

Dr Shawn Walker
James Clerk Maxwell Building 3.21
57 Waterloo Rd
London
SE1 8WA

04/03/2020

Dear Dr Shawn Walker,

NIHR Advanced Fellowship

Our ref: **NIHR300582**

Physiological breech birth: a feasibility study for a pragmatic trial

I am pleased to inform you that the NIHR Advanced Fellowship Selection Committee has recommended your application for funding, and the Department of Health and Social Care, in their capacity as the National Institute for Health Research (NIHR), has confirmed their intention to award funding. This is based upon acceptance of the terms and conditions set out in the Standard Research Contract (link below), and pending agreement to any conditions set by the Selection Committee, details of which will have been communicated to you where relevant.

The Standard Research Contract, between Host Organisations and the Secretary of State for Health and Social Care can be found on the NIHR website at:

<https://www.nihr.ac.uk/researchers/apply-for-funding/how-to-apply-for-career-development-support/apply-for-an-award>

Next Steps

The NIHR is committed to the rapid initiation of research following the decision to fund, in order to ensure that the benefit to patients is realised as soon as possible. Therefore, we expect you and your host organisation to be working towards gaining the necessary contractual agreements and governance approvals required to start the award by 01/04/2020.

The NIHR acknowledges the risk to organisations around committing resource to research before a contract is in place; however, it is rare to not reach contractual terms unless the circumstances of the awardee change. The NIHR, therefore, encourages organisations to commit staff to setting up projects as early as possible, in order to expedite the formal commencement of research.

It is acknowledged that there can be unforeseen delays in starting up a research project, but in order to help reduce these it is your responsibility, with the support of your Host Organisation, to work closely with your organisation's Research and Development department, or equivalent, as well as other colleagues / departments involved in the administration and management of the research, plus to start these discussions at the earliest opportunity.

To ensure that the award starts within the agreed timeframe, with all the required agreements and approvals in place, you, as the awardee, and, where necessary, any other appropriate shared or support staff, need to be in post to enable the award to start on 01/04/2020. These staff costs will ultimately be covered through the research funding award, but your organisation is encouraged to meet them, where possible, from Research Capability Funding (RCF) prior to the research contract being agreed.

To support the often-iterative process towards agreement of the contract, we have set out the guiding timeframes for the submission of responses or information for each step towards the agreement of the Standard Research Contract as well as the anticipated start date:

- Confirmation of acceptance of funding – 2 weeks from the date of this letter
- Responses to Finance and IP queries – 2 weeks following the issue of queries
- Submission of draft collaboration agreements and/or subcontracts (where applicable) – 1 month prior to the contract start date
- Contracted start date – 01/04/2020.

On receipt of information as set out above, the NIHR, through the NIHR Academy, is committed to responding to your submission of information within two weeks or we will update you on progress.

Please take the time to carefully read the enclosures to this letter which detail the feedback on your application, your contact, David Lunn, within the NIHR Academy who will be working with you on the contract, the processes to be undertaken during the next steps, as well as additional information relating to your award.

Yours sincerely



Dr Lisa Cotterill
CEO

Enclosures:

- Feedback – a summary of your reviews is provided separately.
- Managing your award guidance which can be accessed here: <https://www.nihr.ac.uk/researchers/apply-for-funding/how-to-apply-for-career-development-support/managing-your-award.htm>
- Information for Themed Call applications (Annex A).
- Additional information to support the contracting process. (Annex B).
- Ensuring publication of NIHR funded research (Annex C).
- NIHR Clinical Research Network (CRN) Support (Annex D).
- Your contact at NIHR Academy (Annex E).
- Accepting your award offer (Annex F).

Annex A Themed Call applications

This information is only relevant to applicants who have been funded as part of an NIHR wide Themed Call.

If your proposal was funded as part of an NIHR Themed Call, the Department of Health and Social Care may wish to co-ordinate publicity about awards that fall within the scope of the themed call. As a result, the Department of Health and Social Care has requested that projects funded directly from NIHR Themed Calls hold off from any individual project publicity until after this announcement has taken place in order to maximise the impact.

We understand that, in order for the new studies to begin recruiting, details will need to be placed in the public domain (e.g. on websites) and discussions held with organisations supporting or involved in the study. However, aside from activities relating to recruitment or project start up, we ask that you do not actively publicise or promote the award. Please be assured that we will keep you informed of the status of the embargo and the dates of any publicity planned by the Department of Health and Social Care.

FAQs

Q1: Can I issue a press release announcing my award?

R1: No – under the terms and conditions of the embargo you would not be able to issue a press release to announce that you had received funding from NIHR under a Themed Call.

Q2: Can I put up a poster in one of our recruitment sites (for example, a GP surgery) to let patients know we are recruiting to the trial?

R2: Yes – it is fine to issue publicity material to aid recruitment to the study as long as the focus of the release is to aid recruitment and not to solely announce the award. The embargo is not intended to jeopardize the success of the study in any way.

Q3: When will the embargo be lifted?

R3: We will let you know as soon as possible when the embargo is lifted by the Department of Health and Social Care and then, as long as you have signed contracts, you will be free to issue a press release.

Annex B – Additional information to support the contracting process

The following information is provided to help speed up the process of setting up your award contract. By providing this information early it will reduce any delays in getting your contract agreed and signed.

