Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

February 2018

Present:

Name	Capacity	Items
Ms Clare Sanderson	Chair	1.a, 1.b, 1.c, 1.d, 1.e, 1.f.
Dr Martin Andrew	Member	1.b, 1.d.
Professor William Bernal	Member	1.a, 1.c.
Dr Kambiz Boomla	Member	1.f
Ms Sophie Brannan	Lay Member	1.b, 1.c.
Dr Lorna Fraser	Member	1.e,
Mr Anthony Kane	Lay Member	1.f.
Dr Rachel Knowles	Member	1.e,
Mr Andrew Melville	Lay Member	1.a, 1.d.

Also in attendance:

Name	Position (or reason for attending)
Miss Kathryn Murray	Senior Confidentiality Advisor
Ms Wendy Fisher	Confidentiality Advisor

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 18/CAG/0021 - The incidence of hydroxychloroquine retinopathy in England a prospective case-finding study

Context

Purpose of Application

This application from the Oxford Eye Hospital sets out the purpose of medical research which aims to undertake the first population-based study to determine the incidence of hydroxychloroquine retinopathy in the UK. This research is important in order to help quantify the public health burden from hydroxychloroquine retinopathy, and inform the decision making process screening provision. In the USA, screening is recommended: when signs of retinal damage are detected, hydroxychloroquine is stopped before permanent visual loss occurs. This study will directly inform any recommendation for hydroxychloroquine retinopathy screening within the National Health Service.

The information will be collected over a two year period.

A recommendation for class Class 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

- Adult patients (over 18 years of age)
- Male or female
- Diagnosed with hydroxychloroquine retinopathy 240 patients anticipated

Data required from reporting clinicians:

- Local hospital number – validation - retained to allow one year follow-up questionnaire to be sent and to enable local clinicians to identify patients
- Month and year of birth –validation – retained to allow one year follow-up questionnaire to be sent and to enable local clinicians to identify patients and analysis
- Gender –analysis
- Ethnicity – analysis

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application described a clear medical purpose through medical research and it was acknowledged that, by increasing the number of patients identified with hydroxychloroquine retinopathy was within the public interest.

Practicable Alternatives

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

- Feasibility of consent

Members acknowledged that for informed consent to be obtained, the reporting ophthalmologist would be required to call the patient for an additional consultation for no purpose other than obtaining consent. If the reporting ophthalmologist failed to recall the patient or the patient failed to attend the additional appointment, information about that patient could not be included, and the completeness of the study would be compromised.

Not requesting consent is in line with the standard BOSU process of information collection. The Group was assured that consent was not feasible for the proposed activity.

- Use of anonymised/pseudonymised data

Members recognised that the project had been designed in such a way that the applicants would only receive a pseudonymised data set, the patient will not be identifiable to the research team but the data is required in order to contact the clinician for follow up on the patient's diagnosis and treatment.

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.

Researchers have had direct feedback from patients within Oxford who have been affected by hydroxychloroquine retinopathy with permanent loss of sight. It is these patients who have in part encouraged a study of this nature to inform the discussion on the possible role of screening for hydroxychloroquine retinopathy within the United Kingdom.

The patient information sheet and study protocol was sent to the Chief Executive of the Macular Society for feedback, and has been approved.

The CAG recommended that the applicants continued with the public and patient involvement and engagement activity as the study progressed in particular, approach the Macular Society to discuss how study results can be disseminated to patients.

The Group was satisfied that the level of consultation and detail provided was appropriate to the study.

Patient Notification 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 applicant had confirmed that all reporting units will have information displayed in the waiting room which clearly states that patients have the right to desist from the study (reporting of their pseudo-anonymised clinical details).

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.

