NHS
Health Research Authority

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

07 October 2016

Present:

Name	*Profession*	*Present*	*Notes*
Dr Tony Calland (Chair)		Yes	
Dr Harvey Marcovitch	Dr	Yes	
Ms Gillian Wells		Yes	

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 16/CAG/0139 Life threatening bronchopulmonary dysplasia in infants - A rare disease BPSU survey

Purpose of application

This application from Newcastle upon Tyne Hospitals NHS Foundation Trust set out the purpose of collecting data on outcomes and treatment of chronic lung disease in babies born more than 8 weeks early. This condition could be serious, resulting in weeks or months spent in hospital on breathing machines, or even death. As the condition only affected small numbers of babies, very little was known about it. The study was expected to result in improvements in the management of this condition.

The BPSU methodology – an established surveillance methodology supported in principle by CAG – would be used. From 1st January 2017 to 31st December 2017, all BPSU contributing consultant paediatricians would be asked to report each month whether they knew of any premature babies who met the study criteria. Once the clinician had informed BPSU that they had identified a case (no identifiable data would be sent at this stage), BPSU would send them 3 questionnaires over the 13-month period for the study. The clinician would then extract data from the medical record for the questionnaire. Some

identifiers would be included both for linkage and for analysis. The questionnaire would consist of a front sheet containing identifiable data (as listed below) which would be stored separately and linked to the questionnaires by a unique study number. The Principal Investigator for the study would retain the link. Analysis would be carried out on pseudonymised data, which would be labelled with BPSU study number rather than NHS number.

A recommendation for class 2, 5 and 6 support was requested to obtain and use information about past or present geographical location, for auditing, monitoring and analysing patient care and treatment and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to date of birth, date of death, NHS/CHI number, gender, hospital number and ethnicity, to be retained for linkage of data and to avoid duplication. Date of birth, date of death, gender and ethnicity would be retained for analysis.

Confidentiality Advisory Group advice

Public interest

It was agreed that the study demonstrated clear public benefit.

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 Sub-Committee considered this issue. Given the distress that could be caused by approaching parents, particularly those whose children had died, members agreed that it was appropriate not to seek consent even when clinicians did interact with parents directly.

- Use of anonymised/pseudonymised data

It was noted that data would be pseudonymised prior to analysis.

Justification of identifiers

Members agreed that data flows were clearly outlined. The BPSU surveillance methodology was approved in principle by CAG. No concerns were raised in relation to this use of the methodology.

Additional points

Members agreed that patient and public engagement was good and that the parent groups involved were genuinely representative. An opt-out system was in place.

Although it had been stated that the parent information leaflet had been altered in response to feedback from parents, this information leaflet had not been included. Although it would have been preferable to have seen the patient information leaflet, members agreed that the application was of a high standard and that they would have confidence in supporting the application, subject to REC review and approval.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to 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 from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date