NHS
Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

7 April 2017

Present:

Name	Capacity	Items
Dr Malcolm Booth	Reviewer	1a
Dr Tony Calland	Chair	1a, 1b
Ms Gillian Wells	Reviewer	1a
Mr Anthony Kane	Reviewer	1b
Mr David Smallacombe	Reviewer	1b

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0063 REFLECT – Recovery following intensive care treatment

Context

Purpose of application

This research application from Oxford University Hospitals NHS Trust set out the purpose of investigating ways to improve the care of patients on general wards who have been discharged from the intensive care unit (ICU), given the high death rate which had been observed in this cohort (1 in 2 died before leaving hospital).

The applicant would achieve this aim by interviewing patients, relatives of deceased patients, interviews with staff and retrospective case record review of both surviving and deceased patients.

Consent would be sought for all aspects other than the review of the records of deceased patients, for which s251 support was sought.

The project would combine information from several sources with experts skilled at making plans work, with the aim of putting a plan in place at local hospitals with the aim of testing it in a larger trial, and ultimately saving lives. The applicant stated that over 2300 lives would be saved in the UK each year if this plan worked and stopped only a quarter of the unexpected deaths in patients discharged from ICU.

Class 1, 5 and 6 support was requested for the process of extracting and anonymising the information, for auditing, monitoring and analysing patient care and treatment, to allow access to an authorised user for one or more of the above purposes

Confidentiality Advisory Group advice

Public interest

The CAG commented that there was a clear medical purpose and significant public interest in the research. It was agreed that the activity was worthwhile.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members noted that consent was sought for all aspects of the research apart from access to the data of deceased patients, where it was clear that this would not be possible.

- Use of anonymised/pseudonymised data

Members were satisfied that the data would be anonymised at the earliest possible juncture, by the researcher on-site.

Justification of identifiers

Members were satisfied that the identifiers used were necessary and appropriate to identify patients and review case notes.

Additional points

Members commented that useful consultation had been carried out with the public during the process of the application

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to

satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation of Data Protection Registration for hospital sites.

b) **17/CAG/0054 Life and Bladder Cancer: The Yorkshire Cancer Research Bladder Cancer Patient Reported Outcomes Survey**

Context

Purpose of application

This research application from University of Sheffield set out the purpose of developing a PROMS (Patient Reported Outcome Measure) questionnaire that would reflect the experience of patients in patients with bladder cancer, before and after treatment. The information would be used together with clinical data to understand outcomes within the population, to identify gaps in care and barriers to care improvement, and to shape clinical care delivery

Surveys would be sent to eligible patients by Quality Health on behalf of the applicant.

A recommendation for class 4 and 6 support was requested to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to data from participating NHS Trusts in relation to patients alive within 10 years of having a current or previous diagnosis of bladder cancer, who had been treated by one of the participating NHS Trusts.

Name, address, NHS number date of birth and postcode was required for a time-limited period to administer the survey mail-out.

Ethnicity, gender, year of birth and deprivation score would be retained for analysis.

Study ID number would be retained for linkage

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that a medical purpose and strong public interest had been demonstrated within the application.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The applicant had referred to data already collected under consent, the fact that patients who had expressed dissent to research in general would be removed from the sample and the fact that consent was taken for the questionnaires – none of which were relevant to the activity in question. This application was concerned with access to the names and addresses of patients prior to consent. As consent was subsequently taken to participate in the research, the argument that taking consent would lead to bias in the study results also appeared irrelevant.

Members accepted that patients would be missed by the in-clinic consent process and considered the proposed method of contacting patients by post to seek consent to be justified for the purpose of the study, although the justification provided by the applicant was not considered adequate.

- Use of anonymised/pseudonymised data

Members considered the exit strategy: - data to be held for no longer than 6 weeks after the first mailing to patients – to be reasonable.

Justification of identifiers

Members noted that the REC had approved the application, but had asked for the number of reminders to be reduced to one, which reduced the total time that identifiers would be held.

The identifiers were agreed to be justified for the purpose of the application.