Specific Conditions of Support (Final)

1. Support extends to England and Wales only.
2. Patient and public involvement and engagement should be continued with the Macular Society in order to disseminate study findings
3. Patient Dissent, information sent to clinicians should include a reminder to exclude any patient who has dissented from the use of their data
4. Favourable opinion from REC **(Confirmed – 15 January 2018)**
5. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed - Oxford University Hospital NHS Foundation Trust which incorporates Oxford Eye Hospital show a reviewed grade of 99% on Version 14, 2016/17).**

b) 18/CAG/0025 - Improving prediction of outcome in out of hospital cardiac arrest patients – The King's Out of Hospital Cardiac Arrest Registry (KOCAR)

Context

Purpose of Application

This application from King's College Hospital NHS Foundation Trust (KCH) sets out the purpose of medical research with a focus on the outcome of patients that suffer out of hospital cardiac arrest (OOHCA). The data will be used to validate a risk stratification tool to support clinical decision making upon admission. Information on patients suffering from OOHCA and subsequently brought to KCH will be collected from the London Ambulance Service (LAS). Information will be requested from NHS Digital on the mortality status of those patients. Those patients that are still living will be contacted by telephone for a follow up interview to identify the outcome of the OOHCA.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All patients over the age of 18yrs admitted to KCH via London Ambulance Service having suffered an Out of Hospital Cardiac Arrest between 1st May 2012 and 31st December 2017. Sample size: 400 patients approximately 150 survivors for telephone interview

- Data released by LAS: Computer Aided Dispatch Number (CAD), date of reaching admitting hospital – linkage. Data obtained under a data sharing agreement
- Data identified from patient records at KCH: Unique KCH hospital number, NHS number, Occupation, GP and post-code – to facilitate linkage with ONS mortality information at NHS Digital and patient contact

Confidentiality Advisory Group Advice

Conflict of Interest

Members of the Sub-Committee acknowledged that this application had been authorised by Professor William Bernal, an existing CAG Member, in his position as Caldicott Guardian for King's College NHS Foundation Trust. Whilst Professor Bernal was not involved with the review, it was agreed that a reference should be included in the minutes in the interests of transparency.

Public Interest

The Group was assured that the application defined a strong medical purpose and it was acknowledged that it is in the public interest to aid development of risk stratification tools which will help healthcare professionals when treating patients who have had an OOHCA, particularly as prognosis in this area is currently poor.

Scope of Support

The applicants confirmed the data released from LAS to KCH was out of scope for CAG review and was to be obtained under an existing data sharing agreement, by the clinical care team.

The applicants confirmed that the screening log kept to monitor recruitment would not contain confidential patient information and therefore not require support under the Regulations.

With these additional clarifications provided by the applicants, the CAG acknowledged that support under the Regulations was required for the following activities:

- Accessing patient records in order to extract details required for a release of data by NHS Digital,
- To disclose data to NHS Digital in order for mortality status to be checked – NHS Digital would disclose either the date of death for the patient or updated contact details to enable contact to be made with survivors. Contact with survivors will be made by the direct care team.

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 was assured that consent was not feasible for the initial stage of the project as it was likely that a percentage of the cohort would be deceased and contact details held for others were likely to be incorrect. It was acknowledged that surviving patients would be contacted in order to seek consent for a further interview study. Members acknowledged that there was an agreed protocol around the attempts the applicants would made to contact the patients to seek this consent, which allowed two letters and one telephone call. If contact was unsuccessful following this, no further attempts would be made.

- Use of anonymised/pseudonymised data

Members recognised that the project had been designed in such a way that the applicants would only receive an anonymised dataset for analysis; however, processing of confidential patient information was required by NHS Digital in order to create this dataset to be used in analysis.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. Members were assured that the items of confidential patient information requested were proportionate and justified for the proposed activity.

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. Members were content that the patient and public involvement activity which had been undertaken was appropriate to the project and supported the activity proceeding. No further issues were raised in this area.

Patient Notification 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 study team will ensure the study information leaflet is displayed in the outpatient clinic to ensure reasonable measures have been taken to inform the relevant population of the activity. Members acknowledged that the leaflet did not provide detail patients with the opportunity to raise an objection to their involvement in the research study and it was recommended that this was included.

