NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

17 September 2015 at 10:00 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	
Dr Kambiz Boomla	
Dr Robert Carr (from 11am)	
Dr Tony Calland MBE (Vice Chair)	
Mr C Marc Taylor	
Ms Clare Sanderson	
Ms Gillian Wells (Alternate Vice Chair and Chair for item 2a)	Lay
Professor Julia Hippisley-Cox (from item 4a (12:45) until partial review of item 5g)	
Professor Jennifer Kurinczuk	
Professor Barry Evans	
Dr Miranda Wolpert	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Mr Ben Redclift	Confidentiality Advisor
Mr Stephen Robinson	Corporate Secretary, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Dr Patrick Coyle, Mr Anthony Calland, Dr Murat Soncul and Dr Miranda Wolpert.

The following interests were declared:

- Dr Mark Taylor, item 2a. As this applicant derived from Dr Taylors' employing organisation, the University of Sheffield, this item was chaired by Ms Gillian Wells.
- Professor Julia Hippisley-Cox, item 3a. Due to a previously declared potential conflict of interest, Professor Hippisley-Cox had not received papers. This item was considered prior to Professor Hippisley-Cox's arrival at the meeting.

- Professor Jennifer Kurinczuk, item 3a. Professor Kurinczuk indicated that she knew of the co-applicant from the same department and it was decided that Professor Kurinczuk would not be present for the discussion or final recommendation.

2. ITEMS FOR CONSIDERATION

Yorkshire Health Study – ICO advice on non-responders [15/CAG/0114]

Purpose of application

This application from the University of Sheffield set out the purpose of conducting a study which aims to help the NHS provide appropriate service and treatments to prevent and treat obesity in the future by collecting information on the health and weight of a representative sample of adults of all ages (16+) over the next twenty years. The research team recruited randomised GP practices to take part in the study. The appointed GP practices were required to pick randomised patients from their practice in order to send out a letter with an enclosed questionnaire informing them of the study and also to consent for future contact by the research team. A previous outcome dated 18 June 2015 provided full details of the previous scope and discussion.

Confidentiality Advisory Group advice

A CAG recommendation in relation to the fourth cohort group who had not responded to attempts to re-consent had been deferred pending advice from the Information Commissioner's Office. It was this specific aspect that was considered at the 17 September 2015 CAG meeting.
There was a possibility that the fourth cohort had not responded as they felt consent was already in place so the issue was how to interpret this non-response.

General advice received from the Information Commissioner's Office indicated that in these circumstances it is most important to consider what the data subjects' reasonable expectations would be. When considering this, all information provided to patients should be taken into account, not just the consent form, to ensure that the context is fully understood. The consent provided originally should stand unless the newer consent materials suggest that this replaces the original consent taken for any reason. If the newer consent materials make clear that a response is required in order to opt out of continued data collection then this could be determined to inform the data subject's reasonable expectations that their data would continue to be used unless they responded. A complexity is added if consent is requested to access data and the data subject is also told they need to opt out of data linkage. In these situations the information provided may be unfair given the conflicting messages, again this should be looked at in the context of reasonable expectations and with all information provided over a lifetime of a study. If different data sources are specified in newer consent material and an individual does not respond, this would not preclude a request being made to access the data sources specified within the original consent which would still stand unless newer consent materials rule this out.

The original consent had indicated that there would be access to NHS health records and GP/hospital visits. While broad, the view was that this could generally be taken to include HES data but members were aware this was not in line with the current Health & Social Care Information Centre (HSCIC) preferred wording around consent. Taking into account the external advice, members noted that the reasonable expectations of the data subject should be considered and to approach it from the patient

view and what they would reasonably have thought when asked for consent for all relevant records held by the NHS; it was agreed that patients are unlikely to have a detailed understanding of the infrastructure of the NHS and its evolving nature, so this should be taken into consideration when looking at reasonable expectations.

Confidentiality Advisory Group conclusion

Members considered whether the original consent provided a sufficient legal basis, and whether those that did not respond to the further information provision did, in effect, withdraw their original consent.

In light of the external advice, members expressed the view that the original consent was sufficient to enable to enable the relevant data flow. As this legal basis existed, members therefore advised that support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 would not be required as consent could be relied upon.

