Research Project Grants (RG)

Guidance for Applicants 2024

Applicants are strongly advised to read this guidance before they commence writing their application and to note the conditions of acceptance. Failure to follow the format suggested by the guidance may reduce an applicant's chance of success or result in the application being rejected.

About Wellbeing of Women

Wellbeing of Women is the women's health charity saving and changing the lives of women, girls and babies. Led by women's voices, we improve health and wellbeing through research, education and advocacy. Every year we allocate funds towards medical research projects and invest in promising early career women's health researchers. We fund basic science, clinical and translational research on all aspects of obstetrics, gynaecology, midwifery or with a focus on women's reproductive health. Studies in urology and gynaecological oncology are all appropriate to our funding.

The Research Project Grant Scheme

Applicability

Research Projects Grants support independent researchers leading their own work, relevant to our remit of women's reproductive and gynaecological health across the life course. Projects must be undertaken in the UK at an established research institution.

Projects will be considered for basic science, clinical and translational research, including explanatory or feasibility studies and systematic reviews, that seeks to improve the health of women, girls and babies.

We encourage collaborative applications across disciplines, with patient and public involvement and engagement at the centre.

Proposed work must be addressing a clinical or patient need and have clinical relevance within 5 years from the end of the project.

Level of Award

Applications may be made for the financial support, for **up to £300,000** of a project lasting up to three years, to contribute to directly incurred research costs. These awards are intended to support independent researchers leading their own work at an established UK research institution.

The award of a Research Project Grant is subject to the acceptance of the Wellbeing of Women's Standard Terms and Conditions.

Eligibility

The Principal Applicant:

- Will usually hold a postgraduate qualification and must be leading their own work.
- Would be expected to be based at an established research institution in the UK.

The proposed project must be related to women's reproductive or gynaecological health and be capable of being brought to a conclusion within the duration of the grant.

Exclusions

The following costs are excluded from Research Project Grants:

- Indirect and estates costs.
- NHS Treatment and Support Costs.
- The Apprenticeship Levy.
- Charges for administration by University or NHS Authorities.
- Funds to cover PhD fees. Wellbeing of Women will consider applications where doctoral researchers are included in the project team, but for PhD studentships an application should be made to our Research Training Fellowships scheme.

Funds will not be released without evidence of the relevant Research Ethics approval.

Review Process

Please note that as funding is strictly limited, all applications undergo a triage process which follows Association of Medical Research Charities (AMRC) guidance. All eligible applications will be reviewed by at least two members of our Research Advisory Committee (RAC) and assessed against the following core criteria: 'Importance', 'Design and methodology', 'Potential impact', 'People and workplace including PPI' and 'Value for money'. Scores from the RAC are collated and applications scoring above an agreed threshold will then be subject to external peer review.

Applications progressing to external peer review are sent to a minimum of two external reviewers and scored following a full assessment. Appropriate applications will also be subject to a statistical review. Reviewer scores are collated and those scoring above an agreed threshold then proceed to full discussion by the Committee. Systems are in place to ensure the process is as fair as possible.

Response to reviewers' comments (rebuttal): If an application is short listed for peer review, applicants will be given the opportunity to respond to comments given by reviewers. Responses should be clearly presented, concise and must not exceed two sides of A4, irrespective of the number of reviews. Additional pages will only be granted if the Committee specifically requested supporting figures that require additional space. The response is to all reviews received and a subsequent response to any late reviews must also retain response text on all earlier reviews and not exceed the specified page limit. Applicants will be informed of the timing of the rebuttal period if short listed for peer review.

Successful Applicants

Successful applicants will be expected to reasonably aid Wellbeing of Women with publicity and fundraising. This may involve activities such as providing quotes and/or lay write-ups, speaking at our events or hosting visits at your lab. While we would ensure that any requests were not excessive or disruptive, by applying, applicants are agreeing to reasonable assistance in principle.

All grant awardees also consent to:

- Promptly completing a successful applicant questionnaire, including providing a photo and funding video, once notified of the grant award.
- Keeping Wellbeing of Women informed and giving prior notice of any publications and/or publicity arising from the research.

Details of the number of applications received and success rates can be found on our website **here**.

We endeavour to give brief feedback to all applicants, but this cannot be guaranteed.

Completing the Application Form

Applicants should use the application form for a Wellbeing of Women Research Project Grant, in **font size 10-12 pt.** throughout.

