NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

22 June 2017 at Barlow House, M1 3DZ

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr William Bernal	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Ms Kim Kingan	Yes	
Dr Rachel Knowles	Yes	
Mr Andrew Melville	Yes	Lay
Mrs Diana Robbins	Yes	Lay
Ms Clare Sanderson	Yes	Alternate Vice Chair
Mr David Smallacombe	Yes	Lay
Dr Mark Taylor	Yes	Chair

Also in attendance:

Name	*Present*	*Notes*
Miss Kathryn Murray	In Attendance	Senior Confidentiality Advisor
Ms Natasha Dunkley (Item 4 only)	In Attendance	Head of the Confidentiality Advice Service
Ms Amanda Hunn (Item 4 only)	In Attendance	Joint Head of Policy, HRA
Ms Rachel Heron (Items 3a and 4 only)	In Attendance	Confidentiality Advisor
Mr Simon Depledge (Item 4 only)	In Attendance	CAG Assistant

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

No apologies were noted for the meeting.

Declarations of Interest

No other interests were declared.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) has not yet provided response in relation to the advice provided by the CAG in relation to the virtual review of applications held in lieu 25 May 2017 meeting.

HRA Approval Decisions

There were no research applications considered at the virtual meeting held in lieu of the CAG meeting of 25 May 2017.

3. NEW APPLICATIONS – Research

a. 17/CAG/0082 – Teenage and Young Adult Cancer Cohort

Context

Purpose of application

This application from UCL set out the purpose of investigating the effectiveness of services for Teenagers and Young Adults (TYA) with cancer. NICE guidance states that all young people should have access to specialist services but provision in England was variable and there was no clear definition of 'specialist care'. The study began to recruit young people aged between 13 and 24 years in 2012, to complete the BRIGHTLIGHT survey at 5-7 months after diagnosis, and then at 12, 18, 24 and 36 months. The final wave at 36 months is still underway, due for completion in April 2018.

While participants consented to receive surveys at the above intervals, the following activities take place with CAG support:

1. Data linkage with NHS Digital (to obtain HES data) – approved in 2014 under the reference ECC 8-05(d)/2011 under the Precedent Set criteria 'Validity of consent'.
2. Amendment made under the reference ECC 8-05(d)/2011 - Quality Health to administer surveys on behalf of the research team
3. Amendment made under ECC 8-05(d)/2011 – to allow the applicant to obtain demographic data from PHE concerning the total population (TYA with cancer) in order to compare demographic features of the consented cohort with this entire population.

The current application is prompted by PHE, who flagged that data held under consent has been held for longer than the terms of that consent: the consent form stipulated that contact details would be held for 3

years, the expected duration of the study. Due to delays in approvals and recruitment, the three year period has now been exceeded. The applicant wishes to retain the contact details for continued activity necessary to carry out the study, including sending a newsletter to the cohort to inform them of study progress and to use the postcode for data linkages with PHE and NHS Digital.

The applicant was under the impression that REC approval to retain contact details provided an adequate basis for doing so.

Although this aspect is not directly connected to the data linkage with PHE, PHE stated that they cannot release any data as the legal basis for retention of the contact details is in question. They do not consider the consent given by participants to cover the continued retention of patient contact details beyond the time specified in the consent form, and the REC approval does not provide a legal basis for this. The applicant is therefore applying for Section 251 support for this activity.

A recommendation for class 1, 4 and 6 was requested to obtain and use information about past or present geographical location, to link patient identifiable information obtained from more than one source, to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Postal address, email address and phone number – the consent form stated that these details would be held for three years, which time period has now expired for some participants.

These details are retained in order to update participants on the study. The applicant has also mentioned using these details to contact patients about other studies and states that this is included on the consent form.

The following confidential patient information is held under an existing legal basis:

Full address is held in order to mail out surveys to participants for the duration of the study (the legal basis for this aspect is consent).

Postcode is held in order to make the necessary data linkages via HES and PHE (the legal basis for data linkage is s251 support).

Confidentiality Advisory Group advice

Public interest

The CAG agreed that there was considerable public interest and a clear medical purpose in the study overall.

It was established that the legal basis was in place for the mailing out of surveys and for data linkage.

The specific purpose of this application was to retain contact details including email address and telephone number, in order to update participants on the study and to inform them of future studies. Participants had consented to the retention of these details for this purpose for a period of three years.

Members were not convinced that the public interest in updating participants on this and future studies was sufficient to override the confidence of individuals who might reasonably expect their contact details to be deleted after the three year period. Further discussion on this point took place in relation to the feasibility of seeking consent.

