



Version 1.0 Jan 2024

Health and Care Research Wales Integrated Funding Scheme

Guidance Notes for Applicants

Stage 2 applications

Contents

1	Application Summary Information	4
	1.1 Host Organisation	4
	1.2 Application Title	4
	1.3 Research Type	4
	1.4 Start Date (Month & Year)	4
	1.5 Research Duration (months)	
	1.6 End Date	
	1.7 Total Funding Requested	4
	1.8 Previous Submission	
2	Research Team	5
	2.1 Details of Lead Applicant	
	2.1.1 Role in this project	
	2.1.2 %FTE Commitment	
	2.1.3 CV info	
	2.1.4 Are you an Early Career Researcher?	6
	2.2 Joint Lead Applicant	
	2.2.1 Role in this project	
	2.2.2 %FTE Commitment	6
	2.2.3 CV info	6
	2.3 Primary Co-applicant	7
	2.3.1 Role in this project	7
	2.3.2 %FTE Commitment	7
	2.3.3 CV info	
	2.4 Co-applicants	7
	2.4.1 Role in this project	
	2.4.2 %FTE Commitment	
	2.4.3 CV info	
	2.5 Public Research Partner Co-applicants	
	2.5.1 Role in this project	
	2.5.2 %FTE Commitment	
_	2.5.3 Experience	
3	Application Details	
	3.1 Scientific Abstract	9
	3.2 Plain English Summary	10
	3.3 Changes from previous stage	10
	3.4 Detailed Research Plan	11
	3.4.1 Background and rationale	
	3.4.2 Aims and objectives	
	3.4.3 Research plan and methods	
	3.4.4 Dissemination, outputs and anticipated impact	
	3.4.5 Roles and responsibilities and expertise of the research team	
	3.4.6 Project management	14

	3.4.7	7 Success criteria and barriers to proposed work	14
	3.4.8	Outline involvement of any Clinical Trials Unit (CTU) or other methodology	
	supp	oort / advice you have received	15
		P IP, commercialisation and adoption	
4	Puk	olic Research Partners Involvement and Engagement	15
4.		Management and Support	
4.	2	Public Research Partners Involvement Lead	16
4.	3	A summary of Public Research Partners' Involvement	16
5	Det	ailed budget	16
6	Jus	tification of costs	17
7	Ma	nagement and Governance	17
8	Pro	ject Coding	17
8.		UKCRC Research Activity Codes	
8.	2	UKCRC Health Categories	17
8.	3	Research Region	17
8.	4	Lead Applicant's Profession	17
8.	5	Lead Applicant's Place of Work	18
9	Upl	oad Checklist	18
10	Α	dministrative contact	18
11	S	ponsor contact	18
12	Α	cknowledgement And Conflicts	19
12	2.1	Potential Conflicts	
12	2.2	Agreement to Terms and Conditions	19
12	2.3	Privacy Notice	19

Guidance for Completing Stage 2 applications

1 Application Summary Information

1.1 Host Organisation

Provide details of the organisation who will be the contractor if the project is funded. The organisation or institution must be based in Wales. The lead applicant should be employed by the host organisation submitting the application or have an honorary contract. If you have any queries, please contact projectgrants@researchwales.info before submitting your application.

1.2 Application Title

Limit 300 characters

The study title should state clearly and concisely the proposed research. Any abbreviations should be spelled out in full. The title should also reflect the study research design.

1.3 Research Type

Select the appropriate research type. If your proposed study includes any element of primary research, please select 'Primary Research'. If you are carrying out a new analysis of existing data, select 'Secondary Research'. If you are not sure which category to select, please choose 'Other', and briefly specify the type of the research.

1.4 Start Date (Month & Year)

Note this should be from the 1st of the month regardless of whether this is a working day or not. Please be realistic about your possible start date taking account of the necessary contracting, and staff recruitment prior to starting your project. Applicants should note that applications for calls launched in September are required to start 1 October of the following year. Those successful through a March call launch are required to start 1 April of the following year.

1.5 Research Duration (months)

Ensure you include sufficient time to complete all aspects of the research including applications for regulatory approvals (where required) and the final report. This is up to a maximum of 24 months.

1.6 End Date

This field will automatically populate once you have entered the start date and research duration information.