Two copies of the application – one MS Word and one fully signed PDF – should be e-mailed to research@wellbeingofwomen.org.uk by the closing deadline. Electronic signatures are acceptable, and signatures are only required on the PDF copy of the application.

The PDF should include all appendices in a single file (with the exception of the 'Research Questions for Non-standard Animals form' if required).

Late applications will not be accepted under any circumstances. We advise applicants to obtain all necessary signatures as early as possible.

Applicants will usually receive e-mail confirmation within 24 hours that the submission has been received (unless submitted Friday to Sunday). If confirmation is not received, please phone the Wellbeing of Women office on 020 3697 6346**.**

The points below relate to specific numbered sections of the application form and are to guide you through completing the form for the Research Project Grants funding scheme.

Word limits

Applicants should be aware that certain answers must be completed within a maximum word limit. If text exceeds these limits, the passage may be shortened accordingly.

Section 1: Application Details

Research teams should include a range of individuals and be led by a researcher who can demonstrate they will direct the proposed research and be actively engaged in

carrying it through. Wellbeing of Women encourages applications from multi-disciplinary teams and supports collaborative research projects, especially between academic and industry researchers.

There is no limit on the number of research staff included in a project as this will depend on the nature of the research being undertaken. However, applications will be assessed on the basis that the number of staff and their stated time commitment to the work is appropriate and sufficient.

Principal Applicant (Principal Investigator): Each proposal must have one Principal Investigator (PI), who is usually responsible for the intellectual leadership and overall management of the research. If intellectual leadership of the research is shared, the PI should be the individual who will act as Wellbeing of Women's main contact. By the time the grant starts, the PI must be based in the UK at the Host Institution at which the grant will be administered and be able to demonstrate continuous employment at that institution for the duration of the grant.

The minimum formal qualification required is a graduate degree, although most applicants are also expected to have a PhD. Proposals from less experienced PIs should normally include a senior colleague as a Co-Investigator (CoI)

Co-Applicants (Co-Investigators): The PI may be supported by one of more individuals who can be named on the application as Co-Investigators (CoIs). A CoI assists the PI in the management and leadership of the research. CoIs are considered part of the project team and are expected to share responsibility for its successful delivery.

CoIs may include named individuals from the Host Institution and other institutions collaborating on the research, including from overseas organisations, industry and public contributors. CoIs may also include research staff such as post-doctoral research assistants, clinical fellows and technology specialists or equivalent roles.

Host Institution: This should be the lead institution where the PI will be based and that will be responsible for administering the grant.

Host Department: This should be the department where the PI will be based for the duration of the grant.

Start date: The anticipated start would normally be within one month and six months after the decision date. Please see specific call timelines on the Wellbeing of Women website as these may vary.

Duration: The proposed duration of the grant should be provided in months and would typically be from 12 to 36 months. It should reflect the work to be undertaken and may not exceed 36 months.

Total funds requested: The total amount of funding being requested should be provided in pounds (£) and not exceed the upper funding limit of £300,000.

Title of the research: This should be as brief as possible and reflect the aim of the project.

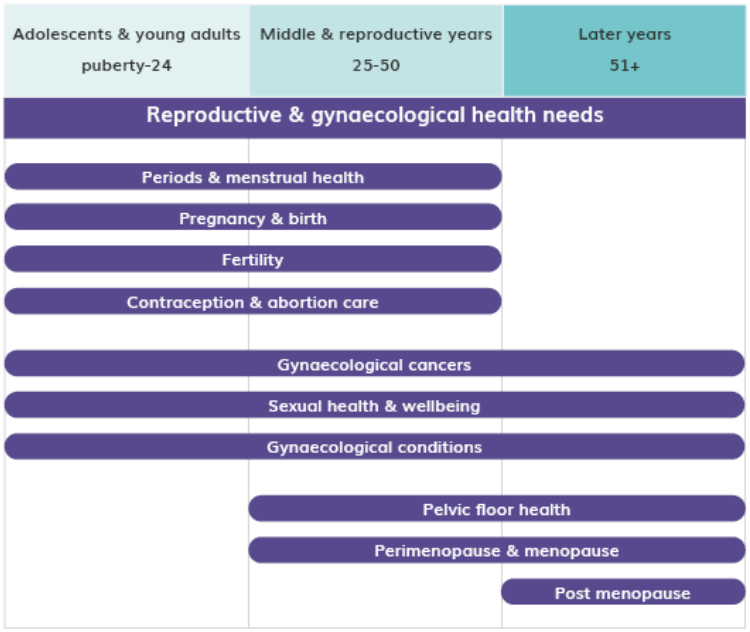
Collaborators: Collaborators normally provide specific expertise on particular aspects of the project but who do not share in the responsibility for the delivery of the project. Collaborators may provide resources either in-kind or financially but are not expected to request Wellbeing of Women funding to participate.

