Health Research Authority

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

OCTOBER 2018

Present:

Name	Capacity	Items
Dr Tony Calland MBE	Chair	1.d.
Dr Patrick Coyle	Vice Chair	1.a, 1.b, 1.c
Dr Martin Andrew	Member	1.b, 1.c.
Ms Sophie Brannan	Lay Member	1.b
Dr Barry Evans	Member	1.a.
Dr Liliane Field	Member	1.d.
Dr Lorna Fraser	Member	1.d.
Mr Myer Glickman	Member	1.d.
Ms Diana Robbins	Lay Member	1.a, 1.c.
Ms Gillian Wells	Lay Member	1.d.

Also in attendance:

Name	Position (or reason for attending)
Miss Kathryn Murray	Senior Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 18/CAG/0168 - Clinical outcomes of a PPS program undertaken in a large UK cohort

Context

Purpose of application

This application from St George's University of London set out the purpose of medical research which aims to follow-up a cohort of patients who underwent voluntary cardiac screening with the voluntary organisation, Cardiac Risk in the Young (CRY). CRY is a charitable organisation that offer pre-participation screening to young adults aged between 14 and 35 years. Since 2008, CRY has screened over 100,000 patients with a health questionnaire and 12 lead electrocardiogram (ECG).

This proposes study aims to ascertain from those patients screened, how many went on to suffer a sudden cardiac arrest and/or sudden cardiac death via linkage of confidential patient information held within the CRY database with HES and ONS Mortality statistics databases held by NHS Digital. The findings will contribute to the ongoing research into the risks of sudden cardiac arrests and deaths in young apparently fit and healthy individuals. The research will build on a previous study (supported via CAG reference 16/CAG/0042), which followed up 5,000 patients within the CRY database.

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

Confidential patient information requested

Cohort

Patients aged between 14 and 35 years who underwent voluntary cardiac screening via Cardiac Risk in the Young from 2008 onwards. This will involve approximately 120,000 patients.

The following items of confidential patient information will be released from the Cardiac Risk in the Young database to St George's University London. Further disclosure from St George's University London to NHS Digital is then required to enable follow-up via HES and ONS Mortality information.

- Name,
- GP Registration,
- Date of birth,
- Date of death,
- Postcode (Unit Level),
- Gender,
- Ethnicity.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that this application defined an appropriate medical purpose, which was medical research. Members acknowledged that the proposed research aimed to gain a better understanding of the risks of cardiac arrest and sudden death amongst seemingly fit, healthy and young patients. The Group was assured that the potential outcomes from the research were within the public interest.

The background information provided within the protocol document was considered – figures around the incidence of sudden cardiac death in America had been quoted within this section (page nine). The document stated '*early estimates of SCD in the US range from 1:16,0000 to 1:30,0000 deaths per year in young competitive sportspeople*'. Members queried whether there was a typographical error within the figures and these should read 16,000 and 30,000 respectively. It was agreed that clarification was required here as if the quoted figures were accurate; it was unclear how the proposed application involving 120,000 individuals would provide scientifically valid results.

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

Patients had provided consent to the use of anonymised data within future research as part of the voluntary screening they had undergone with Cardiac Risk in the Young. The applicant intended to use confidential patient information within the proposed study in order to facilitate wider linkage, which was not covered by the initial consent. Members were assured of the rationale behind the application to seek support under the Regulations in order to legitimise processing of confidential patient information within the study. However, the applicant had not provided justification to explain why patients could not be approached for consent for this specific study. The Group agreed that clarification was required from the applicant to justify why consent was not deemed to be feasible for this project.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage with HES and ONS data held by NHS Digital, which could not be otherwise achieved. No issues were raised in this area.

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. The Group was unclear which items of the confidential patient information were required to facilitate the linkage which would be undertaken by NHS Digital and which items would be required for analysis. It was agreed that further clarification was required from the applicant to justify the requirement of each item of confidential patient information which had been specified within the application as necessary.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The Group was unclear from the detail provided what the proposed exit strategy from support under the Regulations was for the proposed activity.

