

# Clinical Biomarkers Application Guidance Notes



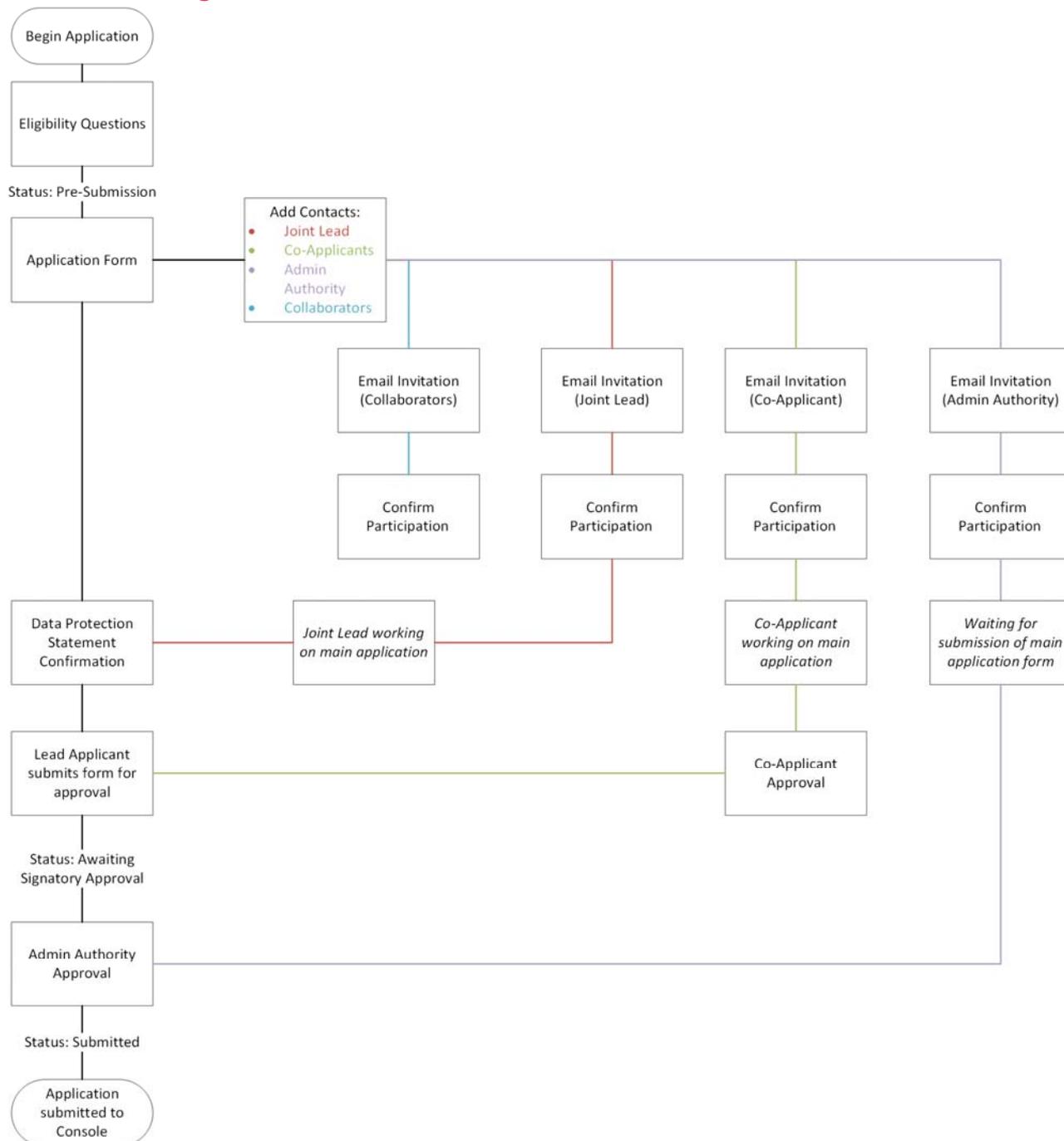
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## Introduction

- This scheme supports the identification, validation, and implementation of clinical biomarkers that will lead us to an early and accurate diagnosis, and/or inform the management of brain tumours.
- Funding of up to £100,000 per year for up to five 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 [thebraintumourcharity.org/PPI](http://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](mailto:research@thebraintumourcharity.org)
  - Phone: +44 (0) 1252 418190

## Workflow Diagram



## 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

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

### Lead Applicant & Joint 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
- Affiliated institutions if applicable
- Expertise

### Clinical Lead and Scientific Lead

Please indicate who is the Clinical Lead and the Scientific Lead on this application.

### 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.

### Time spent on research

For the Lead Applicants 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.

