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02 February 2012

Dr Maria Bitner-Glindzicz
Reader in Clinical and Molecular Genetics
UCL Institute of Child Health
CMGU
UCL Institute of Child Health
30 Guilford St, London
WC1N 1EH

Dear Dr Bitner-Glindzicz

Study title:	**Gentamicin, Genetic Variation and Deafness in Preterm Children**
REC reference:	**12/LO/0005**

The Research Ethics Committee reviewed the above application at the meeting held on 25 January 2012. Thank you for attending to discuss the study.

Ethical opinion

- The Committee for re-assurance that parents of dead babies/children will not be
- The Committee would like re-assurance that the parents of dead babies/children will not be contacted.
- Members would like the researcher to use yes/no tick boxes and add further boxes to the consent form.
- Members discussed the possibility that mal practice could be uncovered when the researcher is looking through records.
- Members discussed pre-term infants might not be captured in the data.
- The Committee would like the researcher to write to the GP if the child is identified as having the MitoGent gene.

Dr Maria Bitner-Glindzick Dr Rahman & Professor Marlow joined the meeting. Discussion took place as follows:

1. The Chair asked the researchers to expand on the research proposal concerning infant mortality and to ensure that parents are protected from being contacted if their baby had died. Professor Marlow assured the Committee that this would not happen because they would not have had a hearing test if they had died, therefore data would not have been recorded.
2. Professor Marlow was asked if there is a possibility of resentment in parents? Professor Marlow assured the Committee that the methodology is explained to parents, and they understand that it is a life and death situation, that the use of the drug is necessary. It was also agreed that you would add yes and no boxes to be added to the consent form.
3. Members commented that the information sheet for the under-five age group is difficult to comprehend; You assured members that an adult would go through the form with the child.
4. The Chair asked you to inform the GP only if a child is identified with the MitoGent gene which you agreed to.

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

NHS 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).

Non NHS sites

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.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study 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 a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

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

1. Re-vamp consent form to include yes and no boxes.
2. Inform GP only if child is identified with having MitoGent gene.

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. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Advertisement		02 November 2011
Covering Letter		23 November 2011
Evidence of insurance or indemnity		
Investigator CV		28 November 2011
Other: Letter of invitation to parents	1	02 November 2011
Other: Reply Slip	1	02 November 2011

Other: Consultant Letter	1	02 November 2011
Other: GP Letter	1	02 November 2011
Other: Letter from Funder		10 August 2009
Other: List of abbreviations		
Other: Audiological Data Record	1	02 November 2011
Participant Consent Form: Parental Consent	1	02 November 2011
Participant Consent Form: Assent Form	1	02 November 2011
Participant Information Sheet: Control group 6-10 years	1	02 November 2011
Participant Information Sheet: Children 6-10 years		02 November 2011
Participant Information Sheet: Information for children aged under 5 years	1	02 November 2011
Participant Information Sheet: Parent information leaflet	1	02 November 2011
Participant Information Sheet: Parent information leaflet for controls	1	02 November 2011
Protocol	1	11 November 2011
REC application		28 November 2011
Summary/Synopsis		

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 and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

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
- Notification of serious breaches of the protocol
- 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.

Feedback

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.

Further information is available at National Research Ethics Service website > After Review

12/LO/0005	**Please quote this number on all correspondence**

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

Yours sincerely

Dr John Keen
Chair

Email: Julie.kidd@nwlh.nhs.uk

Copy to:	*Nima Sharma, Great Ormond Street Hospital NHS Trust* *Miss Siby Warrington-Brown*

NRES Committee London - Central

Attendance at Committee meeting on 25 January 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Sir Adrian Baillie	Financial Investment Advisor	Yes	
Dr Sue Birtwistle	General Practitioner	Yes	
Dr Daniel Bradford	Pharmacologist	Yes	
Dr Peter Brodrick	Consultant Anaesthetist	No	
Mr Clive Carsley	Retired Lawyer	Yes	
Mrs Emma Crawford-Collins	Communications Director	Yes	
Dr Parastou Donyai	Senior Lecturer in Pharmacy Practice	No	
Dr Olivia Festy	Clinical Trials Administrator	Yes	
Mrs Sophie Forsyth	Lawyer	Yes	
Mrs Rosie Glazebrook	Consumer Marketing	Yes	
Dr Frances Goodhart	Consultant Clinical Psychologist	Yes	
Dr Leslie Huson	Consultant Medical Statistician	Yes	
Dr John Keen	General Practitioner	Yes	
Dr Amin Rahemtulla	Consultant Haematologist	Yes	
Ms Dani Singer	Psychotherapist	No	
Professor Lewis Spitz	Emeritus Nuffield Professor of Paediatric Surgery	Yes	
Dr Gareth Tudor-Williams	Consultant in Paediatric Infectious Diseases	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Catherine Lavery	
Ms Julie Kidd	Coordinator
Mr Benjamin Stanfield-Davies	