CLINICAL TRIAL ROUND

Paediatric Clinical Trial Application Guidance Notes

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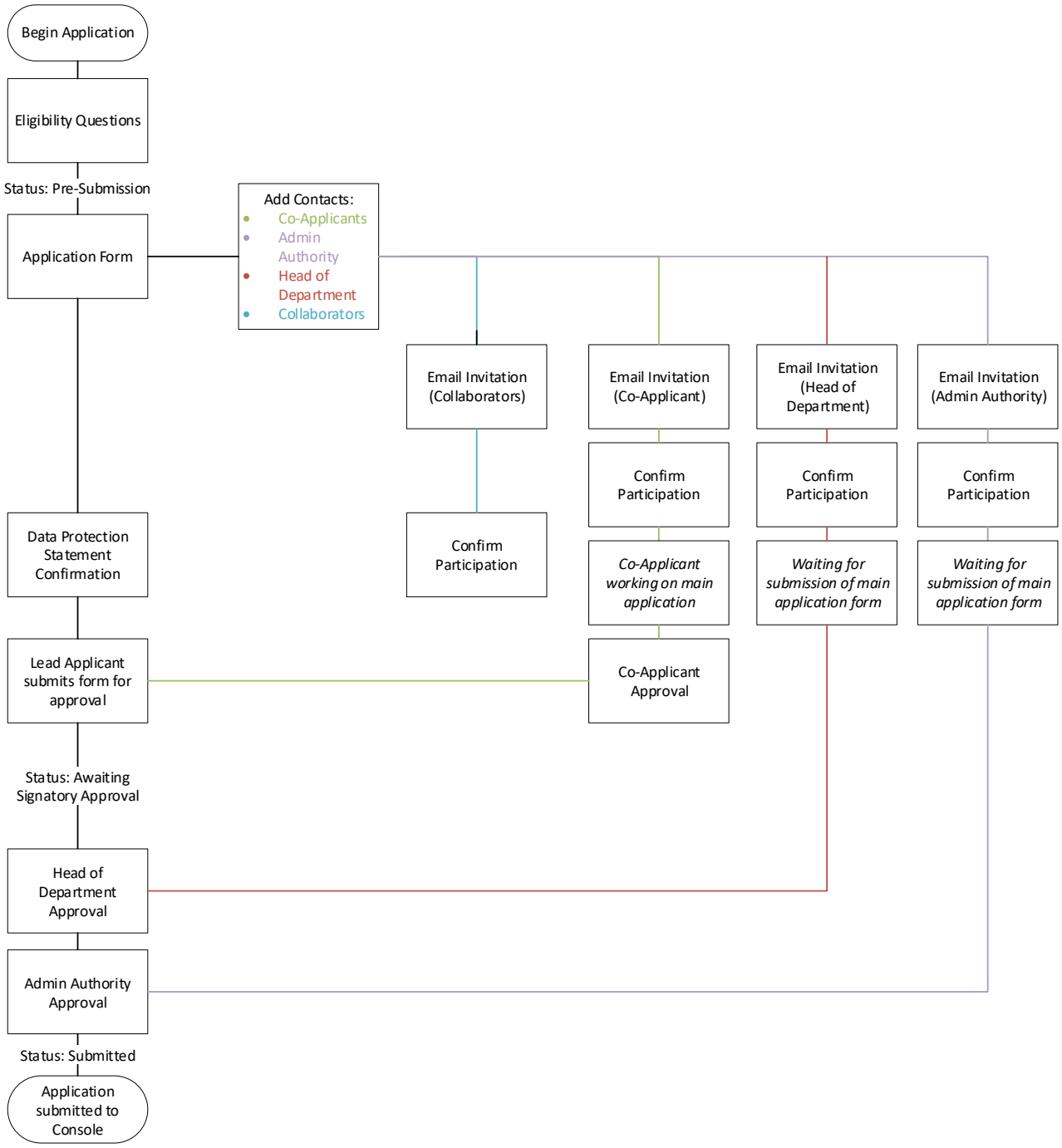
Introduction

- This call has been established to support a molecularly stratified Phase II multicentre, multi-arm adaptive trial, with the ability to accommodate rapid inclusion of novel interventional arms as they become available.
- The trial must be restricted to paediatric high grade glioma.
- The trial should be open to children, teenagers and young adults less than 25 years of age.
- Guidance notes and eligibility criteria are available on our website.
- Please read our **Grant Conditions**, **Finance Guidelines**, and **Data Protection Statement** before applying for funding.
- All applications must have input from those affected by brain tumours as early as possible. To facilitate this you may choose to engage The Charity's Involvement Network (IN), a network of people who either care for someone who has a brain tumour (or has done in the past) or are living with a brain tumour themselves. More information on the IN and how to contact them can be found at **thebraintumourcharity.org/PPI**
- If you have any queries or would like to discuss your application, please do get in touch with us:

