NHS
National Research Ethics Service
Oxfordshire REC A
2nd Floor, Astral House
Chaucer Business Park
Granville Way
Bicester
OX26 4JT

Telephone: [redacted]
Facsimile: [redacted]

12 May 2009

[redacted]

Neonatal Unit
Homerton University Hospital
Homerton Row
London
E9 6SR

[redacted]

Full title of study:	**The probiotic Bifidobacterium breve strain BBG-001 administered early to preterm infants to prevent infection, necrotising enterocolitis and death**
REC reference number:	**09/H0604/30**
Protocol number:	**1**
EudraCT number:	**2006-003445-17**

Thank you for your letter of 09 April 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair, Ms Sara Owen.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, 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.

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming no objection or giving grounds for objection, as soon as this is available.

Other conditions specified by the REC

1. Documents to be seen by participants should have all references to "PREFER" removed to avoid confusion. There were still references in some of the footers of the documents supplied.

2. It is a requirement of the Clinical Trials Regulations that any site not listed on the Application Form before the favourable ethical opinion is provided must be notified to the main REC as a Substantial Amendment. This will then by acknowledged by the REC.

It is the 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 final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Compensation Arrangements	Zurich Municipal	10 February 2009
Peer Review	Professor [redacted]	26 January 2009
Letter from Sponsor	Queen Mary, University of London	06 February 2009
Covering Letter		09 February 2009
Protocol	1	29 January 2009
Investigator CV	Professor [redacted]	06 February 2009
Application	Parts A-D	12 February 2009
Response to Request for Further Information		09 April 2009
Participant Consent Form	2	03 April 2009
Participant Information Sheet	2	03 April 2009
GP/Consultant Information Sheets	2	03 April 2009

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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 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
- 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 [redacted].

09/H0604/30	**Please quote this number on all correspondence**

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

Yours sincerely

[redacted]

Chair

Email: [redacted]

Enclosures: "After ethical review – guidance for researchers"

Copy to: [redacted]

Clinical Trials Unit, MHRA

NHS
National Research Ethics Service
North West London REC 2
Royal Free Hospital NHS Trust
Royal Free Hospital
South House, Block A
Pond Street
London
NW3 2QG

Telephone: [redacted]
Facsimile: [redacted]

29 April 2010

[redacted]

[redacted]

Study Title: **Evaluating the reliability of standardised two-year neurodevelopmental data collected during NHS follow-up in children born preterm**
REC reference number: **10/H0720/35**
Protocol number: **1**

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

Ethical opinion

The main ethical issue was the exclusion of non English speaking people from the study, but
Dr Huetas explained that apart from the cost of the translation, the neurodevelopment assessment tool being used had not been validated for other languages. The paediatric expert member of the committee was present for this item

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.

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:

Document	*Version*	*Date*
REC application		22 March 2010
Protocol	1	18 March 2010
Investigator CV		
Participant Information Sheet	1	18 March 2010
Participant Consent Form	1	18 March 2010
Letter of invitation to participant	1	18 March 2010
GP/Consultant Information Sheets	1	18 March 2010
Student CV		

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 [redacted].

10/H0720/35	**Please quote this number on all correspondence**

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

Yours sincerely

[redacted]

Chair

Email: [redacted]

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" [SL-AR1 for CTIMPs, SL-AR2 for other studies]

Copy to: [redacted]
[R&D office for NHS care organisation at lead site]

North West London REC 2

Attendance at Committee meeting on 21 April 2010

Committee Members:

Name	*Profession*	*Present*	*Notes*
[redacted]	Statistician	Yes	
[redacted]	Co-ordinator	Yes	
[redacted]	Consultant Paediatrician	Yes	
[redacted]	Lecturer (Lay)	Yes	
[redacted]	Head of Pharmaceutical Services	No	
[redacted]	Lay Member	Yes	
[redacted]	Nuclear Medicine	Yes	
[redacted]	Clinical Trial Pharmacist	Yes	
[redacted]	Professor O & G, RFUCMS, Hampstead Campus	No	
[redacted]	Lay Member (Vice Chair)	Yes	
[redacted]	Senior Lecturer and Consultant Neurologist	No	
[redacted]	Chairman	Yes	
[redacted]	Committee Member (Lay)	Yes	
[redacted]	Nurse	No	
[redacted]	Clinical Trial Pharmacist	Yes	
[redacted]	Pharmacist	Yes	

South West London REC 3
Room 4W/12 4 Floor West
Charing Cross Hospital
Fulham Palace Road
London W6 8RF

Telephone [redacted]
Facsimile [redacted]

03 December 2010 (amended and reissued 7 February 2011)

[redacted]

[redacted]

Title of the Database: **National Neonatal Research Database**
REC reference: **10/H0803/151**

The Research Ethics Committee reviewed the above application at the meeting held on 24 November 2010. Thank you for attending to discuss the application.