Scope

The CAG was not clear as to how many participants had been in the study for longer than three years and requested confirmation on this point.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The specific activity under consideration in this application was the retention of contact details beyond the time stipulated in the consent form. While it was acknowledged that participants may have expected their contact details to be held for the length of the study, it could equally be argued that they would expect the contact details to be held only for the specified period. There was no way to ascertain this other than to contact the participant.

The CAG discussed the rationale given by the applicant as to why re-consenting the cohort would not be feasible.

The applicant had put forward the argument that many of the cohort were likely to be deceased (they were aware of over 120). Members queried why, in this case, it would be necessary to continue to update them on the study progress.

The argument that contact addresses were not held for the entire cohort, and that the cohort was too large (over 1000 participants) for the applicant to spare the time and resource to contact them for re-consent was also seen as self-defeating, as the reason for retaining contact details was in order to write to the cohort.

Concerns had been raised prior to the meeting in relation to an argument made by the applicant that there was evidence of previous non-response from participants who had nevertheless continued to be included in the study. The applicant further explained that participants who originally assented between the ages of 13 and 15 had been contacted again once they turned 16 to seek consent. Responses had not been received, and this had been taken as implied consent. The Confidentiality Advice Team had referred the applicant to ICO guidance on non-response, and explained that where consent had been sought and no response received, this must be taken as dissent.

The applicant understood this and advised that those participants who had been contacted for consent and had not replied would now be excluded from the study. After further investigation, they discovered that in fact no participants had been written to. The applicant explained that they had taken over the study after this event was reported, and as no evidence could be found of any such process it was unlikely that it had occurred.

The CAG accepted this explanation.

Given that the sole purpose of holding the contact details was to send out newsletters, members were agreed that the simplest solution would be for the newsletter to include an explanation of the reasons for continuing to hold contact details beyond the terms of the consent, and to seek further consent to hold these details and contact participants again in future.

The CAG was prepared to recommend support for this purpose. Once consent had been sought, the contact details should only be retained if consent was expressly given by the participant. Non-response must not be taken as implied consent – should a participant not reply, their contact details must be deleted.

This was separate to the retention of addresses in order to send out surveys. The CAG assumed that contact details were provided to Quality Health by the applicant in order to send out surveys. The legal basis for this activity was consent. Therefore if a participant did not consent to contact from the researcher for receiving newsletters or information about future studies, but had not received all of the surveys, their email address and phone number should be deleted but the address could be retained until the final survey had been sent. It was noted that participants were given opportunities to opt out at all points of contact, and this should continue.

- Use of anonymised/pseudonymised data

In accordance with considerations related to the public interest in the study, it was observed that the study overall (which was agreed to be in the public interest) could continue without the use of full contact details. Linkage with HES data and with data held by PHE required only the postcode.

Justification of identifiers

For the specified purpose of the application (sending a newsletter to participants) the public interest in this activity did not meet the threshold, in the view of the CAG, to override participant confidence.

There was an existing legal basis for the retention of contact details in order to send out surveys.

Additional points

Patient notifications

In this case, patient notifications were not required as the CAG was recommending support in order to notify and seek consent from patients.

Existing data breach

It was noted that the Trust reporting procedures had been followed in relation to the retention of contact details in contravention of the Data Protection Act.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Please confirm that names and addresses are retained and provided to Quality Health at the requested intervals for mail-out of surveys.
2. Please advise on the scope of the support requested – how many participants have been in the study for longer than 3 years?
3. Please note that support for the continued retention of contact details for these participants is only in place to enable consent to be sought from these individuals.
4. Please confirm that consent will be sought when the newsletter is sent out, and please advise on the timescale for this.

Once received, the information will be reviewed by a sub-committee of original reviewing members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

Specific Conditions of Support

1. Favourable opinion from a Research Ethics Committee. **Confirmed.**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.
    - University College London Hospitals NHS Trust**. v13 published and reviewed. V14 Pending.**
    - University College London. **v13 published and reviewed. V14 Pending.**
    - Quality Health**. V14 published and reviewed.**
    - IPSOS MORI **– not complete – please provide confirmation that the toolkit for this organisation has been reviewed as Satisfactory by NHS Digital**

b. 17/CAG/0094 – The Assessment of Risk and Safety in Mental Health Services

Context

Purpose of application

This application from the University of Manchester sets out the purpose of medical research into which risk assessments are currently used within mental practice within the UK, with a focus on how they are used prior to suicide, particularly in service users who been rated as low/no risk of suicide. The applicants are requesting support under the Regulations to identify a sample of 50 patients within the National Confidential Inquiry into Suicide and Homicide (NCISH) suicide database (covered under application PIAG 4-08(d)/2003), who died by suicide in 2015, following recent interaction with mental health services, where they were assessed as being low/no risk of suicide. Contact will then be made with the treating clinician of the patient to undertake a semi-structured interview around any risk assessment procedures undertaken with the service user.