The project classification had been queried in advance of the meeting, as the proposed activity was currently classified as a research database; however, the applicant had explained it maybe more appropriately classified as a specific project working with data only in response to queries. Members agreed that clarification was required around this point to ascertain whether the resulting linked dataset would be retained for use in wider research projects as a database, or would only be utilised in the analysis for this specific project. If being retained as a research database and in an identifiable format, further justification would be required from the applicant to support this onward retention, together with confirmation of where this would be retained and what security and access arrangements had been put in place for this. If the data was only required for the purposes of this specific study analysis, the applicant would be required to revise the application form in order to accurately reflect the scope of the project.

Class one support, for the process of extracting and anonymising information had been requested to cover the application activity. This suggested that the dataset would be anonymised; however, the application did not describe this process. It was further noted that the application stated that the resulting linked dataset would be retained for a 10 year period and it was unclear whether this was in identifiable or anonymised format. The applicant would be required to provide a clear overview of the proposed exit strategy from support under the Regulations and the anticipated timeframe for this before any recommendation of support could come into effect.

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 application did not describe any patient and public involvement and engagement activity which had been carried out in relation to the project. The detail provided at this section of the application form described the historic consent provided by the cohort for use of anonymised data in research. The proposed activity involved processing confidential patient information for research purposes, which was out of the scope of the consent provided. Members agreed that, in these circumstances, it was important to test the acceptability of using confidential patient information for the study purposes. It was suggested that CRY may have an established group with which the applicant could engage in order to seek views around the acceptability of the study design. The Group agreed that feedback from any activity undertaken in this area would be required prior to any recommendation of support coming into effect. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

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 to objection and mechanism to respect that 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 2018. The applicant had provided a copy of a privacy notice which fulfilled the fair processing requirements for data protection compliance. It was not clear whether this document was intended to serve a dual purpose, and fulfil as well patient notification requirements in relation to the common law duty of confidentiality. Clarification would be required around this point in the first instance. If the document would also be used to promote the study in the public arena for the purposes of patient notification, the text would require revision to include details of how an individual can raise a specific objection to the use of their data within this study.

The applicant also explained that Cardiac Risk in the Young promoted the research activity which it had supported via the website and newsletters. It appeared that the website provided links to published research findings, rather than an overview of research which was ongoing. The Group agreed that further information was required here to understand how CRY promoted research via newsletters.

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 the CAG), and providing a favourable ethical opinion is in place. Evidence should be provided of the favourable ethical opinion issued by the REC prior to any final recommendation of support coming into effect.

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 (Summary)

1. Clarify the figures quoted at page nine of the protocol around the incidence of sudden cardiac death in the USA. Submit a revised protocol document as necessary.

2. Justify why it is not feasible to contact patients in the CRY database in order to seek consent for the purposes of this specific research project.
3. Provide a clear justification for each item of confidential patient information which has been specified as necessary for the application purposes. Response should confirm which items of confidential patient information would be disclosed to NHS Digital in order to facilitate linkage.
4. Confirm whether the proposed activity will proceed as a research database or a specific project only. If proceeding as a research database, further information is required to explain in what format data will be stored, where this will be retained and what security and access arrangements would be in place. If the project will proceed as a specific project only, a revised application form should be provided which accurately reflects the project classification.
5. Clarify the retention period for the resulting linked dataset and confirm in what format this would be retained.
6. Clarify how you intend to move away from support under the Regulations (exit strategy) for the project and the anticipated timeframe for this.
7. Patient and public involvement and engagement activity should be carried out in order to test the acceptability of using confidential patient information without consent for the study purposes with an appropriate group. It is recommended that CRY be approached to see if it had an established group which could assist in this. Detail should be provided around the demographics of the group approached, how the activity was undertaken and what attendees were asked to consider, together with an overview of the findings. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.
8. Patient notifications and dissent – further information is required to address the following points:
    a. Confirm whether the privacy notice supplied is intended to fulfil the dual purposes of fair processing (to comply with current data protection legislation) and patient notifications (in relation to the common law duty of confidentiality requirements),
    b. If so, the document should be revised to include details around how an individual can raise a specific objection to the use of their data in this study, including relevant contact details,
    c. If not, provide an overview of how the project would be promoted in the public arena and how a project-specific dissenting mechanism would be operated. Copies of ay documentation to facilitate this communications strategy would be required,
    d. Provide further details around how CRY promotes the research it supports via its newsletters.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 15 October 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – St George's Hospital Medical School (covering St George's University of London) and NHS Digital have a published satisfactory reviewed grade on Version 14.1, 2017/18**).