Additional points

The Sub-Committee requested confirmation of the legal basis for the data flows from the Cancer Registry to and from the Trusts that treated the patients. It was not clear whether this was part of direct care or agreed under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 where this concerned access to mortality, cancer or GP registration data from NHS Digital.

Members also wished to clarify that where patients had been asked for consent and had not responded, or expressly refused consent, there should be no further access to the data of those individuals.

Public Involvement

It was agreed that there was ample evidence of patient participation.

Patient notification and opt out

It was noted that this issue had not been addressed, as although patients would become aware that their data had been processed and would have the opportunity to withdraw or give consent to further processing, this was after the initial processing without consent.

It was accepted that most of the patients would not be receiving treatment in clinic, however there were alternative methods for notifying patients such as cancer and charity websites. The Sub-Committee agreed that an opportunity should exist for patients to opt out of this access to their data, prior to the seeking of consent, and that patient notification materials should be produced to this end.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Patient notifications should be produced and confirmation given that these would be displayed on prominent cancer websites. The method for respecting patient dissent should be explained.
2. The applicant was asked to confirm the legal basis for access to data from the Cancer Registry.

Specific conditions of support

1. The applicant was advised that if no response is received from the patient, or consent was refused, in both cases no further information could be accessed in relation to this individual patient.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 30 March 2017.**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Review result published and confirmed satisfactory via NHS Digital website.**

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

21 April 2017

Present:

Name	Capacity	Items
Dr Patrick Coyle	Chair	1a, 1b
Dr Kambiz Boomla	Chair	1a
Dr Jenny Kurinczuk	Reviewer	1a
Dr Lorna Fraser	Reviewer	1b
Professor Barry Evans	Reviewer	1b

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0063 REFLECT – Recovery following intensive care treatment

Context

Purpose of application

This research study from Sheffield Teaching Hospitals NHS Trust set out the purpose of furthering knowledge of necrotising enterocolitis (NEC) in premature babies, to be achieved by a retrospective review of medical notes.

Necrotising enterocolitis is one of the most common infections within premature babies worldwide. Causes of the infection are still not clear, and despite extensive research into preventative methods, the rates of infection, often resulting in long term complications and death, are still high. Long term implications could include further health complications that require longer hospital stays.

The research aimed to identify whether early clinical observations could indicate the severity and outcome of the disease, enabling earlier and more effective intervention. It was anticipated that it may be possible to create an additional diagnosis tool for systemic symptoms allowing the identification of NEC in infants earlier.

Medical records would be accessed on site, and anonymised data extracted.

Class 1 and 6 support was requested for the process of extracting and anonymising the information and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from Sheffield Teaching Hospitals NHS Trust in relation to preterm infants that were diagnosed with NEC at the Sheffield Teaching Hospitals Neonatal Unit between 1st January 2014 and 31st January 2017.

The full medical record would be accessed by the researcher.

Data fields to be recorded were listed at Q14 on the IRAS form. No identifiers would be retained for analysis other than gender.

Confidentiality Advisory Group advice

Public interest

Members agreed that this project was an important one which clearly demonstrated a medical purpose and public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

It was agreed that consent would not be advisable for the reasons listed, including the possibility of causing distress to parents whose baby had died and difficulty in tracking down parents who had moved.

- Use of anonymised/pseudonymised data

The Sub-Committee agreed that there was little risk of the patient being inadvertently identified – identifiers would not be retained.

Justification of identifiers

The Sub-Committee considered the dataset to be collected, and agreed that it seemed appropriate.

Additional points

Patient notification

The Sub-Committee of the CAG agreed that efforts should be made to notify the parents of the cohort and provide an opportunity to opt out.

The argument that the majority of babies would not still be on the NICU was accepted, however there were other ways to reach the parents such as a notice in the Outpatients Department or a notice on the hospital website. This should be done for the specific study, as a general notification poster for research could take some time to implement.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. The applicant was asked to provide details of patient notifications, where they would be placed and how opt-outs would be respected.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V14 published on website, confirmed reviewed as satisfactory.**

b) 17/CAG/0075 Incidence of JSLE in CYP and their access to care in UK and ROI

Context

<u>Purpose of application</u>

This research application from the University of Liverppol set out the purpose of determining the incidence of Juvenile-onset Systemic Lupus Erythematosus (JSLE) or ‘childhood lupus’ – a rare disease where the immune system attacks the body.

