justin.kua@doctors.org.uk

From: Reshma Patel <reshpatel@doctors.org.uk>
Sent: Monday, December 23, 2019 3:07 PM
To: justin.kua@doctors.org.uk
Subject: Fwd: NIAA e-grants - Decision on Application ID WKR0-2019-0036

Flag Status: Flagged

Hey J - here is the letter of congratulations we got. Hope it helps.
Reshma

Sent from my iPhone

Begin forwarded message:

> **From:** NIAA e-grants <onbehalfof@manuscriptcentral.com>
> **Date:** 26 June 2019 at 18:13:28 GMT+4
> **To:** reshmachetnapatel@gmail.com, reshpatel@doctors.org.uk
> **Cc:** m.j.wilson@sheffield.ac.uk, robin.russell@ndcn.ox.ac.uk, james.bamber@addenbrookes.nhs.uk
> **Subject: NIAA e-grants - Decision on Application ID WKR0-2019-0036**
> **Reply-To:** stocks.gary324@gmail.com
>
> 26 June 2019
>
> YOU MAY BE RECEIVING THIS MAIL IN COPY FOR INFORMATION ONLY
>
> Dear Dr. Patel:
>
> The NIAA grants committee with representatives from the OAA met today to consider your application for an OAA research grant. I am delighted to be able to inform you that your application was recommended for support for the sum of £54011.49.
>
> This e.mail is a formal notification of funding for which we would request an acceptance e.mail with cc to all. Please note that if we do not hear from you within two weeks of the date of this award notification then the award will be withdrawn.
>
> For your information I attach a copy of your peer review. I would strongly recommend that you take into consideration the concerns voiced by the reviewers about feasibility especially relating to the followup and longer term outcomes. I would also suggest that the project is thoroughly road tested before being rolled out on a national basis.
>
> I have also added to the peer review a copy of the abstract from your application that we will post onto the NIAA (and partner) websites along with funding details. Please have a look at this and let me know if there are any (small) changes that you may wish to make.
>
> In order to claim the funding you (or your finance office) will need to contact the OAA directly and for your information I copy the relevant details below. There may be some additional conditions (e.g., the need for interim/final reports) that the project funder will provide.
>
> All funding queries (and especially finance office claims) should be directed to Dr Robin Russell Chairman of the OAA Research and Grants Committee (robin.russell@ndcn.ox.ac.uk) and NOT NIAA.
>
> Successful applicants should contact their CLRN as soon as the award is made and work with them to

obtain NIHR portfolio approval and support.

To find out which NIAA grants are recognised for inclusion on the NIHR portfolio click here:
http://www.niaa.org.uk/article.php?newsid=877

To find out more about your local CLRN click here:
http://www.crn.nihr.ac.uk/networks/

On behalf of NIAA and its funding partners I would like to congratulate you on the quality of your application and look forward to seeing your results published.

With kind regards

Sincerely,
Dr. Gary Stocks
Grants Officer, NIAA e-grants
stocks.gary324@gmail.com

Reviewer(s)' Comments to Applicant:
Reviewer: 1

National Obstetric Anaesthesia Health Audit Research and patient-Centred outcomes project 1 (NOAH's ARC 1): Neuraxial Anaesthesia for Obstetric Surgery
1. Clarity of hypotheses, aims and/or objectives (specialty relevance if appropriate): Clear and well described
2.Strengths & weaknesses of project: As described below
3. Feasibility of work programme & relevant track-record of applicant (and their suitability for a studentship/fellowship, if applicable).: Feasibility is my major concern, see below
4.For clinical projects have all NHS research costs been met?: No
5.For clinical projects benefit to the NHS (including priorities): Clear priority
6.Cost effectiveness: This may not be cost effective if uptake is poor and the length of set up time will almost certainly not make the project sit in a one year time period especially around the psychology study

I think this is a highly relevant and important project with a great deal of expertise on the research project group. Large surveys have been previously performed (as referenced) but I agree a project on this scale and with this ambition has not. Professor Ramani Moonesinghe has the most experience in the UK to facilitate the project with the relevant expertise from the obstetric anaesthetists on research group.
I think there should be a high priority for funding although I have some major concerns around the feasibility in all aspects of the study which should be clearly addressed before moving forward. I think the very high uptake of the project by maternity units around the UK may not be feasible. A 90% compliance has been used to inform the power calculation so 100 women with failed NA can be studied both looking at the range of problems and in particular psychological outcome. This is going to be very challenging. I worry in particular that the smaller maternity units which are less well organised and may well have a less coherent approach to dealing with failed NA may be systematically excluded. There needs to be a clear approach in the outline how this problem will be approached. Also in units that agree to take part how is the completeness of the data going to be evaluated?
I think the collection of the basic data on failed NA may just be feasible within usual NHS infrastructure and a lot of good will, but I currently don't think the psychological study is feasible. The time consuming process of approaching and consenting women (GCP will be required) hasn't been addressed. To get a good response rate, women will have to be carefully approached by someone trained in research and consent processes and my experience is that this will take an

