EXPEDITION

Loughborough University

Melanie Davies
Professor of Diabetes Medicine
Department of Cardiovascular Sciences
University of Leicester
Leicester Royal Infirmary
Leicester

Direct Line: 01509 223445
Fax: 01509 211516
E-mail: a.j.seddon@lboro.ac.uk
http://www.lboro.ac.uk/business

13 June 2008

Dear Melanie

Novel Approaches to the Early Detection of Cardiac Dysfunction and Health Behaviours in the Young with Type 2 Diabetes Mellitus

I am delighted to confirm that the above project has been awarded £34,000 pilot funding from the Interdisciplinary Bridging Award of Loughborough University and University Hospitals of Leicester NHS Trust.

This letter confirms that the above project was peer reviewed on Friday 18 July 2008 by Cardiologists at the Glenfield Hospital, University Hospitals of Leicester, Diabetologists at the University Hospitals of Leicester, The School of Sport & Exercise Sciences at Loughborough University, and The School of Systems Engineering at Loughborough University and Bio-manufacturing at Loughborough University, with a stakeholder panel comprising the following:

Professor David Williams, Head, School of Health & Life Sciences, LU (chair)
Professor Tom Spyt, Consultant Cardiothoracic Surgeon, UHL
Jan Kovac, Consultant Cardiologist, UHL
Professor Dave Rowbotham, R&D Director, UHL & Clinical Director, Regional Research Network Clinical Director

The funds for this pilot project have been made available by the Medical Research Council and the Engineering and Physical Research Council.

I hope that the above is sufficient information to formally request that the Diabetes research Network adopts this project so that the Network's staff can facilitate the ethics approval.

I wish you and the team every success with the project

Yours sincerely

Anna Seddon
Administrator, Interdisciplinary Bridging Award
Marketing Manager, Enterprise Office, Loughborough University

LYDIA.

21 August 2013

Dr Sarah Griffiths Ph.D
Trials Manager
Leicester Clinical Trials Unit
Department of Health Sciences
University of Leicester
22-28 Princess Road West
Leicester LE1 6TP

Dear Ms Griffiths,

I would like to confirm that Novo Nordisk agreed to fund the **LYDIA study** (Impact of liraglutide on cardiac function and structure in young adults with type 2 diabetes: an open-label, randomised active-comparator trial) led by Professor Melanie Davies as the Chief Investigator from the Leicester Diabetes Centre, University Hospitals of Leicester NSH Trust.

Novo Nordisk will provide the Research Grant to the sponsor up to a maximum of £106,244 exclusive of VAT for the purpose of enabling the sponsor to arrange, initiate, conduct and manage the trial. Payment of the research grant will be made to the sponsor in accordance with the schedule and subject to the conditions specified in the investigator initiated study agreement (currently under review at University of Leicester).

In addition to the above, Novo Nordisk will provide funds to cover the drug costs for the study up to £53,760.60 in total upon receiving pharmacy invoices.

The funds are available on condition that first patient first visit (FPFV) has to happen on/or before 16 September 2013. Should this deadline be missed the study funding will have to be reviewed again through the Novo Nordisk internal processes, with no guarantee that funds will be approved again. The first payment is reliant on contract signature (details available in the schedule of payments).

Funds provided by Novo Nordisk for investigator initiated studies are available to any researcher in the UK on a competitive basis.

Kind regards

Dr Bogdan Milojkovic
Medical Advisor

DIASTOLIC

NHS
National Institute for Health Research

AWARD ACCEPTANCE FORM	
Fellowship Level: CDF	**Name:** Gerry McCann
Project Title: Novel interventions to reverse cardiovascular dysfunction assessed by Magnetic Resonance Imaging	**(Legal Name) of the Host Organisation:** University of Leicester
Legal address of Host Organisation (for contract): **University of Leicester - Fielding Johnson Building - University Road, Leicester LE1 7RH**	
Contact telephone number: 0116 2044746	**Contact email address:** gerry.mccann@uhl-tr.nhs.uk
I would like to accept the NIHR Fellowship Award Yes (Please mark box) If no please give a brief explanation	
I would like to take up my award on: 1st November 2014 **I would like to take up my award at:** **75% WTE**	
National Research Ethics Service (NRES) Ethical Approval **Is NRES ethical approval required for any part of your proposed research work funded by the Fellowship award?** **Yes** **If Yes is a copy of NRES ethical approval enclosed?** **No** **If No has NRES ethical approval been applied for?** **No**	

Please indicate anticipated date of receipt of NRES ethical approval

01/05/2015 **(Date MM/YY Must be specified)**

Is a different ethical approval required (e.g. HEI specific ethical approval) for any part of your proposed research work funded by the Fellowship award?
No

If Yes please provide more details.

