NIGB

Ethics and Confidentiality Committee

[redacted]

5th Floor, Skipton House
80 London Road
London
SE1 6LH
Tel: [redacted]
Email: [redacted]

27 January 2012

Dear Professor [redacted]

ECC 8-05(f)/2010 - A National Neonatal Research Database

Thank you for your application for approval under the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information outside the common law duty of confidentiality. This application was considered by the Department of Health on behalf of the Secretary of State.

The role of the ECC is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health (SofS). Following consideration of the advice, reproduced below, the Department of Health on behalf of the Secretary of State has determined that the application should be approved.

Context

This application proposed to set up a national neonatal research database to be used as a research resource. Support under the Health Service (Control of Patient Information) Regulations 2002 was sought to enable routinely collected patient identifiable data to be populated on this research database. In addition to routinely collected clinical data, the application also included requested use of NHS Number, hospital ID, date of birth, date of death, postcode, gender, ethnicity, maternal NHS number and ethnicity, and postcode of infant at two years old.

ECC Advice

This application was considered by the Ethics and Confidentiality Committee at its meeting on 01 December 2010. Members agreed that this application set out a worthy purpose, would provide a number of benefits and the additional clarity provided following queries was welcomed. In particular, the Committee noted that user involvement had been very good and the continued engagement was to be commended.

Members agreed that as a whole, consent would not be practicable due to the large numbers involved (60,000). However, the Committee was mindful that decisions taken under section 251 could not be inconsistent with the Data Protection Act (DPA) 1998. In particular, Members focused upon compliance with the fair processing aspect of the first principle of this Act. While section 251 permits access to patient identifiable information without consent, Members are clear that the

parents of the cohort should be informed where reasonably possible, thus fulfilling compliance with the fairness aspect of the first principle of the DPA. In addition, the sixth principle permits a number of rights, one of which is the right for data subjects to request that the processing of personal data should cease if demonstrated to cause damage and distress. As such, all applicants should have a mechanism in place to manage this aspect, and Members requested details on how these aspects would be implemented within the application. It was suggested that those involved in patient engagement could be consulted as this would aid in developing an appropriate mechanism.

Members highlighted that a principle of the Committee is that there should not be long-term retention of identifiable data without consent. Members could not identify a clear justification to support this long-term retention, and requested that this issue be investigated by the applicant in order to reduce the identifiability. In particular, Members queried why the HESID could not be used as the key identifier once linkage with HES data had been carried out. It was recommended that the applicant discuss this feasibility with the HES team at the NHS Information Centre.

Members also noted the onward disclosure aspect to the application and queried what controls were in place to ensure that recipients would not seek to render the information more identifiable. Members expected that a data access policy would be in place to handle this situation and requested sight of this, and/or any other controls in place.

Based upon the considerations above, the Committee agreed to recommend provisional support under the Regulations to this study. This was subject to the following clarifications, specific and standard conditions of support. The NIGB Office has now received your response to the request for clarification and to the specific conditions of approval as stated in bold below.

Request for clarification

1. Please investigate options to reduce the identifiability of information in line with the Committee's views on long-term retention of identifiable data without consent. You might find it helpful to contact the NHS Information Centre to explore this option further. Please also consider reducing identifiability of the data items. **We agree with the suggestion of the ECC that the infant HES ID is used as the key identifier once linkage with HES data is carried out. We propose to remove and do not intend to retain either infant or mother's NHS number after HES linkage has been carried out. We will retain the unique anonymous infant ID issued by Clevermed, the NHS hosting company for the electronic records.**

2. Please provide the relevant documentation to support any onward disclosure, such as a data access policy that is in place. **The NDAU data access policy (Neonatal Data Analysis Unit Data Management Version 1/07 October 2010) is provided. (Received by NIGB Office on 01 September 2011)**

Specific conditions of support

1. Confirmation of satisfactory security arrangements. **(Confirmation received from the Department of Health Security Review Team on 08 September 2011)**

2. Provision of a favourable opinion from a research ethics committee. **(Received on 01 September 2011)**

3. Provision of fair processing information to inform parents about this activity and to facilitate a mechanism to permit dissent to be registered and managed. **(Received on 25 November 2011)**

4. This approval covers only data generated within England and Wales; Scotland and Northern Ireland fall outwith the remit of section 251. **(Accepted by applicant on 01 September 2011)**

After reviewing your responses above, the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health.

Conclusion

As the conditions of support have now been accepted and met, this letter provides final confirmation that the Secretary of State for Health had approved your application to process patient identifiable information outside the common law duty of confidentiality.