absolute minimum of 30 minutes time for each woman. Again the 6-week follow up is very time consuming and the dropout rate will be very high. There is nothing in the application to address these serious issues especially as this will significantly impact on the power calculation. In addition to make this meaningful there has to be an attempt to make this consecutive as far as possible with a clear log of the women approached, why they weren't approached or if they wished not to consent. If this is not very clear then it is quite possible that women with the poorer experiences could be systematically excluded. I would also worry that getting this type of feedback after a negative experience from an anaesthetist who may have been involved would be difficult and again skew the results. Apart from a small number of units where research teams are well developed and support may be gained through ABP there isn't enough resource in this project to make this feasible. There will have to be full R&D approval for this study at individual hospitals and as currently described I don't think this will be signed off. This study will be asking obstetric anaesthetists who have no record in research or R&D approval to attempt to do this difficult, bureaucratic and burdensome task. I think there will be some interest and uptake in this part of the study but how the central team is going to support this and what the strategy for the potential for a very low uptake should be explained in the application

Reviewer: 2

Comments to the Applicant
This is a worthwhile project. However, I believe that the proposal has not been adequately prepared.

The 5 Research questions do not mesh with the three Studies (listed as four main parts on page 4).

RQ1 and RQ 2 match Study 2.
RQ3 should be covered by Study 2, but there are problems with the data proforma. Most importantly, caesarean section (CS) urgency is one of the most important risk factors for failed epidural top-up anaesthesia, but is not mentioned in the routine CRF2 form.
RQ4 – this is not clear – is this a part of Study 2? - it is unlikely to be answered by Study 1. It is also unlikely to be clarified by Study 3, as notes review is based on high scores for psychological questionnaires, not whether the woman had intra-operative pain.
RQ5 – intention is to assess long term consequences, but Study 3 evaluates medium term outcomes.

There is a sample size calculation. I infer that Study 2 is intended to be over 28 days, maybe also Study 3, but this is not explicit.

The core study is Study 2. Study 1 could be done as OAA survey, and Study 3 might be important, if it is large enough and answers the RQ (see my hesitations above).

I hesitate about the expected response rate – in my view 80% is very optimistic. Studies such as SNAP1 have collected non-obstetric surgery information, where there is a marked circadian variation; this is much less so on the labour ward, and the on-call obstetric anaesthetist is frequently very busy (and solo) out of hours. The data collection proforma has possibly the right balance between having it filled in, and acquiring enough relevant information, but I strongly believe that this needs to be thoroughly piloted, to gauge how long it takes to complete and the likelihood of completion. Many OAA data collection projects, with much more limited aims, have had very poor response rates outside a small number of enthusiast centres.

Piloting the form would also help to clarify a number of vague aspects, e.g.

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'How many clinician boluses?'. Ironically the number of clinical boluses is a predictor of epidural top-up failure at CS, but has not been demonstrated for instrumental delivery; although it seems reasonable to ask the question here, it is missing from the CS section lower down.

The question also needs clarification. The studies demonstrating this as a factor come from the era of epidural continuous infusions, not PCEA or PIEB. Does it refer to a clinician bolus of more concentrated solution, or the same solution? How about the units using purely midwife top-ups – do all of these count?

Page 30 dates / times of insertion – which? The original, or resite, or both?

First mode of anaesthesia – this needs to be defined carefully. How about a spinal needle in the back but the space is not located? How about epidural top-ups – e.g. 10 ml of 2% lidocaine is given in the room, but in the operating theatre it is decided to go straight to general anaesthesia?

CS –failed instrumental delivery is an important missing indication for CS. How will you deal with anaesthetic details for these cases?

Page 31 Anaesthetic medications – does this apply to instrumental and CS? When are these drugs given – pre-op, pre- and during? Does this include or exclude drugs given to treat discomfort or pain?

In summary, the application is for a worthwhile project, but I believe that the proposal lacks important detail, and I am concerned that there is a high likelihood of a very poor data return rate without careful pre-assessment and piloting.

Reviewer: 3

Comments to the Applicant
Great study, well designed, needs doing.

Minor points:

Think you'll answer RQ1-3 fairly confidently. RQ4-5 more difficult.

If you identify significant PTSD, what and/or will the participating institutions have to put in place to address this outcome? In CRF4 description you say this 'may lead to a referral...'.

Study 2: Is this an audit or a survey? I think its a survey unless the authors want to clarify an existing standards (apologies if I missed this in their introduction).
Study 3: when is consent taken - will it be before the intervention or could they consent after delivery?

I'm not sure that your lay representative is appropriate.