NHS
National Research Ethics Service
Newcastle and North Tyneside 2 Research Ethics Committee
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26 October 2010

Dr Mark Pearce
Senior Lecturer
Sir James Spence Institute
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Newcastle upon Tyne
NE1 4LP

Dear Dr Pearce

Study Title: **Long-term risks associated with radiation doses from fluoroscopic cardiology procedures in children and young people**
REC reference number: **10/H0907/47**

The Research Ethics Committee reviewed the above application at the meeting held on 20 October 2010.

Ethical opinion

This was a well presented study by an experienced researcher and the Committee consider this research will provide valuable information to inform clinicians and patients in the future.

The study involves no patient contact and consent for access to the patient data will not be sought because of the impracticalities involved as this is a retrospective review of data of 15,000 subjects starting mid-1980's. The results could be biased by any exclusion. This was considered reasonable. The researchers have fully explained how confidentiality issues will be managed and this was noted to be acceptable - patient identifiable information will be used but this is required to allow linkage between a number of different data sources and the data will be stored indefinitely.

The only issue the Committee raised was to query that the funding they have may not be sufficient to continue maintenance of the database.

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.

Recommendation: The Committee recommend that consideration is given to the provision of funding to allow continued maintenance of the database.

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.

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	v 3.0 40845/141023/1/441	05 August 2010
Covering Letter	Mark Pearce	05 August 2010
Investigator CV	Mark Pearce	22 July 2010
Protocol	v 1.0	22 July 2010
Evidence of insurance or indemnity	Zurich Municipal for Newcastle University	08 July 2009
Funders letter – Newcastle University		22 February 2010
Funders letter – Newcastle Hospitals NHS Foundation Trust		15 July 2010

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.

10/H0907/47	**Please quote this number on all correspondence**

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

Yours sincerely

pp G·Mayer

Professor Philip M Preshaw
Chair

Email: gillian.mayer@sotw.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 researcher' SL-AR2

Copy to: *Dr Lesley Hall – Joint Research Office, Newcastle upon Tyne Hospitals NHS Foundation Trust*

NIGB

Ethics and Confidentiality Committee

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08 November 2010

Dear Dr Pearce

ECC 7-04 (j)/2010 - Long term risks of paediatric fluoroscopic cardiology

Thank you for your application for support under section 251 of the NHS Act 2006 to process patient identifiable information without consent. This application was considered by the Ethics and Confidentiality Committee at its meeting on 28 September 2010.

Context

The proposal is to establish a registry, for long-term follow up, of children and young adults who underwent fluoroscopic cardiology procedures and assess their cancer risk in relation to the estimated radiation doses they received.

Section 251 support was sought to enable flagging with the Central Register; patients would also be matched with congenital anomaly registers to identify the heart defects involved and infants with Down's syndrome. Exposed individuals will be identified primarily from records of radiology and paediatric cardiology departments in Great Britain where interventional cardiology is performed in paediatric patients.

The application requested access to name, date of birth, hospital ID, and NHS number, date of death, full postcode, address and sex for linkage purposes. For analysis purposes, the following would be retained: date of birth, date of death, postcode for deprivation scoring and gender.

Outcome

The discussions that took place at the Committee meeting are set out in the letter dated 04 October 2010, where the Committee agreed to provisionally provide support under section 251, subject to a number of clarification requests and specific conditions of approval.

These clarifications were provided in the letter dated 08 October 2010, and provided information on the nature of the cohort. Clarification was also provided on the measures takes to separate identifiable information from the other data, and the ability to pilot consent prospectively.

In relation to the specific conditions of approval, a favourable opinion letter from the research ethics committee had been provided on 28 October. In particular, it was noted that the Children's Heart Federation had been approached, and that further information would be provided in the annual review on this aspect.

As such, this letter constitutes your final approval under section 251, and our Register of approved applications will shortly be updated to include this application (http://www.nigb.nhs.uk/ecc/reg).

Annual Review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of this final approval letter and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. Please ensure that this is received approximately 8 weeks prior to this submission deadline.

If you have any queries regarding the outcome of this letter please do not hesitate to contact the NIGB Office on 020 7633 7052. Email queries should be sent to eccapplications@nhs.net.

Yours sincerely

Natasha Dunkley
NIGB Approvals Manager

Ethics and Confidentiality Committee
Standard conditions of approval

The support provided under section 251 is subject to the following standard conditions.

The applicant will ensure that:

1. The requested patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and that there is no disclosure of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

7. Audit of data processing by a designated agent of the Secretary of State is facilitated and supported.

8. The wishes of people who have withheld or withdrawn their consent are respected.

9. The NIGB Office is notified of any significant changes which impact on the approval of the application.