b) 18/CAG/0177 - Evaluation of the medium to long term impact of commercial open-group behavioural weight loss programmes on body weight and diabetes risk in adults with overweight and obesity

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research which aimed to undertake five and 10 year follow-up of participants within the WRAP (Weight Loss Referrals for Adults in Primary Care) trial. The WRAP trial involved the referral of patients to commercial open-group behavioural weight loss programmes, such as Weight Watchers, to help them lose weight and reduce

risk factors for diseases including diabetes, cardiovascular disease and some cancers. The WRAP trial is one of only two trials of this type of programme that has measured weight at a two-year follow-up and has also measured diabetes-related outcomes. It is also larger and has a considerably higher retention rate that the other trial at two years (68% versus 26%). Modelling of the long term impact of these programmes on illnesses and related treatment costs suggests that these programmes are likely to be cost-effective in the long term for adults who are overweight or obese. However, no trials of this type of intervention have measured outcomes beyond two years and uncertainty over the long-term impact of these programmes on body weight, diabetes, and other obesity-related conditions, limits the strength of evidence. It is explained that by undertaking five and 10 year follow-up to evaluate the trial objectives in order to provide valuable information weight regain and diabetes incidence in the medium-term and will enable more realistic estimation of long-term impacts on disease incidence and associated resource use.

The purpose of the application to CAG is to undertake tracing via NHS Digital in order to update contact information for participants in the original trial to ensure that invitations to participate in the follow-up study are correctly directed, or not sent to patients who have died in the intervening period. NHS Digital had confirmed that the consent which was previously taken is sufficient to legitimise the follow-up via records; however, it does not extend to cover the validation of contact details.

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

Confidential patient information requested

Cohort

Participants who took part in the original WRAP study and consented for further follow up will be invited to attend the 5-year and 10-year follow up visits. 1040 participants had consented to further follow-up from the original 1267 baseline cohort.

The following items of confidential patient information are required in order to validate the patient cohort, update the contact details and facilitate the invitation process for the follow-up study:

- Name – sample validation and tracing via NHS PDS,
- GP Registration – sample validation,
- Date of birth – sample validation and tracing via NHS PDS,
- Date of death – sample validation,
- Full address and postcode – sample validation, tracing via NHS PDS and invitation process.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that there was public interest in undertaking a longitudinal follow-up of patients within the WRAP study.

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 recognised that it was not feasible to seek consent for patients for the purposes of tracing, as access to updated confidential patient information was required to facilitate this. No issues were raised in this area.

- Use of anonymised/pseudonymised data

The CAG was assured that processing of confidential patient information was required to verify current contact details for the purposes of the invitation process which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the proposed activity. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The desired exit strategy from support under the Regulations is for patients to provide their consent to the ongoing participation within the study, or formerly dissent to this, which Members were comfortable with.

It was noted that four further attempts would be made to contact patients who did not respond following the initial invitation. In response to queries, the applicant had stated that confidential patient information will be retained for those patients within the cohort who do not respond to the invitation requested in order to facilitate the invitation process at the 10 year follow-up. Members were not supportive of this proposed strategy and further commented that it was unclear how this proposal would be compliant with current data protection legislation. The Group agreed that attempts to contact patients should be limited to two follow-ups (either postal or telephone) following the initial invitation – if no response was received, the additional confidential patient information received with support under the Regulations via this application should be destroyed and these patients should not receive any further correspondence in relation to this project or the 10 year follow-up. The applicant would be asked to provide confirmation to this point prior to any recommendation of support coming into effect. If the ongoing retention of the information was deemed to be necessary, a stronger rationale would be required to support this together with a clear explanation of how this onward retention was compliant with current data protection legislation. If the applicant also determined that the four supplementary follow-ups following the initial invitation were necessary, a stronger justification would be required to support this.

