

Amy Evans

From: queensquare.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: 07 June 2021 14:40
To: John Dark
Cc: SIGNET
Subject: IRAS 288722. HRA & HCRW Approval Status Update - Provisional Outcome

Dear Professor Dark,

I am pleased to provide the following update regarding the status of your application.

Please provide a response to the requested information through IRAS by referring to the [instructions on how to submit a response to provisional opinion electronically](#). Please provide your answers in the table(s) below and then submit this, with revised documentation where appropriate, underlining, tracking or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the IRAS application form unless you have been specifically requested to do so.

Ethical Review – Further information required

The Research Ethics Committee reviewed the application on 20 May 2021 and issued a **Provisional Opinion**. Please provide the following information in order for a final ethical opinion to be issued:

Number	Action Required	Response from the applicant
1	The Committee requests the researchers amend the protocol to provide an approximate timeframe (in regard to the point that organ retrieval will occur) that details the earliest and latest possible time-points that consent will be requested and when Simvastatin can be administered effectively.	
2	The Committee requests the PIS be amended to include details on what action will be taken if the family, friends or Next of Kin become distressed and that contact details for appropriate individuals/organisations they can contact for support be included.	
3	<p>The Committee agreed that the proposed use of a single electronic confirmation of consent for participating in the research and for the organ donation was appropriate, however there was concern that this could result in the research aspects being unclear.</p> <p>The Committee requests text be added to the consent form sticker to specify that the points the individual are consenting to are for research purposes, rather than what would be carried out under standard practice for organ donations.</p>	

4	<p>The Committee agreed that the researchers had taken appropriate measures to protect the research participants by including a data monitoring committee that will cease the trial should the data indicate any risk to participants.</p> <p>The Committee requests the researchers provide confirmation of what specific outcomes would cause the data monitoring committee to cease the study and confirmation that the research team were satisfied this was sufficient to protect the recipient's safety.</p>	
<p>The Committee delegated authority to confirm its final opinion on the application to the Chair in consultation with Miss Rosalyn Stanbury and Ms Danielle Wilson</p>		

Assessment - Further information required

In addition, please provide the following information in order to clarify points raised in the assessment of the application

Assessment - Further Information Required	Response from the applicant
<p>Please provide more information on withdrawal in the Donor Family PIS, specifically at what point withdrawal of the organ transplantation will no longer be possible.</p> <p>Please confirm whether recording verbal consent over the telephone is standard practice or whether it is being conducted solely for research purposes.</p>	

A response should be submitted by no later than 07 July 2021.

Membership of the Committee London - Queen Square Research Ethics Committee Attendance at Committee meeting on 20 May 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Katherine Ashley	Approvals Specialist	No	
Dr Marie E Bardsley	Director (Pharmaceutical Publication)	Yes	
Mrs Maria Brezitski	Senior Clinical Research Nurse	No	
Miss Briony Brock	Student/Nanny	Yes	
Dr Jonathan Clegg	Retired GP	Yes	
Ms Lisa Marie Doherty	Oncology Advanced Nurse Practitioner	Yes	
Dr Charlotte Louise Hall	Research Coordinator	No	
Dr Ciaran Scott Hill (BREAK IN SERVICE)	Neurosurgery Speciality Registrar	No	
Ms Eleanor Rose Lees-Millais	Clinical Standards Administration	No	

Mrs Karen Mitchell	Out of County Independent Reviewing Officer	Yes	
Ms Katherine Nuttall	Senior Clinical Research Scientist & Data Manager	Yes	
Miss Lucy O'Neill	Centre Manager	No	
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Yes	
Miss Rosalyn Stanbury	Ophthalmologist (Retired)	Yes	
Dr Eamonn Walsh	Senior Lecturer and Programme Lead for MSc Neuroscience	Yes	
Ms Danielle Wilson	Clinical Research Operational Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Kevin Ahmed	Approvals Manager
Mr Chris Cole	Approvals Officer

If you have any queries, please do not hesitate to contact me.

Kind regards,

Kevin Ahmed
Approvals Manager

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