    - E-mail: research@thebraintumourcharity.org
    - Phone: +44 (0) 1252 418190

Application Submission Workflow

All contacts added to this application will be sent an email asking them to confirm their participation and approve the application. Your application will not be fully submitted until all contacts have confirmed their involvement AND approved the application. Please see workflow below for more information.



Beginning Your Application

Please read through the introduction and system guidance and, when you are ready, click 'next' to start completing your application.

Application Summary

Title of Project	
Total amount requested (£)	This will be automatically populated as you complete the budget section
Proposed start date	
Duration of project (months)	

Applicant Details

- The Lead Applicant must have an employment contract with their institution that exceeds the duration of the proposed research.
- Please note, all Co-Applicants will have access to edit this application, and Collaborators will have read only access.
- Only the Lead Applicant can submit a grant application.

Lead Applicant

Some of your details will have been pulled through from your CV and any remaining fields should be completed. Please add/amend basic information details in the "Manage My Details" section of the Grant Management Portal.

In addition to the basic contact details please add your Twitter handle. This can be added in the 'Web page' field.

A biographical sketch is required for the Lead Applicant. Please download the template from the application form and attach the completed version using the **Attach** button.

The Lead Applicant's institution will be the Host Institution.

Please note:

- All financial awards will be made in Pounds Sterling (£). It will be the responsibility of the Host Institution to make conversions to other currencies.
- The Charity is not responsible for any fluctuations in exchange rate over the course of the programme. We recommend that the Host Institution establishes a corporate exchange rate agreement if conversion to other currencies is required.

Co-Applicants

Please add the details of the co-applicants. Use the 'Add Contact' button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address. They will receive an email, prompting them to set up a Portal account.

The co-applicants will be required to accept their involvement in the application prior to submission. They also need to ensure all their details are populated correctly and use the “Manage My Details” section of the Grant Management Portal to add/ amend their basic information.

Co-applicants are those individuals with responsibility for the day to day management and delivery of the project. Co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery. Collaborators normally provide specific expertise on particular aspects of the project but who do not share in the responsibility for the delivery of the project.

A biographical sketch is required for each co-applicant. Please download the template from the application form and attach the completed version using the **Attach** button.

Time spent on research

Please include the hours the Lead Applicant, Co-Lead Applicant and Co-applicants will spend on research per week and how much time they will spend on this specific research project per week.

This is not required for Collaborators.

Collaborators

Please use the ‘Add Contact’ button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address. They will receive an email, prompting them to set up a Portal account.

Please upload a letter of collaboration for each Collaborator listed. Letters should be signed by the Collaborator named in the application, and include a brief summary of what they will contribute toward the project.

Head of Department and Senior Administrative Authority

Please provide the details of the Head of Department (HoD) and Senior Administrative Authority (SAA) from your Host Institution. Please use the ‘Add Contact’ button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address.

The HoD and SAA will be sent emails by the system once assigned to the application.

These authorities have two tasks during the submission of the application. Firstly, they will be required to tick a check box indicating they have read and understood the terms of the proposal and accept the role (HoD or SAA) they have been nominated for. Ticking this box constitutes an electronic signature for the application. Secondly, they will need to approve the final submission of the application. This occurs AFTER the Lead Applicant clicks “Submit”.

Please note that the Head of Department and Senior Administrative Authority must both approve the application in order for it to be submitted successfully.

Required attachments for this section:

- Biosketches for the Lead Applicant, Co-Lead Applicant (if applicable) and Co-applicants.
- Letters of collaboration from all named Collaborators.

Lay Section

This section of the application form must be completed in plain English, using non-technical language. The information should be comprehensible to people with no scientific background and abbreviations and acronyms should be avoided. Any unavoidable scientific terminology should be clearly explained.

This section of the application form will be reviewed by the Lay Scientific Advisory Board members as part of the assessment process. Do not include any confidential or sensitive information in this section as this section may be used to publicise the project if the application is successful.

Please note the lay section will be returned to you to be rewritten if it is not easily comprehensible and not written in plain English. You may find it helpful to refer to the AMRC's Guidance for Researchers - Writing Lay Summaries.

