NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

14 January 2016 at 10:00 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair) (To item 3 c)	Chair, item 2a
Dr Robert Carr	
Dr Tony Calland MBE (Vice Chair)	Chair
Ms Clare Sanderson	
Ms Gillian Wells (Alternate Vice Chair)	Lay Chair, items 4c and 4d
Professor Julia Hippisley-Cox	
Professor Jennifer Kurinczuk (To item 3c)	
Dr Murat Soncul	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Diane Pryce	Senior Confidentiality Advisor, HRA
Mr Ben Redclift	Confidentiality Advisor, HRA
Mr Christopher Ward	Observer.

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Dr William Bernal and Mr Stephen Robinson.

Welcomes were extended to Mr Christopher Ward who was anticipated to be joining the Confidentiality Advice Team, and was attending the meeting as an observer.

No declarations of interests were identified.

2. RESUBMITTED APPLICATION

a) 15/CAG/0171 - Risk Stratification in Suspected Acute Coronary Syndrome

This item was chaired by Dr Patrick Coyle due to his previous role as Chair during precedent-set review consideration. It was noted that the consideration had taken longer than usual timescales.

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.

Section 251 support is required for the step in which the identifiers of patients who have been admitted to other hospitals and their clinical data is returned to those undertaking this project. Information related to these admissions will allow the researchers to contact the relevant consultants involved in the direct care of patients.

This application was originally reviewed by members at the Precedent Set meeting on 31st August. Following this the application was escalated to a full committee meeting on 17th September 2015 as members noted that prospective data collections where consent is not intended to be sought were excluded from Precedent set review. Members were still unable to provide a recommendation following the meeting and requested further clarification from the applicant, please see the no recommendation letter dated 1st October 2015.

Access was requested to the original audit database which contains NHS number, to access medical records to extract anonymised data and also to follow up each patient through provision of Hospital Episode Statistics, linked with Office of National Statistics mortality data, by the Health and Social Care Information Centre (HSCIC).

Public interest

Members recognised that this was a very important study into a vital area of research and noted the public interest in studies such as this being conducted.

Members noted that the average cardiac patient was likely to be happy with personal information being used in order to improve services and outcomes. Members were very supportive of studies such as this being conducted where data had the potential to provide useful outcomes for the cohort being researched.

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 acknowledged the justification put forward by the applicant that consecutive patient records were needed in order to reduce bias in the sample.

Justification of identifiers

Members sought advice from an expert advisor, on whether data previously collected through an audit without consent could be used for research purposes.

The expert advisor noted the issues that had arisen as a result of the REC review and confirmed that the outcome of REC review highlighted that the relevant ethical issues had been considered. It was noted that that the applicant appeared to have a valid reason for now conducting research using the previously collected data.

Additional points

Members highlighted that this application should not be seen to represent a precedent set review for access to data previously collected as an audit being used for research purposes. Additionally, members noted that the provision of comprehensive patient information materials from the outset should have been provided to avoid issues such as these arising.

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 covers, in particular, the specified data on patients known to be admitted to other hospitals so that clinical data on these cases can be provided to the researchers by these direct care teams.
2. Support is in place for the transfer of HES (and ONS mortality data) by the HSCIC to the applicant. Support should be limited to a one-off extraction.
3. Other hospitals must ensure that they comply with their responsibilities under the Data Protection Act 1998 particularly in terms of meeting the first principle of fair processing.
4. All data shared with researchers outside the care team must be anonymised.
5. The researchers should ensure that they are complying with the terms of REC approval.
6. This application should not be seen to set a precedent for identifiable data collected for audit purposes being used subsequently for research.
7. Favourable opinion from a Research Ethics Committee. Confirmed 27/08/15
8. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Confirmed 12/08/15

3. ITEMS FOR CONSIDERATION

a) **NHS England CAG/8-02 (a-c)/2014 annual review and duration extension**

CAG 8-02 (a)/2014 Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting
and
CAG 8-02 (b)/2014 Data collection by NHS England Area Teams responsible for commissioning secure mental health and child and adolescent mental health services to populate patient register and reporting.
and
CAG 8-02 (c)/2014 Assuring Transformation: Enhanced Quality Assurance Process Data flow (Disclosure by HSCIC to NHS England)

The overarching purpose of these linked applications, submitted by NHS England, was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of 'case management'. Case management was defined in this context to ensure the continuity and quality of care delivered by healthcare providers over the period of the patient's care and to ensure the appropriate support is provided. This application received support following consideration on 6 November 2016, and came into effect on 20 November 2014. Support had been requested at that time until March 2016.