Support is requested to use the established NCISH database to identify a cohort of relevant patients to enable their treating clinicians to be identified and approached for consent to be involved in an interview around the risk assessment tools which were used in the care of the deceased patient. This additional research purpose of the existing database is not covered in the existing research approval. Support is required for this standalone project.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

A sample of up to 50 patients who have died by suicide in 2015 (January – December) will be included in the study. These patients lived within the UK, were aged over 18 and classified as low/no risk of suicide at the last contact with mental health services (within three months prior to death).

The following data items from the NCISH database will be gathered in relation to the cohort and used for the following purposes:

- Name – validation,
- Date of birth – validation/analysis,
- Date of death – validation/analysis,
- Place of death – validation,

- Gender – validation and analysis,
- Postcode – validation and analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG were assured that the application defined a medical purpose through the investigation into usage and evaluation of existing risk assessment tools within mental health practice. It was agreed that there was a clear public interest in the application through the proposed improvement and refinement of the risk assessment tools which are utilised.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of Consent

The Group acknowledged that consent was not practicable for the project as the target cohort was deceased.

- Use of Anonymised/Pseudonymised Data

The CAG acknowledged that access to confidential patient identifiable information was required to enable identification of the target patients between the applicants and treating clinicians.

Justification of Identifiers

Members were assured that the identifiers required for the project were justified. It was noted that the research team already had legitimate access to the confidential patient identifiable information stored within the National Confidential Inquiry into Suicide and Homicide (NCISH) database, via the existing PIAG application; however, it was acknowledged that the activity described here was outside of the purpose described in this original proposal, hence the requirement for this separate approval.

Patient and Public Involvement and Engagement

The CAG commented that the information which had been provided within the application around involvement and engagement appeared to link to the activity which was undertaken in relation to the overarching NCISH database application. It was acknowledged that there was an independent advisory group which included both lay and service user representation which would remain informed of the project.

The Group agreed that further work should be undertaken to improve the public and patient involvement and engagement within this specific project. Members commented that the focus of the project was around the last risk assessment which was undertaken by the clinician with the patient prior to their death. As such, it was agreed that wider engagement should be undertaken with clinicians working in this area. It was suggested that engaging with the Royal College of Psychiatrists may be a beneficial way to access the relevant clinicians, services users and their relatives to enable discussion about the project. The CAG further commented that appropriate ways to disseminate the project findings would be informed from a more meaningful engagement strategy.

Members acknowledged the importance and value of the project: however, agreed that further work should be undertaken with relevant stakeholders. It was agreed that sight of a plan for patient and public

engagement and involvement would be required before any recommendation of support under the Regulations could be made.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The CAG recognised that the patient population to be included within the project were already deceased, so a notification and dissent mechanism was not appropriate for the project. The Group suggested that a project summary could be included on the main NCISH website to publicise the additional work which is being undertaken. Further recommendations had been within the 'Public and Patient Involvement and Engagement' section above around raising the profile of the project.

Additional Points

Members discussed the participant materials which would be used to invite clinicians to be involved in the project. It was suggested that the tone of the text could be considered to be accusatory of the clinicians involved in the deceased patient's care. It was recommended that the documentation be considered as part of the engagement process with clinicians, to allow open discussion around any recommended revisions.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information (Summary)

1. Patient and Public Involvement and Engagement:
   a. Submit an initial plan for public, patient and clinician involvement and engagement with the project,
   b. Take account of all relevant suggestions from the body of the text above,
   c. Consideration should be given to how involvement and engagement with various stakeholders could inform the dissemination of project findings,
   d. It is recommended that the clinician participant materials are reviewed as part of any engagement with clinical staff.
2. Provide confirmation that the project will be publicised on the wider NCISH website.

Once received, the information will be by a sub-committee of original reviewing members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

Specific Conditions of Support (Provisional)

3. A report should be provided at the time of first annual review around the actual activity which has been undertaken against the patient and public involvement and engagement plan, together with the outcomes/findings of this work.
4. Support extends to England and Wales only.
5. Favourable opinion from a Research Ethics Committee. **(Confirmed – issued on 28 June 2017)**

Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – National Confidential Inquiry into Suicide and Homicide shows a reported grade of 77% satisfactory on version 14, 2016-17).**

c. 17/CAG/0095 – UK Lung Volume Reduction – Multicentre Observational Study

Context

Purpose of Application

This application, from Imperial College, sets out the purpose of medical research into the patient response to lung volume reduction treatments for chronic obstructive pulmonary disease (COPD). The study will focus on both surgical and bronchoscopic treatments and includes both a retrospective cohort (focus of the CAG consideration) and a prospective cohort (which will be consented into the study and are out with the request for support under the Regulations).