Each collaborator must provide a letter of support (see appendices section)

Please note that the role of a subcontractor is distinct from a collaborator. Subcontractors should not be named as part of the project team. They carry out a specific task on a fee-for-service basis, with no potential claim as an inventor over any arising intellectual property (IP). Details of any subcontractors should be specified in the Relevant Expertise and Experience and fully justified in the Justification of Support (sections 4.5 and 6.4).

Life course: The government's Women's Health Strategy is informed by a life course approach, which focuses on understanding the changing health and care needs of women and girls across their lives. In line with this, we have developed our own life course diagram to better convey the research areas that we fund.

Applicants should tick the life course area that best matches the research proposal. Please see the diagram below.



Section 2: Keywords

Applicants should provide keywords which will help us to classify the proposed research, as well as where they found out about this funding call.

Section 3: Lay Description

3.1 Lay Title: This should be as brief as possible and easily understandable by a lay audience.

3.2 Lay Summary: Applicants should provide a simple description of the proposed research which can be used to help communicate Wellbeing of Women research to our

supporters and the general public. Please write concisely and in simple terms e.g. suitable for a 12-year-old child.

The summary should provide context for the research with reference to the issue it will address and including the aims and objectives together with the techniques to be used and potential applications and benefits.

The following points should be addressed and are described in more detail below:

- Brief background/ context.
- Aim of the study.
- How you will go about the research.
- The information the research will provide and potential impact.

Brief background/ context: *Why are you doing the research? What is the motivation behind the research application? Were the questions and outcome measures informed by patients' priorities, experience, and preferences? Provide data on the number of people affected by the condition (e.g. for a specific complication of pregnancy).*

Aim of study: *State clearly the aims and objectives for a lay audience. What do you hope to find?*

How you will go about the research: Describe clearly what you are actually going to do throughout the project. Details of how people affected by the condition being explored will be involved in the study design, delivery and/or as research participants. How will they be supported and what incentives will they receive for their involvement?

The information the research will provide and potential impact on women, girls and babies: Explain how achieving the research objectives will benefit women, girls, babies and their families, and what the next proposed action will be if the research objectives are not met. Timescale to impact on the lives of women/ babies, and reasons why. Basic science applications must clearly demonstrate how your research relates to the condition being explored and how it could provide valuable insights for future research and/or translation into clinical practice.

A good lay summary should avoid:

- Unnecessary jargon, abbreviations and technical terms wherever possible. If you have to use them provide a clear explanation.
- Wordy sentences. Try to keep sentences short and simple.
- The whole scientific story. It is a summary and should describe what the 'take-home messages' are.
- Using the scientific abstract with a few word changes. It is usually obvious when this is done, and it is important to realise that the lay summary is not the same as the scientific abstract.

Please devote some time to this section – it is extremely important, and the quality of the lay summary is considered in awarding grants. The final decision in awarding grants is taken by our Trustee Board which consists predominantly of lay members.

Sharing information and knowledge to our lay supporters is central to our mission and if funded, this summary may be made publicly available along with the applicant's name and institution.

Helpful resources

- NIHR 'Make it Clear' – Guidance on how to ensure each research study has a clear and concise plain English summary.
- Plain English campaign – Guidance on how to avoid jargon when communicating your research.
- Readability calculator - Computer-calculated index which can tell you roughly what level of education someone will need to be able to read a piece of text easily.

Section 4: The Research

Wellbeing of Women are looking for a research proposal of high scientific merit that addresses an area of unmet clinical or patient need. Proposed work should have clinical relevance within 5 years from the end of the project.

Applications will be assessed against the following criteria:

- Importance of the research questions and relevance to Wellbeing of Women's remit
- Research Design and Methodology
- Potential Impact
- People and Workplace including Patient and Public Involvement (PPI)
- Value for Money

As much detail as possible, within the defined word limits, should be provided to help reviewers to assess your proposal.