Members concluded this discussion by advising that the advice from the Information Commissioner's Office was applicable, non-response in this instance did not mean dissent and the spirit of the original letter provided sufficient information to enable consent to be relied upon, particularly as they had been informed about this activity. Members noted that this had been a relatively complex situation with very specific circumstances.

3. AMENDMENTS

Clinical Practice Research Datalink (CPRD) Service – 'high-risk protocol advice 15_116 [ECC 5-05(a)/2012]

CPRD is the output of a government commitment for a managed health research data service where anonymised linked NHS data is utilised within research activities. Support is provided to enable the processing and linkage of confidential patient information to be carried out by the Health and Social Care Information Centre (HSCIC), under governance arrangements agreed by the Medicines & Healthcare products Regulatory Agency (MHRA), of which CPRD is a division of this organisation. Support is provided to the HSCIC to enable this linkage activity. Patient identifiers are separated from clinical research data at data source origin, the HSCIC receive the patient identifiers and carry out linkages on behalf of CPRD and a pseudonymised linked dataset is provided to the CPRD by the HSCIC. In general and following previous work undertaken between CPRD and the CAG, most onward disclosures are considered to be de-identified due to the controls in place. Protocols assessed as 'high risk' are submitted to CAG for individual consideration as they bear a risk that the onward disclosure could be considered identifiable. This was the purpose of this item for discussion.

<u>High risk protocol 15_116R2</u>

Members noted the detail of the protocol and the applicant responses to the Independent Scientific Advisory Committee (ISAC) queries. The CAG noted the ISAC comments and concurred with the ISAC assessment that there could be a potential risk of re-identification. In line with the established process, where high-risk protocols are sent to CAG for consideration and advice on next steps, members agreed that the applicant should submit a full application for subsequent consideration. It was noted that a REC approval would also be required, or written confirmation provided by CPRD to the applicant that the CPRD REC approval would cover this activity; this should be submitted as part of the application.

Members advised that they would consider the application, once received, via sub-committee, rather than within the published meeting schedules. The applicant should provide a copy of this letter when making their final submission.

4. Discussion item – management of patient objections.

Professor Martin Severs from the Health & Social Care Information Centre (HSCIC) attended the meeting in response to a request from the CAG. The specific question asked was how do the HSCIC ensure that patient objection is respected where disclosure is taking place under COPI Regulations? Due to the timing of the meeting and as there was an expectation that this issue would be imminently discussed by the HSCIC with external officials, and therefore may be subject to change, Professor Severs provided the following statement for minute purposes in response.

A system for the "Preventing the Use of" has been in place since April 2013, and prior to this a "Withdrawal of Consent" was set up in 2009 in the predecessor organisation, the NHS Information Centre. It was confirmed that there are about a hundred existing objections where patients have completed a "Preventing the Use of" form available from the HSCIC which requests that the HSCIC does not use any information held about the patient for health and/or social care purposes other than direct care and had their identify confirmed.

Access to this form was either through the HSCIC web site or direct contact with HSCIC. Procedures have been developed internally so that when a person registers a "Withdrawal of Consent" all of their data will either be deleted or anonymised and this applies to all data currently held for that individual and for any data that may come in for that individual in the future.

This is different to a Type 2 objection in that for a Type 2 objection the data is retained and can be used in anonymous form e.g. used in Statistical Publications and in release of aggregate counts or released under certain specified conditions.

On the HSCIC website under Policy and Procedures there is also a form where the public can object to their data used beyond their direct care. This is commonly referred to as the "Withdrawal of Consent" process and is provided to enable compliance with Part II, Section 10 of the Data Protection Act, though the HSCIC does not seek evidence of any damage or distress that may be caused.

5. NEW APPLICATIONS – Research

a) Early life causes of adolescent depression and anxiety [15/CAG/0175]

Context

Purpose of application

This application from the University of Bristol details using linked electronic patient records in order to establish the prevalence of adolescent depression and anxiety to investigate early life causes (maternal smoking and binge drinking in pregnancy) of these. Access to information about GP-recorded depression and anxiety, identified using a specific set of Read codes, is requested.

