Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

01 October 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Mr David Evans	Yes	CAG Member
Dr Liliane Field	Yes	CAG Member
Mr. Myer Glickman	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Professor Jennifer Kurinczuk	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Ms Diana Robbins	Yes	CAG Member
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

1. Introduction, apologies and declarations of interest

Any declarations of Interest are details for each application below.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **03 September 2020** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority decision following the advice provided by the CAG in relation to the **03 September 2020** meeting applications is pending.

3. Consideration Items

a. 20/CAG/0122 (resubmission of 20/CAG/0070) – Eventi

Context

Purpose of application

This application from the Royal Free London NHS Foundation Trust set out the purpose of medical research which aims to determine the value of using the enhanced liver fibrosis test (ELF) as part of an evaluation of liver disease risk in middle life.

An original cohort of 921 participants (497 in the UK) were consented into the EUROGOLF study between 1998 and 2000, which identified and validated the ELF test. In 2008/09 the investigators interrogated the 497 records in the UK which established it was at least equal, if not superior to, a liver biopsy in predicting liver related and all cause mortality at 7 years. It has now been 20 years since participants were enrolled and many patients have likely reached clinical endpoint. The applicants wish to use confidential patient information related to these 497 patients held by the Royal Free London NHS Foundation Trust to link to HES, cancer registry and mortality data from NHS Digital. The resulting data will be used to understand the value of the ELF test as part of an evaluation of liver disease in middle life.

Since the previous deferral the applicants have consulted with legal advice to determine the legal basis, under the common law duty of confidentiality, for holding of the existing data. This concluded that there is no legal basis, and the applicants additionally request support prospectively for the data to be held by the Royal Free London NHS Foundation Trust.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All 497 patients recruited into the original EUROGOLF study
Data sources	1. NHS Digital

Identifiers required for linkage purposes	1. Name 2. Date of Birth 3. Gender
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The group agreed, as with previous applications, this study has the potential for significant benefit and is therefore in the public interest.

Legal Basis

The CAG notes that this application has twice been deferred because of a lack of clarity on the legal basis, under the common law duty of confidentiality, to hold the existing data.

Members were glad to see that the applicant sought advice from the Caldicott Guardian, Data Protection Officer and external legal advice. This determined that there is no legal basis for the holding of existing data and, as such, the applicant requests support for holding of the existing data prospectively. The letter from the Deputy Caldicott Guardian also referenced the learning that has been undertaken in this exercise.

Members were content to provide support on this basis, noting that this support will be prospective only.

Practicable alternatives

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

- **Feasibility of consent**

In line with the previous applications, CAG was assured that, on the basis of the time since original consent and that many patients may have reached a clinical endpoint, it would not be feasible for the research to be carried out on the basis of consent.

- **Use of anonymised/pseudonymised data**

Members noted that the use of identifiable information is required for linkage by NHS Digital. Once the data linkage had been made there would be no further requirement for identifiable information in this study and the data would be pseudonymised.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of 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 General Data Protection Regulation and Data Protection Act 2018.

The group were happy to see that the applicant had sought patient advice on the patient notification material and noted that these were much improved since the previous application. Members queried the necessity for a complex data flow diagram to be provided in the website content, and advised that this may be better placed as a link for those who wish to look further. Note that this is advice only, and not a condition of support.

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 the unconsented activity should go ahead.

As with the previous reviews, members commended the applicant on the Patient and Public Involvement and Engagement that has been undertaken. Particular compliments were given on the richness of the responses obtained from a small pool of applicants, due to the care taken to explain the research.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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. Favourable opinion from REC **Confirmed 23 April 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT review for Royal Free London NHS Foundation Trust and NHS Digital were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 04 October 2020)**

Declarations of Interest

There were no declarations of interest.

4. New Applications - Research

a. 20/CAG/0115 – Flatiron Health UK Oncology Real-World Database

Context

Purpose of application

This application from Flatiron Health UK Ltd set out the purpose of creating a research database to collect real world data (RWD) for cancer patients aged 18 years and over.

