Chair's Action Report

April 2015

Reviewers:

Name	Capacity	Items
Dr. Mark Taylor	Chair	1c
Dr. Tony Calland	Chair	1a, 1b,
Dr. Patrick Coyle	Chair	2a

1 – AMENDMENTS – RESEARCH

a) National Gestational Age Statistics: Linkage, Analysis and Dissemination of National Birth and Maternity Data for England and Wales - PIAG 2-10(g)/2005

Context

This application from City University set out the purpose of a project to acquire data from NHS Numbers for Babies (NN4B) notifications to produce national statistics about gestational age at birth and gestation-specific survival of babies born in 2005 and subsequent years, and to provide information about how the data provided by maternity units for the NHS Numbers for Babies notifications relate to those from birth registration and from the Maternity Hospital Episode Statistics in terms of numbers of events and consistency of common data items. This was a collaborative project between Child Health Statistics, Maternity Hospital Episode Statistics, Health Statistics and Analysis Unit, National Child Health, Department of Midwifery (City University), Confidential Enquiry into Maternal and Child Health, Regional Maternity Survey Office and the British Association of Perinatal Medicine. A recommendation for class 3, 4, 5 and 6 support was requested to cover access to birth registration data.

Confidential patient information requested

Access was requested to baby's NHS number, mother's NHS number and postcode.

Amendment request

The amendment request was submitted to obtain support for the purpose of accessing and linking stillbirths and neonatal deaths data collected by the Centre for Maternal and Child Enquiries (CMACE) now held by the HQIP. CMACE data for 2005 and 2009 have had the identifiers deleted and therefore, the applicant will be required to common data items, such as place of birth, birth weight and gestational age. The common data items will be linked to the birth and maternity HES linked datasets which includes identifiers, by the Office for National Statistics (ONS).

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Chair who was content to support and advised to continue the submission of annual reviews.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

b) DIAMOND-Lewy Work Package 1, version 1.0 - CAG 8-03(PR8)/2013

Context

Purpose of application

This research application from the University of Cambridge set out the purpose of a study to improve the recognition and diagnosis of Lewy Body Dementia (LBD) through development of a new assessment tool, and to improve patient management and outcomes with respect to the same condition through development of evidence based toolkit for clinicians. A recommendation for class 1, 3 and 6 support was requested to cover access to the records of 1,800 adult patients at NHS Trusts in North East England and East Anglia with a diagnosis of dementia or Parkinson's disease, in order to screen these records for LBD and contact the subset of patients with LBD to seek consent for inclusion in further research. It was expected that this subset would be approximately 480 patients.

Confidential patient information requested

Access was requested to name, NHS number, hospital number, date of birth, address, postcode, telephone number and gender.

Amendment request

Authorisation was sought to retain patient contact details, including name, hospital number and full address for a temporary period of time. This was to avoid duplication between different services within the same NHS Trust. Patients who had opted out of the study may potentially be re-contacted about taking part in it.

Confidentiality Advisory Group Advice

This was forwarded to the vice Chair for review. It was noted that the problem was due to duplication of the identifiers and because of the way that the patient had moved through the system there was likelihood that patients who had opted out of the study would be re-contacted. This was not desirable and therefore the vice-Chair agreed that the amendment should be approved.

It was advised that the minimum amount of information necessary should be kept to avoid writing to patients again, and the data should be destroyed following recruitment.

Confidentiality Advisory Group conclusion

In line with the considerations above, it was agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

c) Bariatric surgery and Colorectal Cancer – CAG 4-09(b)/2013

Context

This application from the University of Leeds set out details of a study to confirm whether the risk of colorectal cancer increased after bariatric surgery. The study proposed to use existing health datasets and established methodology to compare the incidence of colorectal cancer in a cohort of patients who had undergone bariatric surgery and a cohort of obese patients who had not undergone bariatric surgery. The original application received section 251 support to enable access to identifiable extracts of bariatric and obesity HES data which was to be linked with cancer incidence data. Linkage was to commence within Public Health England's National Cancer Registration Service.