4.1 Structured Abstract of Research: The proposed research including the aims, objectives, methodology, scientific and medical opportunities of the study should be clearly laid out.

Sharing information and knowledge about Wellbeing of Women's research portfolio is central to our mission and if funded, this abstract will be made publicly available along with the applicant's name and institution. Please consider this when preparing the abstract and do not include commercially sensitive or confidential information. If the abstract should not be published as it is highly confidential, applicants will be able to provide a revised version of the abstract to be made available if awarded funding. Please highlight if this applies.

4.2 Background and Rationale: Applicants should explain the need for the proposed research and the rationale for the particular lines of research planned. Please describe any limitations identified in the evidence base and provide details of the prospective outcomes and expected benefits in terms of improvement to women's, girls' and babies' health.

The scientific statement should be self-contained so that a referee should not need to refer to journals. References to current literature are important but should be limited to

20. If unpublished papers have been referred to, copies should be attached in the appendices.

4.3 Plan of Investigation: Applicants should clearly describe the details of the proposed research plan, including the aims and objectives of the research together with descriptions of the overall research design and methodology (paying particular attention to any technique that is new or not well known). The numbers of experiments proposed (including the validation of this figure) and the availability of patients (if relevant) should be included. If applicable, please indicate your plans for data management, sharing and storage.

It is important to include as much detail as possible on design and methodology, including justification of sample size, power calculations, sample selection and exclusions criteria where appropriate. Statistical methods should be sufficiently described.

This section should also provide detail of any problems/barriers to be anticipated and how they will be mitigated. PPI is a significant component of research and applicants are expected to include appropriate PPI in the proposal. Any applications that do not include PPI need to provide strong justification. Further guidance is available from the **NIHR PPI Resources**.

Applicants should include a timetable of activities in the form of a Gantt Chart/work plan (MS Word or PDF, one-page limit) and any tables or figures to support this section in the appendices.

*Applicants submitting their first research project are strongly advised to seek the guidance of someone with experience in making a grant application or to contact the NIHR **Research Support Service** (RSS). Clinical projects with a scientific component should include a scientist as an applicant and vice versa. If no clinician is mentioned on the application form, applicants should make it clear how they intend to obtain clinical samples. All projects requiring any statistical input, including sample size calculations, should seek the guidance of a statistician in the design stage of the project. All projects requiring substantial statistical input should include a statistician as an applicant. PPI at this stage is always encouraged.*

4.4 Expected Outputs and Potential Impact: Applicants should identify what outputs are expected from the research and discuss how these will be communicated and to whom, and how the research may lead to short- and longer-term impacts.

Wellbeing of Women recognises it may be difficult to provide definitive answers or guarantees on longer term impacts. However, applicants are invited to consider various aspects of pathways and how the likelihood of impact can be maximised. This includes considering what outputs are produced, how these can be best connected to the healthcare environment, what efforts and investment are likely to be needed beyond the project, what barriers are likely to be encountered and what impacts the research is seeking to achieve.

Impacts may include but are not restricted to - patient benefit; healthcare staff benefits; changes in NHS service (including efficiency savings); commercial return (which could contribute to economic growth); public wellbeing.

If the proposed research is likely to generate any commercially exploitable results, please provide detail including any Intellectual Property (IP) that will be generated and how it will be managed. IP may include copyright (software, checklists, protocols, questionnaires, guidelines etc.), trademarks, designs, research tools (assays, cell lines, biomarkers, data analysis techniques etc.) and patents.

4.5 Relevant Expertise and Experience: Details should be provided of the named individuals who will be involved in the research, including their relevant expertise, skills, experience and the role that they will carry out in the team. Please explain how the team will collaborate and why the individuals involved are best placed to carry out this research. Details of collaborators, sub-contractors and any other relevant research support available to the team should also be included.

4.6 References: Please include a full list of scientific references from throughout section 4 (The Research) of the application.

4.7 Impact of COVID-19 (non-mandatory question): This is a new question for the 2022 round, to ensure applicants have an opportunity to inform reviewers and Committee members of the impact of COVID-19 to their:

- Research
- Publications
- Funding
- Research time
- Institutional support
- Other

Please note that providing any information about the impact of COVID-19 is optional and at the applicants' discretion.