For the retrospective cohort, clinicians will enter data into an online database for procedures which have been performed at their site from 01/01/2010. Sites will only enter data if they have a complete dataset for the calendar year (site resource pending); however, data will be requested for the complete years from 01/01/2014. The database will be maintained by Westcliffe Solutions. This data will then be transferred to NHS Digital to be linked with HES data and returned to the applicants for analysis.

A recommendation for class 4, 5 and 6 support was requested to cover activities as described within the application.

Confidential Patient Information Requested

Cohort

Patients aged 18 and up who have undergone a lung volume reduction procedure, either surgical or bronchoscopic. The scope of the cohort is from 01/01/2010 (when complete data for the year is available) or 01/01/2014 where not.

The following items of confidential patient identifiable information have been requested for the purposes defined:

- NHS Number – linkage,
- Date of Birth – analysis,
- Date of death – analysis.

The confidential patient information will be supplied by clinical teams at the NHS Trusts involved with the project and linked with HES information by NHS Digital.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined a medical purpose through the evaluation of treatment methods for chronic obstructive pulmonary disease (COPD). It was acknowledged that COPD was an area of key focus within the NHS which required longer term follow-up. Members were assured that there was a clear public interest in the proposal.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of Consent

The applicants had advised that consent for the project was not feasible for a number of reasons including the potential for some patients to be lost to follow-up or deceased, resource implications between the smaller and larger sites which would participate in the project and the potential for bias in the reporting. The CAG was assured by the rationale provided that consent was not feasible for this project.

- Use of anonymised/pseudonymised data

The Group acknowledged that use of confidential patient identifiable data was required to enable the required data linkage to be undertaken by NHS Digital; however, it was unclear why the research team was required to be involved in this linkage process. Members queried whether there was potential for the data linkage with NHS Digital to be facilitated by Westcliff Solutions, which would reduce the flow of confidential patient identifiable information, through removing the flow of identifiers to the research team. It was suggested Westcliff Solutions would then be able to provide a pseudonymised data set to the research team for analysis. It was agreed that consideration of this proposal was required by the applicants. If it was deemed impracticable, further rationale would be required to support this decision.

Justification of Identifiers

Members discussed the identifiers which were being requested and it was unclear why the local database, which it was understood would be hosted by Westcliff Solutions, included a more extensive list of patient identifiers, including name and hospital number, than that which was required for the research project. Clarification of this disparity was required.

The Group noted that gender and ethnicity were not being requested by the applicants for use in analysis. It was agreed that confirmation would be required that this was correct as it was suggested that these demographics were usually considered important for analysis.

Data Linkage

The CAG discussed the proposal that data linkage would be undertaken by NHS Digital on NHS Number alone. It was acknowledged that past precedent suggested that NHS Digital would require access to additional data to facilitate the required linkage. It was agreed that the applicants would need to approach NHS Digital to seek agreement in principle to link on NHS number alone, prior to any recommendation of support being issued. Members advised that this assurance was required to ensure that the mechanism proposed was feasible and to prevent the requirement for a future amendment prior to any linkage being undertaken.

Exit Strategy

Members were unclear around the exit strategy for the project and it was commented that further information was required around the retention periods for data held by both Westcliff Solutions and the research team. The Group further commented that it was unclear why all patient identifiers, with the exception of the NHS Number, would be retained and it was agreed that further rationale around this proposed data retention was required.

Westcliff Solutions – Data Processor

The Group stated that the involvement and role of Westcliff Solutions within the project was unclear. It was assumed that this organisation would be hosting the national database for the project; however, confirmation of this had not been provided by the applicants within the study documentation. Members agreed a fuller explanation and justification of the role of Westcliff Solutions within the project was required before any recommendation of support could be given.

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory IG toolkit compliance for each organisation processing confidential patient information under the support application. The CAG commented that, as data processor, assurance was required in this area for Westcliff Solutions. It was further acknowledged that confirmation of Westcliff Solutions' Data Protection Registration was also required to ensure that there was appropriate cover for research purposes.

The CAG also agreed that further clarification was required around the data management within the Westcliff Solutions setting as it was unclear from the information provide whether patient identifiable information would be stored separately from clinical information. Further detail was required around the storage of data within the Westcliff Solutions platform, before a recommendation of support under the Regulations could be made.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The Group considered the information which had been presented within the application and it was agreed that the public and patient involvement and engagement activity described was not strong enough and further work would be required by the applicants in this area, before any recommendation of support could be given.