1.7 Total Funding Requested

This will be automatically pulled through from the budget section in Stage 2 applications. To complete this section please follow supplementary finance guidance for applicants.

1.8 Previous Submission

Limit 450 characters

To be completed by the lead applicant only.

Select 'Yes' or 'No' from the drop-down box to indicate whether this or a similar application has previously been submitted to this or any other funding body. Where this application or a similar one has been submitted to this or another programme or elsewhere, please provide the necessary information. You should name and provide dates and outcomes of these applications.

We would like to know if the application has been submitted elsewhere and you must be as open about this as possible. This includes, but is not limited to, any facts that, should they come to light at a future date, could harm the reputation of either the programme or the individual who withheld the fact (e.g. if a member of the team holds a patent or has a financial interest within the research area).

Failure to disclose accurately or fully will be considered by the programme as academic misconduct and treated accordingly.

2 Research Team

Some of the information will be pulled from the Stage 1 application and can be updated. Please note that ORCID ID is not mandatory to complete.

2.1 Details of Lead Applicant

This information is pulled directly from the Lead Applicant's Contact Profile and can be updated via the Update / Update Contact Profile buttons.

2.1.1 Role in this project

Limit 100 words

Explain in addition to your role as Lead Applicant, the role that you will be undertaking in the research, e.g. coordination and project management, analysis, methodological input.

2.1.2 %FTE Commitment

This refers to the percentage of your time that you will commit to this project. If you are funded as part of other projects that will be running concurrently, your time must not exceed 100% overall.

2.1.3 CV info

· Research grants held

Please outline the existing award that this award relates to/is building on.

Publication record

Provide details of a MAXIMUM of 6 of your most recent / relevant publications (in the last 10 years) relevant to this application (using Vancouver or Harvard citation format). Please use (Digital Object Identifiers) reference numbers if needed.

2.1.4 Are you an Early Career Researcher?

An early career researcher is here defined as a person who has no more than 60 months WTE post-doctoral research experience (excluding career breaks, maternity/paternity leave and illness). Applications from early-stage career researchers and those who have not led research before but who are looking to build research portfolios and gain experience of leading research are welcome.

When the lead applicant is an early career researcher, a senior researcher, acting as the Primary Co-applicant, must support the Applicant. The role of the Primary Co-applicant is to advise the Applicant at the application stage and to provide assistance and support throughout the duration of the research project if the grant is awarded.

2.2 Joint Lead Applicant

Where appropriate and justified it is acceptable for the application to be led by joint Lead Applicants. Where this applies, please complete your name, contact details and other requested information. Joint Lead Applicant should be employed by the organisation or institution based in Wales or have an honorary contract.

NOTE: For application/contracting purposes, the joint lead applicant will be counted as a coapplicant.

2.2.1 Role in this project

Limit 75 words

Justification should be given to demonstrate why more than one person would be required to lead this research and how this brings added value to the application. Please also provide a brief overview of their role in the proposed research.

2.2.2 %FTE Commitment

This refers to the percentage of your time that you will commit to this project. If you are funded as part of other projects that will be running concurrently, your time must not exceed 100% overall.

2.2.3 CV info

Research grants held

Please outline the existing award that this award relates to/is building on.

Publication record

Provide details of a MAXIMUM of 6 of your most recent / relevant publications (in the last 10 years) relevant to this application (using Vancouver or Harvard citation format). Please use DOI reference numbers if needed.

2.3 Primary Co-applicant

The Primary Co-applicant should only be included if the Lead Applicant is an early career researcher and their role to provide guidance and mentorship should be clearly defined. It should be noted that it is mandatory for an application from an early career researcher to include a Primary Co-applicant. Where this applies, please complete your name, contact details and other requested information.

NOTE: the Primary Co-applicant will need to register on the system before the application can be submitted.

2.3.1 Role in this project

Limit 25 words

The Primary Co-applicant should only be included if the Lead Applicant is an early career researcher and their role to provide guidance and mentorship should be clearly defined. Please also provide a brief overview of their role in the proposed research.

2.3.2 %FTE Commitment

This refers to the percentage of your time that you will commit to this project. If you are funded as part of other projects that will be running concurrently, your time must not exceed 100% overall.

2.3.3 CV info

Research grants held

Please outline the existing award that this award relates to/is building on.