As part of the statement, applicants are asked **not** to:

1. name any third party individuals;
2. identify the relationship with any third parties;
3. otherwise include anything which might identify the third party.

Wellbeing of Women encourages applicants to use phrases such as 'a close relative had COVID-19 and required significant support in order to recover' or 'I had to carry out caring responsibilities in addition to my research and admin workload, which had an impact on the amount of time I could dedicate to my research'.

Further information for applicants when factoring COVID-19 into grant applications has been compiled by the Academy of Medical Sciences and is available here: **Top tips for factoring COVID-19 into grant applications.**

Section 5: Approvals for Research

In the event of an award being made, funding will be subject to any required approvals being in place and evidence thereof being provided to Wellbeing of Women.

5.1 Involving Human Participants or Human Tissue: Proposals involving human subjects and/or samples must have the appropriate ethical agreement from the **Health Research Authority** (HRA) before the study is commenced.

Clinical studies taking place in the NHS also require approval from the host NHS organisation. Applicants should contact the **NIHR Clinical Research Network** (NIHR CRN) for further information.

5.2 Human Fertilisation and Embryology Authority (HFEA): Proposals involving the use of gametes or embryos must have an HFEA licence. Details on applying for the appropriate licence can be found on the **HFEA** website. Approvals for research are managed via **IRAS**.

5.3 Research on Gene Therapy: For proposals involving research on gene therapy, please state the steps that have been taken to obtain the approval of your Local Research Ethics Committee, the University's Genetic Manipulation Committee, the Gene Therapy Advisory Committee (GTAC) and the **Medicines and Healthcare Products Regulatory Agency** (MHRA).

Details on applying for gene therapy regulatory approval can be found on the **HRA** website.

5.4 Use of Animals or Animal Tissue: Wellbeing of Women is a member of the Association of Medical Research Charities (AMRC) and we support the principle of using animals in research when it is necessary to advance understanding of health and disease and to develop new treatments. Research using animals must only take place where there is no alternative available.

We will only fund research that complies with the law and support the principle of the 3Rs: to refine, reduce and replace the use of animals in research. Further details on the use of animals in research can be found on the **NC3Rs** website.

Guidance for applying for a licence to carry out animal testing can be found **here**.

If you propose research that involves the use of non-human primates, cats, dogs or equines, you must complete the additional '**Research Questions for Non-standard Animals**' form and submit this with your application.

5.5 Licences and Approvals: If you have already secured the necessary licences and approvals, or your research does not require any, then you should answer 'YES'.

If you have not secured all the necessary licences and approvals and are yet to submit the relevant documentation, then you should answer 'NO'.

If you have not secured all the necessary licences and approvals but all the necessary documentation has been submitted to the relevant authority, then you should answer 'Applications in Progress'.

Section 6: Financial Information

This section should be as accurate as possible and must be completed by the relevant Research Grants or Finance Officer of the Host Institution. Full details of how the money requested is to be spent must be provided.

Research Project Grants provide a **maximum grant of £300,000** lasting up to three years.

Wellbeing of Women will only fund Directly Incurred (DI) costs of research and will not fund Directly Allocated (DA) or Indirect costs. Charges for administration levied by the University or NHS Trust concerned will also not be met. Indirect costs of research in universities can be covered by the Charity Research Support Fund (CRSF).

PLEASE NOTE: For research that will be carried out in the NHS, applicants must ensure that all costs are attributed according to the **AcoRD guidance for attributing the costs of health and social care research**, or equivalent.

Please discuss with the relevant NHS Trusts and/or your **Local CRN** (LCRN) early to help with study design, cost attribution and availability of resources.

6.1 Salaries: Please clearly list out all staff salaries being requested and their grade, including names if already known. Wellbeing of Women only funds DI salaries, for example technicians, research assistants and postdoctoral salaries. We do not fund DA salaries, except for in the circumstances detailed below*.

Researchers should be included as DI if the costs are actual, auditable and verifiable e.g. a researcher will dedicate 100% of time to the project. Where a researcher will not work 100% of their time on one project they may still be included as a DI cost, but their time needs to be supported by a full audit trail e.g. timesheets or project records.

Researchers' salaries will be considered DA if their time spent on the project is estimated e.g. a researcher working on several projects and activities. These costs are not eligible.

