NHS
Health Research Authority

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

09 September 2016

Present:

Name	*Profession*	*Present*	*Notes*
Mr Anthony Kane		Yes	
Dr Rachel Knowles		Yes	
Dr Mark Taylor (Chair)		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/0115 Vitamin D Study

Purpose of application

This application from University of Sheffield set out the purpose of determining the most effective treatment for Vitamin D deficiency, specifically whether a very high single oral dose of Vitamin D could have adverse effects. This would be investigated via a clinical study in which postmenopausal, Vitamin D deficient women would be randomised to one of three different single oral doses of Vitamin D. Consent would be taken for the study.

Recruitment via posters and screening emails to Trust and University staff has been lower than expected due to a low prevalence of Vitamin D deficiency in those who volunteered. The applicant is therefore requesting support in order to target recruitment to women who are known to have Vitamin D deficiency. The Sheffield Teaching Hospitals Clinical Research Systems Team would be asked to search the Sheffield Teaching Hospitals database for women over 55 with a recent low Vitamin D result. These women would have had a recent vitamin D measurement via their GP practice, which would be analysed in the STH laboratories. They would return a spreadsheet to the Research nurse via Trust email,

containing the requested identifiable patient data. The research nurse would use this information to screen for eligibility and send an invitation letter to the GP practice, from where it would be forwarded to the potential participant. Any further contact would be initiated by the patient, and the data would be destroyed.

A recommendation for class 3 and 6 support was requested to select and contact patients to seek their consent and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to name, address, GP practice and Vitamin D result.

Confidentiality Advisory Group advice

Public interest

Members agreed that this threshold had been met.

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.

The application concerned access to identifiable data in order to screen potential participants, and to send invitation letters to those meeting the inclusion criteria.

The Sub-Committee considered whether support was necessary, querying whether identifiable information would be accessed outside the care team. On closer examination it was agreed that the Metabolic Bone research team would not be part of the care team, and support was therefore recommended to enable the team to arrange for invitation letters to be sent to potential participants via the GP surgery.

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.

b) 16/CAG/0126 Intraoperative hypotension in elder patients

Context

Purpose of application

This application from University College London set out the purpose of preventing avoidable harm to patients over 65 years as a result of low blood pressure during operations. The study would record how often low blood pressure occurs in older patients having surgery, how long it persists for and how anaesthetists treat the problem.

Patients would be identified by local investigators who were NHS anaesthetic department staff, and therefore able to access operating theatre lists as part of their clinical role. All patients over 65 undergoing surgery would be identified from the list and included in the study, unless they had expressed dissent as a result of posters in the department explaining the study. Consent would not be sought in order to avoid excluding those who were severely ill and unable to consent, which would bias the results given that this group was most at risk from complications due to low blood pressure. Data would be recorded by the local investigator on a paper case report form and anonymised apart from the retention of the patient's gender and hospital ID number. The hospital ID number would be kept with the form on site for 30 days and used to identify the patient after surgery, when surgery outcome data would be recorded. The hospital ID number would then be removed, but gender retained. The data set would be transferred from the paper case report form to a secure encrypted online portal (REDCap) which is managed by RAFT and hosted by NHS Scotland. Local sites would be asked to retain a link between the study number and the hospital number. Once collated, the anonymised data from each site would be transferred to UCL data safe haven for final analysis and data storage.

A recommendation for 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 and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to the anaesthetic record.

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. Further to the letter of 23 September 2016, the CAT team clarified that support from CAG was given for access to the anaesthetic record and surgery outcome data only. The information transferred from hospital sites via the REDCap system did not come under CAG approval as the only identifier to be retained was gender, which was not considered to be identifiable data in this context.
2. Favourable opinion from a Research Ethics Committee. Confirmed 20 July 2016
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Condition rescinded.

Support is here provided for local data processing. Due to the volume of sites and different locations, IG toolkits have not been assessed. To mitigate against this, the expectation is that the local data entry will conform to local IG requirements

CAG support only applies to data generated in England and Wales, and does not apply to data generated in Scotland, or data transferred via REDCap to Scotland (again, to confirm the CAG does not consider gender to be identifiable in this context therefore does not consider that any identifiable data is being transferred).

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

23 September 2016

Present:

Name	*Profession*	*Present*	*Notes*
Dr Kambiz Boomla		Yes	
Dr Malcolm Booth		Yes	
Dr Murat Soncul (Chair)		Yes	

Also in attendance:

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

2. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 16/CAG/0132 Distinct Experiences in Epilepsy

Context

Purpose of application

This application from Cambridge University Hospitals set out the purpose of investigating mystical or religious experiences in patients with temporal lobe epilepsy (TLE). The researcher aimed to understand the meanings people gave to these experiences and the influence of religious tradition or upbringing through interviews with patients, and through MRI and EEG to establish whether there was a universal neurological site or structure associated with these experiences. Four patient groups would be compared: three with various experiences of TLE, and one group of non-patients from religious backgrounds.

The recruitment process would involve screening patient records for eligibility prior to sending invitation letters. Screening medical records was deemed necessary as the phenomenon of mystical experience in TLE was rare and under-reported, and recruitment by other methods would not enable the researchers to reach enough patients. A dedicated researcher employed for this purpose (Dr Tennant) would review records at the hospital site together

with Dr Eriksson (a member of the clinical care team at the site). A record of the patient's name, telephone number and cohort assignment would be kept on a laptop which would be taken off site and shared with Dr Coles (the Chief Investigator). Invitation letters would be sent from the patient's clinical care team. The record would be pseudonymised if the patient subsequently consented to the study, or destroyed if they did not consent.

Confidential patient information requested

Access was requested to medical records to screen patients for eligibility.

Confidentiality Advisory Group advice

Public interest

Members debated whether this application had a medical purpose. On the understanding that the main point of the research was to uncover the physiological basis for mystical religious experiences in those with epilepsy, the Sub-Committee was persuaded that the study was medical research.

Members considered the question of whether the public benefit was sufficient to justify the use of data without consent. The Protocol did not express any expectation of public benefit from the study. However in the application it had been stated that the research would benefit patients, caregivers, and physicians and those involved in pastoral care, if they had a better understanding of the neurophysiology of mystic experiences.

The Sub-Committee agreed that this justification did meet the minimum threshold for 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

Members noted that the application involved screening patient notes in order to identify suitable participants, and subsequently seek their consent. The applicant had justified the impracticability of asking a member of the care team to do this.

- Use of anonymised/pseudonymised data

Names and addresses would be destroyed if a patient did not consent to the study.

Justification of identifiers

Members accepted that it was justified to retain name and address in order to send out invitation letters. As above, it was noted that this information would be destroyed if patients did not consent to take part in the study.

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