These are based on a recent study validating a number of algorithms to identify adults with depression and anxiety from GP records

Confidential patient information requested

Support is requested to allow the disclosure of confidential patient information from GP practices to NHS Wales Informatics Service (NWIS) and the University of Bristol. Data from GPs in relation to mental health of ALSPAC enrolled cohort, NHS number and date of birth are requested to allow linkage of datasets.

Confidentiality Advisory Group advice

Public interest

It was noted that there was a general lack of clarity about the problem the research is aiming to address.

Justification of identifiers

Members were content in principle for access to mental health data for the cohort. However it remained unclear why the additional sensitive data was required. It was similarly unclear if the applicant had linked data for the period that was consented prior to the cohort reaching the age of consent.

Additional points

Members agreed that it appeared that consent was provided historically for those aged under 18 years of age. However it was uncertain from the application why extending the age group past the age of consent to 22 -25 year olds was required.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that there was insufficient clarity of detail to enable a recommendation to be provided. Further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Requested clarifications

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Information was required from the applicant on the requirement for access to the sensitive data.

2. Clarity was requested on the need to extend the age group past the age of consent,

3. Clarity was requested on whether the applicant had linked data for the period that was consented prior to the cohort reaching the age of consent.

It was noted that a satisfactory REC opinion and evidence of suitable Information Governance Toolkit submission would also be required. Once received, the information will be reviewed by a sub-committee of members in the first instance. At this stage it may be necessary to request further information or refer the application to the next available CAG meeting.

b) Chlamydia testing, infection, and sequelae in young people [15/CAG/0176]

Context

Purpose of application

This application from the University of Bristol set out the purpose to determine what proportion of young people are tested for Chlamydia as part of the National Chlamydia Screening Programme and whether the risk of the main morbid sequelae of Chlamydia information (pelvic inflammatory disease, ectopic pregnancy and reduced fertility) are effectively reduced by testing and treatment. The project details the linkage of health care records of the ALSPAC enrolled cohort in order to determine this.

It was noted that support had been provided to link data in relation to the enrolled cohort (ALSPAC), however this excluded data in relation to mental and sexual health as this was considered to be more sensitive and therefore require a higher level of justification for individual projects. The applicant had been required to submit a new application if access to these classes of information was necessary.

A recommendation for class 1, 4 and 6 support was requested to allow the disclosure of confidential patient information from GP practices and the HSCIC to NHS Wales Informatics Service and the University of Bristol.

Confidential patient information requested

Access was requested to data from GPs and HSCIC in relation to sexual health of ALSPAC enrolled cohort. Hospital Episode Statistics data is requested from the HSCIC and GP data extracted via EMIS is requested from GP practices.

NHS number and date of birth are requested to allow linkage.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was an important study with outcomes expected to be in the 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 noted that it would be difficult to get the data using an alternative methodology, particularly as the comparison between reported sexual health and actual health would be compromised by only including patients that had consented.

Justification of identifiers

Feedback from the user group supported access to the data and felt that all medical data could be deemed sensitive. Members agreed that patients were unlikely to be surprised at finding that data

in relation to the cohort had been accessed in this way. It remained unclear if the exclusion of data on mental and sexual health had been communicated to the cohort. It was felt that if mental and sexual health data had been explicitly mentioned to the cohort in communications as excluded then the cohort should be notified at this point that access to mental and sexual health data would now be forthcoming. If this had not been explicitly disseminated to participants no further contact explaining the new access would be necessary.

Additional points

Members felt that greater patient notification was possible through display of study information on the study website. If a newsletter was distributed to the cohort on a regular basis it was recommended that this should also signpost the cohort to information displayed on the website.

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 conditional 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 requested that the study would be included on the website.
2. Confirmation was requested that if a newsletter was regularly provided to the participants that this should signpost to information on the website.
3. Confirmation was required that information about the exclusion of sexual and mental health data from the original study had not yet been provided to participants.
4. Favourable opinion from a Research Ethics Committee.
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Once all responses are provided, the response will be reviewed and if satisfactory, the HRA will confirm final approval. Support only comes into effect once this final approval letter has been received.

c) The effect of substance use in adolescence on mental health [15/CAG/0177]

Context

Purpose of application

This application from the University of Bristol detailed the linkage of information relating to the health, education, benefits and earning and criminal convictions for the Avon Longitudinal Study of Parents and Children (ALSPAC) cohort (around 14,000 individuals).