Please note The Brain Tumour Charity has established an Involvement Network (IN) which is a resource applicants can use to check readability of the lay section of the application. If you would like to learn more about Patient and Public Involvement or the IN and the help they can offer please see www.thebraintumourcharity.org/PPI

What is your research about? *(Up to 300 words)*

Please provide background details for the research, addressing the following questions:

- What problem are you trying to address?
- What is already known about the problem?
- How does this research aim to address the problem?
- What is innovative and novel about the proposed research?
- Why is this research important?
- How does it fit in the current research landscape?

Research methods? *(Up to 300 words)*

Please briefly describe the approaches and techniques you will use to answer the research question and address the aims of the programme.

How will this research benefit people affected by brain tumours? (Up to 300 words)

Please describe the potential benefit for people affected by brain tumours. Please include:

- How will this research (ultimately) benefit people affected by brain tumours?
- What are the further steps needed to achieve benefit?
- What is the likely timescale to achieve this benefit?
- Why is this step needed? What important information will this research provide?
- How could the findings from this research be developed and/or put into practice?

Please note that The Brain Tumour Charity funds research that will ultimately offer benefits to people affected by brain tumours. It is therefore important that all applicants consider how their research proposal could lead to patient benefit and what the steps will be on the route to achieving benefit.

Patient and Public Involvement? (Up to 300 words)

Please outline how people affected by brain tumours will be involved in the research. As a minimum this should include:

- How people affected by brain tumours have been involved in the development of this proposal

- How people affected by brain tumours will be involved in the dissemination of results
- How the findings from the research will be communicated with the general public

Summary of Proposed Research

Scientific Summary

Please provide a summary of the proposed research suitable for a scientifically qualified assessor. Please note this summary will not be published and may contain confidential information.

Keywords and Categorisation

Please select the keywords which best describe your research. In particular, please tick whether the research will focus on high grade or low grade brain tumours, and whether it focuses on adult or paediatric tumours.

Research Proposal

Detailed Research Proposal

Please attach a detailed research proposal as a PDF file (up to 10 pages, minimum size 10 font with single spacing) using the **Attach** button. This should include:

- The research question to be addressed and the scientific rationale.
- Describe the patient population who will be able to access the trial, including detailed inclusion and exclusion criteria.
- Detailed information on the trial design, methodology, analyses and management, including:
    - Setting – where will the study take place? How many centres will be involved? Will there be a Lead Site?
    - Patient recruitment – details of the recruitment plan with a graph of projected recruitment for the duration of the trial and justification for this estimate.
    - Treatment – describe the proposed treatment and regimen.
    - Control – please describe the control/ comparator and explain the differences between the control and treatment pathways in the trial.
    - Follow up – please describe the follow up for participants within the trial.
    - Sample size – state the sample size and provide details of the estimated effect size and power. Please include any power calculations and relevant data. Ideally, the reviewers should be able to replicate the calculations based on the information provided within the application form.
    - Outcomes – please identify the primary and secondary outcome measures. Please describe how these will be collected, the time points for collection and justify the choice of measures.
    - Plans for monitoring safety and efficacy throughout the trial.
    - Results – statistical analysis plan including any plans for interim analysis.
- Risks and contingency plans – please describe any challenges you anticipate the trial may encounter and your contingency plans should they occur.
- Relevant figures, including a schema/ flowchart showing the study design and flow of participants and a graph showing the projected recruitment.

Please provide the citations for your research proposal in a separate document (APA or CSE format please).

Key Questions

Competing Trials *(up to 300 words)*

Please provide details of any competing trials in this space, including:

- Trials competing for the same patient population
- Any similar paediatric trials that are ongoing or may be underway shortly

Please explain how competing trials may impact on the proposed research and how competing demands on the patient population will be managed.

Team members and resources *(up to 500 words)*

Please describe:

- The work which will be undertaken by each team member involved in the project (the list should include the Lead Applicant, Co-Applicants and all employees working on the project). Please provide details of the relevant experience each team member will bring to their role
- The nature and benefits of the collaborations in place
- How the research will be co-ordinated across participating institutions, including details of how all team members and centres will be kept up to date with ongoing progress, if applicable.

Contingency Plans *(up to 300 words)*

Outline any areas where problems may arise and provide details of how such problems may be overcome, including any potential problems which may prevent you from reaching a milestone.