Members considered the annual review documentation, and a duration request for continuing support to March 2018.

The review provided an update on the following aspects:

- No patient objections had been received
- Previous discussion and correspondence had taken place with the advice team regarding interpretation of legacy data. It had been confirmed that the previous condition of support specified that any data collected prior to date of final approval would be excluded, in other words' legacy data'. There had been an issue flagged rearding retention of data arising from CAG 6-07 (a)/2013 however, it was confirmed that when support expired under this reference, as recorded on the Register of Approved Applications, that any subsequent processing of data was taking place under a different legal basis outside the remit of this support.
- The previous reports on patient notification were referenced, alongside the approved amendment to include full home postcode for all patients (previously support had been provided to patients admitted to hospital from their home address).

Confidentiality Advisory Group Advice

Members agreed that the activity appeared to provide a significant benefit and members recognised the complexities, the inroads that had been taken and the challenges faced. It was agreed that the identifiers remained appropriate and justified to ensure monitoring of the inpatient cohort and ensuring that patients receive high-quality care close to their home and family. The previous rationale provided as to why consent would not be feasible, namely that there was

potential for provider conflict of interest, was noted. Members also noted that a right of objection would be offered in this instance under the provisions of the Data Protection Act 1998, which was an approved exception to the typical conditions of support due to this specific activity.

In line with this, members agreed that the duration request was appropriate and was in line with CAG comments when support was originally provided. This was subject to clarifying the precise time period for which support was sought; until March 2018, or whether the retention period specified of 15 months would mean support extended to August 2018. Members also advised that they would wish to see specific information on patient notification materials and any objections raised, at time of annual review.

b) **ECC 3-04 (r)/2011 National Diabetes Audit HQIP – security incident report**

[Paragraph 1 and 3 were updated in line with the discussion in the CAG meeting 17 March 2016.]

Members had been provided with a report from the Healthcare Quality Improvement Partnership (HQIP) regarding an automated transfer of data from a considerable number of GP practice to the HSCIC where data had been extracted without knowledge of the practices. It was noted that this was an extremely important audit and the issue that had arisen had not derived from the practices but was indicated to be a technical issue. It was considered important that the incident did not have a negative impact on audit participation as the issue appeared to be more about clarity of responsibilities and a technical failure of the system.

While members were sympathetic to the issue and impact for the practice, it was noted that this supported the position that the change to the system demonstrated how important it was for practices to be aware of the data extractions taking place from their systems, to ensure that they met their responsibilities under the Data Protection Act 1998.

The CAG expressed some dismay at the initial handling of the incident and how it had arisen as it was noted that this would have gone undetected if not for a single GP raising the issue. The report also indicated that there appeared to be a lack of role clarity between the involved parties and a key issue was how the incident had been internally categorised and the delay in informing HQIP, who should have been informed as soon as possible by the data processors as HQIP were ultimately responsible for the application. It was also noted that it is a standard condition of support that any incidents affecting approved data flows should be reported to the CAG within 10 working days, but due to the breakdown in communication this had not taken place.

Members expressed the view that when new systems are brought in that they should be tested properly before going live to avoid the issue of practices being placed, inadvertently, at risk of breach of confidentiality, and this should be part of any agreements. It was suggested that testing should occur at specified intervals. It was also noted that once made aware of the breach, the information could reasonably have been deleted as it was being held at the time by the data processor without a clear legal basis.