Any other comments The study does require ethics approval. This will be applied for once the protocol has been finalised with appropriate PPI input. The study is not scheduled to begin recruiting until June 2015. Ethics application will be submitted Srping 2015.

Plain English Summary (abstract) – complete only if changes required from application form (100 words max)

There has been a dramatic increase in younger adults with diabetes, linked to obesity. These patients are at high risk of developing heart failure and premature death. MRI scanning will be used to determine what causes early heart failure in 100 younger adults with diabetes. Ninety of these patients will be randomly allocated for 12 weeks to 1) optimal blood sugar lowering treatment and lifestyle advice 2) a very low calorie diet or 3) moderate intensity exercise training, to determine whether early heart failure can be completely reversed. This study will lead to better treatments to prevent premature deaths.

Please be aware that government procurement transparency regulations require us to publish details of all contracts made with the Department of Health on the Department of Health Website. Confidential information including bank details, staff names and Heads of Department names will be removed from the published versions.

Pre-Contracting Information

Finance Department Details (Employing Host Institution with whom Fellowship contract will be made)

(Legal Name) of the Employing Host Institution: University of Leicester

Contact Name: Dr Trudie Wardle

Telephone Number: 0116 2297901

Postal Address: Research Support Office, University of Leicester, University Road, Leicester LE1 7RH

Email Address: ta16@le.ac.uk

Grants and Contracts Contact details (Employing Host Institution):

Contact Name: Dr Trudie Wardle

Telephone Number: 0116 2297901

Postal Address: Research Support Office, University of Leicester, University Road, Leicester LE1 7RH

Email Address: ta16@le.ac.uk

Authorised Signatory in Employing Host Institution to whom the paper copies of the Contract should be sent for signing:

Name: Dr Trudie Wardle

Position: Research Grants and Contracts Officer

Postal Address: Research Support Office, University of Leicester, University Road, Leicester LE1 7RH

Email: ta16@le.ac.uk

Employing Host Institution Bank Details:

Bank Name: Barclays Bank

Sort Code: 20-49-11

Account No: 00072583

Payee Ref No: RM61G0485

(This information is required in order for the Department of Health to commence payments)

Signature Gerry McCann ..... Please type signature for email return, then print and sign returning by post to :-	Date 15/10/2014

Personal Awards Team, **NIHR Trainees Coordinating Centre** **Leeds Innovation Centre** **103 Clarendon Road** **Leeds LS2 9DF**	

Please return the completed form to NIHR TCC Central Email Box awards@nihrtcc.org.uk

PREDICT

NHS
National Institute for Health Research

NIHR Trainees Coordinating Centre
Leeds Innovation Centre
103 Clarendon Road
Leeds LS2 9DF

Tel: 0113 346 6260
Fax: 0113 346 6272
www.nihr.ac.uk

Email: TCCawards@nihr.ac.uk

Professor Gerald McCann
University of Leicester
Cardiovascular Sciences
Glenfield Hospital
Groby Road
Leicester
Leicestershire
LE3 9QP

23rd August 2018

Dear Professor McCann

NIHR Research Professorship
Our ref: RP-2017-08-ST2-007

I am pleased to be able to send you a draft copy of the contract between The Secretary of State for Health and University of Leicester for Professor Gerald McCann recently awarded NIHR Research Professorship award, reference RP-2017-08-ST2-007. I have also copied this draft contract to Trudie Wardle, your named Research Contracts contact. Please also check the highlighted areas in the remainder of the contract for accuracy and identify any inaccuracies to us **within 10 working days from the date of this email**.

Please note that the payment profile will be confirmed in due course with yourselves when any queries over the finances have been resolved. Please advise us of the relevant banking details (bank name, account name, account number and sort code) and payee reference number as well as the contractor's representative details for section 5 – Key Staff.

The Department of Health's policy towards Intellectual Property (IP) is in line with many other research funders, and less rigorous than some. NIHR's aim is not to secure a slice of the profits, but to ensure IP is available to those who need it to conduct research, and that benefits from IP are realised. In this, we do not wish to be unduly prescriptive. The contract recognises pre-existing 3rd Party rights and the complexity of relationships between NHS, HEIs and others regarding IP. It also allows for the use of 'best of endeavours' in assuring the availability of Background & Foreground IP. Two sections have been included within the research contract:

- Schedule C – Third party rights in background IP introduced at the commencement of the research;
- Schedule D – Schedule of anticipated foreground IP arrangements.

Please can you provide wording to add to both these sections.