Annual Review

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

The Register of approved applications will be updated on our website to include this application, http://www.nigb.nhs.uk/s251/registerapp

Please do not hesitate to contact me if you have any queries following this letter, I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

[redacted]

NIGB Deputy Operations Manager

Standard conditions

The approval provided by the Secretary of State for Health is subject to the following standard conditions.

The applicant will ensure that:

1. The specified 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 patients who have withheld or withdrawn their consent are respected.
9. The NIGB Office is notified of any significant changes (purpose, data flows, security arrangements) to the application.
10. An annual report is provided no later than 12 months from the date of your final confirmation letter. Details are available on the NIGB website.

NIGB

Ethics and Confidentiality Committee
On behalf of the Secretary of State of Health

[redacted]

5th Floor
Skipton House
80 London Road
London
SE1 6LH.
Tel: [redacted]

5 March 2013

[redacted]

ECC 8-05(f)/2010 – National Neonatal Research Database

Thank you for the provision of your annual review report under the Health Service (Control of Patient Information) Regulations 2002.

The purpose of the annual review is to provide an update against the conditions of approval where applicable, confirm progress of the study, review the need to process confidential patient information, and ensure the minimum amount of identifiable information is being used.

The NIGB Ethics and Confidentiality Committee provides advice to the Secretary of State for Health on whether an application under these Regulations should or should not be approved, along with any applicable conditions, and the Secretary of State for Health (SofS) considers this advice and takes the final decision.

Secretary of State decision

Having considered the annual review, and following advice from the NIGB Ethics and Confidentiality Committee, the Secretary of State for Health has approved the continued processing of this application for the specified purposes for a further 12 months.

Context

This research application from Chelsea & Westminster NHS Foundation Trust proposed to set up a national neonatal research database to be used as a research resource. Section 251 support was sought to enable routinely collected patient identifiable data to be populated on this research database. In addition to routinely collected clinical data, the application also included requested use of NHS Number, hospital ID, date of birth, date of death, postcode, gender, ethnicity, maternal NHS number and ethnicity, and postcode of infant at two years old.

ECC Advice

Following assessment of the annual review documentation, it was advised that there was a continued justification for access to confidential patient information as stated in the original application. The high public interest in the activity continuing was also noted.

In particular, the following was noted:

1. There had been no changes to the existing security policy.

2. There is still a continued need to access confidential patient information as specified within the original application.

3. The continued patient and service user engagement was noted.

4. As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months. It was noted that the IG toolkit score for Chelsea and Westminster was shown to be 94%, however this is shown to be an unsatisfactory score. Based on the security documentation supplied at the time of original application consideration, no further action is required, but in line with our published procedures all those submitting amendments/annual reviews/applications after 01 April 2013 will be required to provide evidence of a satisfactory IG Toolkit score.

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 your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than 12 months from the date of this letter.

IMPORTANT CHANGES

Administration of applications

Please note that the current administration of applications made under these Regulations by the NIGB Ethics and Confidentiality Committee is due to transfer to the Health Research Authority by 01 April 2013, therefore please be advised that arrangements might have changed by the time the next annual review is due. Such arrangements will be communicated once confirmed.

Security review

Please note that due to a change in Department of Health policy, all bodies processing NHS data will be expected to provide up to date assurance of their security arrangements via the Information Governance Toolkit instead of system level security policy submission. Details on this change are available here http://www.nigb.nhs.uk/s251/security%20review. Please note that prior to your next annual review you will need to have provided a relevant IG Toolkit submission to the IG Toolkit Team. Any queries on this aspect should be directed to [redacted] so as to ensure there are no delays to any future continuing approval.

Yours sincerely,

[redacted]

Standard conditions

The approval provided by the Secretary of State for Health is subject to the following standard conditions.

The applicant will ensure that:

1. The specified 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 patients who have withheld or withdrawn their consent are respected.

9. The NIGB Office is notified of any significant changes (purpose, data flows, security arrangements) to the application.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter. Details are available on the NIGB website.

11. Any breaches of security around this particular flow of data should be reported to the NIGB within 10 working days, along with remedial actions taken.

NHS
Health Research Authority
Confidentiality Advisory Group

[redacted]

Skipton House
80 London Road
London
SE1 6LH

Tel: [redacted]
Email [redacted]

[redacted]

[redacted]

13 February 2014

Study title: National Neonatal Research Database
CAG reference: ECC 8-05(f)/2010
Protocol number: 1
IRAS Project ID: 22304/158892/11/253
REC number: 10/H0803/151

Thank you for the provision of an annual review report for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions. The purpose of the annual review is to provide an update against the conditions of approval where applicable, confirm progress of the study, review the need to process confidential patient information, and ensure the minimum amount of identifiable information is being used.