A recommendation for class 2, 4 and 5 support was requested to cover access to existing Hospital Episode Statistics (HES) and National Cancer Data Repository (NCDR) datasets for the purpose of linkage.

Amendment request

The applicant had submitted an amendment request to re-activate the existing approval and to amend it to support data linkage within the Health and Social Care Information Centre (HSCIC). This would include the linking of HES data, extract of cancer registry data from both Office for National Statistics (ONS) and Public Health England, as well as, mortality data from the ONS.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Chair who agreed to support access to the specified datasets and also the data linkage within the HSCIC.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority**.**

2 – AMENDMENTS: NON - RESEARCH

a) Hip Fracture Audit – CAG 8-03(PR11)/2013

Context

This audit application was originally submitted by the Health and Social Care Information Centre and received approval by the Secretary of State for Health on 11 April 2011. The application set out aims to use case-mix, process and outcome data together with quality standards to improve the quality of care. A recommendation for class 1, 3, 4, 5 and 6 was requested to cover linkage with Hospital Episode Statistics (HES) data. Access was requested to NHS number, date of birth, date of death and postcode.

An amendment request to the original application ECC 3-04(s)/2011 was received on 30 August 2013, following prior discussions with the Confidentiality Advice Team, to change the data processor for this application to the Royal College of Physicians of London. The Healthcare Quality Improvement Partnership (HQIP) would remain data controller. An amended application and details of resultant changes to data flows were provided.

Amendment request

An amendment request was submitted for the purpose of converting the date of death identifier to life status at thirty days and the return of the data to the submitting hospitals to perform root cause analysis of all deaths within thirty days. The amendment request also included to extend the user base to clinical teams within trusts for direct care purposes and also for secondary use of anonymised data for the purposed of audit, service evaluation and research. The applicant would only share anonymised data with credible third party applicants however; the amendment request was to allow the flow of confidential patient information to the HSCIC for the purposes of data linkage of HES data with subsequent flow of a linked (anonymised) dataset to the third party applicant organisation. A further additional amendment was submitted in order to seek support for the purpose of submitting confidential patient information to the NHS Wales Informatics Service (NWIS) for linkage with PEDW and forwarding anonymised data to the relevant third party applicants.

Confidentiality Advisory Group Advice

The amendment request had been forward to the chair for review and noted that ‘thirty day mortality’ was not an identifier, but recognised that it is an advantage to the audit, as the audit had previously only collated hospital deaths. The chair commented that access to community hospital teams could be deemed as direct patient care and therefore, s251 support for this element of the amendment request is not required. The chair agreed that the use of the HSCIC data linkage service which provides effectively anonymised data to third parties was a satisfactory method of achieving the applicant’s objective and would also apply to the submission of confidential patient information to NWIS for data linkage and forwarding anonymised data to relevant third party applicants. Overall, the chair advised support only to parts of the amendment request which required it.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

Specific conditions of support

1. Confirmation from the Health and Social Care Information Centre (HSCIC) of suitable security arrangements via IG Toolkit submission for the Royal College of Physicians. **HSCIC Confirmed satisfactory IG Toolkit submission from Crown Informatics Limited on 3rd March 2015.**

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

April 2015

Reviewers:

Name	Capacity	Items
Dr. Patrick Coyle	Chair	3a, 3b, 3c, 3d, 3e, 3f,
Dr. Tony Calland	Chair	3g, 3h, 3i, 3j
Dr. Kambiz Boomla	Member	3h, 3i
Mr. Anthony Kane	Lay Member	3h, 3i
Professor Jennifer Kurinczuk	Member	3b, 3j
Professor Barry Evans	Member	3b,
Mr. Marc Taylor	Member	3g, 3j
Dr. Murat Soncul	Member	3d, 3e, 3f,
Ms. Clare Sanderson	Member	3a, 3c,
Dr. Robert Carr	Member	3a, 3c,
Ms Hannah Chambers	Lay Member	3f,

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) Structural and functional fronto-hippocampal maturation and neurodevelopmental outcome following very preterm birth in adulthood - 15/CAG/0109

Context

Purpose of application

This application from the Institute of Psychiatry and King's College London set out a study to define patterns of brain growth which made an individual at risk of poor outcome, as well as those that were associated with developmental resilience. The application detailed that in the future this information would enable the development of treatments to reduce or prevent long-term disability in people born very prematurely (VP). The cohort of individuals included had been taking part in a follow-up study from birth to age 19 and they are now between the age of 27 and 32 years.