The Panel may have requested changes to your proposal which could affect the Gantt chart of activities against each work programme, which you included with your original application. If necessary please send the amended Gantt Chart and we will include this in the contract.

All other parts of the contract remain non-negotiable. Once you have returned the completed Schedules C and D, a revised Gantt Chart if appropriate and advised the above details, I will issue hard copies for signature, which will include the agreed payment profiles.

I would also like to draw your attention to the following points:

A. Government procurement transparency regulations require publication of details of all contracts made with the Department of Health on the Department of Health Website. Confidential information including research proposals, detailed finance information, bank details, and departmental staff names (other than the award holder's name) will be removed from the published versions.

B. Awards are granted to individuals on the condition that any part of work of the programme that requires NRES REC (National Research Ethics Service - Research Ethics Committee) approval cannot be undertaken prior to obtaining the necessary NRES ethical approval. You should begin immediately the process of obtaining any required NRES ethical approval if you have not done so already. If your local R+D office is unsure of whether your activities require NRES ethical approval, please contact NRES as soon as possible (http://www.nres.nhs.uk/contacts/nres-committee-directory/ or nres.queries@nhs.net). In addition, if further ethical approvals (e.g. University specific ethical approval) are required, please also begin the process of obtaining these.

In addition to the contractual details, the contract contains a number of sections which are of interest to you as the Award holder.

1. **Section 3:** Details of your proposed research (note that this will be the research proposal from your original application, and is not included with this draft). This work programme details what we expect you to deliver during the lifetime of your Award. It would be helpful to us if you could refer back to this section when completing your reports. If you intend to make any significant changes to your proposed research you must seek support from the NIHR TCC to do this. Significant changes may require further review prior to agreement.

2. **Section 4:** The Financial Arrangements - Payment Schedule. This will contain information about how the finances have been arranged and how much will be allocated to support your research. It is important to note that it is not possible to 'vire' or move money between salary and research costs. The NIHR TCC will not cover overspends on your research costs. As described in the contract, DH holds back your final payment – this is released once your final written report and the final finance report are received.

3. **Section 6:** The Reporting Schedule. This provides an overview of when your written reports and financial reports are due. More detail on Monitoring and Reporting is provided in Section 2, parts 13 and 14, where we explain what we expect from you and your Host organisation (i.e. Contractor) in terms of reports.

Please note that NIHR TCC does not permit you to hold any other award or source of income which would duplicate provision for costs (including salary) provided by this award. If you are unsure about this regulation please contact the office for further information.

In the meantime if you require any clarification about any aspect of the contract please do not hesitate to contact me.

I look forward to hearing from you by 10th September 2018.

Yours sincerely

Leesa Rayton
Senior Programme Manager

NIHR PROGRAMME GRANTS FOR APPLIED RESEARCH (NIHR201165)

NIHR | National Institute for Health Research

Professor Melanie Davies
University Hospitals of Leicester NHS Trust
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
Leicester, Leicestershire
LE5 4PW

CENTRAL COMMISSIONING FACILITY
Grange House
15 Church Street
Twickenham
TW1 3NL

Tel: 020 8843 8000
Fax: 020 8843 8001
Email: ccf@nihr.ac.uk
www.nihr.ac.uk/ccf

20 April 2020

Dear Professor Davies,

NIHR Programme Grants for Applied Research reference number NIHR201165: Type 2 Diabetes (T2D) in 18 – 40 year olds: A Multifactorial Management Intervention to Address Multimorbidity in Early-Onset T2D in Adults (The M3 Research Programme)

I am pleased to inform you that the committee has recommended your application submitted for consideration in Competition 30 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 upon acceptance of the terms and conditions set out in the Standard Research Contract and pending agreement to the suggested *key* amendments recommended by the committee, as detailed in the accompanying document.

The Standard Research Contract, between Contractors and the Secretary of State for Health for all initiatives can be found on the NIHR website at:

https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/manage-my-study/contracts-and-intellectual-property.htm.

The attached outcomes table contains the anonymised median scores from the Competition 30 Stage 2 Committee meeting where your application was assessed. It is intended to aid you in contextualising your feedback from the Committee.

Your anonymised code is: C30-0320-2004

Next Steps

The NIHR is committed to the rapid initiation of research following the decision to fund to benefit patients as soon as possible. Therefore, we expect funded researchers to be working towards gaining the necessary contractual agreements and governance approvals required to start the project by a date mutually agreed by both parties on acceptance of the award.

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 circumstance of the research team changes. The NIHR, therefore, encourages organisations to commit staff to setting up projects at as early an opportunity 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 to work closely with your organisation's R&D department or equivalent as well as other colleagues / departments involved in the administration and management of the research, and to start these discussions at the earliest opportunity.

