Cannabinoid Clinical Trial Application Guidance Notes

Contents

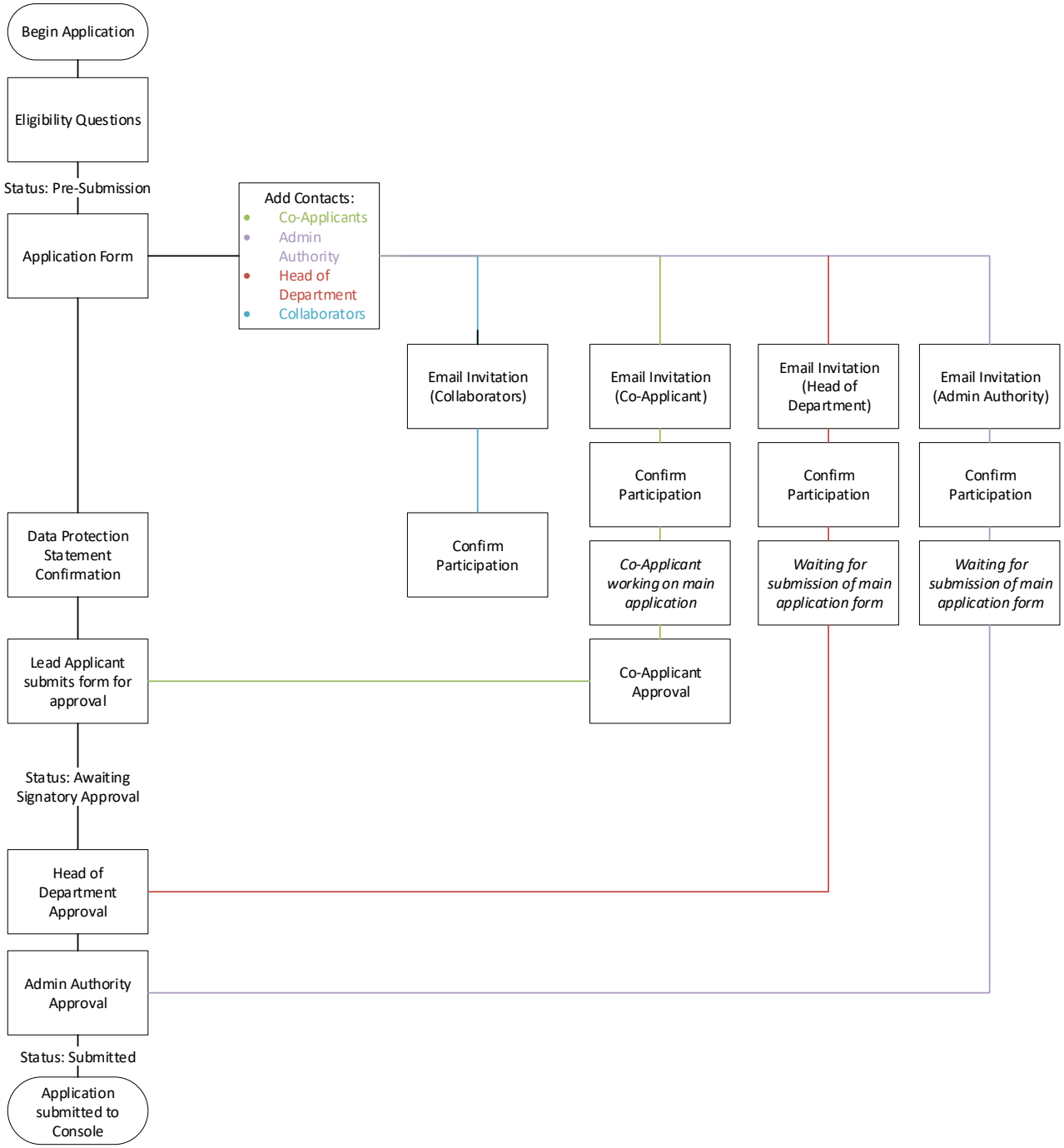
Introduction

- This call has been established to study the clinical efficacy of cannabinoids in the treatment of high-grade glioma tumour types.
- Applications must comprise a Phase II or Phase III multi-centre double-blind placebo controlled trial utilising the Tessa Jowell BRAIN MATRIX infrastructure.
- Funding of up to £450,000 per project for up to three years can be requested.
- Please read The Brain Tumour Charity's **Grant Conditions**, **Finance Guidelines** and **Data Protection Statement** before completing this application.
- 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 Research Involvement Network (RIN), a network of people who either care for someone who has a brain tumour (or have done in the past) or are living with a brain tumour themselves. More information on the RIN and how to contact them can be found at **https://www.thebraintumourcharity.org/funding-for-brain-tumour-researchers/patient-public-involvement/**
- 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

Please add/amend basic information details in the "Manage My Details" section of the Portal.