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 recognised that there was ongoing patient and public involvement from the initial study and continuing with two representatives on the trial steering committee. It was also noted that the applicant's had kept in regular contact with the trial participants in the intervening period through newsletters. Members were assured with the activity which had been undertaken in this area and raised no queries.

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 to objection and mechanism to

respect that 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 2018. Members recognised that regular contact had been maintained with the trial participants in the intervening period via the circulation of newsletters. The applicant had also recently circulated an opt-out form to all patients allowing them an opportunity to dissent to further correspondence about the research programme. It was confirmed that all objections which had been received had been respected. The Group was satisfied with the activity in this area and raised no issues.

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 (Summary)

1. Confirm that the follow-up after the initial invitation for the research follow-up will be reduced to two contacts (phone or email). If the further follow-ups are deemed to be necessity, provide a stronger justification to support this.
2. Confirm that confidential patient information held for patients who do not respond to the invitation request will be securely destroyed and no further follow-up undertaken. If the ongoing retention is deemed necessary, a stronger rationale would be required to support this together with a clear explanation of how this ongoing retention is compliant with current data protection legislation.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 08 December 2017**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital has a published satisfactory reviewed grade on V14.1 2017/18**).

c) 18/CAG/0178 - DEveloping a Complex Intervention for DEteriorating Patients using Theoretical Modelling (DECIDE study)

Context

Purpose of application

This application from City, University of London set out the purpose of medical research which aims to develop an intervention to change the behaviour of nurses when reacting to a patient's 'Early Warning Score' (EWS). EWS is a tool which is used in hospital to assist nurses in recognising deteriorating patients. These tools provide a record of clinical observations, including blood pressure, heart rate, breathing rate, temperature and oxygen levels, which also generating an early warning score every time observations are performed. The higher the score, the risk is greater that deterioration will continue. The tools also instruct staff on what action to take – for example, if a patient has a medium or high EWS, nurses should contact a doctor for assistance. There is however evidence that these instructions are not always followed, leaving unwell patients at risk.

The proposed study involves staff only and has been submitted to the CAG as an element of the project will involve researchers observing nurses undertaking clinical observations on hospital wards. The behaviours which are observed on the wards will be compared to the ideal behaviours set out in the published guidance. The research team do not require access to confidential patient information for the

purposes of the study; however, it is recognised that in observing staff undertaking their daily tasks, it is likely that the researcher will be incidentally exposed to confidential patient information.

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

Confidential patient information requested

Cohort

Staff observations will be undertaken at two hospital wards providing general care for acutely unwell medical and/or surgical patients. Across 6-8 months period, 180 hours of staff observation will be undertaken across the two wards.

The applicant is not seeking support to access any confidential patient information during the observation of nursing on the hospitals wards; however, it has identified that this may incidentally be disclosed. It cannot be foreseen what items of confidential patient information would be disclosed. Some clinical details may be of interest to the study; however, it is confirmed that these would relate to the clinical observations that form part of the EWS and would not fall within the definition of confidential patient information.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application described an appropriate medical purpose, which was medical research. Members were assured that gaining a better of understanding of the care provided to patients with deteriorating health in a hospital setting was within the public interest and there was potential for the research to inform future guidance to improve 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

The Group was assured that as the focus of the study was undertaking observations of clinical staff; it was disproportionate to seek consent from the patients within their care for the purposes of the study. It was acknowledged that appropriate steps had been put in place to inform patients that staff observations were being undertaken, both verbally and through the display of posters. No issues were raised in this area.

- Use of anonymised/pseudonymised data

It was acknowledged that patient information was not required for the purposes of the study; however, this may be incidentally disclosed through the course of staff observations. No issues were raised in this area.