Publication record

Provide details of a MAXIMUM of 6 of your most recent / relevant publications (in the last 10 years) relevant to this application (using Vancouver or Harvard citation format). Please use DOI reference numbers if needed.

2.4 Co-applicants

Add details of all co-applicants and their specific role in the project. Do not include collaborators, who should be mentioned (if necessary) in the Research Plan section of the form.

Co-applicants are those individuals who are involved in the research project (for example the day-to-day management and delivery of the project, leading role on the specific workstream, advising on some aspects of the project) and can include public research partners. Co-applicants, including public co-applicants, are considered part of the project team and are expected to share responsibility for its successful delivery. In contrast, collaborators normally

provide specific expertise on particular aspects of the project but do not share in the responsibility for the delivery of the project.

Allow sufficient time for your co-applicants to complete their sections of the online form before the application deadline. Note that all co-applicants will need to register on the system before the application can be submitted. A maximum of 10 co-applicants is permitted including any other applicants (e.g. Lead applicant and Joint Lead applicant).

2.4.1 Role in this project

Limit 25 words

Please provide a brief overview of their role in the proposed research.

2.4.2 %FTE Commitment

This refers to the percentage of their time that they will commit to this project.

2.4.3 CV info

Research grants held

Please outline the existing award that this award relates to/is building on.

Publication record

Provide details of a MAXIMUM of 6 of your most recent / relevant publications (in the last 10 years) relevant to this application (using Vancouver or Harvard citation format). Please use DOI reference numbers if needed.

2.5 Public Research Partner Co-applicants

2.5.1 Role in this project

Limit 25 words

Please provide a brief overview of their role in the proposed research.

2.5.2 %FTE Commitment

This refers to the percentage of their time that they will commit to this project.

2.5.3 Experience

Limit 150 words

We encourage the inclusion of public co-applicants, where appropriate. Please include a clear description of their role and the reasons why a public co-applicant is joining the team.

Public co-applicants are not obliged to complete a standard CV but are required to provide a summary of any knowledge, skills and experience relevant to their role in the application in a

separate text box. This appears when a co-applicant selects 'yes' to indicate that they are a member of the public.

We recognise and value the varied perspectives that the public / patients / service users and carers bring to a project as applicants. In this section, please provide a summary of any relevant knowledge, skills and experience that you will draw upon to contribute to this project.

This could include information about:

- Previous or present work (paid or unpaid) with any relevant organisations
- Links with any relevant groups, committees, networks or organisations
- Experience of particular health conditions, treatments, use of services or as a member of a particular community
- Knowledge and experience of research including previous research undertaken
- Knowledge and experience of patient and public involvement including previous involvement activities
- Skills from any other roles that are transferable
- Relevant qualifications, training and learning.

The bullet point list above is not exhaustive. Please include anything else that is relevant to the application.

For further information please access the Public Co-applicants in Research guidance.

Applicants may also wish to consult the <u>Health and Care Research Wales guidance: Public Involvement in Research Impact Toolkit (PIRIT)</u>.

3 Application Details

3.1 Scientific Abstract

Limit 500 words

The scientific abstract should be a clear and concise scientific summary of the Detailed Research Plan / Methods.

The following is a list of potential elements / headings that might be included depending on the design and type of the proposed research. It will be for researchers to decide the appropriate elements to be included in the scientific abstract and could include elements outside this list:

- Research question
- Background
- Aims and Objectives
- Methods
- Timelines for delivery
- Anticipated Impact and Dissemination

This section of the application will be used as an overall summary, and therefore, should be a stand-alone section. Therefore, any abbreviations used elsewhere in the proposal should be defined here.

3.2 Plain English Summary

Limit 450 words

A plain English summary is a clear explanation of your research. Please be aware that this summary or part of this summary will be published online.

A good quality plain English summary providing an easy-to-read overview of your whole study will help:

- those carrying out the review (reviewers and board members) to have a better understanding of your research proposal;
- inform others about your research such as members of the public, health and social care professionals, policy makers and the media;
- the research funders to publicise the research that they fund.

If it is felt that your plain English summary is not clear and of a good quality, then you may be required to amend it prior to final funding approval.

It is advisable to involve a public research partner in the development of your plain English summary.