Allowances should be made for employer's contributions for superannuation and National Insurance (NI) and these figures should be listed separately for each individual. Please note that Wellbeing of Women will not pay the 0.5% Apprenticeship Levy and it should not be included in the application.

When detailing costs, applicants should allow for annual increments on the current salary scale and should include any estimated future national pay awards. Stipends for PhD students will be at MRC rates. It is important to double check that the amount of salary requested is in relation to the %FTE that the individual will be working on the research.

**Wellbeing of Women may consider providing a DA salary of an Investigator on a Research Project Grant only if the Investigator meets all these criteria:*

- *Is an early- to mid-career researcher and is spending the majority of their time (at least 50%) on this project.*
- *Has not previously had their salary provided as an Investigator on a Wellbeing of Women project grant (i.e. the Investigator has not relied on this exception before).*
- *If successful, will not have an existing salary (to carry out research) for the proposed duration of the award other than from a grant-funded position that would be relinquished.*
- *The Investigator only requests the salary for the duration of the award.*

We may also consider funding a DA salary to enable a clinician who does not have any of their time funded to carry out research and would otherwise not be able to be involved in the project.

Such requests will be considered on a case-by-case basis and justification for the request must be included in the Justification for Support (see section 6.4).

6.2 Research Expenses: Applicants should only request funds to cover DI research costs. The amount requested, in addition to the salaries, must not exceed £300,000 and all costs must be fully justified in the Justification of Support (see section 6.4).

Materials and Consumables: Please include non-reusable items specific to the research. Please list items and give a brief description. All items must be research specific, not just general office costs which should be covered by indirect costs.

Equipment: Applications for major items of equipment, when supported by an adequate research protocol, will be considered. Charges for servicing to equipment should be included if these are relevant. If similar equipment is available in the department in question, this must be reported, and an explanation given as to why it cannot be used for the project.

The overriding issue when considering the disposal of substantial items of equipment, on completion of a grant, is the benefit to future research. The disposal of such items is a local matter. However, the Research Advisory Committee consider that, in most cases the equipment should remain in the possession of the original grant holder who should acknowledge Wellbeing of Women's funding on the equipment. In the event of a local dispute regarding the disposal of equipment, evidence should be submitted for consideration by the Research Advisory Committee.

Travel and Subsistence: Please include any relevant journey and subsistence costs (excluding any alcoholic beverages). This may include travel for Project Advisory/ Steering Group meetings or for grant holders to present/ disseminate their work, either as an oral or poster presentation, at relevant scientific meetings within the UK or overseas. Full details must be included and will be scrutinised by the Research Advisory Committee. Travel must be by the most economic means possible.

Dissemination: Please include a list of costs related to the dissemination activities of the research, including any conference fees or publication costs. No more than one overseas conference should be included in the costs.

Applicants are encouraged to cost for open access publication. Wellbeing of Women support must be acknowledged in all presentations and publications and copies sent in advance.

Patient and Public Involvement: Please include a list of costs relating to activities involving patients and members of the public within the research. This might include out of pocket expenses, payments for time and any relevant training and support costs for their participation in the research. Further guidance on PPI costs is available on the NIHR website.

Other: Please list any other DI research costs that are not identified elsewhere. This might include animal costs, sub-contractors, specialist technical support or computer licensing.

6.3 NHS Costs: Applications may be made for research costs associated with NHS studies. Costs included in these applications comprise of:

- **Research Costs** - the costs of the R&D itself that end when the research ends. They relate to activities that are being undertaken to answer the research questions
- **Support Costs** - the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided
- **Treatment Costs** - the patient care costs, which would continue to be incurred if the patient care services in question continued to be provided after the R&D study had stopped.

Wellbeing of Women will only fund research costs of a study and does fund NHS support and/or treatment costs, although will take NHS support and treatment costs into account when considering the value for money of the research.

Researchers applying for clinical research funding need to complete a **Schedule of Events Cost Attribution Tool (SoECAT)** to be eligible for the National Institute for Health Research (NIHR) portfolio and the support this provides.

Who needs to complete a SoECAT?

You must complete a SoECAT if:

- You are applying for clinical research funding
- You will carry out your research in the UK
- Your research will use NHS resources
- Your research requires Health Research Authority approval

You must complete a SoECAT even if you don't think your clinical research will involve excess treatment costs.