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 (Provisional)

1. Favourable opinion from a Research Ethics Committee **(Pending).**
   Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - King's College Hospital NHS Foundation Trust shows a review grade of 79% satisfactory on version 14, 2016/17. NHS Digital show a reviewed grade of 92% satisfactory on version 14, 2016/17).**

Recommendation

1. It was recommended that the participant information leaflet be updated to include a paragraph explaining how a patient can dissent from their data being used.

c) 18/CAG/0026 - Dynamic Electronic Tracking and Escalation to reduce Critical Care Transfers – DETECT study

Context

Purpose of Application

This application from Alder hey Children's Hospital sets out the purpose of medical research with a focus on early detection of clinical deterioration in children. The aim is to evaluate the usefulness of an electronic hand held device, VitalPac, that records and alerts clinicians to changes in vital signs that are important in the detection of often rapid deterioration. VitalPac has been shown to be effective in adult care but the important signs in adults differ from those displayed by children.

This cohort study will only take place at Alder Hey Children's Hospital using pseudo-anonymised data from approximately 130,000 inpatient episodes. The clinical data will be collected at six 24 hour time points over six months and will be pseudo-anonymised by the research team. This will provide approximately 630-780K observation sets. The data will be analysed in order to establish the validity of the alert system to clinical staff of observation results that may indicate potential patient deterioration.
Retrospective, standard in patient monitoring data, with a matched time frame, will be collected from a preceding year as a comparator to determine the proportion of deterioration in both populations.

Confidential Patient Information Required

No confidential patient data is being accessed outside of the clinical care team.

Confidentiality Advisory Group Advice

The Group considered the application, together with additional information provided by the applicants in response to queries. The applicants had been asked to clarify why the application had been submitted to the CAG for consideration as it was unclear from the detail provided where the breach of the common law was occurring within the activity described.

The applicants confirmed that the research nurses that were involved in the project were part of the direct care team. It was further commented that within the research database the patients will be identified by their study participant number and their hospital number only. Data being subsequently shared with statisticians or health economists will have their hospital number removed (Q27). The applicant stated that data available outside the direct care team was anonymised and confirmed that there was no breach of patient confidentiality.

Members received the confirmation from the applicants and agreed, on the basis of the confirmation provided by the applicant, that there was no requirement to provide a recommendation of support under the Regulations, as the activity did not involve a breach of the common law as there was no access to confidential patient information without consent outside of the direct care team.

If it was found that the information provided by the applicant had not been understood and the application activity did involve a breach of the common law, a revised application would need to be provided which clearly articulated where the breach of patient confidence was occurring.

d) 18/CAG/0029 - Investigation into the role of Glyceryl Trinitrate (GTN) and Remote Ischaemic Pre-conditioning (RIPC) in cardiac surgery (ERIC-GTN study).

Context

Purpose of Application

This application from University College London sets out the purpose of medical research with a focus on Remote Ischaemic Preconditioning (RIPC) a phenomenon known to protect the heart against ischaemia reperfusion injury. This is an established randomised control trial with four arms comparing the infusion of GTN or a placebo saline infusion during coronary artery bypass surgery.

Information has emerged indicating an increased mortality rate in one arm of the study one year post follow up. The initial trial protocol does not allow follow up of patients after discharge, so the patients consented into the study did not provide informed consent for this access to additional data.

The study is ongoing but new information on the outcomes of the study would be in the public interest and requires further analysis.

A recommendation for classes 1 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All patients enrolled into the ERIC study up to one year post consent and surgery. 260 patients.

Data from trial case report forms and medical records will be reviewed to identify cause of death and the trial arm the patient was randomised to.

The following items of confidential patient information will be released to the non-clinical research team:

- Hospital ID - linkage
- Date of Birth – linkage and converted to age for analysis
- Date of Death MM/YY – analysis
- Gender - analysis
- Ethnicity - analysis
- Lifestyle analysis – analysis

Confidentiality Advisory Group Advice

Public Interest

The Group was assured that the application defined a strong medical purpose and public interest.

Practicable Alternatives

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

- Feasibility of consent

The Group was assured that consent was not feasible for the project as it was likely that a percentage of the cohort would be deceased and contact details held for others were likely to be incorrect.

