North West London REC 2
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NW3 2QG

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03 August 2010

Dr Sanjay Bhagani
Consultant in Infectious Diseases and HIV Medicine
Royal Free NHS Trust
Pond Street
London
NW3 2QG

Dear Dr Bhagani

Study Title:	**Prevalence of, and factors associated with significant liver disease in HIV-infected patients exposed to didanosine and development of a screening strategy using transient elastography to identify sub-clinical disease in such patients.**
REC reference number:	**10/H0720/54**
Protocol number:	

The Research Ethics Committee reviewed the above application at the meeting held on 21 July 2010. Thank you for attending to discuss the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research 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).

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. I 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.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) 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 the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

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

Other conditions specified by the REC.

Regarding the Application

- A – 43 – The committee recommends storing data longer than 3 months.

Regarding the Patient Information Sheet

- Under the heading "Why have I been invited?" - insert the words 'and *are therefore* ' eligible... (2 nd sentence middle).
- Under the heading "What happens if the initial blood tests and the fibroscan reading are abnormal?" 5 th sentence, change the word 'ultrasound *scanner' to* 'ultrasound *technician'.*
- Under the heading "Who is leading the research" Insert the REC name – North West London REC 2.

It is 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).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Investigator CV		
Protocol	1	01 April 2010
CV: Alison Rodger		
Letter from Funder		09 October 2009
REC application		
Covering Letter		03 June 2010
Summary/Synopsis		
Participant Information Sheet	1	01 May 2010
Participant Consent Form	1	01 May 2010

Questionnaire: Non-Validated: DDI and the Liver CRF	1	11 May 2010
CV: Sarah Logan		
CV: Tom Fernandez		
CV: Filipo Ferro		
CV: James O'Beirne		
Letter from Statistician	1	26 May 2010

Membership of the Committee

The members of the Ethics 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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

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.

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
- 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.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0720/54 **Please quote this number on all correspondence**

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

Yours sincerely

Dr Michael Pegg
Chair

Email: Thomas.McQuillan@nhs.net

Enclosures: *List of names and professions of members who were present at the*

meeting and those who submitted written comments
"After ethical review – guidance for researchers"

Copy to: *Ojoma Agbu*
RFH

North West London REC 2

Attendance at Committee meeting on 21 July 2010

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Jacqueline Birks	Statistician	Yes	
Ms Rosemary Brown		No	
Dr Rahul Chodhari	Consultant Paediatrician	No	
Dr Jason Crampton	Lecturer	No	
Mr John Farrell	Head of Pharmaceutical Services	Yes	
Dr Lorna Gibson	Lay Member	Yes	
Dr Andrew Hilson	Nuclear Medicine	Yes	
Rev Robert Mitchell	Lay Member (Vice Chair)	Yes	
Dr Richard Orrell	Senior Lecturer and Consultant Neurologist	No	
Dr Michael Pegg	Chairman	Yes	
Rosa Pizer	Committee Member	Yes	
Sia Rafiee		Yes	
Mrs Wendy Spicer	Pharmacist	No	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Thomas McQuillan	Hub Co-Ordinator
Ms Sasha Vandayar	NHNN Co-Ordinator

Written comments received from:

Name	*Position*
Mrs Wendy Spicer	Pharmacist