Completing an online SoECAT form

When applying for Wellbeing of Women funding, the following steps need to be completed:

- Create an account in the NIHR Central Portfolio Management System (CPMS), and follow the "Apply for a service for a new study" pathway. See online SoECAT guidance.
- Once completed, request authorisation of your SoECAT.

- Append the 'study information' and 'summary' pages of the authorised SoECAT form as a single PDF with your completed grant application. Please include in the appendices section. Wellbeing of Women reserves the right to request a copy of the full form later in the application process.

Contact your local AcoRD specialist through your Study Support Service as early as possible in the application process. They can give advice on completing a SoECAT and provide a bespoke service to meet the needs of your study. There are different ways to contact a specialist, depending on where you are in the UK:

- England: NIHR website
- Scotland: NHS Research Scotland website
- Wales: email research.fundingsupport@wales.nhs.uk
- Northern Ireland: HSC R&D division website

Why you need to do this

The SoECAT makes sure that costs are attributed:

- In line with the AcoRD framework
- Consistently across the UK

In England the tool also supports how ETCs are agreed and paid.

ETCs occur when patient care costs are higher in research than in routine care. The SoECAT is part of an agreed system paying ETCs, which reduces delays in research.

In England, the service commissioner (for example the NHS or a local authority) is responsible for paying ETCs for non-commercial research.

6.4 Justification of Support: Applicants should provide details of all the research costs that have been listed and fully justify why they have been requested.

Section 7: Previous Applications and Current Submissions

It is important that applicants indicate whether any financial support from another funding body has been sought, or is already provided, for the same or closely related research. If a decision is pending, please indicate the month when a decision is expected. Any previous applications made to Wellbeing of Women for this, or closely related research must also be listed.

All resubmissions to Wellbeing of Women must include a covering letter stating how the previous proposal has been modified.

Section 8: Declarations and Signatures

No application will be accepted without completion of this section by the **Principal Applicant** and all listed **Co-Applicants**, as well as the **Head of Department** and the **Finance Officer** responsible for administering the grant. For research involving NHS patients, a signature is also needed from the **R&D Director or Deputy** confirming that

the project will be carried out within the NHS research governance framework. Signatures are only required on the PDF copy of the application.

Section 9: Suggestions for Possible Reviewers

Applicants should provide the contact details (including e-mail) for at least three people who have suitable expertise to act as an independent reviewer. Potential reviewers must not be in the same institution as, or have collaborated with, any of the applicants within the last three years. The nomination of reviewers does not guarantee that they will be contacted.

In addition, applicants may indicate any individuals who they would prefer are not contacted with regards the application. The reasons for this must be clearly stated. Please note that this section may be seen by reviewers.

Section 10: Previous Wellbeing of Women Grants

This section should provide details of any Wellbeing of Women grant that has been held by any of the applicants during the past five years. Please use a new sheet for each grant.

Section 11: Curriculum Vitae

Please provide the CV of each applicant. CVs must not exceed one side of A4 (10-12 font) and should include information relevant to the application only. This should include qualifications with dates awarded; present employment and previous posts; current grants held (title, source, duration and sum awarded); and publications (no more than five, most relevant to the work to be undertaken).

Section 12: Appendices

Only supporting documents from the list provided should be provided. All appendices must be included into a single file in the PDF version of the application.

Please note that this guidance must be *strictly* adhered to. Failure to do so (such as: wrong font size; excessive word count; disallowed additional materials) *will* be taken into account. Applications may be rejected for deviation from the guidance.

Additional Information

Randomised Controlled Trials (RCT)

For additional guidance for grant applications regarding the supporting documentation required for randomized controlled trials see **Appendix 1.**

Open Access

Applicants are encouraged to cost for open access publication and include this expense.

Requests for Cost-Extensions

Cost extensions are not normally considered, but applicants may put in a new proposal for consideration if they wish to continue the work. This proposal would be considered in competition with other applications and should include a report on the work undertaken to date. The request should be in the form of a new application using the guidelines in this document.

Resources

The MRC, NIHR and HRA support toolkits to help researchers and funders:

GDPR resources, supporting research using health data and **using human tissue samples in research** provide advice and guidance on the use of data and tissues in research

Clinical Trials Toolkit: Provides practical help to guide researchers to design and carry out clinical trials of medicines, including links to all approvals that are required.