Members suggested that all Trust's involved with the study should be encouraged to publicise the study on their websites to raise the profile of the important work which is being undertaken. The Group noted from the application that the applicants were in communication with a local Breathe Easy group, which it was agreed would be an appropriate forum to engage with patients and the public.

The CAG agreed that submission of a clear plan around how public and patient involvement and engagement would be improved as the project progressed was required before any recommendation of support under the Regulations could be provided. It was further advised that a report on actual activity undertaken from the plan would be required for submission at first annual review.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members noted that the patient notifications system described was not wide enough in scope, through the reliance on the British Lung Foundation newsletter. As mentioned with the public and patient involvement and engagement section above, it was recommended that the project is publicised at all participating Trusts. Whilst the applicants had stated that patient objections would be respected, it was unclear from the information provided how the dissent process would operate and be managed to ensure all objections were respected.

As data linkage was being undertaken by NHS Digital, it was assumed that they would facilitate the exclusion of any patients that had raised a type 2 objection; however, assurance was required from the applicants around this point.

The Group advised that further work was required in this area by the applicants. Confirmation of a wider meaningful patient notification system was required, together with copies of the documentation for consideration. A clear description of the dissenting mechanism system was required with explanation of how any objection raised would be respected and confirmation was required of which organisation involved in the project would be responsible for the removal of the patient's data.

Data Protection Act 1998 Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the Data Protection Act (DPA) 1998. Applicants must therefore demonstrate through the application that it is consistent with the DPA.

It was noted from the information provided within the application form at question 57 around the DPA principles that identifiable data would not leave the United Kingdom; however, it was acknowledged that the Westcliff Solutions servers were located in Germany and the USA. Clarification was required around where the hosted database would be stored by Westcliff Solutions to ensure this was clearly articulated within the application and storage proposals were compliant with the principles of the DPA 1998.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory IG toolkit compliance. It was noted that a self-assessed score of 78% had been published for the Royal Brompton and Harefield NHS Foundation Trust; however, this self-assessment had not yet been assessed by NHS Digital. It was noted that historic submissions were also published without a reviewed score. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website.

Additional Points

The favourable opinion from the Research Ethics Committee was received; however, it was noted that this was dated July 2016. Confirmation was required that the ethical opinion which was in place covered the activity as described in the application for CAG consideration

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

The request for additional information is referenced in detail above and summarised below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information (Summary)

1. Further information is required around the role of Westcliff Solutions within the project. Provide response which addresses the following points:

a. Provide a clear explanation of the role of Westcliff Solutions in relation to the establishment and management of the database and also within the research project,
b. Security assurance is required in the form of a satisfactory reviewed NHS Digital IG Toolkit for Westcliff Solutions,
c. Provide confirmation of Westcliff Solutions Data Protection Registration,
d. Clarify how the database will be managed and confirm if clinical data will be held separately from the identifiable information,
e. It was noted that Westcliff Solutions servers are located in Germany and the USA. Clarify where the hosted database will be stored.

2. Confirm whether it is feasible for Westcliff Solutions to facilitate the required data linkage directly with NHS Digital, in order to reduce the flow of confidential patient information. If this is not deemed to be feasible, provide a clear explanation to support this decision, together with a stronger rationale to support the additional flow of confidential patient identifiable data via the research team at Royal Brompton Hospital.
3. Provide clarification around why the local database requests submission of a wider range of personal identifiers than is required to undertake the project data linkage.
4. Provide confirmation that gender and ethnicity are not required for project analysis.
5. NHS Digital should be approached around the proposed data linkage to confirm agreement in principle to undertake the required linkage on NHS Number alone – submit correspondence for consideration.
6. Further information is required in connection to the exit strategy for project to clarify how you plan to move away from the requirement for support under the Regulations – consider the following points and provide response:
   a. Confirm how long data will be retained by Westcliff Solutions and the research team,
   b. It is unclear why it is proposed to delete NHS Number from the holding, when it is understood that the wider list of identifiers held by Westcliff Solutions will be retained – provide confirmation.
7. Public and Patient Involvement and Engagement – further work should be undertaken to improve this area of the project, accounting for the suggestions detailed above.
   a. Submit a plan for public and patient involvement and engagement for the project for consideration by the CAG.
8. Patient Notifications and Dissent – further work should be undertaken to improve the notification and dissent mechanism, accounting the suggestions detailed above.
   a. Provide an overview of how and where patient notifications will be advertised,
   b. Provide copies of any notifications for consideration by the CAG,
   c. A clear description of the dissenting model for the project should be provided, together with detail of how any by whom objections would be managed,
   d. Provide assurance that type 2 objections which have been raised with NHS Digital will also be respected.
9. Confirm that the ethical opinion issued by the London – Fulham REC back in July 2016 covered the activity described in the CAG application.