Permission to access medical records without consent (ref: ECC 1-05(b)/2012) has already been obtained for ALSPAC participants who did not respond to the consent campaign. One condition of this approval was that mental health data would be excluded from any data extracts unless subsequently approved by the committee on a study specific basis.

For this current project, the researchers wish to extend this approval to extract data on mental health from Hospital Episode Statistics (HES), GP records, and the Mental Health and Learning Disabilities Dataset. This would allow them to investigate the association between self-reported substance use in adolescence and diagnosed mental health difficulties, particularly depression, anxiety and psychosis.

These data would be linked to de-identified ALSPAC data, for all those young people with a history of participation in ALSPAC and who have not explicitly withdrawn from the study or denied consent for record linkage to their health records. The study will examine the associations between mental health and the three most commonly used substances: tobacco, cannabis and alcohol.

A request for class 1, 4 and 6 support was made to enable the extraction of confidential patient information without consent from a number of sources, including:

1. Primary care data held by general practices. This data would be provided by NWIS and linked by the Secure Anonymous Data linkage (SAIL) system at Swansea University.
2. HSCIC - Hospital Episode Statistics (HES); Mental health data
3. HSCIC - MHLDDS – Mental Health and learning disabilities dataset

Confidential patient information requested

NHS number, date of birth and postcode were requested to allow the linkage of data using services provided by the HSCIC and NHS Wales Informatics Service (NWIS). Only pseudonymised data which included a unique reference number (ALSPAC ID) for each individual would be available to the applicant.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was an important study in the 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 noted that it would be difficult to get the data using an alternative methodology, particularly as the comparison between reported sexual health and actual health would be compromised by only including consenting patients.

Justification of identifiers

Feedback from the user group supported access to the data and felt that all medical data could be deemed sensitive. Members agreed that patients were unlikely to be surprised at finding that data in relation to the cohort had been accessed in this way. It remained unclear if the exclusion of data on mental and sexual health had been communicated to the cohort. It was felt that if mental and sexual health data had been explicitly mentioned to the cohort in communications as excluded then the cohort should be notified at this point that access to mental and sexual health

data would now be forthcoming. If this had not been explicitly disseminated to participants no further contact explaining the new access would be necessary.

Additional points

Members felt that greater patient notification was possible through display of study information on the study website. If a newsletter was distributed to the cohort on a regular basis it was recommended that this also signpost the cohort to information displayed on the website.

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 requested that the study would be included on the website.
2. Confirmation was requested that if a newsletter was regularly provided to the participants that this signpost to information on the website.
3. Confirmation was required that information about the exclusion of sexual and mental health data from the original study had not yet been provided to participants.
4. Favourable opinion from a Research Ethics Committee.
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Once confirmation that the above conditions have been accepted and/or met, the response will be reviewed and, if satisfactory, the HRA will confirm final approval. Support only comes into effect once this final approval letter has been received.

d) Risk stratification in suspected acute coronary syndrome [15/CAG/0171]

Context

Purpose of application

This application from Aintree University Hospital sets out a purpose of conducting a cohort observation study and database analysis to determine which of the three established methods of risk stratifying patients (predicting risk in suspected heart attacks) namely, the Global Registry of Acute Coronary Events (GRACE), Thrombolysis in Myocardial Infarction (TIMI) and HEART score in the era of high sensitivity troponins performs more effectively. The study also aims to determine whether the results of a high sensitivity troponin and electrocardiogram (ECG) on admission could be used alone to direct care. The cohort would consist of patients who had presented with suspected cardiac chest pains at Aintree University Hospital between 3rd June 2011 and 4th November 2011. All consecutive patients who presented to the emergency department of Aintree University Hospital, Merseyside with suspected cardiac chest pain would be identified by the admission coding of 'chest pain' and prospectively recruited into the database.

Confidential patient information requested

Access was requested to the database which contains NHS number, to access medical records to extract anonymised data and also to follow up each patient by linking Hospital Episode Statistics and Office of National Statistics mortality data.