Ethical opinion
You clarified that the application was requesting ethics approval for the creation and use of the database. The projects listed will use or are using the data and have already received REC approval. All studies will require ethics approval.

The Committee asked for clarification about whether ethics approval was also being sought for the studies detailed briefly in the application and in the protocol. You confirmed that the application was just for creation of the database. A new application would be submitted for each study considered as research. The database will also be used for service evaluation and ethics approval would not be requested for this.

You confirmed that applications for access of the database will be considered by a steering committee and that the database is a national resource and so will be available to everyone.

Members asked for clarification about the charge that will be levied to database users., and you stated that the project would not make a profit from this fee but it will be levied to cover the cost of the staff that manage the database because they do not have a grant for this.

No fee has been set at the moment but the fee charged to a recent study was based on the number of hours the database was used.

The Committee asked who would have ownership of the data. You confirmed that each Trust owns its own data and has access to its own data and it would not be necessary for a Trust to ask for access to its own data. However, problems may arise because of the form in which the data is released. Each Trust would have to manage its own data.

You stated that all parents were given an information sheet with details of all uses of the data held on the database. There is a provision which allows parents to opt out but none have done so as yet

The Committee stated that they believe the data will be used appropriately and only appropriate access will be allowed.

The members of the Committee present gave a **favourable ethical opinion** of the above research database on the basis described in the application form and supporting documentation.

Following further clarification being sought by you after receipt of this opinion letter, the Sub Committee provided the following further information:

This ethical approval extends to those projects listed in the application form, without the need to pursue further ethical approval. Any additional (research) projects (not listed) would need research ethics approval gained through a new research ethics approval application process.

Duration of ethical opinion
The favourable opinion is given for a period of five years from the date of this letter and provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research database.

Approved documents
The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
National Neonatal Research Database Items	1	11 October 2010
NIHR Award Letter		22 October 2008
REC application		07 October 2010
Covering Letter	from [redacted]	22 October 2010
Chief Investigator CV [redacted]		23 October 2010
NIHR Grant Application - Medicines for Neonates	RP-PG-0707	
Letter of Support - Dr [redacted]		07 October 2010
Protocol for Management of the Database	1	07 October 2010
Summary of Research Programme(s)	1	07 October 2010

Research governance
A copy of this letter is being sent to the R&D office responsible for Chelsea and Westminster NHS Foundation Trust.

Under the Research Governance Framework (RGF), there is no requirement for NHS research permission for the establishment of research databases in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the RGF.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the database has ethical approval.

Site-specific assessment (SSA) is not a requirement for ethical review of research databases. There is no need to inform Local Research Ethics Committees.

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

Here you will find links to the following:

a) Providing 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.
b) Annual Reports. Please refer to the attached conditions of approval.
c) Amendments. Please refer to the attached conditions of approval.

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 [redacted]

10/H0803/151	**Please quote this number on all correspondence**

Yours sincerely

[redacted]

[redacted]
Chair
[redacted]

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

Approval conditions

South West London REC 3

Attendance at Committee meeting on 24 November 2010

Committee Members:

Name	*Profession*	*Present*
[redacted]	Consultant Cardiologist	Yes
[redacted]	Senior Lecturer / Consultant Paediatrician	Yes
[redacted]	Consultant Obstetrician & Gynaecologist	Yes
[redacted]	Consultant Chest Physician	Yes
[redacted]	Lay Member	Yes
[redacted]	Clinical Nurse Specialist	Yes
[redacted]	Lay Member	Yes
[redacted]	Professor of Anesthesia	Yes
[redacted]	Consultant Radiologist	Yes
[redacted]	General Practitioner	Yes
[redacted]	Consultant Surgeon	Yes
[redacted]	Senior Lecturer in Medical Statistics	Yes
[redacted]	Pharmacist	Yes
[redacted]	Chaplain	Yes
[redacted]	Lay Member	Yes

Also in attendance:

Name	*Position (or reason for attending)*
[redacted]	Co-ordinator
[redacted]	Co-ordinator

NHS
Health Research Authority
NRES Committee London - Wandsworth
Room 4W/12 4 Floor West
Charing Cross Hospital
Fulham Palace Road
London W6 8RF
Telephone: [redacted]
Facsimile: [redacted]

13 January 2012

[redacted]

[redacted]

Title of the Database: National Neonatal Research Database
REC reference: 10/H0803/151
Amendment number: 1
Amendment date: 25 November 2011

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Participant Information Sheet	4	16 November 2011
Notice of Substantial Amendment	1	25 November 2011
Covering Letter		25 November 2011

Membership of the Committee

The members of the Ethics Committee who took part in the review 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.

