Minutes of the meeting of the Precedent Set Sub Committees of the Confidentiality Advisory Group

September 2015

Reviewers:

Name	Capacity	Items
Dr Patrick Coyle	Chair	1a, 1b, 2a
Dr Miranda Wolpert		1a, 2a
Professor Barry Evans		1a, 2a
Hannah Chambers		1b
Robert Carr		1b

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) The RECENSUS Study: A Medical Chart Review of Patients with X-Linked Myotubular Myopathy (XLMTM), sponsored by Audentes Therapeutics - 15/CAG/0168

This retrospective medical chart review (RECENSUS) of approximately 70-100 XLMTM patients will provide further knowledge about the clinical manifestations and recorded medical management of XLMTM and potentially inform the design of future therapeutic intervention studies. Patient records from approximately 70-100 subjects (with at least 50 deceased and 20 living) may be reviewed at approximately 10-12 clinical sites in the US and Europe with 2 of these in the England. XLMTM is a disease that presents at birth, children as young as 1 day of age may be included in the research database. Some patients die shortly after birth, while some (milder and rarer cases) may live into their teens. Few XLMTM patients live into adulthood.

A CRA (Clinical Research Associate) trained in GCP (Good Clinical Practice) at each hospital will identify potential participants that meet the inclusion criteria. A search of electronic medical records and/or paper medical records system may also be used to identify potential participants.

Support is requested to provide access to the personal patient information held in the medical records by the research team in order to determine if potential participants meet study entry criteria.

Due to limited number of XLMTM patients (a rare and often fatal disease) available and the difficulty in reaching and getting a response from authorized legal representative(s) of deceased patients, support is also requested for the disclosure of identifiable patient data for deceased patients for this study. Data extracted from medical records will be entered into a secure, password protected anonymous electronic database. No identifiable data will be transferred outside the EEA

A recommendation for class 2, 5 and 6 support was requested to obtain and use information about past and 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 to date of birth, date of death and country of birth are requested to allow for identification of cases by the research team.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was an important study into a rare disease.

Data flows

It was noted that this was a potential problem area as data was going outside the European Economic Area (to the USA). No names would be collected but a significant percentage of male children would die in the first few weeks and therefore knowing date of birth and date of death was quite important in calculating age at which ventilation or other procedures happen. Members agreed that if full date of birth and date of death were part of the record transferred outside the EEA this would effectively mean that is the dataset was not completely anonymised. The applicant has confirmed that this data could be limited to month and year of birth and death if really necessary, but that they would prefer full date of birth and date of death if possible. The applicant was asked to confirm whether it would be possible to restrict this data to month and year of birth and death. If so the application could be recommended for support via the precedent set process, however if the applicant is not able to conduct the study with these restricted data fields then the study would fall outside the precedent set criteria (g) the transfer of confidential patient information outside of the European Economic Area (EEA), or to organisations who intend to use the data for commercial purposes, and would require review at a full committee meeting (please see the referral to full committee letter dated 25/08/2015). The applicant confirmed that only non-identifiable data would be transferred outside the EEA. Members agreed that this satisfied the criteria for precedent set review and were able to provide a decision on the application.

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.

b) PUMA - Paediatric early warning system (PEWS) -15/CAG/0172

This application from Cardiff University and the South East Wales Trials Unit sets out the purpose to develop an evidence based paediatric track and trigger tool, in order to evaluate its feasibility and potential effectiveness in predicting deterioration and triggering timely interventions, identify the contextual features and factors necessary to ensure successful implementation and normalisation. Researchers will observe staff, who may have sight of patient documentation such as observation charts, to record how vital signs are recorded and how patient deterioration is recognised and acted upon.

The applicant sought support in order for members of the research team to undertake observations of members of the clinical care team, whereby they may be privy to confidential patient information and also to access patient medical records at 4 NHS hospital sites to extract anonymised data.

Confidential patient information requested

Access was requested to name, NHS number, date of birth, post code, medical details (predominantly observation charts).

Confidentiality Advisory Group advice

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 agreed that there were currently no practical alternatives unless deferred consent is considered following patient admission to Intensive Care Units (ICU). It was noted that the deterioration of a child's condition leading to transfer to ICU was not considered to be an appropriate time to seek informed consent and that deferred consent would be difficult if the child does not survive this, with outcome data being skewed as a result.

Justification of identifiers

It was noted that the identifiers were necessary for initial details at the time of the event and for monthly follow up and were not considered to be excessive.

Additional points

Members noted that the opt out statement was not on the general poster or the parent flyer and although it was clearly stated on the observations poster this needed to be clearer about which staff members would process an opt out decision. Members requested that this information be included on the parent flyer which should be given to all parents present during an observation visit.

It was noted that the Data Flow diagram suggested that the research team would not have access to identifiable data, but the poster ("use of medical records …") provided the correct facts. Members requested that the data flow diagram was amended to reflect that the research team will be accessing identifiable data.

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.

2. NEW PRECEDENT SET REVIEW APPLICATIONS –NON RESEARCH

a) Quality Health and NHS England: National Cancer Patient Survey-15/CAG/0173

This non-research application from NHS England and Quality Health sets out the purpose of conducting a survey in order to collect and analyse data to secure continuous improvement for provider performance, assess local improvements and provide an overview in cancer patient experience, improve provider quality and to enable patients to make informed choices on where to go for cancer treatment. The applicant is seeking section 251 support in order for NHS Acute Trusts to disclose confidential patient information to Quality Health and for Quality Health to liaise with Trusts in order for patient questionnaires to be sent to patients under cover of appropriate Trust letter headed paper.

Confidential Patient Information Requested

Access was requested to name and address including full postcode, NHS number, gender and ethnicity. Access is also requested to year of birth, admission and discharge dates, admission type, ICD10 code, speciality code and referring CCG.

Confidentiality Advisory Group advice

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 indicated by the return of the questionnaire and non-consent by return of a blank questionnaire or by no return at all. It was noted that the proposed methodology followed the standard set by previous applications and that CAG had agreed that prior consent to receive a survey would not be feasible and the transfer of identifiable data to administer the survey would be necessary.

Justification of identifiers

Members agreed that the identifiers were needed in order to write to patients.

Additional points

It was noted that this was in the public interest through improving services for cancer patients based on feedback and that there were currently no other practical alternatives to seeking support.

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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

3. A comparison of risk scores in consecutive, unselected chest pain presentations with suspected acute coronary syndrome in the era of high sensitive Troponin – 15/CAG/0171

In general, members noted that prospective data collections where consent is not intended to be sought are excluded from precedent set applications. There was lack of clarity within the application on whether the project involved prospective data collections without consent and for these reasons the committee advised escalation to review by full CAG committee if the applicant was not able to conduct the study through a consented approach.

Following consideration of the application, the sub-group referred to a full review at the Confidentiality Advisory Group meeting which is to take place on 17/09/2015. For full details of this application please refer to the minutes of the meeting held on 17/09/2015.