### Administrative Authorities

Please provide details of the Senior Administrative Authority from the institution you wish the financial award to be made to; this could be either the Clinical or Scientific Lead host institution. This institution will be responsible for financial administration for any other participating institutes.

## Required attachments:

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

## Research Summary

### Scientific Summary

Please provide a summary of the proposed research suitable for a scientifically qualified assessor. This should include details of the research's potential to bring us closer to an early and accurate diagnosis, and/or inform the management of brain tumours (*up to 500 words*).

### Lay Summary

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. Use the following sub-headings to structure the summary:

#### ***Aims and background***

- What is already known about the problem that the project will address?
- What do you hope to find out?

#### ***Why this research is needed***

- How the results of the research could benefit those affected by a brain tumour – be as specific as possible.
- How does the research offer value for money?

#### ***Methodology***

- Describe the methods and techniques you plan to use in your research.
- Detail how the research aims to identify / validate / implement clinical biomarkers into clinical use.

#### ***Patient and Public Involvement***

- Describe any involvement of those affected by a brain tumour, including engagement with our Research Involvement Network (RIN)\*
- Outline any plans to involve the RIN in the dissemination of results\*
- How can the findings from the research be developed or put into practice after completion of the project?

\*To learn more about Public Patient Involvement and the help our RIN can offer, please see:

[www.thebraintumourcharity.org/PPI](http://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 (*up to 500 words*).

## Keywords and Categorisation

Please include keywords that best describe your research, being as specific as possible.

Please select all categories 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 as a PDF file (up to 4 pages, minimum size 10 Arial font with single line spacing). This should include:

- Background and research question to be addressed.
- Aims and key deliverables.
- Methodology.
- Statistical analysis showing results will be significant and meaningful.
- Include justification for the number and types of samples to be collected/ used and evidence that they are fit for purpose.
- Detail how the research aims to identify / validate / implement clinical biomarkers.
- Relevant figures.

Please provide citations for your research proposal in full, including title of paper and all authors. Please note this is separate to the main research proposal and does not need to be included in the 4 pages.

## Key Questions

### **Relevance to research priorities (up to 300 words)**

Detail how the proposal addresses the research priorities outlined in our research strategy: [A Cure Can't Wait](#).

### **Research potential (up to 200 words)**

Outline how you expect the project to benefit people affected by brain tumours.

### **Research Pathway (up to 300 words)**

Outline the potential pathway to clinical or practical applications of the project, including how you might expect the findings to be taken up and funded by the NHS following The Charity's investment?

### **Team members (up to 500 words)**

Describe:

- The work that will be undertaken by each team member involved in the project (the list should include the Scientific and Clinical Leads, Co-Applicants and all employees working on the project).
- The nature and benefits of any collaboration that is in place, including details of any multidisciplinary approach, if applicable.
- How the research will be co-ordinated across participating institutions, including details of how all team members will be kept up to date with ongoing progress, if applicable.

### **Facilities and resources available to the team (up to 300 words)**

Outline the facilities and resources available to the team for the duration of the project. The use of infrastructure and/or samples, already in use for a funded trial, is strongly encouraged.

### **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 plans and working with The Brain Tumour Charity (up to 300 words)**

Describe:

- How you will disseminate research results to a scientific audience and the general public.
- How you will work with The Charity to promote the research during the project and after its completion date.

## **Milestones**

Please detail your key milestones for the entire duration of your research proposal and include an estimated timeframe at which milestones will be completed.

## **Gantt chart**

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

## **Budget**

Please note that only directly incurred costs can be requested. Please refer to our [Finance Guidelines](#) before completing this section.

Please provide all amounts in Pound Sterling (£).

## **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**

For each item, please include:

- Species and number of animals to be used
- Cost category (purchase cost or maintenance cost)
- 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.

## **Justification**

Please provide justification for all of the requested funds and include as much detail as possible.

## **Current Funding**

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

- Status
- Team member
- Funding source
- Project Title
- Funding start date
- Funding 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

- 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.
- Where applicable, 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.
- Where applicable, please justify the number of animals to be used per experiment, including details of any sample size calculations and/or statistical advice sought.
- Where applicable, 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

## Relevant publications

Please list the most relevant and recent publications relating to this research proposal, including any that are currently in press. Please include:

- Status
- Title
- Year
- PMID
- DOI
- Authors
- Journal

## Reviewer Suggestions (not mandatory)

Please provide the details of any suggested reviewers and/or non-preferred reviewers. If identifying non-preferred reviewers, please also include a brief explanation.

## Summary of Required Attachments:

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

## Confirmation

Lead Applicants, Co-Applicants and the Administrative Authority 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.