Once received, the information will be reviewed by a sub-committee of original reviewing members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

Specific Conditions of Support (Provisional)

1. Support extends to England and Wales only.
2. A report will be required at the time of first annual review around actual activity which has been undertaken in relation to the patient and public involvement and engagement plan detailed at point seven above.
3. A report will be required at the time of first annual review around actual activity which has been undertaken in relation to the patient notifications and dissent plans described in response to point eight above.

4. Favourable opinion from a Research Ethics Committee. (**Pending Confirmation – issued 21 July 2016 – confirmation required that this ethical opinion covers the activity described in the CAG application**).
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Pending – arrangements for Westcliff Solutions remains outstanding. Confirmation of a reviewed score the Royal Brompton and Harefield NHS Foundation Trust from NHS Digital is also required**).

d. 17/CAG/0101 – AD-CARE Work Package 3

Context

Purpose of Application

This application from University College London set out the purpose of medical research into the impact of the availability of Acute Day Units (ADU's) on the acute readmission rates for mental health patients. ADU's offer intensive, short-term community responses to mental health crises and aim to reduce costly and unpopular admissions, either by avoiding them or facilitating early discharge.

The applicants are requesting information from the Mental Health Services Dataset (MHSDS) held by NHS Digital to assess admission rates to acute psychiatric units, as well as compulsory admissions within 2014/15 and 2015/16. The aim of the study is to assess whether acute readmission rates are reduced in areas/Trusts with a more enhanced care pathway (defined as having an ADU in the pathway). The study will also examine whether patients in areas with ADU's in the care pathway have different outcomes to similar patients who have an acute episode but do not have access to an ADU.

A recommendation for class 2, 4 and 6 support was requested to cover activities as described within the activity.

Confidential Patient Information Requested

Cohort

The cohort will be established from all service users with records within the MHSDS who have used any acute (urgent) mental health care services for the two year study period (2014-2016). This will be defined by the use of in-patient, Acute Day Unit (ADU) or Crisis Resolution Home Treatment (CRT) services. Access to and use of these services will be used to identify the start and end of episodes of acute care. Service users will be able to contribute more than one episode of acute care. The MHSDS contains information in relation to over 1 million service users.

The following items of confidential patient identifiable information have been requested for the purposes defined:

- NHS number – data linkage by NHS Digital,
- MHDS ID – data linkage and analysis,
- Date of birth – data linkage and analysis (MM/YY format),
- Gender – for analysis,
- Postcode – district level for analysis (district level),
- Ethnicity – for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined a medical purpose as it aimed to investigate the outcomes for mental health patients which was in line with priorities for the NHS. Members agreed that the project defined a public interest as it aimed to examine an alternative to expensive inpatient NHS Care, assessing a type of service which increased service user choice, which provided support to help prevent crisis and may be more acceptable to service users.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The CAG acknowledged that the MHSDS contained records in relation to 1 million patients and it was assured that consent for this retrospective project was not feasible on a cohort this size.

- Use of anonymised/pseudonymised data

The Group was unclear what information was being returned from NHS Digital as it was noted that the MHSDS contained quite a number of identifiers. It was agreed that clarification around this was required to gain an understanding of the identifiability of the dataset returned.

The CAG acknowledged that the applicants proposed undertaking mapping of the data returned from NHS Digital with information recorded in the census and it was queried what the purpose of this activity was as there may be potential for NHS Digital to provide a richer dataset which could achieve these goals. Clarification around this point was required as there was potential that a complete and anonymous dataset could be provided by NHS Digital, which would not require support under the Regulations.

Justification of Identifiers

Members acknowledged that the MHSDS identifier was required by the applicants to enable the same patient to be tracked across the returned dataset for additional presentations to the system and it was agreed that this rationale was sound.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The CAG acknowledged that the applicants had a commitment to patient and public involvement and engagement in the wider research programme. It was acknowledged that the applicants were working with the McPin Foundation around this activity, which was a respected organisation in this area. Members were satisfied that the activity which had been described for the overarching programme appeared appropriate and no further assurances were required in this area.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The Group was satisfied that the patient notification system proposed appeared to be appropriate to the activity described and no further information was required in this area.
Additional Points

Members queried whether the applicants had already approached NHS Digital around the project and it was unclear whether the request to establish a legal basis had been determined from direct correspondence. Confirmation around this point is required.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Provide a complete list of every data item which will be returned from NHS Digital.
2. Clarify the purpose of the additional data mapping which will be undertaken with information from the census. Consider whether these outcomes could be achieved through the request for a richer dataset from NSH Digital.
3. Clarify whether any correspondence has previously been undertaken with NHS Digital around the requirement to establish a legal basis for the activity described within the application.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 06/01/2017)**
2. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - University College London – School of Life and Medical Sciences shows a reviewed reported score of 66% satisfactory on Version 14, 2016-17).**

e. 17/CAG/0103 – West Midlands Regional Children's Tumour Registry (Previously: 15/CAG/0179)

Context

Purpose of Application

This application from Birmingham Children's Hospital NHS Foundation Trust set out the purpose of medical research through the ongoing development of a research database. 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 living five 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 previously taken place with Public Health England prior to application consideration and the view provided that an individual application should be made.

