If ethical approval has already been obtained at the time of submission, please attach the final letter of approval from the Research Ethics Committee with your application. The administering organisation must ensure that ethical approval is in place at all relevant times during the research study. For research carried out at multiple sites, ethics committee approval must cover each site.
The Medicines for Human Use (Clinical Trials) Regulations: Confirm that the study is covered by The Medicines for Human Use (Clinical Trials) Regulations in the UK.
Trial registration: Confirm that the trial will be registered on the International Standard Randomised Controlled Trial Number Register (ISRCTN), ClinicalTrials.gov, or another register listed on the WHO International Clinical Trial Registry Platform (ICTRP).
Membership of Trial Steering Committee and the Data Monitoring and Ethics Committee: List the proposed membership of both committees.
Patentable or commercially exploitable results: If appropriate, please provide information on the Intellectual Property (IP) potential of your research, if there is any existing IP associated with your research study and how this will be managed.
IP is defined as patents, copyright, trademarks, trade names, service marks, domain names copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them.
Where appropriate, explain how you will engage with your Technology Transfer/Enterprise Office. (500 words max.)
Data sharing: Outline your proposed data sharing plan. Blood Cancer UK expects valuable data, reagents and software arising from Blood Cancer UK-funded research to be made available to the scientific community with as few restrictions as possible so as to maximise the value of the research and for eventual patient and public benefit. Such data must be shared in a timely and responsible manner, making use of online open repositories, public databases and community-led reagent stores.

Conflicts of Interest: Describe any conflicts of interest which might affect your ability to carry out the proposed research and/or to share or commercialise the research outputs. Please consider the following in your response: Does anyone involved in your research proposal hold any consultancies, advisory roles, or equities in, or directorships of, companies or other organisations that might have an interest in the results of your proposed research? Confirm in each case whether the conflict has been disclosed to your organisation.

Related applications

Currently Submitted Elsewhere: If this application is currently being submitted elsewhere, please add the organisation and date of decision.
Previously Submitted Elsewhere: If this application been submitted elsewhere in the past year, list the organisation and result of the submission.

Additional documents to provide with your application

- A Gantt chart with realistic key milestones and dates for the study;
- A graph showing patient recruitment numbers and timelines;
- Draft or finalised Patient Information and Consent forms (if available at the time of submission);
- Letters of support from collaborators and industry partners, if relevant for the study;
- A letter of support from the Chair of the relevant NCRI group or sub-group;
- A letter confirming Research Ethics Committee approval (if available at the time of submission);
- Organisation salary scales for the posts requested;
- If appropriate, written cost estimates for equipment;
- A completed SoECAT must be submitted before your application is reviewed by our Clinical Trials Committee (refer to the NHS costs section of this guidance for further information).

Attachment Summary

Attachments requested and uploaded to your application will also be saved in a separate zipped file and referenced in the application form on the 'Attachments' page.

Administrators

The pre-award administrator role is for someone in addition to the Head of Research Office equivalent or the CI, to help with input of aspects of the application, e.g. finances or text. They will not be able to validate or submit the application (that can only be done by the CI) and their role is only relevant during the pre-submission stage. The individual to be the pre-award administrator should register with Grant Tracker.

Signatories

Please add the details of the signatories required to sign-off the application. The Head of Department and Finance Officer details should be completed. Once the application has been submitted, the signatories will be asked to approve the application online. A workflow diagram can be found here.

Major Disease Area Classifications

Please select one classification from the list. This will help Blood Cancer UK categorise the applications we receive.

Focus Classifications

Please select one classification from the list. This will help Blood Cancer UK categorise the applications we receive.

CSO Classifications

Please select up to four classifications from the list. This will help Blood Cancer UK categorise the applications we receive.

End

You have now completed the application form. Please save and close if you need to work on the application at a later date.
To submit your application, please click 'validate' then 'save' and 'close'. If you are sure you are happy with the application form, then click 'submit'.

Once you have submitted your application, an automated email will be sent firstly to your Finance Officer. Once they have approved the application, a second email will be sent to your Head of Department. It is only upon your Head of Department's approval that the application is finally submitted to Blood Cancer UK. This must be completed by the deadline. You will receive an automated email containing an acknowledgement that we have received your application.