Dissemination and Future Implementation *(up to 300 words)*

Please describe:

- How you will disseminate research results to both a scientific audience and to the general public
- How will you work with the NHS and regulatory bodies to promote the trial?
- What considerations have been given to future implementation, including health economics and requirements to for adoption into guidance? Please describe any steps that will need to be taken following completion of the trial

Working with The Brain Tumour Charity *(up to 200 words)*

Please describe how you have worked with The Charity previously and how you plan to work with The Charity promote the research during the project and to aid dissemination.

Research Infrastructure and Governance Arrangements *(up to 500 words)*

The Charity expects the trial to take advantage of available clinical research infrastructure and to ensure strong governance arrangements are in place to ensure the robustness of the trial.

Please describe how the trial has been developed with input from independent experts, how it will utilise the available infrastructure and what governance arrangements will be in place. These should include, but are not limited to:

- NCRI Clinical Studies Group (CSG) – describe any interaction and feedback from the NCRI CSG.

- BRAIN MATRIX – how will the trial work within the existing infrastructure for brain tumour clinical research?
- Clinical Research Network (CRN) – describe any interaction with the CRN and Cancer Network Leads to date.
- Trial Steering Committee (TSC) – identify the members of the TSC, including independent experts and PPI.
- Data Monitoring Committee (DMC) – identify the members of the DMC.

Equity, Diversity and Inclusion *(up to 300 words)*

The Charity is committed to ensuring our research funding practices are inclusive. Please could you outline any steps your Host Institution is taking to improve its EDI practices. This can include specific initiatives and schemes, training or the overall approach to ensuring equal opportunities.

In addition, please describe any steps that have been taken to ensure the trial is inclusive.

Milestones

Please complete the table detailing the key milestones for the each year of the trial, including estimated month of delivery.

Please attach a detailed Gantt chart for the proposed research, referring to the milestones detailed above, using **Attach** .

Budget

Please note that only directly incurred costs can be requested. Costs should be calculated in line with the Department of Health and Social Care's Guidance on Attributing the Costs of Health and Social Care Research and Development **(AcoRD)**.

As an AMRC member charity, The Charity will cover costs identified in Part A of the AcoRD guidelines. Costs identified in Part B will be covered by the Department of Health and Social Care through the NIHR CRN.

The per participant research costs, as defined in Part A, should be included as Miscellaneous costs in the budget breakdown below. Please include the per participant costs per year within the budget and provide a clear breakdown and description of these costs in the justification section.

Please refer to our **Finance Guidelines** before completing this section and provide all amounts in Pound Sterling (£). All amounts should be rounded to the nearest whole pound. If no costs are required for a specific budget category (e.g. animals) please state 'NA' in the justification section.

Salaries

For each staff member, please include:

- Staff name (if known)
- Role
- Period on grant (total months)
- % of full time
- Total salary costs per year

Materials and consumables

For each item, please include total costs per year.

Animals

If applicable, for each item, please include total costs per year.

Travel

For each item, please include total costs per year. Please ensure that the requested travel costs are in accordance with our financial guidelines.

Miscellaneous

For each item, please include total costs per year.

Please use this section to detail the per participant research costs (e.g. costs for randomisation, patient assessments for research purposes, follow up etc.).

NHS Support and Treatment Costs

NHS Support and Treatment Costs should be calculated in line with the **AcoRD** guidelines. These costs will not be covered by The Brain Tumour Charity but will be awarded by the NIHR CRN.

These costs are now attributed using the Schedule of Events Cost Attribution Tool (SoECAT) form. The totals for NHS Support and Treatment Costs are calculated using this tool. The form should be completed with the Local CRN and an AcoRD specialist will be able to sign off the form to verify the costs have been attributed correctly.

Please enter the total NHS Support Costs and the total NHS Excess Treatment Costs (ETCs) for the duration of the research. The form will calculate the total NHS costs.

Please attach the Schedule of Events Costs Attribution Tool (SoECAT) form using Attach Document Attached View or Delete . The form should be completed with support from the local CRN and signed off by an AcoRD specialist. If a complete form is not ready to be submitted with the application form, it will be required for review before an award can be confirmed.

Indirect and Leveraged Costs of Research

The Brain Tumour Charity monitors the indirect cost of the research we support. Unlike some other funding bodies, such as the research councils, AMRC member charities will not fund the indirect costs of research, or a proportion of these. The figures provided should include the standard indexation rate used by the institution to calculate indirect costs.

The Charity will only cover the direct costs included in the budget breakdown. Acceptance of a grant, if awarded, will imply that the institution is prepared to meet the full economic costs from its own sources of funding.