10/H0803/151 **Please quote this number on all correspondence**

Yours sincerely

[redacted]

[redacted]
Chair

[redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *R&D, Chelsea & Westminster NHS Foundation Trust*

NRES Committee London - Wandsworth

Attendance at Sub-Committee of the REC meeting on 03 January 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
[redacted]	Lay Member	Yes	
[redacted]	Lay Member	Yes	

NHS
National Research Ethics Service
NRES Committee London - Dulwich
Room 4W/12, 4th Floor
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Telephone: [redacted]
Facsimile: [redacted]

28 September 2011

[redacted]

Dear [redacted]

Study title:	**The National Neonatal Collaborative Necrotising Enterocolitis Study: Using operational clinical data captured electronically at the point of care for surveillance and research.**
REC reference:	**11/LO/1430**
Protocol number:	**CRO1531**

The Research Ethics Committee reviewed the above application at the meeting held on 21 September 2011. 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

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

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:

Document	*Version*	*Date*
Covering Letter		17 August 2011
Investigator CV		
Letter from Sponsor		17 August 2011
Other: Student CV: [redacted]		17 August 2011
Protocol		18 August 2011
REC application		

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

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

11/LO/1430	Please quote this number on all correspondence

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

Yours sincerely,

[redacted]

[redacted]

Chair

Email: [redacted]

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: [redacted]

[redacted]

NRES Committee London - Dulwich

Attendance at Committee meeting on 21 September 2011

Committee Members:

Name	*Profession*	*Present*	*Notes*
[redacted]	Consultant Paediatrician	Yes	
[redacted]	Consultant Liver Intensivist	No	
[redacted]	Assistant Director of Pharmacy	Yes	
[redacted]	Barrister	No	
[redacted]	Head of Clinical Research Statistics	No	
[redacted]	Lay Member	Yes	
[redacted]	Professor Emeritus, Oral Pathology	No	
[redacted]	Consultant Rheumatologist	Yes	
[redacted]	Consultant Cardiologist	Yes	
[redacted]	Senior Nurse	Yes	
[redacted]	MHRN Service Users in Research Coordinator	Yes	
[redacted]	Stroke Research Coordinator	No	
[redacted]	Consultant Old Age Psychiatrist	No	
[redacted]	Coordinator	Yes	
[redacted]	Research Development Manager	Yes	
[redacted]	Research Nurse	Yes	
[redacted]	Consultant Midwife	Yes	

Written comments received from:

Name	*Position*
[redacted]	Consultant Liver Intensivist
[redacted]	Barrister

NHS
National Research Ethics Service
NRES Committee North West - Cheshire
Research Ethics Office
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: [redacted]
Facsimile:

21 November 2011

[redacted]

[redacted]

Study title: **Understanding parents' attitudes towards the use of nhs data for research purposes in the context of neonatal services**

REC reference: **11/NW/0765**

The Research Ethics Committee reviewed the above application at the meeting held on 09 November 2011.

Ethical opinion

1. The Committee queried whether the questionnaire being used in this study has been validated. Dr [redacted] clarified that is has been reviewed by the statistician and they have looked at the questions. Therefore it is not a common validated tool used widely for research of this type.

2. The Committee asked whether there is an element of bias in terms of somebody helping the participants to fill out the questionnaire. Dr [redacted] explained that the research nurses are trained in this area and are skilled at that practice; therefore they are best placed to do it and as it is a necessary thing to do they cannot think of another way around it.

3. The Committee questioned whether pressure will be put on participants to participate; how long will potential participants have been on the neonatal unit? Dr [redacted] commented that there will be a considerable variation and they will have to use their own judgement on whether an individual should be approached to participate.

4. The Committee commented that they will get a mixture of sick and well babies and felt that they will get a very different and varied response. Dr [redacted] commented that this is what they expect and hope occurs so it can be written up in the analysis.

5. The Committee felt that that there may be an element of pressure/coercion on the patient to take part. Dr [redacted] clarified that somebody from the research team will be involved in the asking rather than somebody from the direct care team.