Salary confirmation

As part of the contracting process, NIHR Academy will re-calculate your salary to ensure it is accurate. In order for us to expedite this process, please provide by return to academy-awards@nihr.ac.uk the following information:

1. current salary
2. increment date
3. a copy of, or link to, your host organisation's salary scale
4. any other salient information regarding your salary.

Contracts and Intellectual Property

A draft contract can be viewed through the link in the letter above. It is recommended that the individual, or department at your Host Organisation, responsible for reading and signing off your contract looks at this draft contract at the earliest opportunity. This is to ensure they are aware of the terms and conditions of the funding and what the organisation will need to sign up to. We also strongly recommend the relevant people with intellectual property (IP) expertise at your host organisation look at Schedules C and D of the draft contract which refer to the ownership of IP and agree the relevant wording for these sections. In our experience where third party or collaboration agreements need to be in place it can take a number of weeks to get this wording agreed so we suggest starting this process as early as possible.

Please contact NIHR Academy if you have any queries.

More information including some FAQs on intellectual property can be found on the NIHR website (<https://www.nihr.ac.uk/researchers/manage-your-funding/manage-your-project/intellectual-property.htm>).

Annex C – Ensuring publication of NIHR-funded research

Current estimates suggest that 40-50% of research undertaken is never published.¹

However, we expect that all NIHR funded research will be reported fully and publicly available when the research has been completed. The standard NIHR contract with researchers includes the following statement:

“17.7 The Contractor shall ensure that the outcome of the Research is prepared for publication in a suitable peer-reviewed journal”

We expect that all researchers who have a contract with the NIHR to undertake research shall ensure that the outcome of the research is prepared as a research paper for publication in a suitable peer-reviewed journal. There is also a contractual obligation that the researchers should, at the time of submission of their research paper to a peer-reviewed journal, send a copy of this to the NIHR Programme issuing the contract. This is to fulfil reporting requirements. It will also allow a mechanism by which NIHR Programmes can monitor the contractual obligation of researchers to prepare such a research paper on all NIHR funded research.

Full reporting should include: full title, structured abstract, full report to include aims, methods, results, conclusions and research recommendations. Depending on the publication, research materials should also be included, for example, patient questionnaires. Reporting must be in line with best guidance (eg CONSORT for clinical trials) according to study design listed on the EQUATOR website www.equator-network.org.

Publicly available means that the paper should be available on the web, able to be found using a recognised search facility, and as a minimum the abstract should be freely available.

It is expected that research funded by one of the NIHR Programmes that now has its own peer-reviewed journal as part of the NIHR Journals Library will publish a full and complete account of that research in the NIHR Programme specific journal. This will ensure that this research is reported fully, is publicly available with the abstract and full report freely available via the NIHR Journals Library website and the abstract freely available via Europe PubMed Central. The NIHR Programmes with journals in the NIHR Journals Library are: Efficacy and Mechanism Evaluation Programme; Health Technology Assessment Programme; Health Services and Delivery Research Programme; Public Health Research Programme; and Programme Grants for Applied Research.

We expect that research funded by a NIHR personal research training award shall ensure that the outcome of the research is prepared as a research paper for publication in a peer-reviewed journal. Where this research paper is not accepted for publication by a suitable peer-reviewed journal an alternative solution should be sought to ensure that this research is able to be reported fully and be publicly available.

We would also encourage all researchers to disseminate their research findings to the broader public community as well as to the research participants when the study has completed.

Reference:

1. Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. *Lancet* 2009;374:86-89

Annex D - NIHR Clinical Research Network (CRN) Support

If your study involves the NHS or NHS patients, we expect you to apply, where appropriate, for NIHR CRN support and subsequent inclusion in the NIHR CRN Portfolio of studies to fully benefit from the support that the CRN offers through their Study Support Service. To find out more, please visit www.supportmystudy.nihr.ac.uk.

If your study is deemed eligible for consideration for NIHR CRN support in England, and/or its equivalents in the Devolved Administrations, we expect you to:

- Keep your study record on the CRN's Central Portfolio Management System (CPMS) up to date; and
- Upload your recruitment data into CPMS on a monthly basis. Please note that the NIHR CRN will share this data with the NIHR Academy through the production of quarterly reports.

HRA Approval

If your study involves NHS sites in England you will need to apply for Health Research Authority Approval and follow the appropriate process for setting up sites. Please visit: <http://www.hra.nhs.uk> for further information.

Annex E – Your contact at NIHR Academy

From the point of being awarded NIHR funding you will have an assigned Senior Programme Manager who will be your point of contact at NIHR Academy for the duration of your award. Details of your assigned Senior Programme Manager are given below:

Senior Programme Manager: David Lunn
Email address: academy-awards@nihr.ac.uk
Telephone: 0113 532 8444

Annex F – Accepting your award offer

It is important that you formally accept this offer of funding from NIHR and do so within 2 weeks of the date of this letter. If you are unable to respond within this time frame please contact NIHR via your named contact above at the earliest opportunity.

To accept this offer of funding please complete the online award acceptance form which can be accessed through your ARAMIS account (<https://aramis.nihr.ac.uk>). You will need to go to 'My Reports' and select the 'Award Holder Acceptance' report by clicking 'Edit' and follow the online instructions.

The sooner this form is completed, the sooner we are able to start preparing a contract for your award.