The report made clear that communications, both within and outside the HSCIC appeared in this instance to be less than optimal. It was noted that the HSCIC IG team had not been informed until sometime after the incident. The CAG requested that the applicant provide assurance that its data processors, the HSCIC, had in place a clear set of procedures for the reporting of incidents, including how they were categorised as it was clear that the incident involved patient information.

The report indicated discussions had taken place with the data processors but members requested greater clarity on the assurances that had been provided. Members advised that a brief report should be provided now, and, in light of the reporting to the Information Commissioner's Office, that at time of annual review a detailed report should be provided focusing particularly on the lessons learnt. In the meantime, it was expected that the applicant would ensure all appropriate measures would be taken to ensure compliance with the Data Protection Act 1998 and guidance issued by the ICO, by all parties.

c) **Healthcare Quality Improvement Partnership (HQIP) – the future role of 'section 251 approvals for the National Clinical Audit and Patient Outcomes Programme (NCAPOP)**

This paper was provided by HQIP as a six month update in their capacity as commissioner of a number of national clinical audits, and as the lead applicant for these audits. Previous discussions with the CAG had asked them to consider and report back on whether there may be a practicable alternative – in this case reliance upon a different legal basis – to the Health Service (Control of Patient Information) Regulations 2002. The paper provided an update against this.

In the previous paper NHS England, the Health and Social Care Information Centre (HSCIC) and the Healthcare Quality Improvement Partnership (HQIP) agreed to work collaboratively to scope the implications of legal changes within the Health and Social Care Act 2012, plan for any changes to NCAPOP delivery which might be required and detail early findings. CAG members had advised that they were required to consider if there were practicable alternatives to processing of confidential patient information under the Regulations and that the focus of considerations should move more generally to alternatives,
rather than focusing solely on Directions. Therefore, where support under the Regulations continued to be required, data flows of confidential patient information in each of the audits should be reduced where possible and justified fully within future applications.'

At a previous meeting it has been agreed that HQIP would collaboratively undertake a detailed analysis of data flows for one audit and consider options for each data flow, e.g. where Directions could be applied, where support under the Regulations would be required and where alternatives to the use of confidential patient information could be adopted. This information should be presented to CAG with an estimated timescale of pursuing Directions or alternatives in this scenario.

Members recognised the work that had been undertaken and wished to thank HQIP and partners for their continuing engagement with this request. It was agreed that the report had shown that Directions could be used in appropriate places, In light of the report, it was agreed that each audit would be assessed at time of annual review for a practicable alternative, with particular focus on reduction of identifiability where feasible, where privacy enhancing technologies could be applied, pseudonymisation upon landing or at source, alternative legal bases including consent, and assessment of identifiability and de-identification.

Members also noted that the time of the re-commissioning process would also provide a key opportunity to instigate change.

In reviewing the documentation, members highlighted that embedded documents did not work with all devices, and these should be avoided where feasible.

4. NON-RESEARCH APPLICATIONS

16/CAG/0008 - The management and risk of patients with personality disorder prior to suicide and homicide

This application from The University of Manchester sets out the purpose of this study which is to inform clinical policy and practice by recommending safety improvements which may reduce patient suicide and homicide by people with personality disorder.

Recommendations will be highlighted in a report and will form part of the NCISH toolkit for use throughout the service.

The study aims are to:

- Describe the characteristics of patients with PD who died by suicide or committed homicide.
- Examine the care pathway for patients with PD who died by suicide or committed homicide.
- Examine the extent to which care received adhered to NICE guidelines for personality disorder.
- Evaluate the quality of risk management intervention (assessment, planning and implementation of risk plans) in the 3 months prior to death or homicide.

A mixed methodology will be used to examine the care and risk management of patients with personality disorder (PD) who died by suicide in 2012/13 or were convicted of homicide in 2010-2013 in the UK. Cases will be identified from the existing National Confidential Inquiry into Suicide and Homicide by People with Mental Illness [NCISH] database. (PIAG 4-08(d)/2003))

Additional information will be obtained through a number of data sources, such as a web based survey, medical records, focus groups with clinical teams across the UK, and interviews with support and representatives groups for patients with PD.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to allow the study's participating organisations to correctly locate the medical records held on the participants, and for access to their medical records in order to extract information.