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has approved the continued processing of this application for the specified purposes for a further 12 months from the anniversary of your original final approval outcome letter, therefore until 27 January 2015

Context

Purpose of application

This research application from Chelsea & Westminster NHS Foundation Trust proposed to set up a national neonatal research database to be used as a research resource. Section 251 support was sought to enable routinely collected patient identifiable data to be populated on this research database.

Confidential patient information requested

In addition to routinely collected clinical data, the application also included requested use of NHS Number, hospital ID, date of birth, date of death, postcode, gender, ethnicity, maternal, NHS number and ethnicity, and postcode of infant at two years old.

Confidentiality Advisory Group advice

1. A satisfactory Information Governance Toolkit was confirmed with IG Toolkit Helpdesk, 02/02/2014.

2. There is still a continued need to access confidential patient information as specified within the original application.

3. As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter, to the date specified below.

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 your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. We are also streamlining the process to facilitate the service we provide to applicants. This means that annual reviews will be batched and reviewed on the last day of the preceding month before the date of approval. An annual review should therefore be provided no later than 31 December 2014 and preferably 4 weeks before this date.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

[redacted]

Email: [redacted]

Enclosures: Standard conditions of approval

Copy to: NRESCommittee.London-WestLondon@nhs.net

Standard conditions of approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

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

2. Confidentiality is preserved and there are no disclosures 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 is facilitated and supported.

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

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.

NHS
Health Research Authority

[redacted]

[redacted]

Skipton House
80 London Road
London
SE1 6LH

Tel [redacted]
Email [redacted]

3rd March 2015

[redacted]

Study title: National Neonatal Research Database
CAG reference: ECC 8-05(f)/2010
Protocol number: 1
IRAS Project ID: 22304/158892/11/253
REC number: 10/H0803/151

Thank you for the provision of an annual review report for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions. The purpose of the annual review is to provide an update against the conditions of approval where applicable, confirm progress of the study, review the need to process confidential patient information, and ensure the minimum amount of identifiable information is being used.

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has approved the continued processing of this application for the specified purposes for a further 12 months from the anniversary of your original final approval outcome letter, therefore until 27th January 2016.

Context

Purpose of application

This research application from Chelsea & Westminster NHS Foundation Trust proposed to set up a national neonatal research database to be used as a research resource. Section 251 support was sought to enable routinely collected patient identifiable data to be populated on this research database.

Confidential patient information requested

In addition to routinely collected clinical data, the application also included requested use of NHS Number, hospital ID, date of birth, date of death, postcode, gender, ethnicity,

maternal, NHS number and ethnicity, and postcode of infant at two years old. Following initial linkage to HES data at the Health and Social Care Information Centre (HSCIC) HESID only would be used for continued linkage and NHS number would not be retained following initial linkage.

Confidentiality Advice Team advice

Security arrangements

A satisfactory Information Governance Toolkit score of 87% was noted.

Study progress

It was noted that the specified conditions of approval continued to be met. In line with the original approval there had been a number of publications published and the database was being used for a growing number of service evaluations. Anonymised information was provided for analysis purposes.

Steps taken to anonymise the information or obtain consent from individuals

It was noted that the carers of infants on neonatal units were provided with a parent information leaflet explaining that their baby's electronic record would be used to populate the NNRD. If the parents wished to opt-out they needed to notify a member of the neonatal staff who then informed the supplier(s) of the NNRD to prevent the records from flowing to the NNRD.

Project changes

It was confirmed that there had not been any changes to the data controller, purpose, scope, data flows, data sources or identifiable data items requested.

Practicable alternatives/exit strategy

The applicant advised that as linkage of NNRD/HES data was ongoing, receipt of the limited number of patient identifiers was still needed. The final product from the NNRD/HES data linkage would be a pseudonymised database containing lined NNRD and HES data.

Patient/Service user involvement

The current involvement of users in a current project funded by the Academy of Medical Sciences was noted.

Justification for ongoing support

It was noted that in line with the original outcome, NHS number would not be retained beyond the establishment of linkage with HES data. It was confirmed that there was still a continued need to access confidential patient information as specified within the original application.

Confidentiality Advice Team advice conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter, to the date specified below.

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 your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided 4 weeks before the date indicated above.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

[redacted]

[redacted]

On behalf of the Health Research Authority

Email: [redacted]

Enclosures: Standard conditions of approval

Standard conditions of approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

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

2. Confidentiality is preserved and there are no disclosures 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 is facilitated and supported.

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

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.