6. The Committee asked whether the questionnaire will be anonymised. Dr [redacted] confirmed that they will be anonymised but parents have the option of giving their contact details if they wish to do so; this is if they wish to be considered for a separate research study or wish to be contacted for the results. The Committee asked why they are asking for consent because the return of the questionnaire would imply consent. Dr [redacted] explained that they have done this to be on the safe side.

7. The Committee queried the section 'What will happen if I don't want to carry on with the study?' and asked what would happen if the participant had submitted the questionnaire; would this mean that it could not be withdrawn as it would have been anonymised. Dr [redacted] agreed, once the questionnaire has been anonymised there is no way of tracing back therefore participants will not be able to withdraw after that point. Dr [redacted] agreed to reword the information sheet to reflect this.

8. Dr [redacted] clarified that if at any point a participant shows signs of distress and does not want to continue then the interview will be stopped. She explained that the research nurses are highly experienced and have worked with this group of patients before. She also added that the survey has been designed by parents so it should be user friendly. The Committee pointed out that the option of not wanting to answer any particular question should be stated at the top of the list rather than the bottom. Dr [redacted] agreed.

9. The Committee asked why participants would be asked about politics. Dr [redacted] explained that this is just to obtain a picture of what type of person will say 'yes' or 'no' and it is up to the participant if they wish to give this information.

10. The Committee asked whether this research is 'mother' biased. Dr [redacted] clarified that they are keen to involve fathers as much as possible in this research.

Dr [redacted] was thanked for attending and left the meeting.

The Committee considered Dr [redacted] responses.

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).

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

Other conditions specified by the REC

1. Please revise the information sheet under the heading 'What will happen if I don't want to carry on with the study?' as follows. 'If you decide to take part and then later change your mind, either before or during the study you can withdraw. However, once the questionnaire has been filled out and sent back it will have been anonymised therefore withdrawing will not be an option as we will not be able to trace the questionnaire back to you.'
2. Please revise the questionnaire as follows;
    a. Please move the option 'do not wish to answer' to the top of the list of options so that participants are aware that they do not have to answer any of the questions. This should be an option for all questions. It should be made clear at the beginning of the questionnaire in bold that if they do not wish to complete the form or answer any questions then they do not have to.
    b. Under question 10, there is a formatting error; the word 'least' needs to be replaced before the word 'happy' so it reads 'least happy'
    c. Under question 13, the options of 'least happy' and 'most happy' are missing and need to be included.
3. The Committee noted that on the project filter questions on IRAS it states that this is a project involving qualitative methods only. The Committee felt that this study involved a bit of both qualitative and quantitative methods and is also administering a questionnaire. Please clarify this; if it is the latter, then the IRAS form will need to be amended on the project filter questions to reflect the correct study type. Once amended and saved please submit the form with a new submission code (this is found on the bottom right hand corner of the page) to the co-ordinator for the file. The code should be slightly different to the one previously submitted. If you have any problems with this please contact the co-ordinator.

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	Flier - Version 1	01 July 2011
Advertisement	Poster - Version 1	01 July 2011
Covering Letter	email	20 October 2011
Evidence of insurance or indemnity	University of Manchester	17 October 2011
Investigator CV	[redacted]	
Letter from Sponsor	University of Manchester	17 October 2011
Participant Consent Form	1	01 July 2011
Participant Information Sheet: Information Booklet	1	01 July 2011
Protocol	1	01 September 2011
Questionnaire	1	01 July 2011
REC application	3.1	18 October 2011

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

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

Yours sincerely

[redacted]
Chair

Email: [redacted]

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: [redacted] The University of Manchester

[redacted] Teaching Hospitals NHS Foundation Trust

NRES Committee North West - Cheshire

Attendance at Committee meeting on 09 November 2011

Committee Members:

Name	*Profession*	*Present*	*Notes*
[redacted]	Senior Lecturer	No	
[redacted]	GP	Yes	
[redacted]	Vicar	No	
[redacted]	Consultant ENT Surgeon	Yes	Chair
[redacted]	Consultant Clinical Psychologist	No	
[redacted]	Lay Member	Yes	
[redacted]	Consultant Member	No	
[redacted]		Yes	
[redacted]	Consultant Paediatrician	Yes	
[redacted]	University Lecturer in Health Research	Yes	
[redacted]	Pharmacist Member	Yes	
[redacted]	Consultant Member	Yes	
[redacted]	Lay member	Yes	
[redacted]	Lay Member	Yes	
[redacted]	Lay Member	No	

Also in attendance:

Name	*Position (or reason for attending)*
[redacted]	Co-ordinator
[redacted]	Assistant Co-ordinator