Progress in cancer treatment is dependent upon high-quality evidence to demonstrate that specific interventions are safe and effective. The gold standard for evidence development has traditionally been prospectively conducted clinical trials. Approximately 1 in 5 cancer patients in the UK are enrolled in clinical trials. For the 80% of patients who are not part of a clinical trial, “real world data” has the potential to contribute to the understanding of what happens in routine clinical care. A gap has historically existed between the depth and quality of data available in clinical trials and in real world setting. Electronic Health Records (EHRs) are used to capture clinical decisions, but documentation practices differ across care team and information may be accidentally omitted.

Flatiron have developed processes and software to create real-world data that matches the richness, quality and depth of information available in prospective clinical trials. NHS trusts will provide data about cancer patients treated within that trust and the patient-level data will be provided back to trusts in order to power local research, benchmark quality of care and operations, and to support data-driven treatment decision-making by NHS clinicians at the point of care. Data from multiple trusts will be aggregated and anonymised, to create population-level cohorts. An aggregated dataset, which represents multiple institutions across England, can enable a more representative set of analyses, generalisable to broader patient populations, which can potentially be used to support researchers in the development of ways to improve patient care and outcomes.

The applicants sought support under Regulation 5 for participating trusts to disclose confidential patient information about the care of adults with cancer to Flatiron Health UK Ltd. This data will be collected retrospectively by the NHS trusts and will include structured and unstructured clinical data relating to patients’ cancer treatment journey. An initial data extract of "historical" data will be carried out. This will include data about patients who are deceased and those who are no longer being actively treated by the trust. This initial data delivery will be defined and agreed with each trust, based on the point at which electronic health records and/or clinical systems were implemented. The applicants anticipate that this will be 10 years, or the point at which electronic records began to be used. Subsequent data extracts, of data

relating to patients currently receiving treatment, will be performed on a monthly basis. Confidential patient information will be stored by each NHS trust in a locally operated database, from which Flatiron Health UK will extract, process and curate this data. Data minimisation will be carried out, including removing identifiers where possible, such as patients' names and addresses, prior to Flatiron Health UK receiving the data. However, while the structured data can be pseudonymised, the unstructured data cannot be reliably pseudonymised by the trusts. Flatiron UK staff will carry out an abstraction process on the unstructured data to convert it to structured data, and create a pseudonymised dataset. Flatiron Health UK plan to partner with one or two trusts initially, and then expand the network to 10-15 large Trusts over time. High-quality "curated" patient data will be returned to the NHS trust and used for patient care, service planning, and research. Flatiron Health UK will anonymise the data before it is accessed by any researchers, in academia or industry.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	The initial cohort will be inactive and deceased patients treated within two participating trusts, aged 18 years and over with a diagnosis of cancer
Data sources	1. Clinical information systems, including Electronic Health Records, chemotherapy ordering system, scheduling system, PACS and others, within participating trusts
Identifiers required for linkage purposes	1. NHS Number 2. Hospital ID number 3. Date of birth 4. Postcode – sub-sector level
Identifiers required for analysis purposes	1. Date of death 2. Postcode 3. Gender 4. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The CAG agreed that the application had a clear medical purpose and was in the public interest. Cancer outcomes in the UK are less favourable that those in 'peer countries' and the applicants were seeking to collect information to be used to address this.

Scope

The applicants sought support to allow confidential patient information to be disclosed from trusts participating in the project to Flatiron UK Ltd. The participating trusts would anonymise the data as much as possible before it was sent to the data repository but could not guarantee that all items of confidential patient information would be removed.

The CAG noted that the applicants intended to seek support 'in principle' however the CAG are unable to recommend Regulation 5 support in principle and the application needs to be specific in terms of data flows (e.g. detailing the specific named organisations). Members agreed that the applicants needed to identify one or two trusts who were willing to take part and work with them to create a more detailed application, which clearly sets out the processes to be followed within the Trusts, including how the extraction of data at trust level will be undertaken.

The CAG queried whether support was also needed for the staff working at the trusts to process confidential patient information, or whether the trusts would ensure this processing was conducted by staff with an existing legal basis, as part of the direct care team. Members noted that little detail had been provided about the processes that would be followed by

participating trusts. This was likely because the participating trusts had not yet been identified, which meant that many of the factors that needed to be considered by the CAG when deliberating whether support should be recommended were not available.

The number of patients that may be involved was also unclear. From information in the application it appeared that 3,000 patients would be included. Members queried whether this was the number of patients the applicants estimate would be included in the 10-year retrospective data extraction, or if this was the number of new patients.

