Trent Multi-centre Research Ethics Committee

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Your Ref:

08 September 2004

Professor Stuart Tanner
Professor of Child Health, University of Sheffield
University of Sheffield
Academic Unit of Child Health
Children's Hospital
Western Bank
S10 2TH

Dear Professor Tanner

Full title of study: Wilson Disease: Creating a European Clinical Database and designing randomised controlled clinical trials.
REC reference number: 04/MRE04/65
Protocol number: 'Annex 1 - Description of Work'

The Research Ethics Committee reviewed the above application at the meeting held on 02 September 2004.

Documents reviewed

The documents reviewed at the meeting were:

Document Type: Application
Version:
Dated: 12/08/2004
Date Received: 13/08/2004

Document Type: Investigator CV
Version:
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Protocol
Version: 'Annex 1 - Description of Work'
Dated: 20/07/2004
Date Received: 13/08/2004

Document Type: Covering Letter
Version:
Dated: 10/08/2004
Date Received: 13/08/2004

Document Type: Summary/Synopsis
Version: Introduction to the Workplan
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Summary/Synopsis
Version: Graphical presentation of the tasks
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Letter from Sponsor
Version: Dr Jim Bonham, Director of Audit, Sheffield Children's Hospital
Dated: 11/08/2004
Date Received: 13/08/2004

Document Type: Peer Review
Version: European Commission
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Details of DMC
Version: Data Monitoring Information
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Compensation Arrangements
Version: Statement regarding compensation arrangements
Dated: 11/08/2004
Date Received: 13/08/2004

Document Type: GP/Consultant Information Sheets
Version: Designated version 1 - GP letter
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Participant Information Sheet
Version: 1 - Patient Information Sheet June 2004
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Participant Information Sheet
Version: 1 - Information for Young People June 2004
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Participant Information Sheet
Version: 1 - Information for parents of a child with Wilson's DiseaseJune 2
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Participant Information Sheet
Version: Information booklet for younger people - Designated Version 1
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Participant Consent Form
Version: Patient Consent Form - Designated Version 1
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Participant Consent Form
Version: Parent Consent Form - Designated Version 1
Dated: 17/08/2004
Date Received: 13/08/2004

Document Type: Participant Consent Form
Version: Consent for a young person - Designated Version 1
Dated: 17/08/2004
Date Received: 13/08/2004

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 below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chairman.

Further information or clarification required

Details of study (aims, objectives, design, statistics)

1. The aims appeared confused between setting up a database of newly presenting patients with Wilson Disease with aim of designing RCTs in the future, doing genetic tests and establishing a tissue bank.
2. An assurance is sought that the stated aims could be achieved in the 3.5 years for which the study is funded. Otherwise the ethics are challenged of collecting data that may not be able to be used (the application states that data will be destroyed after 3.5 years). It would be usual for a study setting up a database to have an undetermined end date.
3. Therefore it is suggested that this study should be limited to collecting data on newly presenting patients, and sample storage. Then future phases should be submitted as separate applications to Trent MREC as the REC approving the original database.

Recruitment

AF Q26 appears to assume that children of 8 years old may be assumed able to give consent. This is in accurate and such an assumption can only be made for 16 & 17 year olds in relation to clinical trials.

Risks/ethical problems

1. Clarification is required regarding what would happen to data if consent were withdrawn. This will need to be explained in the PIS.
2. The concept of 'gifting' sample/data should be more clearly explained in application and PIS.
3. Please advise whether participants would be informed if no further funding meant that samples would be destroyed, and how this would be dealt with.

Confidentiality

Data is coded and should be described as such. The PIS and CF should reflect the fact that data will leave the EEA. Please see attached fair processing checklist.

Patient information sheets

Specific changes are required as follows:

1. The purpose of the study should be more succinct and accurate.
2. Information about future RCTs should be included in the PISs (also see consent below).

Child PISs

These should be rewritten in more child-friendly terms (particularly under 12 PIS).

Consent
To avoid the need for reconsent in the future to take part in planned RCTs regarding Wilson Disease, the CFs should include the facility to consent to this at the outset, with a warning that participants may be approached in the future.

General Comments
Whilst not part of the research application, and provided for information, members commented that the Wilson Disease clinical patient information for children was excellent.

