

Postdoctoral Research Fellowships (PRF)

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 Postdoctoral Research Fellowship Scheme

Applicability

Postdoctoral Research Fellowships are intended to support research-active lecturers, or lecturer equivalent level, to gather data and strengthen their bids for longer-term substantive funding. These awards are open to both clinician and academic researchers, but research must be in obstetrics, gynaecology or focused on women's reproductive health. Fellowships must be undertaken in the UK.

Fellowships 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.

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

Thanks to a generous donation from our former Trustee Chair and his family, we are encouraging applications addressing the following themes but the scope of the call is not limited to only these areas:

- Preventing and managing pre-eclampsia
- Addressing pelvic floor problems which lead to bladder, bowel, vaginal, and sexual dysfunction
- Endometriosis
- Ovarian Cancer

• Amniotic Fluid Embolism

For WoW-BGCS Postdoctoral Research Fellowships:



These awards will fund postdoctoral researchers in a basic science, clinical or translational research project to improve evidence-based practice and ultimately lead to better outcomes for women with gynaecological cancers.

Applicants must be members of the BGCS.

For WoW-BSCCP Postdoctoral Research Fellowships:

Co-funded by:

bsccp | The British Society for Colposcopy and Cervical Pathology

These awards will fund postdoctoral researchers in a basic science, clinical or translational research project focused on the prevention of cancer of the cervix and lower genital tract.

Applicants do not have to be members of the BSCCP, but successful candidates are expected to join the Society on receipt of their award.

For WoW-BSSVD Postdoctoral Research Fellowships:



These awards will fund postdoctoral researchers in a basic science, clinical or translational research project into the cause and management of vulval diseases, to improve evidence-based practice and ultimately lead to better outcomes for women with vulval conditions.

Applicants do not have to be members of the BSSVD, but successful candidates are expected to join the Society on receipt of their award.

Lichen sclerosus is a particular research priority area identified by the BSSVD, as informed by the James Lind Alliance Lichen Sclerosus Priority Setting Partnership (LSPSP). However, as vulval disease is a subspecialty area which is typically under-researched and under-funded, research proposals that address other aspects/conditions of vulval disease will be considered.

For WoW-RCM Postdoctoral Research Fellowships:



These awards will fund postdoctoral midwives for research that seeks to improve the practice of midwifery and maternity services, including postnatal care, but will be considered for basic science, clinical and translational research that seeks to improve the health of women, girls and babies in any of Wellbeing of Women's key areas above.

Applicants must be members of the RCM. For midwives who don't have an existing research time commitment within their current role, funds may be requested for a contribution towards salary.

In line with RCM's <u>Race Matters</u> campaign and our intent to increase involvement and engagement from and support to midwives who identify as Black, Asian or an ethnic minority, we welcome applications from midwives from these communities and/or whose project aims to improve the health outcomes from people from Black, Asian and ethnic minority communities.

Level of Award

Applications may be made for the financial support, for **up to £30,000**, of a fellowship, lasting up to three years, to cover new and directly incurred costs of research. The award is intended to support early career researchers (lecturers or lecturer equivalent level) to gather data and strengthen their bids for longer-term substantive funding. They are not intended for applicants who have already obtained substantial funding from other sources for the proposed work.

Applications may be made to support projects that are already in progress, or for a new project, provided a substantial element of the project is carried out during the course of the fellowship. However, these awards are not intended to 'top-up' existing project grants and the candidate must be central to the application.

The award of a fellowship is subject to the acceptance of the <u>Wellbeing of Women's</u> <u>Standard Terms and Conditions</u>.

Eligibility

Applicants for a Postdoctoral Research Fellowship:

- Must have been awarded an MD or PhD no more than 7 years ago, taken from the date of award to the application deadline date. Any breaks in employment, for example as a result of a career break or parental leave, will be taken into consideration in relation to the 7-year stipulation.
- Must be employed by the NHS, HEI or on a postdoctoral research fellowship with at least 40 percent of their time funded to undertake research (with the exception of midwives applying for a WoW-RCM Partnership Fellowship, where 40 percent dedicated research time is not required).
- Must be carrying out a research project related to women's reproductive or gynaecological health.

• For Partnership Fellowships: Where stipulated, must be a member of the partner organisation that is co-funding the award.

Applicants must provide evidence of previous research experience and future research career intentions. Research projects must be capable of being brought to a conclusion within the duration of the fellowship.

Exclusions

The following costs are excluded from Postdoctoral Research Fellowships:

- Sub-specialty training.
- Funds to pay for salary costs or to employ research assistants, PhD students or postdoctoral staff (with the exception of the WoW-RCM Partnership Fellowships, where funds may be used for salary).
- Indirect and estates costs.
- NHS Treatment and Support Costs.
- Charges for administration by University or NHS Authorities.