When writing your summary please include the following information (where applicable):

- Aim(s) and objective(s) of the research
- Background to the research, specifically what is the problem being addressed and why is this research important
- What you hope to discover
- How public research partners have been and will continue to be involved in the research
- How the findings are expected to make a difference, how they will be communicated and to whom

The plain English summary is not the same as a scientific abstract - please do not cut and paste this or other sections of your application form to create the plain English summary.

Further guidance on writing in plain English is available online at Plain English summaries.

3.3 Changes from previous stage

Limit 2,000 words

Please list the feedback received at the first stage and under separate headings indicate what has changed as a result. Describe and explain any additional changes that have been made to this proposal since the stage 1 application e.g., in the light of new research.

Please note, if you are submitting a single stage, straight to stage 2 proposal please ignore this question as it is not applicable. If this is the case, please enter 'not applicable' in the box.

3.4 Detailed Research Plan

Limit 10,000 words

Using all of the headings (in the order presented) and guidance below, clearly explain your proposed research. Schematics, tables, illustrations, graphs, and other types of graphics can be embedded to clarify the research plan, but they should not clutter the central narrative. Images do not count towards the overall word count but inclusion of them to overcome word limits is not permitted. Images may only be included within the 'Research Plan.' Images included in other sections will be removed from the application and not seen by reviewers.

As this is the main part of your application which will be considered by reviewers and the board, you should ensure that the information is accurate, succinct, clearly laid out and provides adequate methodological detail.

Applicants should therefore aim to reserve a significant proportion of the word limit for the research plan to ensure methodological approaches are fully specified.

The research plan should follow the format set out below:

- Background and rationale
- · Aims and objectives
- Research plan and methodology
- Dissemination, outputs and anticipated impact
- Roles and responsibilities and expertise of the research team
- Project management
- Success criteria and barriers to proposed work
- Involvement of any Clinical Trials Unit (CTU) or other Health and Care Research Wales research centre or any methodological or statistical support or advice
- IP, commercialisation and adoption

3.4.1 Background and rationale

Explain why this research is needed now, both in terms of time and relevance. We will only fund primary research where the proposed research is informed by a review of the existing evidence.

Briefly describe:

- the research gap in this area, drawing particularly from systematic reviews (including NHS Wales, public health or social care context and relevant literature), and the rationale for the particular lines of research you plan to pursue;
- past and current research that justifies the proposed research and shows that it will add distinct value to what is already known, or in progress;
- work undertaken previously by the research team which has led to the proposed project (e.g. describe any pilot or feasibility data).

Applicants should be aware of ongoing research in this area and comment on any other research which might be deemed to overlap with the contents of the proposal. Applicants are

advised to use both PubMed Central and Europe PubMed Central for recent material on the relevant topic area(s).

Any applications that include primary research should include reference to the existing evidence and explain how this evidence has informed the proposed research. Where a systematic review already exists that summarises the available evidence, this should be referenced, along with any relevant literature published subsequent to that systematic review.

Where no such systematic review exists, it is expected that the applicants will undertake an appropriate review of the currently available and relevant evidence (using as appropriate a predetermined and described methodology that systematically identifies, critically appraises and then synthesises the available evidence) and then summarise this in their proposal. All applicants must also include reference to relevant ongoing studies, e.g. from trial registries such as the International Standard Randomised Controlled Trial Number (ISRCTN) registry, ClinicalTrials.gov and the European Union Clinical Trials Register.

3.4.2 Aims and objectives

Please outline the key aims and objectives of your project and provide a concise statement of the proposed research.

3.4.3 Research plan and methods

 Outline the project plan and methods - provide a justification for the research design, methodologies and techniques of data collection and analysis, demonstrating how the hypotheses or research questions will be addressed.

Detailed information on the research design should include (where appropriate) descriptions of the following:

- Target population
- Justification of sample size
- Power calculation
- Inclusion and exclusion criteria
- Method of allocation
- o Planned interventions and who will deliver them

Please describe the overall research design, including strong justification for the proposed sampling strategies, methods of data collection and analysis. Applicants should note that for pilot or feasibility studies, clear progression criteria to the substantive study should be provided, including identification of the potential funder of the substantive study. In some cases, it will be appropriate to include discussion of dissemination and implementation here in addition to your response to a specific question on this. The key is that the reasoning underlying all stages of the proposed research should be transparent.

 Provide overview for how patients/service users/carers/public will be involved as research participants.