- Use of anonymised/pseudonymised data

Members recognised that the project had been designed in such a way that the applicants would only receive an anonymised dataset for analysis.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. Members were assured that the items of confidential patient information requested were proportionate and justified for the proposed activity.

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. Members were content that in this study, further patient engagement would not be an option.

Patient Notification 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 were content that further information about the update to the study follow-up should be made available on the Hatter Institute website, including the outcome of the research.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from CAG), and providing a favourable ethics opinion is in place. The applicants had explained in response to queries raised in advance of the application review that the study protocol had not been updated to include the proposed additional follow-up. Members commented that a favourable ethical opinion would need to be in place to support the extension to the study, to include follow-up, before any final recommendation of support could come into effect. The applicants would be required to submit a substantial amendment, including a revised protocol, to the REC in relation to this element and provide a copy of the favourable opinion.

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.

Request for Further Information

1. Favourable opinion from a Research Ethics Committee for the additional follow-up which has been described in the application to the CAG, together with the revised protocol document.

Specific Conditions of Support (Provisional)

1. Patient Notification and Dissent – information should be included on the Hatter Institute website to inform patients and the public around the additional follow-up which is not included in the study. Study results should also be disseminated via this forum.
2. Favourable opinion from a Research Ethics Committee. **(Pending – Confirmation of a REC Favourable Opinion for the extended follow-up not cited in the initial study protocol is required).**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - University College London Hospitals NHS Foundation Trust show a reviewed grade of 80% satisfactory on Version 14, 2016/17 Bart's Health – show a reviewed grade of 77% satisfactory on Version 14, 2016/7).**

e) 18/CAG/0009 - The Maternal Response to Sepsis (Version 4)

Context

Purpose of Application

This application from Imperial College London sets out the purpose of medical research to investigate whether severe infection (sepsis) develops more rapidly in pregnant women than in non-pregnant women, and whether pregnant women with sepsis experience greater morbidity and mortality when compared with non-pregnant women with sepsis.

The retrospective data collection, which is the element requiring consideration by the CAG, will be performed at the NHS site Addenbrooke's Hospital. Non-pregnant women who are of reproductive age

and pregnant women and who have had a pyrexia triggering collection of blood cultures will be identified from coding. Data will be collected from the patient's electronic record by the main applicant, who is not part of the direct care team. Data to be collected will include information related to the clinical assessment and outcome, haematological, biochemical, microbiological and radiological results. The applicant will undertake a comparison between the two groups with regard to the rates of development of sepsis and septic shock and the rate of progression to both sepsis and septic shock.

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

Confidential Patient Information Requested

Cohort
Women aged between 16-50 years of age, both pregnant and non-pregnant, who have had a pyrexia triggering collection of blood cultures, which was treated at the Addenbrookes Hospital over the previous five year period. It is estimated that there will be 250 patients included within the retrospective sub-study.

The following items of confidential patient information are requested for the purposes as stated below:

- NHS Number – record linkage,
- Hospital Number – record linkage,
- Date of birth –calculation of age and analysis
- Date of death – analysis of clinical outcome
- Sex – analysis,
- Ethnicity – analysis,
- Occupation – analysis

The applicant will require access to the complete patient record in order to extract the data. Wider clinical information will be required for analysis.

The study ID will be generated as the study reference e.g., MJSPS/001 in numerical order from 001, 002 etc. in accordance with the chronological timing of recruitment of the patient to the study such that the earliest recruited patient will be assigned study number reference MJSPS/001. The study reference will not include patient initials or their date of birth or other patient identifiers.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application described a clear medical purpose through medical research and was in the public interest.

Cohort

The Group was unclear whether there was potential for the retrospective cohort, whose data would be accessed with support under the Regulations and the prospective cohort, which would provide fully informed consent to their participation, to overlap. It was agreed that confirmation of the start and end date of the inclusion period for the retrospective cohort was required to ensure overlap was mitigated.

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 members considered the feasibility of consent. The applicant asserted that the proposed retrospective cohort was relatively large and the introduction of consent had the potential to introduce selection bias, which needed to be avoided.