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

Review Process

All eligible applications will be reviewed by at least two members of our Research Advisory Committee and assessed against the following core criteria: 'Importance', 'Design and methodology', 'Potential impact', 'People and workplace including PPI' and 'Value for money'.

Taking into consideration the core assessment criteria, applications will be scored in three inter-related areas of 'Qualifications and ability of the candidate', 'Quality of the project' and 'Standard of the host institution, training plan and supervisory team'. 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. Review feedback will be shared with all applicants.

For Partnership Fellowships: Additional reviewers from each partner organisation will be involved assessing all eligible applications and represented on the Committee.

Successful Applicants

Please be aware that 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 you 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 of any publications and/or publicity arising from the research, where possible in advance.

For Partnership Fellowships: On receipt of an award, awardees may be required to be interviewed and a photo provided to the co-funding partner organisation, for use on their website or magazine/newsletter. Where applicable, awardees may also be required to submit an abstract or article for presentation or publication to the relevant partner organisation's conference or journal.

Details of the number of applications received and success rates can be found on our website <u>here</u>.

Completing the Application Form

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

Two copies of the application – one <u>MS Word</u> and one fully signed <u>PDF</u> – should be e-mailed to <u>research@wellbeingofwomen.org.uk</u> 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 <u>any</u> circumstances. We advise applicants to obtain all necessary signatures as early as possible.

Applicants will receive e-mail confirmation within 24 hours that the submission has been received. 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 Postdoctoral Research Fellowship 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

Applicants should provide their contact details and those of their proposed Supervisor(s) and Head of Department.

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

Host Department: This should be the department where the Applicant 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 <u>website</u> as these may vary.

Duration: The proposed duration of the grant should be provided in months and may not exceed 36 months.

Total funds requested: The total amount of funding being requested should be provided in pounds (\pounds) and not exceed the upper funding limit of £30,000.

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

Life course: The government's <u>Women's Health Strategy</u> 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.



Focus of research: This should be the focus area that best matches the research proposal.

Section 2: Keywords

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

Section 3: The Applicant

3.1 Current Post: In this section, you should provide details of your current post and the area in which you are undergoing any specialty training. Please note that you are

required to have a research commitment of at least 40 percent of your time in order to be eligible to apply (with the exception of midwives).

For midwives who don't have an existing research time commitment within their current role, please detail in section 3.1.i what protected time this grant will allow you for your research and how the arrangement will work in practice. You must include a 'plan' that reassures the Committee that you will have sufficient time for research within an appropriate work-life balance. The expectation is that successful candidates will work part-time within the Trust/HEI and negotiate a %FTE for their research time post-award. Arrangements must be discussed with your Line Manager and others responsible for your workload and approval in principle given ahead of making an application. Please detail in your 'plan' what discussions have already been had and with whom.

3.2 Qualifying Higher Award: To be eligible for this grant, you are required to have been awarded an MD or PhD no more than 7 years ago (full-time equivalent) and you must have been awarded the MD/PhD before the application deadline date. The qualifying date of award will be taken back from the application deadline date. If your answer to this question is 'NO', then you are ineligible to apply unless you have had a notable career break, for example due to maternity or parental leave, caring responsibilities or health problems. Applicants that have had interruptions in their academic career for these reasons will be favourably received but must provide details in this section.

3.3 Academic and Professional Qualifications: Please list any academic or professional qualifications relevant to this proposal. If you have an MD that has been obtained in another country, please confirm that it was a research-based MD, rather than clinical training.

3.4 Prizes and Awards Obtained: Please list starting with your most current award and reading in reverse chronological order.

3.5 Specialist Clinical Training Details: If your answer to 3.5.i is 'NO', then please explain why not i.e. you are an academic researcher. Please note that if you have already attained your CCT you are not eligible to apply unless you are a Clinical Lecturer in Primary Care. If you answer to 3.5.i is 'YES', then please go on to complete 3.5.ii and 3.5.iii.

3.6 Postgraduate Career: Please do not include a separate CV. Details of previous posts must be contained within this section of the form. Your list should read in reverse chronological order.

3.7 Professional Body Memberships: Please list any relevant professional bodies of which you are currently a member.

3.8 Publications: In this section, you should list all research papers in peer-reviewed journals, reviews and contributions to books. You may list publications that are still in press but should not include any abstracts or conference proceedings.

Please use the format from the example below when citing publications. Use an asterisk (*) to highlight your name:

Tamblyn JA*, Hewison M, Wagner CL, Bulmer JN, Kilby MD. Immunological role of vitamin D at the maternal-fetal interface. J Endocrinol. 2015 Mar;224(3):R107-R121.

3.9 Other Research Outputs: In this section, you should list any other notable outputs emanating from your previous research that is not included in section 2.8 (Publications).

3.10 Research or Other Relevant Experience to Date: In this section, you should provide detail of your previous research including training that is relevant to this application.

3.11 Current Post Aims and Objectives: In this section, you should talk about your broad aims and objectives within your current post.