The application also contained references to rare occasions when regulators will request data. The US Food and Drug Administration (FDA) was specifically mentioned. The applicants had clarified in response to queries from the Confidentiality Advice Team that no confidential patient information would be sent to the USA and it was not clear how the FDA would have access to the confidential patient information held within the UK. The CAG asked that further details on the regulators that may access the data were provided if the application was resubmitted.

Data flows

The information given in the data flow diagram contradicted details given in the application form. The data flow diagram described the return of pseudonymised data to the participating trusts, whereas the application form advised that identifiable data would be returned. A clearer description of the data flows would need to be provided in a resubmitted application, with precise detail on where flows are identifiable or pseudonymised. The CAG also noted that the participating trusts would need to be made aware that the trusts cannot rely on any s251 support that may eventually be given to Flatiron to do any research using identifiable data provided by Flatiron back to the trust, even if the data was initially provided by the trust.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that the initial collection of confidential patient information would be from patients no longer receiving treatment for cancer and from deceased patients. It was not possible to seek consent from latter group. The former group will not be contacted for consent due to the potential distress this contact may cause.

The collection of confidential patient information will be expanded to include patients currently being treated by the participating trusts. Support under Regulation 5 would be required initially, but the applicants intended to carry out, alongside the trusts involved, educational programmes to inform patients about the project, so that patients would expect their information to be used. The applicants stated that they were relying on the "reasonable expectation" standard to access confidential patient data. The patient notification strategy they intended to devise would be used to inform patients about the project. The CAG noted that, while those processing confidential patient information should endeavour to inform patients as widely as possible about the potential uses of their information, the reasonable expectations standard does not form a legal basis for processing of confidential patient information outside of the direct care team without consent from individual patients. The applicants intended to use an 'opt-in' approach, which was not the same as a consented approach, and support would still be required to process confidential patient information after the educational programmes were running, if consent was not sought from individual patients.

The CAG agreed that it was not feasible to seek consent from deceased patients or the retrospective cohort, noting that the patient and public involvement undertaken supported the view that it would be too distressing to seek consent from these patients or their families. Members determined that adequate justification for not seeking consent from patients receiving current treatment had not been provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to develop the research database. The applicant advised that data will be sourced from multiple internal systems, which do not always have robust common data linkage indexes. Patient data will be linked by the participating NHS trusts and, in order to safely link structured and unstructured data from these sources, at least three identifiers are required. As the identifiers vary in availability between source systems, more than three identifiers are required. All of the obvious direct demographic identifiers are removed, truncated or otherwise treated to reduce the identifiability whilst maintaining the safety of linkage. The applicants noted that it will not be possible to remove all identifiers from the data transferred from the trusts to Flatiron Health UK. The unstructured data will be processed into structured data by specialist oncology nurses and/or data professionals employed and trained by Flatiron Health UK, using Flatiron's proprietary approach and software.

Members requested that further information was provided on the oncology nurses who will be employed to perform the abstraction of data. The CAG asked if the nurses would be recruited within the UK, and whether they would be employed by Flatiron Health UK Ltd or by the participating trusts. The CAG noted that a large amount of data would be processed and queried whether all abstraction of the data would be carried out manually or if other methods, such as machine learning, would be used.

Exit strategy

The applicants had advised that confidential patient information will be retained in the research database, but only that anonymised data will be supplied to researchers who request information from the database. The CAG agreed that the applicants had not clearly explained the items of confidential patient information that would be retained in the research database and whether this contained structured data only, or whether unstructured data, possibly containing sensitive free text data, would be retained. Further details needed to be provided on the information that would be stored.

The CAG also noted that the information that will be sent from trusts into the file repository was not well-described. It was possible that a large amount of unstructured data, potentially including sensitive information that was not relevant to the purpose for which the database was created, would be included in these disclosures. If the application was resubmitted, further details would need to be provided on the steps undertaken by the trusts supplying information to minimise the potentially sensitive data that may be shared, in order to demonstrate that the applicants were in compliance with the Data Protection Act and the Caldicott Principles.

The CAG asked that further details were provided on what happened to the 'raw' unstructured data once it was extracted into structured data. If any items of confidential patient information would be retained after extraction, then justification needed to be provided.

