

North West 9 Research Ethics Committee - Greater Manchester West

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11 November 2009

Professor Ian Bruce
Professor of Rheumatology
The University of Manchester
arc Epidemiology Unit,
Stopford Building
Oxford Road, Manchester
M13 9PL

Dear Professor Bruce

Study Title:	BILAG Biologics Prospective Cohort: The Use of Novel Biological Therapies in the Treatment of Systemic Lupus Erythematosus (SLE).(Lay title: Long-term Safety of New Biologic Treatments in the Management of SLE)
REC reference number:	09/H1014/64
Protocol number:	1.2

The Research Ethics Committee reviewed the above application at the meeting held on 06 November 2009. The Committee thanks Dr Pattison and Dr Watson for attending to discuss the study.

Ethical opinion

The Chair welcomed Dr Emily Pattison and Dr Kath Watson to the North West 9 REC- Greater Manchester West and thanked them for submitting the application. The Chair commented that this was a very well put together application. They were asked by the Committee to clarify the following issues;

The Committee advised Dr Pattison and Dr Watson that it was not appropriate for the clinician who is looking after the patient to ask them whether they would like to take part in this study. The patient may feel obliged to say yes and therefore the clinician would be coercing the patient to participate. The Committee suggested that they make a reply box and keep it in the reception area for the patient to then drop the consent form into indicating whether or not they wish to take part. Once consent has been obtained the clinician can then go through and explain the points of consent on the form. Dr Pattison and Dr Watson agreed.

The Committee pointed out that the Information Sheet states that the GP will be notified of the study but the Consent Forms do not have a point of consent for the patient to agree to this. Dr Pattison and Dr Watson agreed to include this on the Consent Forms. The Committee also requested that point 6 on the Consent Form be amended to reflect the Information Sheet and change 'genetic and biomarker research' to 'DNA and biomarker research' so as to avoid confusing the participant. They agreed to amend that point.

The Committee advised that the full study title should be included on all supporting documents i.e. Information Sheets and Consent Forms. Dr Pattison and Dr Watson agreed.

The Committee pointed out that there were some typographical errors on the Information Sheets and Consent Forms as set out below. Dr Pattison and Dr Watson agreed to amend the errors.

Dr Pattison clarified for the committee that they would be using a standard validated questionnaire for children. The committee requested that a copy be kept on file for their records. Dr Pattison and Dr Watson agreed to submit these.

The Chair thanked Dr Pattison and Dr Watson for attending and advised them that they must not start the study until they have received a favourable opinion and that NRES is seeking feedback from applicants on their experience of the research ethics process which might help to improve future service. The final opinion letter will give details of how about to go about this.

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).

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.

- a. The Committee would like to see the full study title on all the supporting documents i.e. The Information Sheets and Consent Forms.
- b. The Committee would like to see the Participant Information Sheet (For Adults) to be revised to;
 - i. Under the heading 'Will my taking part be kept confidential?' at the final bullet point include the word 'to' between 'choose' and 'withdraw' so it reads 'choose to withdraw at any time,'
- c. The Committee would like to see the Information Sheet for Parents revised to;
 - i. Under the heading 'What will I have to do?' at point b) include the word 'child' between 'your' and 'to' so it reads 'your child

to'.

- d. The Committee would like to see the Consent Forms revised to
 - i. Include consent for the GP to be notified of the study.
 - ii. At point 6 of Consent replace the word 'genetic' with 'DNA' so it reads 'I agree to donate blood samples for use in DNA and biomarker research,'
- e. The Committee would like to see the standard validated questionnaire for children so that they have a record on file.

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).

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		13 October 2009
REC application	2.2	12 October 2009
Protocol	1.2	01 October 2009
Investigator CV		09 October 2009
Participant Information Sheet: Adults	1	09 June 2009
Participant Information Sheet: Children	1	03 July 2009
Participant Information Sheet: Parents	1	09 June 2009
Participant Consent Form	1	31 July 2009
Participant Consent Form: Assent	1	31 July 2009
Participant Consent Form: Parental Consent	1	31 July 2009
GP/Consultant Information Sheets	1.0 - Adults	16 September 2009
Evidence of insurance or indemnity	1	12 October 2009
Questionnaire: EQ5D - European Quality of Life Questionnaire		24 September 2009
Questionnaire: SF-36 Health Survey		24 September 2009
Questionnaire: LupusQoL Questionnaire		24 September 2009
Questionnaire: Patient Diary	1	24 September 2009
Questionnaire: Participant Lifestyle Questionnaire	1	29 September 2009
Advertisement	1	16 September 2009
Questionnaire: BILAG 2004 Index		24 September 2009
Questionnaire: SLICC SLE Damage Index		24 September 2009
Questionnaire: SLEDAI-2K		24 September 2009
Questionnaire: Consultant Baseline Questionnaire	1.0	08 June 2009
Questionnaire: Consultant Follow up Questionnaire	1.0	10 June 2009
GP/Consultant Information Sheets	1.0 - Children	16 September 2009

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.

09/H1014/64

Please quote this number on all correspondence

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

Yours sincerely

Dr Lorraine Lighton
Chair

Email: Shehnaz.ishaq@northwest.nhs.uk

*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: Dr Richard Sherburn
Dr Lynne Webster*

North West 9 Research Ethics Committee - Greater Manchester West

Attendance at Committee meeting on 06 November 2009

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Ian Beaumont	Director, Quality Control North West	Yes	
Ms Ann Benn	Lay member	Yes	
Dr Peter Donnelly	Semi-Retired Industrial Chemical Risk Assessor	Yes	
Dr Eddy Estlin	Macmillan Consultant in Paediatric Oncology	Yes	
Mr Michael Harnor	Lay member	No	
Ms Margaret Hughes	Lay Member	No	
Mrs Sue Jepson	Senior Lecturer	Yes	
Mr Simon Jones	Podiatrist	Yes	
Mr Geoff Lamb	Lay Member	Yes	
Dr Lorraine Lighton	Consultant in Communicable Diseases	Yes	
Dr Barry Miller	Consultant Anaesthetist	Yes	
Mrs Patricia Morgan	Non-Exec Director	Yes	
Dr Angelia Ong	Consultant Histopathologist	Yes	
Mrs Anne Stoddart	Lay Member	No	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Shehnaz Ishaq	Committee Co-ordinator