Confidentiality Advisory Group discussion

This application had been reviewed under the Precedent Set process but members had noted that prospective data collections where consent was not intended to be sought were excluded from precedent set review. For these reasons the committee had advised escalation to review by full CAG committee if the applicant was not able to conduct the study through a consented approach.

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 noted that the investigators had dismissed the possibility of achieving this through a prospective consented study on the grounds that the numbers of patients needed that would enable valid conclusions to be drawn would be >1800 and the estimates to be screened would be >3500 patients. The resources required would therefore be considerable and the researchers would not be able to recruit consecutive unselected chest pain patients. Similarly recruiting a subset of this population through informed consent would grant a skewed picture potentially resulting in erroneous conclusions being drawn. Members noted the information provided on why consent would not be feasible, however, believed that as the study did not involve a unique cohort that a prospective consented approach was potentially feasible. Members asked that the issue of prospective consent be considered again in light of this comment.

Use of anonymised/pseudonymised data

It was noted that the applicant believed that use of anonymised data would be extremely challenging. However members felt that a practical alternative existed which would not involve disclosure of identifiable patient data outside those who have a legitimate basis to access the data through local audit. Members referred to similar studies using readily-available computer programmes which allowed a person with legitimate access to the data to quickly and easily pseudonymise NHS numbers, provide a pseudonymisation key to the HSCIC to link the data who could then provide an anonymised dataset to the researchers. This approach would not involve any disclosure outside the care team. Similarly, if this approach was not possible, it was noted that the datasets required by the researchers might be potentially provided by the HSCIC in an anonymised format.

Additional points

The applicant was to be reminded that only those with a legitimate legal basis to access the data should currently do so.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided, and therefore recommended that an outcome be deferred.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Confirmation should be sought from the HSCIC that pseudonymised data could not be provided to the applicant.
2. Consideration of the feasibility of prospective consent in light of member comments above.

Once received the information will be reviewed by a sub-committee of members in the first instance. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

e) Incidence of Childhood Female Genital Mutilation (FGM) in the UK and Ireland [15/CAG/0178]

Context

Purpose of application

This application from Central and North West London NHS Foundation Trust / Royal College of Paediatrics and Child Health (RCPCH) set out the primary aims to identify the number of new cases of childhood FGM presenting to doctors; to identify the circumstances of FGM, including where it is being done and by whom, and to identify the reasons for referral and so inform referral guidelines and identify groups that may be missed. The information generated will be used to plan health services, educate professional and produce guidelines. The study will run over a 13 month period.

A recommendation for class 1, 3, 5 and 6 support was requested to cover disclosure of confidential patient information from NHS Trusts to the Royal College of Paediatrics and Child Health and Document Capture Company in their capacity as data processors.

Confidential patient information requested

Access was requested to date of birth, NHS number, Hospital ID and sector level postcode in order to carry out de-duplication and collect follow up data from consultants. Postcode and date of birth would be used to determine geographical incidence and accurate age of the child. This data would be sent by NHS Trusts in relation to any child aged under 16 years old who was not already known to have FGM who was:

a) Seen because of suspected FGM
b) Seen for another conditions and FGM is suspected following assessment
c) Has a genital piercing or
d) Has had a female cosmetic genital surgery including labiopolasty

The total estimated cohort size is 150 and it was noted that data would be anonymised following data collection (approximately 13 months) and follow up as specified within the application.

Confidentiality Advisory Group advice

The application indicated that in order to maximise ascertainment further there would be a number comparison against those reported through the Health and Social Care Information Centre (HSCIC) who have been collecting data on new presentations of FGM in acute care trusts in England. The first HSCIC dataset was published in April 2014 and from March 2015 this dataset will include some patient identifiable information. The detail stated there had been provisional agreement that the HSCIC will share information on any child with a new presentation of FGM within the age range of this study. The application indicated that although it is likely that these children should be picked up by the BPSU alone, this will reduce the chance of any cases being missed. The patient identifiable information collected by the HSCIC could be used to exclude duplicates. If a new presentation of FGM has not already been reported through the BPSU system the applicant would be able to contact the relevant department of the Trust in question and send the questionnaire. Members noted this aspect but as the application implied that support would not be required to cover this interaction with the HSCIC, no further discussion took place on this aspect.