A recommendation for class 3 and 6 support was requested to cover access to current contact details from the Health and Social Care Information Centre (HSCIC) for individuals who were previously consented within the project but for whom contact information were no longer accurate. The applicant stated that if this method would not be deemed as acceptable, the study team would like to obtain support for GP address in order to contact the relevant surgery and ask the practice staff to forward a letter to the patient regarding the study and the desire to re-contact them.

Confidential patient information requested

Access was requested to address and GP registration from the HSCIC.

Confidentiality Advisory Group advice

Public interest

Members noted the assertions that this was a major public health issue and agreed that the proposed outcomes were of significant 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.

It was noted that the applicant did not have the current contact details for the previously consented cohort. Members noted that participants, including the control conhort, had been contacted on several occasions in the past and therefore agreed it was acceptable for the applicant to make direct contact with the cohort.

Contact with cohort

Members requested confirmation whether a follow up would be sent if a reply was not received from an individual. If this was the case, members suggested that the letter was clear that if the individual did not respond to the letter no further contact would be made. If this was not the case, members advised that reply slips should include an option to object to further contact.

Members requested that the information provided to individuals provided clear information in relation to how the applicant received up to date contact details.

Consent for future contact

If the applicant was likely to be contacting individuals again members advised that consent could be obtained for future contact details to be obtained from the HSCIC and that this would avoid further applications for support. It was advised that the applicant consult with the HSCIC to determine appropriate and sufficient wording for consent forms

Retention of identifiable data

Members queried how long identifiable data would be retained for and requested confirmation that this information would only be retained in relation to those who had provided consent.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending condtional support to the Health Research Authority, subject to the specific and standard conditions of support as set out below.

Specific conditions of support

1. Please confirm how long identifiable information will be retained for those individuals that do not provide consent.
2. Please ensure that if further contact is to be made to those who don't respond this is clear within the letter and that a reply slip to allow objection is included.
3. In line with advice above, please ensure that consent to obtain contact details in future is provided if you intend to contact individuals again.
4. Favourable opinion from a HRA Research Ethics Committee.

Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) Surveillance of Childhood Acute Rheumatic Fever (SCARF) - 15/CAG/0111

Context

Purpose of application

This application from Birmingham Children's Hospital NHS Foundation Trust set out the purpose of utilising the BPSU surveillance methodology to ascertain a dataset to assess the epidemiology for the surveillance of childhood acute rheumatic fever (SCARF). Clinicians participating within the BPSU

reporting mechanism will be reporting cases of incidence to the BPSU office. The BPSU office will notify the lead investigator and the research team will send a proforma consisting of specified identifiers and associated clinical data to the clinicians to complete and return. The identifiers will be kept separately from the clinical data for case verification and to de-duplicate the dataset. The applicant also requested support to utilise the specified identifiers for the purposes of linking with Hospital Episode Statistics (HES) data to ensure cases have not been missed.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to an authorised user for the process of extracting and anonymising data, to obtain and use information about past or present geographical location, to link patient identifiable information obtained from one or more sources and also for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to date of birth, NHS Number, Hospital identifying number, gender, ethnicity and partial postcode.

Public interest and Medical Purpose

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activities carried out provided a public interest as there is need to assess the epidemiology and improve knowledge of a rare childhood condition, Acute Rheumatic Fever.

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. Members noted the approved BPSU methodology for rare conditions will be implemented for this study. Members agreed that consent would not be feasible as it would be important for maximum ascertainment, and agreed that to pursue a consent based approach would lead to bias due to small numbers involved in a study of a rare condition.

Data Flows and Justification of identifiers

The members agreed that the data flows and identifiers specified within the application are necessary and standard practice for a BPSU study. The members noted that the use of the identifiers is

necessary for the purposes of case verification, to de-duplicate the dataset and for linkage with HES data to ensure cases have not been missed.