Specifically; the study will be receiving data from the following sources:

1) Service providers: Medical records of the individuals in cases included in the study.

2) Data from the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness cases of people in contact with mental health services in the 12 months prior to their death

Other aspects of the project listed in the application do not require support as consent is to be obtained and are therefore not part of this request:

3) Responses from the Web based survey

4) Transcripts of the focus groups with clinicians

5) Transcripts of the telephone interviews with patient group representatives

Confidential patient information requested

Access was requested to Date of birth, Date of death, gender, last name, first name and address – required for validation purposes

Date of birth, date of death, post code, gender and ethnicity is to be retained for analysis.

Confidentiality Advisory Group advice

Public interest

Members agreed that this project is in the public interest and that it has clear benefits for patients by identifying the type and standard of care.

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 were in agreement that consent was not practicable for this project.

Justification of identifiers

Members discussed the request by the applicant for full date of birth and date of death for linking and analysis purposes. They agreed that full dates are required for linkage purposes but did not agree that this was justified for analysis. Members requested that the applicant use either month and year of birth and or death or age at death only for analysis purposes.

Patient objections

Members commented that they were disappointed with the response from the applicant that it was not possible to record individuals' dissent from the use of their records for research purposes. Instead they were relying on the participating organisations that do not permit access to patient data. Members asked that the applicant is reminded that objections must be respected and a process put in place to manage this.

Fair processing

Members requested that the applicant is reminded of their responsibilities under the Data Protection Act to provide clear information to patients about how they make use of their data.

Additional points

Members raised a concern about the transfer of data proposed by the applicant, particularly as the standard for security was to be BS7799. This standard is out of date and has been replaced with the ISO27001 standard. However, the requirement for a satisfactory Information Governance Toolkit would address the security concerns raised.

National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH) database. (PIAG 4-08(d)/2003)

Members understood that the cohort for this project would be identified from the existing NCISH database. However, members noted that the applicant had advised the CAT that this data was due to be deleted on 13 January 2016. Members requested clarification about how the cohort are to be identified.

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

Clarification

1. The applicant was asked for clarification on how the cohort are to be identified.

Specific conditions of support

1. Confirmation that identifiers for the analysis would be reduced to either month and year or age. Or provide justification why this is not possible.
2. Favourable opinion from a Research Ethics Committee.
3. To put a process in place to manage patient objections.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

15/CAG/0187 - Evaluation of Bowel Cancer Screening Helper Kit Withdrawn. 08/01/16

This application had been withdrawn from the meeting by applicant due to changes in processing arrangements that were not reflected in the application.

16/CAG/0005 - Learning Disabilities Mortality Review (LeDeR) Programme

This application from The University of Manchester sets out the purpose of this study which is to inform clinical policy and practice by recommending safety improvements which may reduce patient suicide and homicide by people with personality disorder.

Recommendations will be highlighted in a report and will form part of the NCISH toolkit for use throughout the service.

The study aims are to:

- Describe the characteristics of patients with PD who died by suicide or committed homicide.
- Examine the care pathway for patients with PD who died by suicide or committed homicide.
- Examine the extent to which care received adhered to NICE guidelines for personality disorder.
- Evaluate the quality of risk management intervention (assessment, planning and implementation of risk plans) in the 3 months prior to death or homicide.

A mixed methodology will be used to examine the care and risk management of patients with personality disorder (PD) who died by suicide in 2012/13 or were convicted of homicide in 2010-2013 in the UK. Cases will be identified from the existing National Confidential Inquiry into Suicide and Homicide by People with Mental Illness [NCISH] database. (PIAG 4-08(d)/2003))

Additional information will be obtained through a number of data sources, such as a web based survey, medical records, focus groups with clinical teams across the UK, and interviews with support and representatives groups for patients with PD.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to allow the study's participating organisations to correctly locate the medical records held on the participants, and for access to their medical records in order to extract information.