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 applicant confirmed that following discussions at a meeting with the Patient and Public Involvement (PPI) department at Imperial College London, all patient information leaflets, patient consent forms and study advertisements used in the study would be reviewed by a group of female patients and a group of female lay people (not patients, scientists or health professionals). The applicant also advised that a patient focus group could be performed in isolation or in combination with a postal or online survey as the project progressed. It was explained that Imperial College London had a Patient Experience Research Centre (PERC), which provided training and support for researchers in public engagement and involvement and were able to assist in the facilitation of this additional patient and public engagement.

Members agreed that the applicant should move forward with the plans to undertake additional patient and public involvement and engagement as the project progressed in order to test the acceptability of the study design, with particular reference to using confidential patient information without consent. Feedback would be required at the time of first annual review in relation to the activity undertaken in this area. If the outcomes were negative, the CAG would take this into account when considering whether support can continue, or whether further actions may be required.

Patient Notification 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 as a right a 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 agreed that the process for patient notification and dissent is insufficient. It was agreed that as a minimum, notification should be placed on the hospital's website with details of the project and how patients raise an objection to the use of their data in the study. This should include an explanation of the project, how data will be used in the project and what data will be accessed together with information about opt-out. The applicant should decide what the appropriate form of consultation should be.

Other Points

Members noted that information materials had been submitted for consultees of potential participants who did not have capacity to consent for themselves. It was commented that as patient's who lacked capacity were excluded from the study, it was unclear why these documents were included. Clarification was required from the applicant in connection to this point.

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. Confirm the start and end date for the inclusion of patients within the retrospective cohort.
2. Clarify why information materials for patient consultees have been submitted when adults who lack capacity have been excluded from the project.
3. Patient notifications and dissent – further work is required in this area by the applicant to establish a communications strategy for the project. Copies of any documentation should be submitted for consideration, together with an overview of how a meaningful objection mechanism will be operated for the study.

Specific Conditions of Support (Provisional)

1. Patient and Public Involvement and Engagement – further work should be undertaken in this area as per the proposal set out by the applicant as the study progressed. A report will be required at the time of first annual review around the activity which has been undertaken in this, together with an overview of the findings. If the outcome of the activity is negative, the CAG would take this into account when considering whether support can continue, or whether further action is required.
2. Favourable opinion from a Research Ethics Committee**.** (**Pending**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed – Cambridge University Hospital achieved 82% Satisfactory on version 14, 2016/17).**

f) 18/CAG/0031 - Unexplained visual loss following silicone oil removal in patients presenting with retinal detachment in the United Kingdom: results of a prospective surveillance study

Context

Purpose of Application

This application from County Durham and Darlington NHS Foundation Trust sets out the purpose of medical research with a focus on unexpected loss of vision following removal of silicone oil used to treat retinal detachment. This is a prospective study utilizing the BOSU methodology.

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

Confidential Patient Information Requested

Cohort

All patients, aged 18 years and over, the following confidential patient information will be released by BOSU to the applicant:

- Local hospital number – to allow reporting clinicians to be able to identify patient
- Month and year of birth –validation
- Gender – analysis of demographic factors

Confidentiality Advisory Group Advice

Public Interest

The Group was assured that the application defined a strong medical purpose and it was acknowledged that, identifying patients with unexplained visual loss following silicone oil removal was within the public interest.

Practicable Alternatives

The agreed BOSU methodology exists to allow access to rare cases that would not normally be available by any other means.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient. Members were assured that the items of confidential patient information requested were proportionate and justified for the proposed activity.

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. Members were content that the patient and public involvement activity which had been undertaken was appropriate to the project and supported the activity proceeding. No further issues were raised in this area.

Patient Notification 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.

Patients will be able to dissent through their ophthalmologist. Information will be made available in Hospital Eye Units to inform them of the study and information will be displayed for patients explaining how they can dissent.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for County Durham and Darlington NHS Foundation Trust had been published in respect of version 14 (2016/17) of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. 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. This would need to be addressed by the applicant.

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 (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 19 December 2017).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(PENDING - County Durham and Darlington has not been reviewed.**