Justification of identifiers

No confidential patient information would be recorded or intentionally accessed during the course of the project. No issues were raised in this area.

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 acknowledged that two patient advisors had been specifically recruited to provide guidance around the project. These individuals were previously patients within an intensive care unit and Members acknowledged that they provided an informed perspective about the study. The CAG noted that applicant had explored the potential for presence of an observer to alter clinical staff actions with the patient representatives. It was agreed that the activity undertaken here was appropriate and proportionate to the proposed activity and no issues were raised by the Group.

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 to objection and mechanism to respect that 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 2018. The applicant provided a copy of the poster which would be displayed in the clinical areas where staff observation was being undertaken. Members agreed that this was a proportionate communications mechanism to support the study. The Group agreed that the paragraph within the document which explained the patient's right to dissent to observation was confusing and would be more appropriately replaced with clear bullet points. A revised poster should be provided prior to any recommendation of support coming into effect.

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 (Summary)

1. Replace the text in the poster to provide a make clearer how a patient can object to the researcher's observation – provide a revised document for review.

Once received, the information will be reviewed by the Confidentiality Advice Team 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 (**Pending**).
2. 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 – has a published satisfactory reviewed grade on V14.1, 2017/18**).

d) 18/CAG/0181 - Cost effectiveness modelling for adaptive liver surveillance in uveal melanoma patients screened with Magnetic Resonance Image or Ultrasound using the Liverpool Uveal Melanoma Prognosticator Online (LUMPO)

Context

Purpose of application

This application from the University of Liverpool set out the purpose of medical research which aims to assess the cost-effectiveness and sensitivity of a mathematical model (LUMPO) that estimates prognosis and screening intervals for patients with uveal melanoma, a cancer of the eye. A retrospective analysis will be undertaken of the predictions made by LUMPO compared with the actual screening and outcome data for the same individuals, to enable a determination of the effectiveness and sensitivity of LUMPO to improve quality of life by reducing the number of unnecessary scans to be made.

It is explained that despite being associated with a high metastatic risk, there is no consensus in the ophthalmology or oncology community on the frequency of liver surveillance for the detection of metastatic disease in patients with uveal melanoma. Currently, prediction for patients with uveal melanoma is undertaken using a mathematical model called LUMPO, by inputting clinical and histological features of the tumour together with genetic information. It is explained that it is now important to determine the effectiveness of this system to determine surveillance screening intervals in patients at high risk of developing metastatic disease.

Patients will be identified from the Ocular Oncology Biobank, established by Royal Liverpool and Broadgreen University Hospital NHS Trust. Patients have provided their consent to the use of their tissue samples and data in the biobank; however, this consent extends to the use of anonymised data only. This application requires the release of Hospital Numbers to the student investigator, working under an honorary contract, to enable access to hospital records in order to view ultrasounds and MRI reports. Pseudonymised data will be extracted from records and returned to the biobank. A pseudonymised dataset will be provided for the research analysis.

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

Confidential patient information requested

Cohort

Patients between 18 – 100 years who were diagnosed with uveal melanoma and underwent MRI or ultrasound screening, between August 2008 and August 2018, and are registered in the Ocular Oncology Biobank, established by Royal Liverpool and Broadgreen University Hospital NHS Trust. It is estimated that 500 patients would be included in the study.

Hospital Number will be disclosed from the Ocular Oncology Biobank to facilitate access with wider hospital records. The student investigator will access patient records via hospital systems in order to view MRI and ultrasound scans.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised the potential value in the mathematical model to be evaluated, as it may

be able to determine the required surveillance screening intervals for patients at risk of developing uveal melanoma. It was agreed that there was a public interest in this activity proceeding.

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

Patients were included within the Ocular Oncology Biobank on a consented basis; however, the consent provided clearly stated that researchers would only have access to anonymised data and as such, was not valid for the activity proposed in this study. The Group was assured that the proposed research was consistent with the overarching aims of the biobank. It was determined that seeking project-specific consent was not feasible for this retrospective cohort.

