EXPEDITION

North Nottinghamshire Research Ethics Committee
A Standard Court
Park Row
Nottingham
NG1 6GN

Telephone: 0115 8839280 (Direct Line)
Facsimile: 0115 9122800

13 March 2009

Professor Melanie J Davies
Dept of Diabetes
Victoria Building
Leicester Royal Infirmary
Leicester
LE1 5WW

Dear Professor Davies

Full title of study:	**EXPEDITION: Early dEtection of carDiovascular dysfunction and healTh behavIOurs in the youNg with type 2 diabetes**
REC reference number:	**09/H0407/9**

The Research Ethics Committee reviewed the above application at the meeting held on 2 March 2009. Thank you for sending Co-investigators to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Participant Consent Form	1	13 February 2009
Participant Information Sheet: Patient Information Sheet	1	13 February 2009
Advertisement	1	13 February 2009
Covering Letter		
Protocol	1	13 February 2009
Investigator CV		
Application	18212/25957/1/579	13 February 2009
GP Letter	1	13 February 2009
Letter of invitation to participant	1	13 February 2009
Interview Schedules/Topic Guides	1	13 February 2009
Statistician Comments		13 February 2009
Peer Review		12 June 2008
Summary/Synopsis	Flowchart - Version 1	13 February 2009
Questionnaire: Brief Illness Perception Questionnaire		
Questionnaire: Exercise Self-Efficacy		
Questionnaire: DINE Food Frequency Questionnaire		

Questionnaire: EQ-5D		
Questionnaire: International Physical Activity Questionnaire (IPAQ)		

Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

Further information or clarification required

1. Clarification is required as to what mechanism would be in place should any abnormalities be identified e.g. early cardiac dysfunction etc., will GPs be notified etc.? There should be a clear process to pre-empt this. Provision should be made in the Participant Information Sheet (PIS) and be explicit. A suggested introduction in the PIS could begin 'The tests are not designed for clinical diagnosis, but in the unlikely event that we may find an abnormality...' etc.

2. Clarification is required as to whether you envisage any language problem whilst undertaking the Focus Groups, as it is intended to use non-English speakers, and how any such problem will be addressed

3. A PIS and Consent Form should be submitted to the Committee for the Healthy Volunteer arm of the study

4. On the Consent Form, the statement 'I give consent to be contacted by the School of Sport and Exercise Sciences at Loughborough University with information on further studies that I may be a suitable candidate for', is unclear. Are you seeking consent for Loughborough University to retain a database of personal details on participants? This should be amended to clearly indicate what the participant is agreeing to, and fully explained in the PIS. Also, on the Consent Form, it should be made clearer as to which boxes need to be initialled by the participant in order to take part in the study, and which (if any) are optional

5. In statement no. 1 of the Consent form, the version number and date of the corresponding PIS should be amended accordingly

6. <u>Participant Information Sheet (PIS)</u>

   - There should be a brief explanation of what an MRI scan is. If supplying another document to potential participants e.g. usual hospital information sheet regarding MRI scan, a copy of this should be supplied to the Committee, and also referred to in the PIS

   - Under the heading 'Who has reviewed the study?', the name of the Research Ethics Committee needs amending from 'Leicester' to 'North Nottinghamshire'

   - Under the heading 'What if something goes wrong?' in the PIS, there should be a name and contact telephone number where participants may complain should they wish to. This should be a department independent of the research e.g. the Trust's Patient Advice and Liaison (PALS) service

- Any reimbursement of travel expenses and the maximum amount given, should be detailed in the PIS

If you have any queries about the content of this letter, please contact the Co-ordinator.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 11 July 2009.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. However, all researchers and local research collaborators who intend to participate in this study at NHS sites should seek approval from the R&D office for the relevant care organisation.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H0407/9	**Please quote this number on all correspondence**

Yours sincerely

Dr David Walsh
Chair

Email: trish.wheat@nottspct.nhs.uk

Enclosures:	*List of names and professions of members who were present at the meeting and those who submitted written comments.*
Copy to:	*Ms Carolyn Burden - R&D Department for NHS care organisation at - UHL*

LYDIA

Re-issue FIFO, 16 December 2013

NHS
Health Research Authority
NRES Committee West Midlands - Edgbaston
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 883 9390

14 October 2013

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

Dear Professor Davies,

Study title:	**Impact of liraglutide on cardiac function and structure in young adults with type 2 diabetes: an open lable, randomised active-comparator trial.**
REC reference:	**13/WM/0311**
Protocol number:	**1**
EudraCT number:	**2012-002422-78**
IRAS project ID:	**107728**

Thank you for your letter of 04 October 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Assistant Miss Rebecca Morledge, NRESCommittee.WestMidlands-Edgbaston@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Re-issue FIFO, 16 December 2013

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites listed in the application, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