Public Interest

In noting that there was a separate statutory duty on those diagnosing FGM to notify the relevant bodies, members agreed that there was a significantly strong public interest in this activity being undertaken as it was researching an extremely sensitive and current issue, with subsequent links to safeguarding children.

Practicable alternatives

Members noted that the BPSU 'orange card' methodology will be used and the 'orange card' will be sent to all consultant paediatricians and paediatric surgeons in the UK. (Members noted that support under Regulation 5 could only cover data generated in England and Wales). Where a case is identified consultants will be asked to complete a questionnaire, either online (via Document Capture Company (DCC)) or by hard copy. After 12 months a follow up questionnaire will be dispatched.

Members agreed that they could not identify a different alternative to the methodology proposed.

Management of dissent

It is a standard condition of support under these Regulations that any patient objection should be respected. This is separate to a data subjects rights under the Data Protection Act 1998 (noting that approval under these Regulations does not remove the need to comply with the Data Protection Act 1998 requirements). In looking at this specific context, members queried whether respecting dissent under these Regulations would potentially damage the public benefits to this study in terms of its outcomes. It was questioned whether dissent would result in a significant proportion of opt-out taking place, which in turn could affect scientific validity and impact the intended public good, which in this case was considered to be extremely significant. It was considered whether patient objection under this approval may have the unintended consequence of notifying parents that FGM is being studied, which could have the risk that this may affect behaviour that may impact on the child.

Members recommended on an exceptional basis that in this instance dissent should not be respected under these Regulations. The rationale was that as this activity has a strong link to safeguarding children, it was considered essential to understand the reality of the problem in order to design potential solutions. Additionally, it was considered to be a key consideration that in respecting dissent this could have the unintended consequence of modifying parent behaviour. As there would be a leaflet provided, this was considered sufficient to meet the requirement to provide notification of the activity so there would be a minimum level of transparency.

Research Ethics Committee approval

Following notification received on 01 October 2015, a letter was forwarded from the REC that indicated that this activity was not considered to be research, and this was service evaluation.

Confidentiality Advisory Group advice conclusion

The CAG therefore 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 for Health, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support applies only 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 satisfactory Information Governance Toolkit (IGT) submission. **Confirmed 07 September 2015**

f) West Midland's Regional Children's Tumour Registry [15/CAG/0179]

Purpose of application

This application was from Birmingham Children's Hospital NHS Trust. The West Midlands Regional Children's Tumour Registry (WMRCTR) holds data on all patients diagnosed with a childhood malignancy (or benign central nervous system tumour) aged 0-15 year inclusive within the West Midlands region. Demographic, diagnostic, treatment, outcome and follow-up data are collected. An additional long term follow up database is maintained of patients who are alive 5 years from diagnosis. This is carried out by postal follow up with the patient's GP.

Historically, this specialist registry used to operate under the overarching support provided to the UKACR via Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002. Following organisational structure changes from April 2013, it was noted that correspondence had taken place with Public Health England and the applicant prior to application consideration and the view provided that an individual application should be made to provide a clearer legal basis.

The registry was stated to be vital in allowing in-depth epidemiological, pathological and aetiological studies to be carried out on a population basis. Since its formation the WMRCTR has been involved in establishing incidence rates and trends in childhood cancer for the West Midlands region, and has been subject to peer review both in publications and presentations at national and international meetings. Other potential benefits from the WMRCTR were stated to include the continual monitoring of the health of survivors of childhood cancer through clinic based and postal follow-up. 1 in 1000 adults is now a survivor of childhood cancer. The National Cancer Survivorship Initiative and the new "Living with and Beyond Cancer" programme aims to develop and commission risk stratified pathways of post treatment management and improved management of the consequences of treatment. Risk stratified management is already in place in the late effects service at BCH, and the data collected through the Registry's LTFU database will assist with further understanding of the consequences of treatment.

A recommendation for class 1, 2, 4, 5 and 6 support was requested. The application also conversely indicated that it was seeking support under Regulation 2.