Communication and Transparency

Members agreed that there was not sufficient patient information for this study. Members noted that it is an important principle for activities taking place with support to provide a clear mechanism to manage the right of patient objection. Members had advised that patient information and notifications should clearly state that this can be done, either by informing the hospital clinical team, or by contacting the BPSU admin direct, with contact details supplied, and should state that this will not affect ongoing medical care. Members requested feedback on how this greater clarity can be enabled.

Retention

Members asked for clarification regarding whether the data which was to be retained for the requested twenty years included personal confidential information.

Additional Point - Application Inconsistencies

The members noted inconsistencies and errors within the application form. Members noted that the applicant stated that the research study is to only take place within England and noted that BPSU studies cover UK in its entirety. For the purposes of this support, please note that approval only covers data generated In England and Wales.

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. Support only applies to data generated in England and Wales.

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Request for clarification

6. Confirmation if the data which was to be retained for the requested twenty years included personal confidential information.
7. Please provide feedback in line with the comments above on providing further information for patient notifications and to incorporate how patient objection would be managed.

c) Human pituitary growth hormone recipients - 15/CAG/0112

Context

Purpose of application

This application from UCL Institute of Child Health set out the purpose of a data collection in relation to 1883 individuals in the UK treated with pituitary derived growth hormone are at risk of developing Creutzfeldt-Jakob Disease. The unique data is collated on incidence of hGH related CJD, relate this to treatment, and improve the advice we give to professionals and the patients themselves, who contact the applicant through the National Helpline. It facilitates collaborate clinical correlations with illness details, in liaison with the National Prion Clinic and CJD Surveillance Unit. It is the only UK database of these individual with details of patient locations, development of cancers, and details of deaths. From this, the applicant can inform relevant authorities/DH about the size of the risk to the population from transmissibility of CJD. It also enables epidemiological and clinical study relating to the illness and its cause, in particular relating to the dates of hGH treatment and types of HGH implicated.

A recommendation for class 4, 5 and 6 support was requested to cover access to The applicant is submitting to seek s251 support to link data supplied by HSCIC with the applicant's existing the patient database to update mortality and cancer data. The original data fields were not obtained from HSCIC/ONS/OPCS, other than primary health care registration location, life status, causes of death and cancer registrations. The following four items were previously supplied under Section 60 approval:

- Latest primary care registration
- Date and type of cancer - study into epidemiology of possible link to cancers
- Date and causes of death (certificates) – to ascertain cases of CJD and assess any other associations
- Autopsy details where present – to improve ascertainment of cases

The applicant previously contacted all individuals through their local services to inform them of their risk, and plan to retain knowledge of their location so that they could be retraced to primary care should there be a significant development, such as diagnostic testing or treatment which might have an impact on the risk to them and the public. However, the whereabouts and contact

details of the patients is not known to the applicant (unless they reside where they did in 1994) or others.

Confidential patient information requested

Access was requested to data from the Health and Social Care Information Centre (HSCIC) in relation to the above items.

Confidentiality Advisory Group advice

Members were of the view that the activity was strongly in the public interest and agreed that they were supportive of the application in principle.

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.

Specific conditions of support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

d) UK Collaborative Trial of Ovarian Cancer Screening - 15/CAG/0115

Context

Purpose of application

This application from University College London set out the purpose of conducting a large trial with 200,000 participants across twelve centres for ten years to identify if screening could effectively identify women with risk of ovarian cancer prior to the occurrence of symptoms. The research will consist of investigating the effectiveness, acceptability and complications of screening for early detection, survival rates and cost. The information from the outcome of the study could determine the need for a national screening programme. The applicant had previously conducted a trial between 2001 and 2005 with explicit consent of the participants to take part within the trial and for access to medical records.

A recommendation for class 4 and 6 support was requested to allow access to an authorised user access to confidential personal information for the purpose of data linkage.

Confidential patient information requested

Access was requested to confidential patient information in order to identify incidence of ovarian and fallopian cancers, followed by other cancers and to link with cancer and mortality data from the Officer for National Statistics (ONS).