The successful recruitment and retention of study participants is important. If your proposed study involves patients/service users/carers/public as research participants, please use the

following bullet points to summarise their characteristics and what would be expected of them throughout the research project lifecycle. The potential burden on study participants can then be understood as well as whether or not the proposed strategies are practical, inclusive and feasible. Please also signpost to where further information on these points can be found in the detailed research plan and application.

Points to cover:

- Inclusion and exclusion criteria to help ensure that certain groups were not being excluded without justification;
- ∉ Recruitment method and consent process to ensure it is practical and fair;
- ∉ Type and content of participant information materials;
- ✓ Overview of research methods to capture data from participants and their frequency
 e.g. questionnaires/tests/intervention/focus groups/ interviews;
- ∉ Methods for sharing study progress and findings with study participants;
- ∉ Payments, rewards and recognition for study participants.

3.4.4 Dissemination, outputs and anticipated impact

The purpose of this section is for the applicant to describe the planned outputs of the research, how these will be communicated and to whom, and how the research may lead to short and longer-term impacts.

It is expected that as part of the long-term research and/or implementation strategy, all research funded by Health and Care Research Wales through the Welsh Government should be able to demonstrate that it is capable of generating outcomes that are likely to contribute to the benefit of those who use the services of the NHS in Wales.

In addition to traditional publication routes, please indicate also how any findings arising from the research will be disseminated to promote or facilitate uptake by users. It is particularly important to identify forms of presentation that will maximise impact on practitioners and service managers if appropriate. Please also include brief information of proposed conference attendance and presentations planned, if possible, particularly international ones. Please note that usually only Lead Applicant(s) can attend international conferences, and only if they are presenting at them.

Describe also how you will engage with service users or service user groups, health care commissioners, social care planners, practitioners and/or policy makers, where appropriate.

Please also provide information about plans for sharing the findings of the research with the research participants and service users/members of the public who were involved in the research project.

3.4.5 Roles and responsibilities and expertise of the research team

Explain how each applicant will contribute to delivering the research described in this application. For example, outline why each of the applicants are well qualified to carry out the proposed research, briefly describing the track record of the research team, including

publication outputs, grant income and impact on health and/or care policy in Wales. Include details of any related (completed, planned or active) awards held by members of the research team in the area (or similar area) to that set out in the research specification.

Also, explain how the applicants work together (or propose to work together if they have not done so previously), and identify other major collaborations important for the research.

If the salary costs of members of the research team are not being sought via this application, you should explain how their contribution will be supported within the Finances section.

3.4.6 Project management

Outline of the proposed milestones and delivery timetable (referring to GANTT chart)

Describe the progression of the research plan, including the timetable, key milestones and deliverables of each work stream or work package. This should be completed with reference to the Gantt chart uploaded with the application.

• Management structure

All project proposals should include details of how the project will be managed. This should include the roles and responsibilities of those individuals undertaking the proposed research and set out reporting lines, steering committee involvement, and the schedule of meetings of the proposed research group to permit coordination, evaluation of progress and dissemination of findings. You should set out how co-applicants in different institutions will communicate and monitor progress of the project.

NOTE: This section should also highlight the role of any Advisory or Reference Groups associated with the proposed research.

• Ethics and regulatory approvals

Outline any ethical issues associated with this research and the arrangements for handling them. If there are no plans to obtain ethical review, this must be clearly justified. Note that work outlined in your application/protocol must adhere to the UK Framework for Health and Social Care Research. Please note that time to obtain ethical approval should be incorporated into the project timetable.

3.4.7 Success criteria and barriers to proposed work

Please set out the measurements of success you intend to use, the barriers/risks to the proposed research and how you intend to mitigate against them. A barrier/risk is defined as any factor which may delay, disrupt or prevent the full achievement of a research objective. Typical areas of risk for a research application might include patient recruitment, staffing, resource constraints, technical constraints, data access, timing, management and operational issues (please note that this list is not exhaustive). A concise (one page) risk assessment table can be uploaded in the non-mandatory uploads section of the application, where appropriate.

NOTE: It is expected that when feasibility and pilot studies are proposed, clear progression criteria to the substantive trial will be provided, including identification of the potential funder of the substantive trial.