To ensure that the project starts within the agreed timeframe with all the required agreements and approvals in place, appropriate staff (such as project and/or study managers) need to be in post as early as possible after receiving this letter of intent. These staff costs will ultimately be covered through the research funding award, but you are encouraged to meet them 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 – no later than 27 April 2020
- Responses to Committee feedback and queries – no later than 04 May 2020
- Responses to Finance and IP queries – 04 May 2020
- Submission of draft collaboration agreements and/or subcontracts (where applicable) – At a mutually agreed date
- Contract signature – 6 months from the date of letter
- Contracted commencement start – A mutually agreed date

On receipt of information as set out above, the NIHR through the Central Commissioning Facility 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 details the feedback on your application, the processes to be undertaken during the next steps, as well as additional information relating to your award.

Yours sincerely,

RS Flora

Rajinder Flora
Assistant Director, Programme Grants for Applied Research

cc: Dr David Hetmanski
Assistant Director of Research & Innovation

Annex 1

Additional Information

Publicity

We must remind you to refrain from publicising this funding recommendation until negotiations have been completed and a contract has been signed.

Response to feedback

Your response to the concerns of the sub-committee should form no more than 6 pages. An annex (e.g. for references, diagrams, tables *etc.*) of no more than 10 pages is permitted. Where applicable, your response to finance and intellectual property queries should each form no more than 6 pages. Annexes are not permitted.

Once you have completed all the relevant steps above, please email your completed response to programme.grants@nihr.ac.uk.

Intellectual Property

In order to expedite the IPR and Warranties and Liabilities terms and conditions, please clarify with local R&D management whether there are any third party rights in the background IP which may affect the research, as these will need to be stated clearly in schedule C of the contract. Please also ensure that your plans for managing the foreground IP are in line with the local IPR policy of the host organisation. As described in condition 15.2, our preferred position is that the foreground IP of this research project shall vest in the contractor, given that an NHS body or other provider of NHS services is best placed to realise any patient benefits flowing from the research. We will request clarification on all of these issues during the contractual negotiations. Please note that the terms and conditions of this contract are subject to review and amendment at the discretion of DH. **An overview of contractual responsibilities can be found in *Annex 2*.**

Notification of start date

In order to ensure that payments for research projects are not made in advance of need, PGfAR will require confirmation of the actual start date.

The PM will email the R&D contact (copying in the Chief Investigator) for the award to officially confirm the start date on behalf of the host organisation.

DH wishes to see a dramatic and sustained improvement in the initiation of clinical research. In the event that the actual start date is more than three months after the contracted start date, the host organisation will be required to sign a variation to contract that will be issued by the PM. Please be aware that a drop dead date (six months after the estimated start date) is included within the contract to prevent serious delays.

Clinical Research Network (CRN)

If your study involves the NHS or NHS patients we expect you to apply, where appropriate, for consideration for CRN support in England and/or its equivalents in the devolved administrations and subsequent inclusion in the CRN Portfolio Database. If your study is deemed eligible for consideration for CRN support in England and/or its equivalents in the devolved administrations we expect you to:

- Keep your study record on the Portfolio Database up to date.
- Upload your recruitment data into the Portfolio Database on a monthly basis. Please note that the CRN will share this data with us through the production of quarterly reports.

Information on the CRN support available to researchers can be found at https://www.nihr.ac.uk/explore-nihr/support/study-support-service.htm and information about gaining NHS permission for clinical research and using the NIHR Coordinated System for gaining NHS Permission (CSP) can be found at https://www.nihr.ac.uk/documents/user-guide-for-the-nihr-study-support-service-industry-route-map/19960.

Clinical trials

All primary research studies should also be assigned an International Standard Randomised Controlled Trial Number (ISRCTN). You can find further information at the ISRCTN website at www.isrctn.org. Please note that the remit of this database has been widened to include all primary research projects, even those that are not randomised controlled trials. There is no registration fee for NIHR funded trials and it is advised that you register your trial prior to initiation of patient recruitment.

Finally, we must remind you again to refrain from publicising this funding recommendation until negotiations have been completed and a contract has been signed.

IRAS

HRA Approval is for all project-based research that involves NHS organisations in England where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers. References to participants include people whose data or tissue is involved in a research project.

It brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that you only need to submit one application.

This page provides an overview of the HRA Approval process. For detailed guidance, go to the Integrated Research Application System (IRAS).

A series of top tips have been created to offer support with writing and submitting applications for HRA approval; these can be found in the IRAS help section. We also recommend you visit the research planning section for help before you begin your IRAS application.