Regarding the deceased patients, the CAG queried whether the identifiers for deceased patients would be deleted once the linkages were completed as no further information could be obtained for these patients.

'Patient Notification' and mechanism for managing dissent

Patients will be provided with information on the data that will be collected, how data is processed and used, and how this work benefits cancer patients, as well as what risks there

might be, and who they can contact if they have any questions or concerns. Patients will be provided information about the National Opt-Out, and local opt-out options. The materials will be developed in collaboration with trusts, local patient representative groups and national disease-specific representation groups. The applicant advised that these materials had not been created at the time the application was submitted.

Flatiron Health UK will undertake a wide-reaching multi-channel communications programme. This will include seeking advice from independent patient and public involvement and engagement specialists, and their recommendations will be followed. The communications campaign will be run for 3 months, or until the participating trust is satisfied that patients have been appropriately notified. The campaign will include; posters and leaflets displayed in waiting rooms and other high-traffic areas of the trust, the inclusion of leaflets or description of work in patient appointment letters and other patient-facing communication, patient-tested web content on Flatiron's UK website, and on Trust websites, where agreed, and the display of electronic posters within participating Trusts. These materials had also not yet been prepared.

The applicants advised that the Trusts will remove data from any patients who have registered an opt-out via local or NHS opt-out mechanisms.

The CAG noted the patient notification that the applicants had planned, however no details or patient notification materials had yet been created. Members agreed that these materials needed to be submitted for review by the CAG before any support could be recommended. The applicants would need to discuss the patient notification strategy and dissent mechanism during patient and public involvement and also work with the participating trusts in order to create suitable materials. These would need to be supplied for review with the resubmitted application.

Patient and Public Involvement and Engagement

The applicant advised that Flatiron is working closely with patients to develop a comprehensive strategy to involve patients in key decisions around data collection, use, and research oversight. The applicants have engaged patients via NIHR and DATA-CAN (the cancer focused HDR UK Innovation Hub).

Consent was covered in these discussions, including that Flatiron Health UK would offer an 'opt-out' rather than 'opt-in' approach. Educational programming was planned to ensure patients were aware of how their data would potentially be used and how they could opt-out.

Patients agreed that it would cause unnecessary distress to contact former patients or their families to seek consent.

The CAG noted the comprehensive patient and public involvement that had been carried out. The views sought around consent and patient notification were focused on the 'opt-in' approach, rather than exploring whether patients currently being treated for cancer should be consented and, if so, how this should be done. The Group asked that further patient and public involvement was undertaken around this specific issue and used to inform the design of a consent process and appropriate materials. The Group also asked that it was made clear during patient and public involvement the amount of information that would potentially be processed and that this will include the processing of a large amount of free text data and sensitive information.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

The CAG noted the considerable amount of work undertaken by the applicant when completing the application and agreed that they were supportive of the aims of the project. However, not enough information had been provided for the CAG to recommend support to the HRA Decision Maker. Members agreed that further work needed to be undertaken in collaboration with one or two trusts who were willing to participate, in order to provide the further details needed on the specific organisations, data flows, items of confidential patient information and processes involved in the activity. The Confidentiality Advice Team are also willing to provide further advice when preparing a future application,

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised applications submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Further details around the scope of support need to be provided. This includes clarifications on the following:

a. How the data will be extracted within trusts, including whether the staff undertaking the extraction would be members of the direct care team, and whether support under s251 is required for this activity.
b. Whether any data will be shared with the USA, including with regulators.
c. The number of patients it is anticipated will be included.
d. The data flows, including whether pseudonymised or identifiable data is provided back to the participating trusts.

2. Further details need to be given on the information that will be sent to the file repository, and the steps that will be undertaken by both participating trusts and the applicants to minimise the risk that sensitive information and information not relevant to the purpose of the database will be transferred.

3. Further information needs to be given on the holding of structured data, including where this will be stored and how long it will be retained for.

4. Details on what will happen to the 'raw' unstructured data once it is extracted into structured data need to be provided. If any items of confidential patient information will be retained after extraction, then justification for this needs to be given.

5. A process to seek consent from patients currently receiving cancer treatment needs to be created and details provided to the CAG. If the applicants determine that consent cannot be sought, then justification for this needs to be given.