Experimental Medicines Toolkit: Experimental medicine is research undertaken in humans to understand how diseases develop or demonstrate proof-of-concept information. It is often done before clinical trials, although it may involve NHS patients.

UK Stem Cell Tool Kit: For regenerative medicines regulatory advice and support, please contact the MHRA Innovation Office.

NIHR Research Study Support Service (RSS): The RSS helps researchers to develop and design high quality clinical research applications.

Ethical Review: The HRA have developed 2 tools to help researchers work out if **their project is research**, and if it needs **NHS REC approval**.

PPI (Patient and Public Involvement) resources for applicants can be found on the NIHR website.

The **AcoRD guidance**: Guidance for attributing the costs of health and social care research. This guidance provides a framework for the NHS and its partners to identify, recover and attribute the costs of health and social care R&D (ACoRD), in a transparent, and consistent way. It provides a mechanism for the Department of Health and Social Care to meet some of the costs of charity-funded research in the NHS.

Organisations

Health Research Authority (HRA) was set up in 2011 to create a unified approval process for clinical research and to promote proportionate standards for compliance and inspection. It manages the National Research Ethics Service and is piloting a single application package for both ethics and NHS permissions.

Human Fertilisation and Embryology Authority (HFEA) regulates the use of gametes and embryos in fertility treatment and research. Approvals for research are managed via the Integrated Research Application System (**IRAS)**

Human Tissue Authority (HTA) regulates organisations that remove, store and use tissue for research, medical treatment, post-mortem examination, teaching and display in public. Approvals for research are managed via **IRAS.**

Medicines and Healthcare Products Regulatory Agency (MHRA) regulates medicines, medical devices, medicinal products containing gene therapies, cell therapies or tissue engineered products and blood products used in healthcare. It also investigates harmful incidents and regularly inspects organisations that host or sponsor clinical trial.

Research Ethics Service is in charge of ethical review of all research involving NHS patients, their tissue or data. Researchers apply for ethical review via the **IRAS.**

NIHR Clinical Research Network (NIHR CRN) provides the infrastructure that allows high-quality clinical research to take place in the NHS. The network structure is being modified and from April 2014 will be made up of twelve NIHR CRN themes that will work via six national thematic research delivery divisions and 15 local research networks.

NIHR PPI Resources supports public involvement in NHS, public health and social care research. The NIHR provides a host of resources for applicants applying for research funding programmes.

National Centre for the Replacement Refinement & Reduction of Animals in Research (NC3Rs) supports the research community to replace animal studies or, where the use of animals is still required, they support researchers to design the best experiments.

Appendix 1: Additional guidance for grant applicants regarding the supporting documentation required for Randomised Controlled Trials

For proposals which include a randomised controlled trial, the following additional guidance is given.

Wellbeing of Women requires a succinct summary of your proposed research. The following headings should be considered, as appropriate:

- Target population: Define the population from which the trial sample will be recruited.
- Intervention(s) being evaluated: Give a clear definition of the intervention to be evaluated.
- Measurement of outcomes and duration of follow up: Details should include the justification of the use of the proposed outcome measures, the proposed duration of the treatment period and the frequency and duration of follow-up.
- Sample size: State the required sample size, giving details of the estimated effect size, power and/or precision employed in the calculation.
- Planned analyses: Please give details of the planned method(s) of analyses.
- Project timetables including recruitment rate: Indicate the anticipated duration of the study, paying attention to the expected recruitment rate and a justification for your estimate.

Required Expertise

Randomised controlled trials almost always require multidisciplinary expertise. They usually need to draw on the expertise and knowledge of clinicians and of those trained in health service research methodologies such as health economics, medical statistics, study design and qualitative approaches. Wellbeing of Women will usually expect teams proposing multicentre randomised controlled trials to include input from a registered clinical trials unit, or one with equivalent experience. Applicants will also be expected to engage a qualified Trial Manager for appropriate projects.

Public Involvement

Wellbeing of Women recognises the importance of active involvement of patients and members of the public in research and expects to see evidence of public involvement in the development, running or oversight of randomised controlled trial proposals.

Governance and Regulation

Applicants are asked to follow the **Clinical Trials Toolkit** which provides practical advice to researchers in designing and conducting publicly funded clinical trials in the UK. Using an interactive route map, this site provides information on best practice and outlines the current legal and practical requirements for conducting clinical trials.