Annex 2

Overview of Provider's contractual responsibilities

Below is an overview of some of your responsibilities as the holder of a Programme Grant award. This is not an exhaustive list; for a full list of the terms and conditions please refer to the standard agreement (https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/manage-my-study/contracts-and-intellectual-property.htm), and subsequently the agreed contract for your award.

1. Completion of progress reports

Award holders must submit annual progress reports throughout the duration of the programme. Template progress report forms will be made available either by email or through CCF's online research management system (RMS) https://ccfrms.nihr.ac.uk/Login. The report is designed to capture any material changes to the research or staffing, a summary of progress to date, progress against the project milestones, a list of presentations and publications, background and foreground intellectual property (IP) positions and matters requiring further attention by the PM.

Please note, NIHR reserves the right to ask for *ad hoc* reports or information in specific circumstances.

2. Variations to agreement

If at any time it appears likely that the contract, in particular the research, needs to be varied, please notify the PM as soon as possible about the nature and rationale for the anticipated change. The PM may ask you to complete an extension request form which may be sent for review by one or more of the Programme's authorities.

If the variation is granted, a formal variation to contract will be issued for signing by an authorised signatory (typically Chief Executive or Chief Financial Officer) to capture the changes.

3. Provide 28 days advance notice of publications

To keep the Department of Health in step with the dissemination of NIHR research, all chief investigators (whether an individual researcher or a research team) should observe the '28-day rule'. This currently involves submitting an electronic copy of the proposed research output, as it will be issued, to the PM responsible for your award, at least 28 days before it is published. NIHR should also receive full citations of research outputs when these become available.

If you are unsure as to whether you should inform us about a particular type of output, please seek your PMs guidance. Please note that the 28-day rule also applies to news releases to be issued by your host institution, e.g. university, NHS Trust or hospital. All research reports issued by individual researchers and/or research teams should:

- credit the NIHR as a funding organisation
- carry the NIHR disclaimer (see below).

NIHR disclaimer example:

This report/article presents independent research funded by the National Institute for Health Research (NIHR) under the Programme Grants for Applied Research programme* ***[insert programme reference number]****. The views expressed in this publication* are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.*

*Insert type of output as appropriate.

Award holders are also reminded of NIHR's support for the principle of Open Access to research as set out in its statement supporting Euro PubMed Central:

https://www.nihr.ac.uk/documents/nihr-open-access-policy/12251

4. Completion of a final report

In order to promote the data and results of its funded research, the NIHR has created the Journals Library. The Journals Library will help disseminate the findings of the research commissioned by a subset of its funding schemes and will provide an important permanent and comprehensive record of the work which has been funded.

All Programme Grant research should be published in the Journals Library in the form of a final report. The report must be submitted **14 days** after the contract end date.

Further information regarding the format of the final report can be found on the Journals Library website (http://www.journalslibrary.nihr.ac.uk/), from which the *Information for Authors* guidance document can also be downloaded (http://www.journalslibrary.nihr.ac.uk/authors).

Under the terms of the contract, the Authority has been granted rights, on a non-exclusive basis, to publish your final report and the information contained therein. It is therefore essential that when seeking to publish your research in an appropriate peer reviewed journal, you only enter into **non-exclusive** copyright arrangements.

Most journals have suitable non-exclusive licences for government-funded research but if you do, in error, sign an exclusive copyright agreement with a publisher, it is your responsibility to alert both the publisher and your PM as soon as possible.

5. Provision of financial information (spend to date) to permit reconciliation on request

Award holders will be required to submit an annual financial statement detailing programme spend to date. Where total expenditure varies from the amount of funding awarded in any given financial year, justification for this deviation, along with plans for the recovery of any over/under spend must be provided. Where there is a significant over/under spend, further action may be taken, including revision of payment schedules or return of unspent income to the NIHR. A final financial statement will also be due on completion of the programme.

Please note that the host organisation is required to maintain proper financial records relating to the research at all times during the research period and for six years after the project's end. The Department of Health reserves the right to request further financial information about projects funded through the NIHR programmes at any time.

6. Exploitation of IP

Award holders are expected to be aware of the terms and conditions in relation to the IP rights of the research contract. You should work with the host organisation to identify, protect and maintain IP in accordance with their standard institutional IP policy. In particular, you are required to inform the PM of any results which are capable of being exploited either by direct adoption into the healthcare service or via commercialisation. The host organisation will also need to seek prior written approval from CCF if it wishes to use a third party (excluding professional advisors) to carry out exploitation

activities with respect to the foreground IP funded through this award. CCF is interested in following up on the impact of research funding, so further information on directly exploitable IP arising from your project may be requested once the project is complete.