Confidentiality Advisory Group advice

Public interest
Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely provide a significant public interest due to the need to investigate the effectiveness, acceptability and complications of screening for early detection and survival rates for Ovarian Cancer.

Feasibility of Consent

Members commented that the consent of 200,000 participants had been recorded during the recruitment stage of the initial study and agreed that the consent remains sufficient to access medical records. Members agreed that repeat consent would be disproportionately difficult to obtain, due to the retrospective nature of the cohort.

Justification of Identifiers

Members highlighted that the specified identifiers are justified for the purpose of data linkage in order to flag mortality and cancer diagnosis within the Health and Social Care Information Centre (HSCIC). Members noted that the HSCIC will forward pseudonymised data to the applicant for further analysis.
Information Governance Toolkit Submission
Members commented that the applicant was currently progressing their Information Governance Toolkit (IGT) and noted that satisfactory compliance with the IGT requirements was due to be submitted by the end of April 2015.

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. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 19th March 2015**

e) aTTom - 15/CAG/0123

Context

Purpose of application

This application from University of Birmingham set out the purpose of is a clinical trial to compare and study the long term effects of patients taking tamoxifen for five and ten years. Over a million women worldwide took tamoxifen after surgery for oestrogen receptor (or ER) positive breast cancer. The aTTom trial was designed to determine if taking tamoxifen for 10years compared with the standard of 5years would improve patients' outcome. Patients with breast cancer were randomised to Stop tamoxifen or Continue for a further 5 years. The trial commenced in 1991 and closed to recruitment in 2005 having accrued 8863 women from 178 UK hospitals. The last patients completed treatment in 2010. Patients taking part in aTTom are followed up by their hospital (or GP where possible) but many patients become lost to follow-up. Information on patient death had also been collected from the Office of National Statistics.

A recommendation for class 4 and 6 support was requested to cover access to new cancers, date and cause of death from the Health and Social Care Information Centre (HSCIC). Written informed consent was obtained for patients participating in the aTTom trial in accordance with the guidance that was available at the time. Specific consent for accessing data from national data sets was not required at the time and was not sought.

Confidential patient information requested

Access was requested to Date of death, Cause of death, Date of cancer diagnosis, Site of cancer. The following personal data is used for identification of the patient by the Office of HSCIC, Name, NHS Number, Date of Birth, National Insurance Number, Postcode. (Address if NHS number is not provided with combination of other identifiers).

Confidentiality Advisory Group advice

Public interest

Members noted that this was a long established trial of giving Tamoxifen following mastectomy for early breast cancer for either five or ten years to measure if there was any improved mortality in longer use of Tamoxifen and if there was any increase in side effects.

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.

It was noted that in order to link the subjects' data to HSCIC/ONS data, identifiable information would be required. Members noted that the trial was originally fully consented using consent material appropriate for the day and subsequently was given section 60 support. It was agreed that seeking renewed consent would be disproportionately difficult.

Additional points

Members noted that the application form referred to data that had been pseudonymised but still contained date of birth and advised that if date of birth was retained this would be considered as 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.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Provided**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

f) Retrospective Cohort Study of standard dose versus low dose isotretinoin treatment for acne vulgaris - 15/CAG/0124

Purpose of application

This application from Betsi Cadwaladr University Health Board set out the purpose of conducting a retrospective comparison between the standard dose and the low dose of Isotretinoin for the treatment of acne in Glan Clwyd Hospital from 2009 to 2013. Isotretinoin is a hospital – only prescribed drug and the researcher is required to extract a list of prescribed patients between the specified time period from the hospital Pharmacy department's system. From this, it is intended that the Chief investigator will collect the identifiers for medical record staff to collect the selected patient notes.

A recommendation for class 1 and 6 support was requested to allow access to an authorised user for the purpose of extracting and anonymising the information.

Confidential patient information requested

Access was requested to Name, NHS Number, Hospital ID Number, Date of Birth and Postcode.

Confidentiality Advisory Group advice

Medical Purpose

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006.