Confidential patient information requested

Support was requested to allow the disclosure of confidential patient information from GPs, Public Health England and Birmingham Children's Hospital to the registry based within Birmingham Children's Hospital. Access was requested to NHS number, date of birth, date of death and unit level postcode for the purpose of secondary linkages between HES data and the registry. Date of birth, death and postcode, Census Output Area, OS grid reference, gender and ethnicity would be retained for analysis purposes.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a valuable resource with a clear public interest and appropriate steps should be supported to ensure that data is appropriately held and maintained, and that it is operating to current legal frameworks with a clear legal basis.

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. While agreeing that historically there was no other practicable alternative, members questioned whether there would be opportunities for consent to be obtained prospectively, and requested a detailed response setting out this consideration to be provided in six months' time.

Justification of identifiers

Members expressed the view that while these seemed appropriate, questions were raised on the necessity of retaining identifiable information on deceased patients. A response to the question on whether deceased person's data could be converted to 'pseudonymised' data was therefore requested.

Onward access

Members noted that the application specified that "*Researchers who wish to use WMRCTR data for audit or research must complete a Data Access form (one for audit and one for research) outlining the aims, purposes and methodology of their project and the type of data they require. If patient identifiable data are required they must justify the reason*".

Members were very clear on their understanding that support under the Regulations does not permit onward access to identifiable data without consent and questioned the current legal basis that was currently enabling this to take place. It was strongly advised that identifiable onward disclosure cease until a clear legal basis is established to ensure that the data controllers are operating within the current legal frameworks such as the Data Protection Act 1998; noting that the Health Service (Control of Patient Information) Regulations 2002 could not be relied upon. An update on this situation should be provided in six months' time.

Patient involvement

It was noted that patient engagement had previously been undertaken in 2006, however members felt that some time had passed since then and that a refresh or improvements should be made as this would support the continued approach of processing of patient information without consent.

Patient dissent

Members advised that the current dissent mechanism directed applicants to the NCRS opt-out provisions, however members were left unclear on how these separate entities joined together to ensure dissent was effective. Members therefore advised that a clear mechanism for receiving and implementing dissent should be provided in six months' time, taking into account the increased national importance on this aspect.

Research purposes

It appeared that some data was held for the purpose of research; members advised that it is a requirement under Regulation 5 that any activity collecting data for a research purpose is required to have a favourable ethical opinion before support can come into effect. In order for this proposed interim approval to come into effect, a research ethics committee approval must be obtained and a copy of the favourable outcome provided to the CAG; at this point a final approval letter will be issued. It was noted that an application had been made to the REC and would be considered on 3rd September; please ensure a copy of this letter is provided once available.

Regulation 2 and 5

Members noted that this application potentially sought support under Regulation 2 and 5 of the Regulations. Noting that only one Regulation could be applied and that this had previously operated under Regulation 2, members took into consideration the improvement and clarification aspects noted above and concluded that support should be provided for a period of six months, under Regulation 5, to enable the applicant to consider and provide responses to the questions above. In addition, should the applicant wish the activity to be placed under the broader remit of Regulation 2, there should be discussions with the registries within Public Health England to identify their handling of data under this regulation, and a refreshed application submitted that is aligned as far as possible with those operating under Regulation 2 to enable a recommendation to be provided on this aspect. At present, members advised that there were too many areas for clarification before a request for approval under Regulation 2 could be considered, and that an interim recommendation for support under Regulation 5 could therefore be provided to enable time for these developments.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the registry provided a significant benefit and it was important for it to be operating within the current legal frameworks. It was therefore advised that interim support under Regulation 5 should be provided for a period of six months to enable the applicant to progress the actions listed above.

Specific conditions of support

1. Support applies for a period of 6 months from date of final approval once in place

2. Detailed responses to points raised should be submitted prior to expiry of the 6 month period, in addition to a revised application that captures these points and addresses the seeking of support Regulation 2 if considered appropriate.

3. Favourable opinion from a Research Ethics Committee to be provided. **PENDING**

4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Current v12 score published as 84%**

g) Realist Evaluation of Adapted Sex Offender Treatment Programs [15/CAG/0180]

This application from the University of Leeds set out the following overarching purpose: Adapted Sex Offender Treatment Programs (ASOTPs) have been modified from mainstream treatment to meet the learning needs of offenders with intellectual disability (ID). This project explores what works on ASOTPs, for whom, in what contexts, why and how. It seeks to make sense of these programs in the contexts in which they take place, in order to illuminate what social factors may help or hinder treatment success. In particular, it examines how effective links between these forensic healthcare interventions and the offender's living context and social care provision, for instance the nature and level of supervision they receive to manage risk during and after treatment can enhance outcomes.