3.12 Career Intentions: In this section, you should talk about your career aspirations beyond your current post.

3.13 Current and Previous Grants or Fellowships: Please list all current and previous grants and fellowships that have been awarded to you. Your list should read in reverse chronological order.

Section 4: Lay Description

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

4.2 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, girls and 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 'takehome 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 '<u>Make it Clear</u>' Guidance on how to ensure each research study has a clear and concise plain English summary.
- <u>Plain English campaign</u> Guidance on how to avoid jargon when communicating your research.
- <u>Readability calculator</u> 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 5: 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.

5.1 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.

5.2 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.

5.3 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. <u>If applicable</u>, 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 <u>NIHR PPI</u> <u>Resources</u>.

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 are strongly advised to seek the guidance of someone with experience in making a grant application or to contact the NIHR <u>Research Support Service</u> (RSS).

5.4 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.

5.5 Training and Development Plan and Research Support: In this section, you should include the special features or facilities that will be available to you at your host institution, and the training and development programme to be undertaken. This should cover both the training you may need to undertake the proposed research, but also training designed to support your future development.

Training may include, but is not limited to; formal courses, training in specialist skills and research methodologies, placements with other research groups or centres, leadership skills, conference attendance and overseas research visits. It is important that the training and development programme is tailored to your specific needs and complements the research being proposed.

Details should be provided of the experience each supervisor will bring and the support they will provide. Please also explain any collaborations you intend to establish to support your research and, if applicable, training and development programme.

5.6 References: Please include a full list of scientific references from throughout section 5 (The Research) of the application.

5.7 Impact of COVID-19 (<u>non-mandatory question</u>): This question was added in 2022, 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: <u>Top tips for factoring COVID-19 into grant applications</u>.

Section 6: 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.

6.1 Involving Human Participants or Human Tissue: Proposals involving human subjects and/or samples must have the appropriate ethical agreement from the <u>Health</u> <u>Research Authority</u> (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 <u>NIHR Clinical Research Network</u> (NIHR CRN) for further information.

6.2 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 <u>HFEA</u> website. Approvals for research are managed via <u>IRAS</u>.

6.3 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 <u>Medicines and Healthcare Products</u> <u>Regulatory Agency</u> (MHRA).

Details on applying for gene therapy regulatory approval can be found on the <u>HRA</u> website.

6.4 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 <u>NC3Rs</u> 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.

6.5 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 7: 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.

Postdoctoral Research Fellowships provide a **maximum grant of £30,000**, 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 <u>AcoRD guidance for attributing</u> the costs of health and social care research, or equivalent.

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

7.1 Salary (for WoW-RCM Partnership Fellowships only): For midwives who don't have an existing research time commitment within their current role, they may include a request for a contribution towards salary to allow them to negotiate a %FTE for their research time post-award. The amount should be as accurate as possible and should include estimated pay awards.

7.2 Research expenses: Applicants should only request funds to cover DI research costs. The amount requested must not exceed £30,000 overall and all costs must be fully justified in the Justification of Support (see section 7.4). Funds cannot be requested to cover personal salary costs (with the exception of midwives) or to support research assistants, PhD students or postdoctoral staff. You should only request funds to cover DI costs such as materials, consumables and equipment or for necessary technical support.

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: Please include any items of equipment that are essential for the research. All equipment must be justified in section 7.4 (Justification of Support), detailing why the item is needed and why it cannot be used/borrowed from elsewhere. 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.

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 fellows 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 our 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 and our partner funder's 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.

7.3 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 <u>Central Portfolio Management System</u> (CPMS), and follow the "Apply for a service for a new study" pathway. See <u>online SoECAT</u> <u>guidance</u>.
- 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: <u>NIHR website</u>
- Scotland: NHS Research Scotland website
- Wales: email <u>research.fundingsupport@wales.nhs.uk</u>
- Northern Ireland: <u>HSC R&D division website</u>

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.

7.4 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 8: Previous Applications and Current Submissions

It is important that you 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 9: Declarations and Signatures

No application can be accepted without completion of this section by the **Applicant**, their **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 10: Supporting Statements

Your current Supervisor and Head of Department should complete this section. If you have recently moved departments and have been working in your new department for less than six months, you may prefer to seek a statement from your previous Head of Department.

Section 11: 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

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 application 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:

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

<u>Clinical Trials Toolkit:</u> 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 <u>MHRA Innovation Office</u>.

NIHR <u>Research Study Support Service</u> (**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 <u>their</u> project is research, and if it needs <u>NHS REC approval</u>.

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

The <u>AcoRD guidance</u>: 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

<u>Health Research Authority</u> (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.

<u>Human Fertilisation and Embryology Authority</u> (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)

<u>Human Tissue Authority</u> (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 <u>IRAS</u>.

<u>Medicines and Healthcare Products Regulatory Agency</u> (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.

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

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.

<u>NIHR PPI Resources</u> 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.