Data Flows

The members noted that the data flows were mapped to one NHS organisation. The members considered the legitimate relationship between the researcher and the cohort of patients and agreed that the researcher did not appear to form part of the patient clinical care team.

Use of anonymised/pseudonymised data

The members agreed that the specified identifiers were necessary in order to trace the patient records for the researcher to record the data.

Feasibility of consent

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.

Members advised at the previous precedent set review that where it is possible for consent to be obtained as a practical alternative, this should be explored in full noting the requirements of the regulations. The applicant did not provide a response regarding the possibility of obtaining consent within the IRAS form and members concluded that as the cohort was small and within one NHS organisation, requesting consent may had been feasible for the applicant. The applicant was required to demonstrate the reasons why consent is not feasible for this study.

Members reviewed the documentation subsequently provided and agreed that the applicant had provided sufficient justification for the use of identifiable clinical data for the project.

Communications and Transparency

The members had previously noted that there had been no information provided in relation to notifying patients that their information was to be used for research and for these purposes, individuals outside of the care team will have access to their record. The members had advised the applicant to consider their obligations under the Data Protection Act 1998.

Members reviewed the patient notification material provided and advised that the fair processing notice should be aligned with the recommendations set out within the Information Commissioner's' Privacy Notice Code of Practice.

Security Assurances

The members noted that the applicant should provide clarification surrounding the data extraction arrangements. This included confirming the organisation's compliance against the Wales Caldicott Principles into Practice.

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. Fair processing notice should be aligned with the recommendations set out within the Information Commissioner's' Privacy Notice Code of Practice.
2. Confirmation of compliance against the Wales Caldicott Principles into Practice.

g) 28 Year Follow-up of Patients with Neurotic Disorder - 15/CAG/0125

Context

Purpose of application

This application from Imperial College London set out the purpose of completing the long-term assessment of classification and management of patients who suffer from anxiety, depression and personality disorders. The cohort of patients had initially consented to participate within the long–term study and were allocated in a randomised trial in order to review who had been seen before treatment and also to record personality status before treatment, the differences in outcome by personality status and which are expected to continue to experience in the long term. The applicant had aimed to assess as many patients as possible after 28 years, and at the 12 years assessment point, all except 4 agreed to be seen at this last point in the assessment.

A recommendation for class 3 and 6 support was requested to cover access to allow access to an authorised user for the purpose of selecting and contacting patients to seek their consent.

Confidential patient information requested

Access was requested to obtain current contact details from the Health and Social Care Information Centre (HSCIC) for individuals who were previously consented/enrolled within the study but for whom contact information is no longer accurate and to also obtain date of death and cause of death data to complete the overall study. The applicant would need to submit name and date of birth to HSCIC and the applicant will receive address, GP registration, date of death and cause of death from HSCIC.

Confidentiality Advisory Group Advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a public interest due to the need to evaluate classification and management of patients who suffer from anxiety, depression and personality disorders.

Feasibility of Consent

Members commented that the consent of the participants had been recorded during the recruitment stage of the initial study. Members agreed that the purpose of the application was to acquire contact details in order to obtain updated consent from the patients and also to determine whether the patient was deceased.

Justification of Identifiers and Retention

Members highlighted that the specified identifiers are justified for the purpose of obtaining updated contact details to seek consent from patients and to establish whether the patient was deceased.

Members advised that once the activity of tracing and obtaining contact details had been completed, the identifiers should be removed for patients who had not responded or provided consent.

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

8. Remove identifiers from dataset for patients who had not consented or provided a response.
9. Favourable opinion from a Research Ethics Committee. **Confirmed 15th May 2014**
10. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 4th December 2014**

h) QUEST Follow – UP - 15/CAG/0126

Context

Purpose of application

This application from Kings College London set out the purpose of assessing the epidemiology of ASD Spectrum Disorder (ASD), which is a severe and lifelong developmental disability affecting about 1% of children and characterized by pervasive impairments in social communication, and also stereotyped and restricted interests. The application related to the follow-up of the QUEST children now aged between ten to fourteen years in order to identify the personal, family and wider environmental risk/protective factors that later predict severe maladaptive behaviour in adolescence. The applicant

will intend to conduct a further follow –up of the cohort in two years' time to determine which children have persistent severe maladaptive behaviour and to determine which factors were predictive.