6. Clarify if the identifiers for deceased patients will be deleted once all the linkages have been completed.

7. Patient notification materials need to be created, in collaboration with participating trusts. The finalised materials need to be submitted to the CAG for review.

8. Further patient and public involvement needs to be undertaken. During this activity, methods of seeking consent from patients currently receiving treatment needs to be explored to inform the creation of the consent process. It also needs to be made clear to patients the amount of information that would potentially be processed, and that this will include the processing of a large amount of free text data and sensitive information.

9. Further information needs to be provided on the oncology nurses who will be employed to perform the abstraction of data, including clarification on whether the nurses will be recruited within the UK, and whether they will be employed by Flatiron Health UK Ltd or by the participating trusts.

10. Clarify whether all abstraction of the data will be carried out manually or if other methods, such as machine learning, will be used.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0118 - CardioPulmonary Resuciation Induced Consciousness (CPRIC): Case Series from a Prehospital Critical Care System

Context

Purpose of application

This application from the London Ambulance Service NHS Trust set out the purpose of medical research that seeks to investigate the need for internationally recognised guidelines to manage cardiopulmonary resuscitation induced consciousness.

Cardiopulmonary resuscitation induced consciousness (CPRIC) is an umbrella term used to describe awareness in patients who are in cardiac arrest. Signs of awareness may include eye opening and tracking, vocal noises, respiratory effort and purposeful or non-purposeful movements. Patients who show a higher level of awareness may disrupt the resuscitation attempt, by resisting chest compressions, removing mechanical CPR devices or by pulling out airway adjuncts. This presentation can be distressing for patients, the health care professionals and any witnesses to the resuscitation attempt. Evidence suggests that CPRIC is becoming more common, due to improvements in resuscitation with an emphasis placed on quality cardiopulmonary resuscitation. Patients with this condition are often difficult to manage and no internationally recognised guidelines are currently in place. The majority of previous research conducted has been individual case studies. The applicants aim to conduct a more thorough case series, involving approximately 20 patients.

Advanced Paramedic Practitioners from the London Ambulance Service will volunteer case studies from incidents they have attended. Patient report forms will be reviewed by the applicant to confirm suitability for inclusion. The applicant will then extract the required data from the patient report form, the internal clinical database and will obtain further details from the treating paramedic, if necessary. Outcome data, including whether the patient died on scene, obtained a return of spontaneous circulation, was transported to hospital and survival information will also be sought from the NHS spine. Support is sought to allow the applicant to process confidential patient information held in the patient report form and clinical records, and to use patients' name and date of birth to access 30-day mortality information from the NHS spine.

A recommendation for class 1 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 18 years and over, attended to by Advanced Paramedic Practitioners (Critical Care) within the London Ambulance Service, in cardiac arrest and showing signs of awareness. 20 cases will be included
Data sources	1. Patient report forms, paper and electronic health records held at the London Ambulance Service 2. NHS Spine
Identifiers required for linkage purposes	1. Name 2. Date of birth
Identifiers required for analysis purposes	1. Gender

Confidentiality Advisory Group informal advice

The following sets out the informal Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The CAG agreed that the application had a clear medical purpose and was in the public interest. CPRIC was potentially distressing for patients and health care professionals to experience. The condition was worthy of further investigation, and the CAG encouraged the applicant to consider the points below before submitting a revised application.

Scope

The CAG agreed that it was unclear what support was being sought for. It appeared that support was needed for paramedics who reported an eligible case to disclose confidential patient information to the researcher, who was a paramedic but would not necessarily be considered a member of the direct care team for each patient. The applicant would also access patient clinical records to collect information and outcome data from the NHS Spine.

Members noted the feedback given by the REC and agreed that a clear research protocol needed to be provided. The CAG asked that the applicant clarify the flows of data and the items of confidential patient information that will be used for linkage and analysis in the protocol and resubmitted CAG application, so that it was clear where breaches in the common law duty of confidence would occur, for which support under Regulation 5 was needed.

Practicable alternatives

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

- **Feasibility of consent**

The applicant advised that it was likely that many patients will be deceased, as the patient population is comprised of those treated for cardiac arrest. The CAG noted that a significant number of patients would be deceased or in critical care and agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicant requires access to confidential patient information in order to link information on the case report forms to outcome data obtained from the NHS Spine. The CAG agreed that the items of confidential patient information that would be used to facilitate the data linkages were unclear and clarification on the data flows would need to be provided in the resubmitted application. Prior to such an application, the applicant should clarify with NHS Digital whether they are able to collect information from the NHS Spine for research purposes using support under Regulation 5.