Re-issue FIFO, 16 December 2013

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of insurance or indemnity		12 July 2013
Investigator CV	Melanie Jane Davies	17 April 2013
Letter from Sponsor		15 July 2013
Letter from Statistician		18 March 2013
Letter of invitation to participant	Invite Letter 1 V1	13 April 2013
Letter of invitation to participant	Invite Letter 2 V1	13 April 2013
Letter of invitation to participant	Invite Letter 3 V1	13 April 2013
Other: Participant Invitation Leaflet	1	20 September 2013
Other: Letter to GP	1	13 April 2013
Other: Confirmation Letter 1	V1	13 April 2013
Other: Confirmation Letter 2	1	13 April 2013
Other: GP Letter 2	1	13 April 2013
Other: GP Letter 3	1	13 April 2013
Other: Appointment details	1	13 April 2013
Other: Telephone Calls	1	13 April 2013
Other: Thank you Letter	1	13 April 2013
Other: Information for research patients having an MRI cardiac stress perfusion scan	1	16 September 2013
Other: Exercise Test Information Leaflet	1	20 September 2013
Other: Letter to Patient confirming consent appointment	1	20 September 2013
Other: Reply slip expressing interest	2	20 September 2013
Participant Consent Form	2	20 September 2013
Participant Information Sheet	2	20 September 2013
Protocol	2.0	20 September 2013

Re-issue FIFO, 16 December 2013

Questionnaire: LYDIA	1	13 April 2013
REC application	107728/477841/1/260	15 July 2013
Response to Request for Further Information		04 October 2013

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

Re-issue FIFO, 16 December 2013

13/WM/0311	Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely,

pp

Mr Paul Hamilton
Chair

Email:NRESCommittee.WestMidlands-Edgbaston@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Ms Carolyn Maloney, University Hospitals of Leicester NHS Trust*

CODEC

NHS
Health Research Authority

West Midlands - Black Country Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

16 November 2016

Professor Melanie Davies
Professor of Diabetes Medicine
University of Leicester
Leicester Diabetes Centre (Bloom Wing)
Leicester General Hospital
Gwendolen Road, Leicester
LE5 4PW

Dear Professor Davies

Study title:	**Chronotype of Patients with Type 2 Diabetes and Effect on Glycaemic Control: The CODEC Study**
REC reference:	**16/WM/0457**
Protocol number:	**0590**
IRAS project ID:	**202758**

Thank you for your letter of 16 November 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Miss Georgia Copeland, nrescommittee.westmidlands-blackcountry@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [CODEC Recruitment Poster]	V1	05 August 2016
Costing template (commercial projects) [CODEC Costing]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters [CODEC Study GP Letter]	V1	05 August 2016
GP/consultant information sheets or letters [CODEC Study Patient Letter Primary Care]	V1	05 August 2016
IRAS Application Form [IRAS_Form_15112016]		15 November 2016
IRAS Application Form XML file [IRAS_Form_15112016]		15 November 2016
IRAS Checklist XML [Checklist_15112016]		15 November 2016
Letter from funder		
Letter from sponsor		
Letters of invitation to participant [CODEC Study Participant Invitation Letter Secondary Care]	V1	05 August 2016
Letters of invitation to participant [CODEC Study Participant Invitation Letter Primary Care]	V1	05 August 2016
Letters of invitation to participant [CODEC Study Appointment Letter]	V1	05 August 2016
Other [Confirmation of NIHR Senior Investigator Funding]		
Other [Provisional Opinion Further Information]	V1	15 November 2016
Participant consent form [CODEC Study Consent Form Primary Care]	V2	10 November 2016
Participant consent form [CODEC Consent Form Primary Care HL]	V2	10 November 2016
Participant consent form [CODEC Consent Form Secondary Care HL]	V2	10 November 2016
Participant consent form [CODEC Study Consent Form Secondary Care]	V2	10 November 2016
Participant information sheet (PIS) [CODEC Study Participant Information Sheet Primary Care]	V2	10 November 2016
Participant information sheet (PIS) [CODEC Study Participant Information Sheet Primary Care HL]	V2	10 November 2016
Participant information sheet (PIS) [CODEC Study Participant Information Sheet Secondary Care]	V2	10 November 2016
Participant information sheet (PIS) [CODEC Study Participant Information Sheet Secondary Care HL]	V2	10 November 2016

Referee's report or other scientific critique report [Joint Office Peer Review (Sam Seidu)]	V2	01 September 2012
Referee's report or other scientific critique report [Joint Office Peer Review (Jim Horne)]	V2	01 September 2012
Research protocol or project proposal [CODEC Study Protocol]	V1	05 August 2016
Sample diary card/patient card [24-hour Dietary Recall Background and Guidance]	V1	05 August 2016
Sample diary card/patient card [CODEC GeneActiv Activity Monitor and Food Intake Log]	V1	05 August 2016
Summary CV for Chief Investigator (CI) [Chief Investigator CV (Melanie Davies)]		
Validated questionnaire [Your Questionnaire Booklet]	V1	05 August 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/WM/0457	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Hilary Paniagua
Chair