Specifically; the study will be receiving data from the following sources:

1. Service providers: Medical records of the individuals in cases included in the study.
2. Data from the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness cases of people in contact with mental health services in the 12 months prior to their death

Other aspects of the project listed in the application do not require support as consent is to be obtained and are therefore not part of this request:

3. Responses from the Web based survey
4. Transcripts of the focus groups with clinicians
5. Transcripts of the telephone interviews with patient group representatives

Access was requested to Date of birth, Date of death, gender, last name, first name and address – required for validation purposes

Date of birth, date of death, post code, gender and ethnicity is to be retained for analysis.

<u>Public interest</u>

Members agreed that this project was in the public interest and that it has clear benefits for patients by identifying the type and standard of care.

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 were in agreement that consent was not practicable for this project.

Justification of identifiers

Members discussed the request by the applicant for full date of birth and date of death for linking and analysis purposes. They agreed that full dates were required for linkage purposes but did not agree that this was justified for analysis. Members requested that the applicant use either month and year of birth and or death or age at death only for analysis purposes.

Patient objections

Members commented that they were disappointed with the response from the applicant that it was not possible to record individuals' dissent from the use of their records for research purposes. Instead they were relying on the participating organisations that do not permit access to patient data. Members asked that the applicant was reminded that objections must be respected and a process put in place to manage this.

Fair processing

Members requested that the applicant be reminded of their responsibilities under the Data Protection Act to provide clear information to patients about how they make use of their data.

Additional points

Members raised a concern about the transfer of data proposed by the applicant, particularly as the standard for security was to be BS7799. This standard is out of date and has been replaced with the ISO27001 standard. However, the requirement for a satisfactory Information Governance Toolkit would address the security concerns raised.

National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH) database. (PIAG 4-08(d)/2003))

Members understood that the cohort for this project would be identified from the existing NCISH database. However, members noted that the applicant had advised the CAT that this data was due to be deleted on 13 January 2016. Members requested clarification about how the cohort were to be identified.

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

Clarification

1. Clarification on how the cohort are to be identified.

Specific conditions of support

1. Confirmation that identifiers for the analysis would be reduced to either month and year or age. Or provide justification why this is not possible.
2. To put a process in place to manage patient objections.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

16/CAG/0006 - UK National Flap Registry (UKNFR)

This application from the British Association of Plastic, Reconstructive and Aesthetic Surgeons sets out the purpose of setting up the UK National Flap Registry (UKNFR). Currently, there are no figures on the numbers of flap reconstructive procedures that are carried out in the UK for reconstruction of the head and neck, breast, trunk, upper and lower limb, perineal and after sarcoma resection. It is estimated that approximately 7000 such procedures are carried out in the UK. These reconstructions are necessary for a variety of indications such as tumour excision, after trauma, burns, or infection. The aim of the UK National Flap Registry Database is to collect information about all major flaps and assess the quality of care provided for these patients.

This audit would also allow for comparison of clinical performance with national and international standards, and provide useful data on changing trends in reconstruction.

The Registry s cross-speciality with input from plastic, maxillofacial and breast surgeons and is collaboration between 5 National Surgical associations: British Association of Plastic Reconstructive and aesthetic Surgeons (BAPRAS), British Association of Oral Maxillofacial Surgeons (BAOMS), British Association of Head and Neck Oncologists (BAHNO), Association of Breast Surgery (ABS) and British Society of Surgery of the Hand (BSSH).

In line with Consultant outcome publication by HQIP, the long-term goal is to publish surgeon specific outcomes for flap reconstruction procedures in England.

A recommendation for class 4, 5 and 6 support was requested in order to allow disclosure of confidential patient information to Dendrite Clinical Systems for the purpose of data linkage to the Head and Neck Audit (HANA) and for flap operations audit purposes.

Access was requested to Name, NHS number, date of birth, gender.

Public interest

Members agreed that this project was in the public interest and that it has significant patient benefits.