Please include:

- Full name (including title)
- Institution
- Position
- Department
- Address
- Telephone number
- Email address
- Twitter handle (if applicable) – please note this is included as the 'Web address' in the application form
- Affiliated institutions (if applicable)
- Expertise

Co-Applicants & Collaborators

Please search for contacts within our database. If the person you searched for was not found, please add this person to our system. They will receive an email, prompting them to set up a Portal account.

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 do not share in the responsibility for the delivery of the project.

Time spent on research

For the Lead Applicant and all Co-Applicants, please include:

- Time spent on research (hours/week)
- Time spent on this research project (hours/week)

This is not required for Collaborators.

Head of Department

Please provide details of the Head of Department from your host institution.

If the Lead Applicant is also the Head of Department, please include their next superior in the Head of Department role for this application.

Administrative Authority

Please provide details of the Senior Administrative Authority (e.g. finance manager, senior contract manager or senior administrative officer) from your host institution. This institution will be responsible for the financial administration for any other participating institutes.

The Head of Department and Administrative Authority will be sent emails by the system once assigned to the application. They will be required to tick a check box indicating they have read and understood the terms of the proposal and accept the role they have been nominated for. Ticking this box constitutes an electronic signature for the application.

Please note that the Head of Department and Administrative Authority must both tick the checkbox to confirm their participation AND approve the application before the application can be submitted. The 'Submit' button will not become available until both steps are completed.

Required attachments:

- Lead Applicant & Co-Applicant Biosketches.
- Letters of collaboration for all collaborators. Letters should be signed by the collaborating organisation's named contact, and include a brief summary of what they will contribute towards the project.

Research Summary

Lay Summary *(up to 500 words)*

Please provide a summary of the research proposed in plain English, using non-technical language. The summary should be comprehensible to people with no scientific background and describe the full scope of the project. Define any unavoidable scientific terminology and avoid using unexplained abbreviations or acronyms. Note that this summary will be used by the Lay Scientific Advisory Board members as part of the assessment process. The summary should aim to address:

- The main aims of the trial
- Why this trial is needed and how it will benefit patients
- Methods – how the trial will be carried out, including projected timelines for recruitment and analysis
- Dissemination – how will the results be shared with different audiences?
- Public involvement – how will people affected by a brain tumour be involved in the research?

To learn more about Public Patient Involvement (PPI) and the help our Research Involvement Network (RIN) can offer, please see: **www.thebraintumourcharity.org/ppi.**

You may also find it helpful to refer to the AMRC's **Guidance for researchers - writing lay summaries.**

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.

Scientific Summary *(up to 300 words)*

Please provide a summary of the proposed research suitable for a scientifically qualified assessor.

Keywords and Categorisation

Please include all keywords that best describe your research, being as specific as possible. Click on the plus icon to select keywords.

Please then select the category/categories from the following that are relevant to the research:

- High-grade tumour(s)
- Low-grade tumours(s)
- Paediatric tumour(s)
- Adult tumour(s)

Research Proposal

Please attach a detailed research proposal (up to 10 pages, minimum size 10 font with single spacing). 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 and stop/go criteria for Phase III trial.

- 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

Patient and Public Involvement *(up to 300 words)*

Please outline how you plan to involve patients and the public in the research.

- Have people affected by brain tumours been involved in the development of the application?
- How will they be involved during the trial?
- Will you involve people affected by brain tumours and members of the public in dissemination?
- Please include examples of activities.

If you consulted The Brain Tumour Charity's Research Involvement Network (RIN), please describe any feedback received and the steps taken to address this.

Potential for patient benefit *(up to 300 words)*

Please explain how you expect the project to lead to benefit for people affected by brain tumours, in particular the patients in the UK health system and indicate the likely timescale. Please consider:

- How the proposal will lead to benefits for patients and outline the anticipated route to impact.
- The potential for clinical translation.
- Any other benefits expected from the proposed research and collaboration.

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 cannabinoid 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.

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

Please describe:

- How you will disseminate research results to a scientific audience?
- How will you disseminate research results to the general public?
- How will you work with the NHS and regulatory bodies to promote the trial?
- What consideration has been given to future implementation, including potential health economic analysis and requirements 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.

Leveraged Funding or Resources *(up to 300 words)*

Please outline if any other funding or support is available for the trial.

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.

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

Not applicable.

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.

Other Indirect Costs

Please provide a figure for the indirect cost of this research (e.g. estates, general consumables, research support services etc.).

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.
- 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.

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.