'Patient Notification' and mechanism for managing 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 General Data Protection Regulation and the Data Protection Act 2018.

Although often confused with a requirement to seek consent, patient notification is not the same as seeking consent from individual patients. Patient data is still accessed without consent, however information is provided to patients so they have the option to find out about this use of their data and to express an objection if they so wish. The method for respecting any such objections should be described in the application and a copy of the information must be provided as well.

The notification should provide a description of the activity, listing the purpose of the study and who is carrying out the study. It should explain how service users can opt out or dissent, where appropriate, to the use of their information for this purpose.

From the information provided within the application, it does not appear that a communications strategy has been established to promote the proposed activity within the public arena and offer patients an opportunity to dissent to the inclusion of their data.

A patient notification and dissent strategy had not been created. The CAG agreed that any revised application should include a patient notification and dissent strategy.

Patient and Public Involvement and Engagement

The CAG agreed that patient and public involvement would need to be undertaken. Members suggested that the applicant make contact with cardiac groups in order to carry this out.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided and the issue of a REC unfavourable opinion, they did not have sufficient information to undertake a full review and to provide a recommendation under the Regulations. The CAG agreed that the area of research had significant public interest and was very supportive of the aims of the study.

Informal advice for a future application

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Discuss with NHS Digital whether the NHS Spine can be accessed for research purposes under Regulation 5 support.

2. The research protocol needs to clarify the flows of data and the items of confidential patient information that will be used for linkage and analysis, so that it is clear exactly where the breach in the common law duty of confidence will occur, for which support under Regulation 5 is sought.

3. A patient notification strategy and dissent mechanism needs to be created and fed back to the CAG.

4. Patient and public involvement needs to be undertaken with suitable patient groups, and feedback from this provided to the CAG.

Declarations of Interest

There were no declarations of interest.

c. 20/CAG/0119 - Screening for papilloedema to diagnose brain tumours

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research that seeks to determine the positive predictive value of nerve swelling at the back of both eyes (papilloedema) for the diagnosis of brain tumour.

Regular visits to the optician for eye tests are an important factor in maintaining eye health. Serious health problems can be picked up during eye tests, for example, only 50% of people who experience nerve swelling at the back of the eye due to a brain tumour have any symptoms. This means that opticians may be the first health professionals to detect signs of a brain tumour, including during routine eye examinations where patients are not experiencing symptoms. Brain tumours may cause headaches and nerve swelling at the back of the eye, however they are not the only cause of headaches and most patients who seek advice from their GP for headaches will not have a brain tumour as the cause. Brain tumours are also not the only cause of nerve swelling at the back of the eye. Little information is available to work out the risk of brain tumour in patients with nerve swelling at the back of the eye and the applicants are conducting this study in order to identify the percentage of patients affected by nerve swelling at the back of the eye due to brain tumour.

Pseudonymised data will be obtained from the National Cancer Registration and Analysis Service (NCRAS) at Public Health England. Patients diagnosed with a brain tumour will be identified in NCRAS by the ICD-10 diagnostic codes for benign and malignant brain tumours and their data linked to HES inpatient, outpatient and A&E data. A pseudonymised dataset will be returned to the applicants at the University of Bristol. The applicants advised that a second stage was planned, in which pseudonymised Clinical Practice Research Datalink (CPRD) data will be linked to HES inpatient, outpatient and A&E data. This was outside the scope of this application.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Adults and children diagnosed with a primary brain tumour between 01 January 2015 and 31 December 2019 in England. Adults and children referred to hospital ophthalmology services with papilloedema. 5000 patients per year are expected to be included, with a total of 25,000 patients across the 5-year period.
Data sources	1. The National Cancer Registration and Analysis Service at Public Health England will provide data from: a. Cancer Registration Patient table b. Cancer Registration Tumour Table c. Cancer Registration Treatment Table d. Index of Multiple Deprivation Income domain e. Route to Diagnosis f. National Radiotherapy Dataset g. Systemic Anti-Cancer Therapy Dataset h. Cancer Waiting Times i. Diagnostic Imaging Dataset
Identifiers required for linkage purposes	1. NHS number 2. Date of death 3. Postcode – District Level
Identifiers required for analysis purposes	1. Date of death 2. Postcode – District Level 3. Gender 4. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.The CAG agreed that the application had a medical purpose and was in the public interest.