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

Overall members were not convinced with the line of reasoning from the applicant that seeking consent was unfeasible, and felt that if following GMC guidelines this could be achieved. However, members agreed that seeking consent retrospectively was not feasible and agreed that full ascertainment was important.

Members were of the opinion that consent should be feasible prospectively.

Justification of identifiers

It was agreed that identifiable information would be required for validation and linkage purposes.

Patient notification

Members noted that the patient information was difficult to understand and included a lot of clinical terms which patients may not understand and that the information would benefit from being simplified.

Members were also of the opinion that it would be beneficial if patient information and posters were put into surgeries where flap reconstruction was being carried out.

Patient objection

Members agreed that although there is a statement in the information leaflet about not having information added to the UKNFR, overall, the information available to patients about the process was limited and did not address how patients could object to the further use of their data.

Members advised that the applicant should ensure they have a clear process in place and this should be made accessible to patients.

Exit strategy

Members noted that in the CAT advice form the applicant has stated that once UKNFR uptake and use amongst surgeons becomes an integral part of surgical life (and information for appraisal and revalidation), consent will be more acceptable. It was not clear to members if the applicant intends to move to a consent model and request clarification about this.

Members noted that the applicant has also stated in the CAT advice form that it is planned to carry out anonymisation or pseudonymisation of some or all of the data.

However, no details about the timeframe for either of these proposals or details of the anonymisation or pseudonymisation standards had been given. Members requested that the applicant confirms at the time of the first annual review, which option they intend to adopt.

Additional points

One of the outcomes in setting up the UKNFR is to make information held on the registry available to researchers. Members requested clarification on the process for managing these requests, and what and how information would be made available to researchers. Clarification i requested on

whether data disclosed would be identifiable and what checks are to be implemented to ensure there is no further onward disclosure of identifiable information.

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

Specific conditions of support

1. Support would be for 12 months from the date of the final approval letter.
2. In order for support to continue after the 12 months a clear exit strategy must be provided at the first annual review for this application. This should detail;
    a) What decision has been taken about moving to a consent model or for the information to be anonymised, pseudonymisation or combination of these approaches and when or if this is to be implemented.
    b) Provide details of the anonymisation or pseudonymisation standard and process for consent, copies of the consent materials should also be provided if applicable
    c) Confirmation of exactly when support will no longer be required or provide clear justification why support continues to be required.
3. Provide details of the process for managing access to the UKNFR for researchers and provide details of what and how data will be made available for example, disclosure and access policies and assurance that there will be no further onward disclosure of identifiable information.
4. Provide a revised version of the patient information literature in clear lay language removing clinical terms.
5. Provide details of how patients will be informed about this project
6. Provide details of how patient objections will be managed, and how patients will be informed about this process
7. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission for Dendrite Clinical Solutions.

5. MINUTES OF THE MEETING HELD ON 26 November 2015

The minutes were agreed as an accurate record.

6. FOR INFORMATION

a) REC and CAG information exchange

Members were provided with a copy of this recent HRA update for information.

b) Chair's Report (previously circulated December 2015)

The chair's report, originally disseminated via email to all members, was provided for information and comment.

Members noted that some minutes had not yet been published on the website and highlighted the importance of the minutes providing transparent information on the CAG recommendations. Members were advised this delay was due to recent staffing issues as previously advised and the minutes would be published as soon as available.

Members were advised that a further round of recruitment would be undertaken within the next few weeks, and that five current members terms of office were due to expire at the end of March 2016. Members would be welcome to reapply, and for those who did not choose to, information would be sent explaining the requirement to delete all information relating to CAG and its role prior to departure. The Group would be advised of the dates once finalised.

c) ANY OTHER BUSINESS

- Away day –members were advised that there is likely to be an away day in April and potentially this will be combine with an induction for newer members. Dame Fiona review is likely to have been concluded by then, and government response and status of Regulations known. A Doodle poll will be sent to members and the CAT next week.

The minutes were agreed as an accurate record.

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date