The application was originally considered at the CAG meeting held on 17 September 2015 when a provisional outcome was issued. The issues identified within the provisional response were not resolved until 24 October 2016, at which stage conditional support was recommended for a six month period under application reference 15CAG0179, pending resubmission of a revised application, addressing some outstanding issues.

A recommendation for support under Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002 was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The cohort is all patients diagnosed with a childhood malignancy (or benign central nervous system tumour) aged 0-15 year inclusive within the West Midlands region. Patients for inclusion will be identified by the Registry Manager and Data Manager from a number of sources including MDT meetings, the local patient administration system, pathology and radiology systems and direct correspondence from clinicians. Notifications of eligible patients from the region who were not treated at Birmingham Children's Hospital will be provided by the West Midlands NCRAS service.

The following items of confidential patient identifiable information have been requested for the purposes defined:

- Name – held in the database used for standard clinical care,
- Address – held in the database used for standard clinical care,
- NHS Number – for data linkage,
- Hospital ID – held in the database used for standard clinical care,
- GP registration – held in the database used for standard clinical care and data linkage,
- Date of birth – data linkage and analysis,
- Date of death – data linkage and analysis,
- Postcode – data linkage and analysis,
- Gender – for analysis,
- Ethnicity – for analysis.

The data sources identified in the project are HES (inpatient, outpatient, A&E and mental health datasets), primary care data, NCRAS, NCRAS West Midlands and British Childhood Cancer Survivor Study (held at the University of Birmingham under the leadership of Professor Mike Dawkins, who is a Director of this WMRCT Registry).

Confidentiality Advisory Group Advice

The CAG commented that review of this resubmission would focus upon the conditions which had been attached to the previous recommendation of support under application reference 15CAG0179.

Public Interest

The medical purpose and public interest in the project had previously been defined and it was agreed by the CAG that this continued to be a valuable resource.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The Group considered the rationale which had been supplied by the applicants to support the argument that recruitment to the registry was not practicable on a consented basis. It was acknowledged that a precedent had been set in relation to the establishment of cancer registries and it was agreed that support should be recommended in line with this. Members agreed that the activity should continue on an unconsented basis.

- Use of anonymised/pseudonymised data

The CAG acknowledged that access to confidential patient identifiable information was required to enable the data linkage to be undertaken.

Justification of Identifiers

The applicants had been required to provide further justification for the retention of identifiable information in relation to deceased patients. It had been advised that the retention of patient identifiers for the full cohort was important for late mortality studies. It was also advised that survivors of childhood cancer were likely to develop and die from a secondary cancer later in life – the applicants advised that the removal of identifiers would prevent follow-up in this area. The CAG was satisfied with the rationale provided and agreed that support should be recommended on the basis of retaining identifiers in relation to deceased patients.

It was queried whether patient identifiable data was held in a separate place to the clinical information and Members agreed that clarification on this point was required.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The applicants had been asked to improve patient and public involvement and engagement activities and provide a report around actual and planned activities for consideration. Members commented that it did not appear that much work had been undertaken in this area; however, it was acknowledged that plans and proposals for exploration had been included within the response.

The CAG agreed that progress on improving engagement with the specialist patient engagement group within the Oncology/Haematology department at Birmingham Children's Hospital was a key objective for the applicants as this was a relevant patient cohort to be involved with the registry.

It was agreed that the applicants would be required to take forward the activities which had been proposed and make clear progress in this area to be reported back at annual review. At this stage, a revised involvement and engagement plan would be required for the following year.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The applicants had been required to provide more detailed information around the patient notification and dissent model for the study. Members considered the information which had been provided in this area. It was acknowledged that information leaflets had been provided at a local level and also for the national cancer registration service.

It was noted that the local level leaflet offered an opt-out mechanism through speaking to the patient's clinician. The CAG agreed that alternative options to raise an objection should be provided as it was acknowledged that speaking directly with a clinician could be considered difficult. The Group agreed that an interim report would be required six months from the recommendation of support to provide details of the additional opt-out arrangements which would be provided and assurance around how these mechanisms would be operated and respected. Copies of the revised notification materials would be required for consideration.