Email:nrescommittee.westmidlands-blackcountry@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Dr Diane Delahooke*

Mrs Carolyn Maloney, University Hospitals of Leicester

DIASTOLIC

NHS
Health Research Authority

West Midlands - Coventry & Warwickshire Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

28 October 2016

Dr Gerry McCann
Consultant Cardiologist
University of Leicester
Glenfield Hospital
Groby Road
Leicester
LE3 6DR

Dear Dr McCann

Study title:	**Diabetes Interventional Assessment of Slimming or Training to Lessen Inconspicuous Cardiovascular dysfunction: The DIASTOLIC Study**
REC reference:	**15/WM/0222**
Amendment number:	**Substantial Amendment 04 06/10/2016**
Amendment date:	**06 October 2016**
IRAS project ID:	**182089**

The above amendment was reviewed on 28 October 2016 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster_Advert healthy volunteers]	2	30 August 2016
Copies of advertisement materials for research participants [Participant Recruitment Poster Track Changes]	2	30 August 2016
Copies of advertisement materials for research participants [Participant Recruitment Poster]	2	30 August 2016
Copies of advertisement materials for research participants [Poster_Advert healthy volunteers Track Changes]	2	30 August 2016
Covering letter on headed paper		06 October 2016
GP/consultant information sheets or letters [GP Letter Patient Withdrawal]	1	03 October 2016
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 04 06/10/2016	06 October 2016
Other [Thank you Letter Track Changes]	2	03 October 2016
Other [Diastolic Feedback form]	1	03 October 2016
Other [Thank You letter participant]	2	03 October 2016
Other [Patient Letter - Randomisation and Medication]	1	03 October 2016
Other [PIL main study]	4	30 August 2016
Other [PIL main study Track Changes]	4	30 August 2016
Other [PIL SHORT Track Changes]	3	30 August 2016
Other [PIL Healthy Volunteer Track Changes]	4	30 August 2016
Other [PIL Healthy Volunteer]	4	30 August 2016
Participant consent form [Consent form main study Track Changes]	4	30 August 2016
Participant consent form [Consent form main study]	4	30 August 2016
Participant consent form [Consent form Healthy Volunteer Track Changes]	4	30 August 2016
Participant consent form [Consent form Healthy Volunteer]	4	30 August 2016
Participant information sheet (PIS) [PIL SHORT]	3	30 August 2016
Research protocol or project proposal [Track Changes]	4	30 August 2016
Research protocol or project proposal [Clean]	4	30 August 2016
Sample diary card/patient card [Participant Unsupervised Exercise Diary]	1	03 October 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/WM/0222:	**Please quote this number on all correspondence**

Yours sincerely

P.P

Dr Helen Brittain (Chair)
Chair

E-mail: NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mrs Carolyn Maloney, University Hospitals of Leicester NHS Trust*
Mrs Wendy Gamble

West Midlands - Coventry & Warwickshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 28 October 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Helen Brittain (Chair)	Clinical Psychologist Retired	Yes	
Dr Ronald Jubb	Retired Consultant Rheumatologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Teagan Allen	REC Assistant

PREDICT

NHS
Health Research Authority

West Midlands - Solihull Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS
Tel: 0207 1048310

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

02 March 2021

Dr Gaurav Singh Gulsin
Department of Cardiovascular Sciences
Cardiovascular Research Centre, Glenfield General Hospital
Groby Road, Leicester
LE39QP

Dear Dr Gulsin

Study title:	**Prevalence and Determinants of Subclinical Cardiovascular Dysfunction in Adults with Type 2 Diabetes**
REC reference:	**17/WM/0192**
Amendment number:	**0580_7_SA05**
Amendment date:	**05 February 2021**
IRAS project ID:	**226498**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [Amendment Toolkit]	N/A	05 February 2021
Participant consent form [	3.0	17 February 2021

PREDICT_MEMRI_PIL_v3.0_17.02.2021_MARKED]		
Participant consent form [PREDICT_MEMRI_consent_v3.0_17.02.2021_MARKED]	3.0	17 February 2021
Participant information sheet (PIS) [PREDICT_MEMRI_consent_v3.0_17.02.2021_CLEAN]	3.0	17 February 2021
Participant information sheet (PIS) [PREDICT_MEMRI_PIL_v3.0_17.02.2021_CLEAN]	3.0	17 February 2021
Research protocol or project proposal [PREDICT_protocol_UoL_v6.0_17.02.2021_CLEAN]	6.0	17 February 2021
Research protocol or project proposal [PREDICT_protocol_UoL_v6.0_17.02.2021_MARKED]	6.0	17 February 2021

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 226498:	**Please quote this number on all correspondence**

Yours sincerely

Dr Rex J Polson
Chair
E-mail: solihull.rec@hra.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

West Midlands - Solihull Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 14 February 2021

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Lynne Gray	Retired - Senior Biomedical Scientist	Yes	
Dr Rex J Polson	Consultant Physician - Chair	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Mr Wai Yeung	Approvals Administrator