This disease was difficult to diagnose and its effects could vary from mild to severe. The study aimed to increase knowledge of the number of cases, how long it took to diagnose, the impact of new diagnostic criteria, the severity of the disease effects, and treatments used within the first year.

The study would use the BPSU ‘orange card’ reporting system, a compulsory reporting system which enabled study of rare conditions. Paediatricians in the UK would be obliged to report to the BPSU whether or not they had come across a case of the condition listed (in this case JSLE). The clinician details would be passed from the BPSU to the research team, who would send a questionnaire to the clinician, requesting minimally identifiable, clinical information on the patient.

For this particular study the researcher would also identify other clinicians who might see patients with JSLE, through the British Society for Paediatric Dermatology (BSPD), the British

Association for Paediatric Nephrologists (BAPN), the British Isles Lupus Assessment Group (BILAG) and the Barbara Ansell National Network for Adolescent Rheumatology (BANNAR) group. These clinicians would be asked to report all new cases meeting the surveillance case definition directly to the study team, who would proceed to send the questionnaire as above.

A recommendation for class 1, 2, 4 and 6 support was requested for the process of extracting and anonymising the information, to obtain and use information about past or present geographical location, to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to data from clinicians in relation to children identified by clinicians as having Juvenile-onset Systemic Lupus Erythematosus (JSLE) or 'childhood lupus'.

There was some discrepancy on the application form, however the applicant clarified in the advice form that they would collect the following data items:

Partial date of birth (month/year), date of death, NHS number and partial postcode (first part only).

Confidentiality Advisory Group advice

Public interest

Members agreed that the study had a clear medical purpose, and that it was in the public interest to find out more about JSLE, its effects and treatment. The purpose of the study was considered important.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The BPSU methodology was approved in principle by the CAG, and the argument that taking consent in such a small sample would considerably bias the results was generally accepted. The Sub-Committee agreed that this study fell within the BPSU criteria – the disease was rare and complete ascertainment was needed to ensure validity of the results.

- Use of anonymised/pseudonymised data

The application had contained some conflicting information about the data items to be returned to the research team, however it was confirmed that date of birth would be reduced to month and year of birth, and postcode to partial postcode. However the full date of death would be retained.

Justification of identifiers

Concerns were raised in relation to the retention of date of death. The Sub-Committee noted that date of birth was reduced to month and year to reduce the risk of identifiability, and queried why the same could not be done for date of death. It did not appear necessary to retain the full date in order to answer the research question – as full date of birth would not be retained, it would not be possible to calculate survival time in days. Members agreed that further justification would be required for the retention of full date of death. If it was confirmed that full date of death was to be retained, this would render the dataset identifiable and therefore necessitate a referral to a CAG meeting.

Additional points

Public involvement

The Sub-Committee was content with the level of public involvement which was agreed to be appropriate for the study.

Patient notifications

It was noted that patient notification was addressed via the BPSU, who had standard materials which could be adapted for individual studies. However, the application had not addressed the fact that the study would involve clinicians who had been contacted directly by the research team rather than BPSU.

The patient notification implied that patient opt outs would be dealt with via the consultant paediatrician. The patients who were included in the study via other clinicians may not have seen a consultant paediatrician.

It was agreed that patient notifications should be provided to these patients, and consideration given to how opt outs from this part of the cohort would be respected. This would be a requirement of support from CAG.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

The applicant was asked to provide confirmation that the full date of death will be retained, and if this was the case to provide the justification for retaining this identifier.

Specific conditions of support

1. The applicant was advised that CAG approval applied to England and Wales only and asked to confirm that approvals would be sought from the relevant bodies for any processing of data outside England and Wales, as the application referred to the UK and Ireland.
2. The approach to patient notification for patients not referred by a consultant paediatrician should be described, including the route to be taken by these patients in order to opt out, and the procedure for ensuring that opt outs would be respected.
3. Favourable opinion from a Research Ethics Committee. **Confirmed.**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. .