The Newcastle upon Tyne Hospitals

NHS Foundation Trust
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JP/SS

14th September 2012

Professor of Liver Immunology,
Newcastle University,
[redacted]

Dear Professor Jones,

Trust R&D Project:	5997
Title of Project:	*Rituximab for the Treatment of Fatigue in Primary Biliary Cirrhosis (RITPBC}*
Principal Investigator:	Professor David Jones
Number of patients:	78
Funder {proposed):	NIHR Efficacy and Mechanism Evaluation Programme & Department of Health
Sponsor {proposed):	The Newcastle upon Tyne Hospitals NHS Foundation Trust
REC number:	12/NE/0095
EudraCT number:	2012-000145-12
CLRN ID:	90909

Having carried out the necessary risk and site assessment for the above research project, Newcastle upon Tyne Hospitals NHS Foundation Trust grants NHS Permission for this research to take place at this Trust dependent upon:

(i) you, as Principal Investigator, agreeing to comply with the Department of Health's Research Governance Framework for Health and Social Care, and confirming your understanding of the responsibilities and duties of Principal Investigators by signing the Investigator Responsibilities Document. A copy of this document will be kept on file within the Joint Research Office.

(ii) you, as Principal Investigator, ensuring compliance of the project with all other legislation and guidelines including Caldicott Guardian approvals and compliance with the Data Protection Act 1998, Health and Safety at Work Act 1974, any requirements of the MHRA (*eg* CTA, EudraCT registration), and any other relevant UK/European guidelines or legislation (*eg* reporting of suspected adverse incidents).

(iii) where applicable, you, as Principal Investigator, should also adhere to the GMC supplementary guidance *Good practice in research* and *Consent to research* which sets out the good practice principles that doctors are expected to understand and follow if they are involved in research – see http://www.gmc-uk.org/guidance/ethical_guidance/5991.asp

Sponsorship

The Newcastle upon Tyne Hospitals NHS Foundation Trust w/11 act as Sponsor for this project, under the Department of Health's guidelines for research in health and social care.

In addition, the Trust has a Research Governance Implementation Plan, agreed with the Department of Health, in order to fully comply with Research Governance and fulfil the responsibility of a Sponsor.

As the Trust is acting as Sponsor for the research and where some of the research Is taking place outside of Newcastle upon Tyne, then all costs must be met for research governance audit visits to those sites. It is the responsibility of the PI to provide confinnation to the Trust of who will pay these costs. Audit is required under the Research Governance Framework for Health and Social Care. (Please note that the Trust randomly audits 10% of approved research projects annually.)

NHS Permission applies to the research described in the protocol and related documentation as listed on the favourable ethical opinion(s) from Newcastle & North Tyneside 1 Research Ethics Committee, dated 16 May 2012, 17 May 2012, 29 June 2012 and 28 August 2012. Specifically, the following versions of the key documents are approved:

Document	Version	Date
Protocol	4.0	07 August 2012
Summary of Product Characteristics	Rituximab	10 January 2012
Participant Information Sheet	3.0	15 May 2012
Participant Consent Form	2.0	23 April 2012
GP Letter	1.0	20 February 2012
Fatigue Diary	1.0	20 February 2012
Validated Questionnaire: PBC40		
Validated Questionnaire: PROMIS HAQ		
Validated Questionnaire: COGFAIL		
Validated Questionnaire: ESS		
Validated Questionnaire: OGS		
Validated Questionnaire: HADS		

Any changes to these documents, or any other amendments to the study must be submitted to the Research Ethics Committee and MHRA (if relevant) for review (see http://www.nres.npsa.nhs.uk/applications/after-ethical-review/amendments/ for guidance). All amendments must be submitted to the R&D office for review in parallel with ethical and regulatory review so that implications of the amendment can be assessed. You must send a copy of all amendment documents to the R&D office and if the changes or amendments to the study have implications for costs or use of resources, you must also submit details of these changes.

It is the Principal Investigator's responsibility to ensure that all staff involved in the research have Honorary Research Contracts or the necessary Letters of Access. These must be issued prior to commencing the research.

In addition, unless otherwise agreed with the Trust, the research will be covered for negligence under the CNST (Clinical Negligence Scheme for Trusts), however cover for no-fault harm is the responsibility of the Principal Investigator to arrange if required.

Please also note that for any NHS employee who generates Intellectual Property *in the normal course of their duties,* it is recognised that the Intellectual Property Rights remain with the employer and not the employee.

Yours sincerely

Research Management &. Governance CRM&.GI Manager