Confidential patient information requested

There are three phases of data collection. Phase 2 entails three different types of fieldwork with NHS patients.

1. The first involves patient focus groups, to which patients have given their full and informed consent. This aspect is excluded from potential scope of approval.
2. It is for this second aspect that support was sought: the applicants will review all of the patient files of those who have completed or are currently on the Adapted Sex Offender Treatment Program.
3. In the UK, ten case studies will be identified from the review of patient files for further investigation. Here, interviews will be conducted with course tutors and (where appropriate) patients. The respondents will consent to this therefore this aspect was excluded from potential scope of approval.

A recommendation for class 1 and 6 support was requested to undertake the second activity.

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a public interest in this activity however they felt this to be a significant application in terms of confidentiality aspects and sensitivities of the cohort balanced against the intended outcomes of the activity. In particular, it was noted that the approach proposed did not offer a right of patient objection which is a key principle of most application activities that have support.

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 first and third stages would be undertaken with consent, and participants would be identified via their case worker or key worker. Members felt that there needed to be a stronger rationale as to why consent could not be sought for this specific aspect of the second stage as members were not currently persuaded by the proposed approach that this would not be feasible. This point is further developed under 'patient notification' below.

- Use of anonymised/pseudonymised data

It was noted that the applicant stated information is not available from other sources in an already de-identified format. The query sheet specified that access to records is required by the chief investigator in order to generate the new statistical evaluation method and that partial information may result in the oversight of important factors that could have been included. Members agreed with this assertion based upon the information.

Justification of identifiers

Members raised concerns that in a small cohort, it would be difficult to de-identify the patients and also questioned the indefinite retention period in light of this.

Patient notification and management of dissent

Members noted the methodology proposed that patients would not be given an opportunity to opt-out and the rationale included the view that this could have the consequence of skewing the data and outcomes. Members were uncomfortable with the proposal that a mechanism to manage patient objection was not in place. In reaching this conclusion, they referred to other stages of the project and noted that information would be provided in advance for these as a precursor to a full information session. It was queried why this approach could not be undertaken for this specific phase and members requested greater consideration of this approach, including a right of patient objection.

Members indicated that they would review more positively a refinement to the methodology with a more robust approach to patient notification to take reasonable steps to inform them of this activity, and allowing a facility for patient objection, and asked that this be considered in the response.

User involvement

Members noted that user involvement had not yet commenced and thought it would be important to ensure this took place and feedback provided as this would add weight to the considerations of public interest.

Clarification

Clarification was requested over the status of the key worker referred to in the protocol, in terms of their role under the Mental Capacity Act 2005 when undertaking research where there is loss of capacity. Members were unclear as to whether these were the appropriate persons under the Act and 2007 Regulations, and asked for evidence/information that this was the case.

Confidentiality Advisory Group advice conclusion

The CAG agreed that while supportive in principle of the outcome, that a recommendation would be deferred to allow the applicant to consider steps to improve patient notification in line with the other phases of the project, and to reconsider the right of patient objection; both of which are important principles underpinning the CAG advice, and to address the other points raised.

6. MINUTES OF THE MEETING HELD ON 06 August 2015

The minutes were agreed as an accurate record, subject to minor amendments.

7. CAG OFFICE REPORT

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 06 August 2015 meeting applications.

Health Research Authority approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 06 August 2015 meeting applications.

Operational and CAT advice updates

Key Performance Indicators update

7 amendments were completed in August and all were within the 30 day target.

7 full meeting applications were completed in August and all were within the 60 day target.

No PS applications were completed in August.

Working Groups update

Practicable alternatives working group

Following agreement at the August meeting, the guidance tool in relation to reducing the disclosure of confidential patient information has been updated and published.

8. ANY OTHER BUSINESS

The Chair provided an update that Mr Bill Davidson had advised that there had been a delay in producing the CAG Governance document, and when available this would be circulated to members for comment.

Professor Hippisley-Cox highlighted that a review of the precedent-set review criteria was overdue and this was noted.