A recommendation for class 3 and 6 support was requested to cover access to allow access to an authorised user for the purpose of selecting and contacting patients to seek their consent.

Confidential patient information requested

Access was requested to seek support for the purpose of obtaining current contact details from the Health and Social Care Information Centre (HSCIC) for individuals who had previously consented or enrolled within the project but for whom contact information is no longer accurate. The identifiers required would include name, NHS number, date of birth, date of death, postcode and gender.

Confidentiality Advisory Group Advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a public interest due to the need to determine the factors which may be detrimental or beneficial to patients who are suffering from ASD.

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.

Members commented that the consent of the participants had been recorded during the recruitment stage of the initial study. Members agreed that the purpose of the application was to acquire contact details in order to obtain updated consent from the patients and also to determine whether the patient was deceased. Members advised that the applicant should retain an up to date record of consent obtained from families for future follow-up purposes.

Justification of identifiers

Members highlighted that the specified identifiers are justified for the purpose of obtaining updated contact details to seek consent from patients and to establish whether the patient was deceased.

Members advised that once the activity of tracing and obtaining contact details had been completed, the identifiers should be removed for patients who had not responded or provided consent. Members advised that identifiers acquired from updated consent from patients, should be retained for future follow-up studies.

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. Support only applies to health/patient data.
2. Applicant should retain an up to date record of consent sought from families for future follow-up purposes.
3. Favourable opinion from a Research Ethics Committee. **Confirmed 22 December 2014**
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

i) Cellular Immunity to Herpesvirus infection: Studies with EBV & CMV - 15/CAG/0127

Context

Purpose of application

This application from University of Birmingham set out the purpose of investigating the way in which the human immune system, particularly a type of white blood cell known as a T lymphocyte, normally controls infection caused by two human herpes viruses, Epstein−Barr virus (EBV) and Cytomegalovirus (CMV). This study will inform the effects on patients who are immunosuppressed where viruses can cause more serious problem and also the immune response to EBV and CMV in patients with acute primary infection and in long−term healthy virus carriers. The outcome will support the development of future treatments of virus−associated disease in immunosuppressed patients.

A recommendation for class 3 and 6 support was requested to allow access to an authorised user for the purpose of selecting and contacting patients to seek consent.

Confidential patient information requested

Access was requested to seek support for the purpose of identifying a cohort of patients who tested ‘monospot-positive’ by the hospital haematology departments and to provide a member of the research team with patient name, date of birth and GP contact in order to seek consent from the GP and subsequently the patient, to participate within 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.

Public Interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a public interest due to the need to investigate how various viruses behave in glandular fever, in order to determine the effects on patients who are immunosuppressed and where it can lead to more serious problems.

Feasibility of Consent and Data Flows

Members noted that it was justifiable for access to be permitted to the researchers who are outside of the care team, as it would not be feasible to consent patients prior to their lab results being known, as only the positives are of interest and the researchers do not have direct access to the patients. Members commented that the data flows are satisfactory in that unconsented confidential patient information flows from the lab to the researchers in order to contact the patient's GP. Members highlighted that confidential patient information of individuals who do not consent, or whose GPs do not respond would be destroyed after one week.

Justification of Identifiers

Members agreed that the identifiers specified are necessary for this study and not excessive.

Communication and Transparency

Members highlighted that there were no patient notification or involvement within the planning of the project and an opportunity for patient opt –out at the initial stage, prior to seeking consent. Members advised that patient notification materials within GP surgeries would be most beneficial and best practice. However, the members noted that the effort required to effectively inform all patients regarding the study would be disproportionate and patients would later be provided with an opportunity to opt-out through their GP.

Specific conditions of support

11. Favourable opinion from a Research Ethics Committee. **Confirmed 12th January 2015**

12. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 5th March 2015**

j) Case-Control Study For Campylobacter in the under 5s - 15CAG0128

Members agreed to refer the application to the next full CAG Meeting