Additional Points

The Group discussed information within the protocol around the transmission of data by post. It was recommended that the applicants ensure that the procedure described here adhered to NHS policies and guidance.

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 is recommended on the basis that confidential patient identifiable data can be retained in respect of deceased patients. Confirmation is required in the interim report at six months from this approval around whether the patient identifiers and clinical data are stored separately within the database.
2. Patient Notifications and Opt-Out – an interim report around the below details is required six months from the date of this approval letter:
    a. Local patient information materials around the registry should be updated to provide an alternative means of raising dissent than speaking to the treating clinician,
    b. Assurance should be provided around how this alternative dissenting mechanism would be managed to ensure any dissent is respected.
3. Patient and Public Involvement and Engagement – a report is required at first annual review to account for the following points:
    a. Provide a detailed overview of the actual activity which has been undertaken in this area,
    b. Specific progress is expected with the specialist patient engagement group within Oncology/Haematology at the Birmingham Children's Hospital,
    c. Provide an updated plan around how this activity will be carried forward through the project.
4. Favourable opinion from a Research Ethics Committee. **(Confirmed – issued 28 September 2016).**
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Birmingham Children's Hospital NHS Trust IG Toolkit score on Version 14, 2016/17, is 66% reviewed satisfactory with an improvement plan in place).**

4. ITEMS FOR CONSIDERATION

a. NHS Digital – Anonymisation

The Chair welcomed Dr Martin Severs to the meeting. Ms Amanda Hunn, HRA Joint Head of Policy and wider members of the Confidentiality Advice Team also joined the meeting for the presentation.

Dr Severs provided an overview of information in relation to work which was being undertaken towards developing an anonymisation approach for health and social care data.

Discussions ensued and it was agreed that the CAG should be involved in the developmental stage of this work, through being part of the programme board once this had been set up.

5. MINUTES OF THE MEETING HELD ON 25 MAY 2017

The minutes were agreed as an accurate record of proceedings, with no amendments raised.

6. CAT OFFICE REPORT

The Confidentiality Advice Team Office Report for May 2017 was circulated ahead of the CAG meeting. The following key points were noted.

<u>CAG Assistant Appointment</u>

Further to recent interviews, Simon Depledge was appointed to the position of CAG Assistant and took up his position on Monday 13 June 2016. Simon is based in the Manchester office and his role will involve supporting the work of the CAG and providing wider administrative support to the CAT.

<u>Update on Previous Applications</u>

- 17CAG0018 – Implementation of a Telephone-Based Case Management Intervention for Patients at risk of High Emergency Department Utilisation in the English NHS

This application was reviewed by a Sub-Committee in correspondence back in January/February 2017; however, due to outstanding REC approval, the final outcome was issued on 04 May 2017.

- 17CAG0020 - Clinical and Biological factors associated with relapse and length of survival following relapse in UK neuroblastomas

This application was originally reviewed at the CAG meeting on 09 February and issued with a provisional opinion. Following a further response from the applicants which was reviewed by a Sub-Committee of Members, Conditional Support was recommended on 05 May 2017.

- 16CAG0140 – British Association of Urological Surgeons (BAUS) Audits

This application was originally considered by the CAG at the meeting held on 31 October 2016, during which it was acknowledged that there was a potential data breach which the applicants were requested to report to the Information Commissioner's Office (ICO) as a Serious Incident Requiring Investigation (SIRI). The applicants received a response from this review on 22 February 2017 in which it was confirmed by the ICO that it appeared BAUS had contravened the first principle of the DPA. Within the response the ICO noted that there was no apparent detriment to patients from the disclosure of confidential patient

information without consent and they did not anticipate taking any further regulatory action. The Sub-Committee recommended conditional support for the application which was issued on 30 March 2017.

- 17CAG0044 - S-AVANT. Follow-up to the AVANT study up to 8 and 10 years (median follow-up) in patients with colon carcinoma

This application was originally reviewed at the CAG meeting held on 23 March 2017, when a provisional outcome was recommended. As part of the original provisional outcome, the French Sponsor organisation had been asked to provide evidence of an IG Toolkit assurance as they had been incorrectly identified as a data processor. The initial provisional outcome was reissued correcting the incorrect guidance previously issued. Conditional support for the project was recommended in late May 2017.

7. CAG CHAIR REPORT

The Chair confirmed that there was no requirement for a report due to lack of additional business.

8. ANY OTHER BUSINESS

Dr William Bernal

On behalf of all CAG members, the Chair extended warm congratulations to Dr William Bernal on the award of his professorial chair. Well-deserved recognition of his outstanding contribution to the field of liver intensive care medicine

The Chair thanked members for their time and consideration and the meeting was concluded.