3.4.8 Outline involvement of any Clinical Trials Unit (CTU) or other methodology support / advice you have received

If a Trials Unit is to be involved, please provide the Unit name, registration number and explain the involvement of the Unit at all stages of your research, including design and follow up, should the study be funded. If the CTU is involved a CTU letter of support is **mandatory** and should be uploaded in the Uploads section.

In addition, the <u>UKCRC CTU Network</u> provides a searchable information resource on all registered units and CTU ID numbers in the UK and lists key interest areas and contact information. Researchers undertaking trials may wish to consult the <u>NIHR Clinical Trials Toolkit</u>. Where appropriate, you are expected to engage with relevant Health and Care Research Wales infrastructure groups or support (other than a trials unit).

3.4.9 IP, commercialisation and adoption

Set out the background IP for the research and the nature of any foreground IP likely to be generated, and any commercialisation plans.

It is essential that any Intellectual Property (IP) which may arise from Health and Care Research Wales funded research is recognised, captured and utilised in the most appropriate way, to ensure that the potential benefits of the research are realised effectively for service users and the taxpayer.

Health and Care Research Wales takes a broad definition of IP which might include research outputs such as new or improved software, training materials, manuals, checklists, scales, protocols, questionnaires, toolkits, guidelines or similar, service innovations or new service delivery models, research tools, such as data analysis techniques, assays, cell lines, antibodies, biomarkers, materials, as well as patentable inventions such as new/improved products, tests or devices. Such new developments of IP are known as 'foreground IP'. In addition, the proposed research is likely to build on IP generated previously by others or yourselves as Applicant. This is known as 'background IP'. IP may be protected via a number of methods including Copyright, trademarks or Patents. Taking this into account we can assume that much of the research funded by Health and Care Research Wales is likely to generate or modify IP.

4 Public Research Partners Involvement and Engagement

Limit 1000 words

Please describe how the public research partners (patients or those who need (or use) services, carers and the public) have been involved in developing this proposal and will be involved in the proposed research, including any training and support provided. You should describe who has been involved and why this is appropriate, what role(s) they have played and what influence or change has happened as result of their involvement.

Health Care and Research Wales expects appropriate and well-designed involvement of public research partners in the research it supports, so please refer to the <u>UK Standards for Public Involvement in Research</u>.

4.1 Management and Support

- Explain why your approach towards public research partners involvement is appropriate for this proposal. In your description you will need to say who will be involved and why.
- Please use this opportunity to describe how you plan to manage and coordinate the public research partner involvement activities in your project.
- Describe how you will support and enable patients/service users, carers, the public and members of relevant communities to contribute to your research (e.g., access, payments, training).
- We would also encourage you to outline plans for the capturing, evaluating and reporting the impact of public research partners involvement activities.

4.2 Public Research Partners Involvement Lead

There should be a named person with appropriate skills and experience who is responsible for leading the public research partners involvement element within the project. This role should be an adequately costed and resourced research team member who is able to manage the public research partners involvement plans and related activities.

4.3 A summary of Public Research Partners' Involvement

Please provide a summary of the proposed public research partners involvement activities embedded throughout the research project lifecycle. For example, sitting on oversight committees, being a member of the research team involved in activities such as recruitment, data collection, analysis, producing study materials and sharing findings. You should also outline how public involvement has informed the development of the project so far. For example, the involvement of patients/service users, carers or the public in shaping the research question and study design. These activities could include the development of feasible, relevant and acceptable recruitment plans, data collection tools, information materials, outcome measures, follow-up, intervention design and delivery.

Please clearly signpost to other sections of the Detailed Research Plan where the public research partners involvement is described further in relation to the relevant project stage e.g. dissemination, intervention design, data collection, analysis.

5 Detailed budget

Please refer to the associated <u>Detailed Budget Guidance for Applicants</u> document to aid filling in this section.

Schedule of Events Cost Attribution Template (SoECAT)

Please be aware that applications to this scheme should be accompanied by the 'Funder Export' from the online SoECAT (if required). More information on this is obtainable via Health and Care Research Wales website. The research award does NOT include NHS support and/or treatment Costs.

6 Justification of costs

Limit 700 words

- Please provide a narrative stating how the research costs have been calculated and allocated.
- Provide justification for the requested funding and state how the research provides value for money. You may wish to describe likely cost savings or benefits in terms of numbers of patients treated, treatment times, service users, or carers supported etc
- Explain how the NHS Support and Excess Treatment costs have been calculated and allocated, if applicable. If there are no NHS support and Excess Treatment Costs (ETCs), please briefly explain the reason for this. Please note that NHS Support and Excess Treatment costs are not mandatory but must be included if relevant to the study proposed.