- Data Extraction by the Direct Care Team or Biobank staff

The applicant had confirmed that both the University-appointed biobank staff and treating clinicians involved in patient care did not have capacity to undertake the data extraction on behalf of the research team. Members received the assurance and no further issues were raised.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required in order to facilitate the linkage with wider hospital records to enable scan report data to be extracted. This could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The applicant would use hospital number alone to link the biobank records with wider hospital records, which was appropriate. Members were unclear what information would be extracted from hospital records and the existing biobank information to be included within the resulting pseudonymised dataset for analysis. It was agreed that clarification was required around this point.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicant had specified that support under the Regulations was required for the duration of the associated PhD programme, which was scheduled to run until 30 September 2021. Members recognised that the project analysis would be undertaken on a pseudonymised dataset and were unclear why, on this basis; confidential patient information would need to be retained after the data extraction and linkage process had been completed. It was agreed that the applicant would be asked to confirm the destruction of confidential patient information at an earlier stage in the project, in order to establish an exit strategy from support under the Regulations. Alternatively, a stronger rationale would need to be provided to support the ongoing retention.

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 has stated that they plan to establish a patient

group from links with OcuMel UK and the European Melanoma Patient Network to assist with this project and more widely with the work of the biobank. However, no active work had been undertaken to seek patient views in connection with the proposed activity.

The Group commented that as the study would involve researchers accessing confidential patient information, which contradicted the explicit consent patients had provided on inclusion in the biobank, seeking patient views around the acceptability of this methodology was important. It was noted that as patients at risk of developing uveal melanoma would be returning for surveillance screening, approaching a relevant cohort about the study should not be too difficult. Members agreed that some activity was required in this area to seek the views of an appropriate patient group before a final recommendation of support could be given for the project. An overview of the activity undertaken was required together with the feedback provided. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

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 to objection and mechanism to respect that 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 2018. The applicant confirmed that information about the study would be made available on the Liverpool Ocular Oncology Research Group website; however, this text was not provided for review. A project-specific dissenting mechanism had not been described in the application.

Members agreed that a project-specific communications strategy and dissenting mechanism would need to be established. It was suggested that this could involve posters within the three hospital clinics which would be treating this patient population. This would need to include contact details to facilitate patient objection, including telephone, postal and email address. It was recommended that a lead-in time was provided for the dissenting mechanism to allow sufficient timeframe for objections to be raised and respected prior to any data release to the research team. An overview of how the dissenting mechanism would be operated was required together with sight of the documentation to facilitate this, including the text of the webpage.

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 the CAG), and providing a favourable ethical opinion is in place. It was noted that the application had been submitted for review by the Liverpool Central REC; however, the outcome was pending. Confirmation was required that a favourable ethical opinion was in place for the study prior to any final recommendation of support coming into effect.

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.

Request for further information (Summary)

1. Clarify what data items would be included within the pseudonymised data set produced for the project analysis.
2. Confirm that confidential patient information extracted for the purposes of the study will be destroyed upon completion of the extraction and linkage process, in order to establish a timely exit strategy from requirement for support under the Regulations. If there is a requirement to retain this information until the end of the PhD programme (cited as 30/09/2021), a stronger rationale is required to support this.
3. Activity should be undertaken to test the acceptability of the proposed methodology, of enabling access researcher access to confidential patient information, with an appropriate patient group. Feedback should be provided around the activity which was undertaken, how this was carried out and overview of the outcomes of this activity for consideration. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.
4. A project specific communication strategy and objection mechanism should be established to satisfy the patient notification requirements. The following points should be considered:
    a. Information should be displayed in the hospital clinics treating this patient group, which described the study and provided details of how an objection to the use of information could be raised. A copy of this document is required for review,
    b. A lead-in time for patient dissent should be established to enable any objections to be respected prior to any access to confidential patient information by the research team,
    c. A copy of the webpage text should also be provided for consideration.
    d. An overview of how the objection mechanism would operate is required for consideration.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Royal Liverpool and Broadgreen University Hospital NHS Trust has a published reviewed grade on V14.1, 2017/18**).