Indirect Costs of Research

Please provide an estimate of the total indirect costs for the research. This should include the Principal Investigators salary, estate costs and other indirect costs of research, such as administration costs, library expenses and utility charges.

Please briefly outline the costs that have been included in the indirect costs of research total.

Leveraged Funding and Resources

Please provide an estimate of the total leveraged funding or support available for the trial. If no funding is provided please enter 0 for the total leveraged funding and resources amount.

Please describe what the funding or resources in kind are, when they'll be made available and any requirements for access to this support. Where funding or support has been given to cover parts of the research proposal please explain how this will complement The Brain Tumour Charity award.

Current Funding

Please list existing and pending research funding for the Lead Applicant and all Co-Applicants. Please include:

- Status
- Team member
- Funding source
- Project title
- Funding start date
- Finding end date
- Total amount

Assurances

Commercial Exploitation and Competing Interests

- Do any of the Applicants have consultancies, or any equity holdings in, or directorships of, companies or other organisations that might have an interest in the results of the proposed research? If yes, please give brief details.
- Will the proposed research use technology, materials or other invention that, as far as you are aware, are subject to any patents or other form of intellectual property protection? If yes, please give brief details.
- Please outline any licences or rights to access the above technology, material or intervention that are in place or will be obtained prior to commencing the research.
- Is the proposed research, in whole or in part, subject to any agreements with commercial, academic or other organisations? If yes, please give brief details.
- Is the proposed research likely to lead to any patentable or commercially exploitable results? If yes, please give brief details, including the IP management arrangements.

Ethical and Legal Requirements

- Please provide the details of the trial sponsor.
- Does your proposal involve human subjects? If yes, please provide details in regards to the Ethics Committee approval, and approved or pending date.
- Does your proposal involve vertebrate animals? If yes, please give status of relevant approval, and approved or pending date.
    - If yes, please detail the animal species being used, why the species/model is most appropriate and whether there are any alternatives approaches that could be used instead.
    - If yes, please justify the number of animals to be used per experiment, including details of any sample size calculations and/or statistical advice sought.

- If yes, please select the severity of the procedures being used and describe how they have been optimised to reduce discomfort of the animals being used: Mild / Moderate / Severe.

Evidence of ethics approval, personal and project licences should be uploaded as attachments.

Additional Information

Summary of Required Attachments:

- Lead Applicant and Co-Applicant Biosketches
- Letters of collaboration for all listed collaborators
- Detailed research proposal
- Gantt chart
- Ethics approval, personal and project licences
- Letters of support

Please ensure you have uploaded the required attachments.

Confirmation

The Lead Applicant, Co-Applicants, Administrative Authority and Head of Department will need to confirm that they have read and understood The Brain Tumour Charity Data Protection Statement and other undertakings as detailed below:

Information that you supply to The Brain Tumour Charity in connection with this application (which includes all information sent to The Charity that relates to your grant application including personal data) will be used to process and administer your application and for the purpose of audit, statistical analysis, administration and/or evaluation. It will be disclosed to external peer reviewers, some of whom may be based outside the EU/EEA, and may be shared with co-funders or other potential funders. All parties with whom this information is shared will be required to keep it securely and in confidence and we have safeguards in place to ensure secure transfer of any data. The Brain Tumour Charity may publish basic details of successful grant applications (e.g. on its website or in its Annual Report). The Brain Tumour Charity may also release details of successful applications (including your name and employing institution, the programme title and the summary of proposal for scientifically qualified assessors and lay summaries of the research) into the public domain (e.g. via the internet or publicly accessible databases). The Brain Tumour Charity may contact you about the work of The Charity and other award schemes and initiatives that may be of interest to you, or for your views on its funding schemes and application processes. If you would prefer not to receive further communications please let us know. The information you provide will be held on our secure database and in accordance with all data protection legislation and our **privacy policy.**

- I confirm that I (and all those providing personal information in the application) have read and understood The Brain Tumour Charity's Data Protection statement above.
- I confirm that I have read, understood and accept the The Brain Tumour Charity's **Grant Conditions**
- I have read and approve the completed application form. If granted, the work will be accommodated and administered in the department/institution in accordance with the grant conditions. I also

confirm that there are no existing matters which would be a breach of any conditions which have not been brought to your attention in writing.

- I understand that the provision of any false or inaccurate information in this application would be considered very seriously and may result in disqualification of the application. To the best of my knowledge, the information provided in this application is accurate and complete.