7 Management and Governance

Is Clinical Trials Authorisation required? Yes / No

Does your project require ethics approval? Yes / No

If yes, has ethics approval already been obtained? Yes / No

8 Project Coding

This information is required for monitoring purposes by Health and Care Research Wales. The majority of the boxes offer a choice from a drop-down menu or simply require you to tick boxes relevant to them. Please note it is mandatory to complete this section.

8.1 UKCRC Research Activity Codes

See HRCS Research Activity Codes information at https://hrcsonline.net/research-activities/

8.2 UKCRC Health Categories

Select all that apply to the research. See information at https://hrcsonline.net/health-categories/

8.3 Research Region

Please select the relevant regions from the list available.

8.4 Lead Applicant's Profession

Select the relevant profession from the list available.

8.5 Lead Applicant's Place of Work

Please enter the Lead Applicant's place of work stating what type it is, e.g., university, hospital, other organisation or institution.

9 Upload Checklist

Please note that all supporting documentation uploaded should be given concise and clear file name descriptions. These should be headed by a numbered 'Appendix' and a brief filename description that clearly describes the file (e.g. Appendix References).

No more than 5 separate files are permitted. The total file size should not exceed 6Mb (this includes the SoECAT form uploaded under the Detailed Budget section). Total file sizes larger than this may not be considered as part of this submission.

We strongly recommend that only .doc or .pdf files are uploaded as some file types are not supported by the system (such as .xls and .zip file types which will not render out into the final version of the application form). Should you wish to upload documents of other file types, we encourage you check that they appear in the PDF of the application form prior to submission as changes cannot be made after the deadline has passed.

Please ensure that the document uploaded containing the list of references does not contain its own page numbering.

The following file is mandatory to submission for all applicants, please attach:

- A list of references cited in the application
- A Gantt chart/ Project Management Plan

The following file(s) are considered non-mandatory to submission (please number your files and attach):

- Any further supporting documentation (flow diagrams, pictures, logic models, trial protocols etc.).
- A completed Funder Export from the online Schedule of Events Cost Attribution Tool (SoECAT) as appropriate; if this is not applicable an explanation should be added to the Justification of Costs section.
- CTU letter of support (if applicable)

10 Administrative contact

Please provide the details of an administrative lead as a secondary point of contact for any queries. The Lead Applicant must submit the completed application and will still receive all emails automatically generated through the system.

NOTE: This person does not need to be a co-applicant.

11 Sponsor contact

Please provide details of a representative from the Sponsor/Host organisation. All research projects must have a nominated sponsor responsible for the management and conduct of

the project. A sponsor is taking responsibility for securing the arrangements to initiate, manage and finance a study.

NOTE: This person does not need to be a co-applicant.

12 Acknowledgement And Conflicts

12.1 Potential Conflicts

Limit 200 words

Please declare any conflicts or potential conflicts of interest that you or your co-applicants may have, including any facts that, should they come to light at a future date, could lead to a perception of bias. Include any relevant personal, non-personal & commercial interest that could be perceived as a conflict of interest. Examples include (this list is not all encompassing) secondary employment, consultancy, financial or commercial gain (pensions, shareholdings, directorships, voting rights), honoraria, etc. In a case of commercial sector involvement with the application or the study, please state clearly the relationship to ownership of data, access to data, and membership of project oversight groups.

12.2 Agreement to Terms and Conditions

In confirming your role as Lead Applicant in this application you confirm that:

- the information given in this form is complete and correct;
- you have spoken to your co-applicants and gained their agreement to participate in a Stage 2 proposal;
- you take full responsibility for the accuracy of this submission;
- you shall be actively engaged in, and in day-to-day control of the project;
- the host institution is aware of and supports submission of this application.

Ticking this box constitutes an electronic signature of the Lead Applicant with regard to this Stage 2 proposal application.

12.3 Privacy Notice

The Welsh Government Grant Privacy Notice states how the Welsh Government will use the information provided at application stage. It is available here: https://www.gov.wales/privacy-notice-welsh-government-grants