No local investigator status
With regard to your declaration at Q A6 on the application form that this is a study with no local investigators, the Committee did **not** agree with the statement on the application form that this research has "no local investigators" because local researchers will be taking written consent. The research procedures to be undertaken at each site require an assessment to be made locally of the suitability of the investigator, site and facilities. The lead researcher at each site should be designated as the local Principal Investigator.

You should therefore arrange for Part C of the application form (complete with all signatures), together with a copy of the Principal Investigator's curriculum vitae, to be submitted to the Local Research Ethics Committee (LREC) for the site as soon as possible. No further documents need to be submitted.

The local assessor will be either the LREC itself or another assessor approved for the site by the relevant Office for Research Ethics Committees. Local assessors have 30 days in which to notify this Committee whether or not there is any objection on site-specific grounds. We would then confirm the favourable ethical opinion for each site in writing to you.

When submitting a 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. Failure to do this will delay consideration of the revisions.

The Committee will issue a final ethical opinion on the application 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.

The Committee expects to receive a response from you by no later than 06 January 2005, otherwise we shall consider the application to have been withdrawn.

Membership of the Committee

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

Communication with sponsor and host organisations

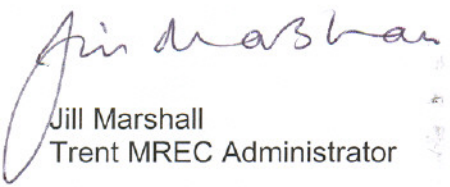
This communication is confidential but you may wish to you to forward copies to your sponsor and/or host organisation(s) for their information.

Statement of compliance *(from 1 May 2004)*

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.

REC reference number: 04/MRE04/65	Please quote this number on all correspondence

Yours sincerely



Jill Marshall
Trent MREC Administrator

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

List of Names and Professions of Members who were Present at the Meeting

Dr Robert Bing
Consultant Physician

Professor Deryck Beyleveld
Professor of Jurisprudence

Dr Eric Button
Consultant Clinical Psychologist

Mrs Lin Freeman
Pharmacist

Dr Ian Gaywood
Consultant Rheumatologist

Dr Christine Johnson
General Practitioner

Ms Victoria Owen
Statistician

Mr Kevin Power
Senior Lecturer in Nursing

Mr Mike Spencer
Lay Member

Mr Terence Wiseman
Lay Member

Mrs Wendy Witter
Lay Member

TRENT MREC

FULL AND FAIR PROCESSING INFORMATION – CHECK LIST

TO BE INCLUDED IN APPLICATION FORM AND PATIENT INFORMATION SHEET, *WHERE APPLICABLE*

Full information about the data to be collected, including:

- **all intended and foreseeable uses** (including possible patents – if applicable use wording below **(1)** in PIS)
- **information about the researcher**
- **who employs the researcher**
- **exactly who will be collecting data**
- **who is the data controller**
- **who will have access to the data/to whom it will be disclosed, and in what form**
- **who will be analysing it**
- **whether it will be anonymised* or coded (and if coded, how)**
- **where and how it will be stored**
- **whether data will be sent outside the European Economic Area (EEA)** (if so use standard wording **(2)** below in PIS and CF) **NB if you think there is a chance, now or in the foreseeable future, that data may be sent outside the EEA, you should include this section now to avoid having to re-consent for this transfer of data at a future date.**
- **when it will be destroyed** (it is recommended that it should be destroyed at the end of the study, not before)

* NB - Information is *not* anonymised if anyone is likely to be able to identify the person directly or indirectly, particularly the data controller.

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1 Patents (PIS):

The results of this study may lead to the development of patents and/or to commercial benefits for the sponsors and researchers. A patent is a right to the exclusive use of an invention, such as a new test or new drug, for a fixed period of time. You would not be entitled to receive any financial benefit.

2 Data outside European law:

PIS:

Will my taking part in this study be kept confidential?

If you agree to take part in this study, then your information will be passed on to researchers or regulatory authorities [or whoever] in countries that do not provide the same protection as in the UK.

Consent Form:

I agree that data about me relating to this study may be sent to countries that do not have data protection laws that are similar to those in the UK.

November 2001