CAG noted that the element of the project involving data from CPRD is not included in the scope of this application and, as a consequence, only true positive cases will be identified from the research which is in scope. Only once the CPRD data are available will it be possible for the researcher to estimate the positive predictive value of the screening.

Identifiers required

The CAG agreed that support under Regulation 5 was sought by the applicants in order to provide a legal basis for PHE to link NCRAS data to HES data for the purposes of this application. The committee were concerned that identifiers which are required to link NCRAS data to HES data are not fully reflected in the list of identifiers given under the linkage section in the IRAS form. The CAG asked the applicant to confirm with NCRAS what identifiers will be used to carry out the linkage.

Practicable alternatives

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

- **Feasibility of consent**

The CAG agreed that the applicants had not made a strong argument as to why consent cannot be sought and asked the applicants to provide further justification as to why patients would not be asked to consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link patients across different datasets. Only pseudonymised data will be provided to the applicants.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of 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 General Data Protection Regulation and Data Protection Act 2018.

A patient notification strategy had not been devised. The applicants explained that this was because the proposed use of PHE data did not extend beyond the remit of NCRAS. The applicants advised that patients were able to request the removal of their data from NCRAS at any time.

The CAG disagreed that the application activity came within the remit of NCRAS, as the applicants were seeking support under Regulation 5 for linkages to HES data. Members agreed that the applicants needed to create a project specific patient notification and dissent mechanism and provide the details to the CAG. This needed to include how the study would be promoted, including whether the study would be promoted on suitable websites, such as PHE and relevant brain cancer charities.

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 the unconsented activity should go ahead.

The applicant advised that a patient and public involvement group had been set up, consisting of 10 volunteers from the Brain Tumour Support Group who had been diagnosed with a brain tumour after presenting to their optician with visual problems. A meeting with the group was held on 10 March 2020 at which the application was discussed. The group were supportive of the project.

The CAG noted the patient and public involvement that had already been carried out. Members agreed however, that it was not clear that the specific issue of the processing of confidential patient information without consent was discussed during the patient involvement meeting. Details need to be provided about the discussions around this specific issue and the views expressed by the patients consulted. If this specific topic had not been raised during the course of the meeting March CAG requests that further engagement is carried out to consult the group about this issue.

Exit strategy

The CAG asked that the applicant clarify how long the data linkage process was expected to take, in order to estimate the duration of support required and thus when exit from support would occur.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Clarify the identifiers that will be used to conduct the linkage between the NCRAS and HES datasets held by Public Health England.

2. Clarify how long the data linkage process is expected to take, in order to estimate the duration of support required.

3. Further justification needs to be provided as to why consent cannot be sought from patients.

4. A project specific patient notification and dissent mechanism needs to be created and the details provided to the CAG. The patient notification strategy needs to explain how the study will be promoted and whether the study would be promoted on suitable websites, such as NCRAS, PHE and relevant brain cancer charities.

5. Details about the discussions around the use of confidential patient information without consent held during patient and public involvement need to be provided. If these specific discussions have not already been held then further engagement with the PPI group is required to consult on this particular issue.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

    - **Confirmed: University of Bristol (by check of the NHS Digital DSPT tracker) and National Cancer Registration and Analytical Services (NCRAS) at PHE (by check of the NHS Digital DSPT tracker) have confirmed 'Standards Met' grade on DSPT 2018/19.**

- **Public Health England - NHS Digital have confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training.**

  As a result, the following specific condition of support has been added: all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.

Declarations of Interest

There were no declarations of interest.

5. New Applications – Non-Research

a. 20/CAG/0116 - Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS)

Context

Purpose of application

This application from Saving Faces set out the purpose of undertaking a series of audits to collect data indicative of effectiveness or quality of care.

Oral and Maxillofacial Surgery (OMFS) is a unique surgical speciality, covering a wide range of conditions of the head and neck. This includes neoplasm, trauma, congenital malformations, diseases of the salivary glands. Due to the complexity of this speciality, the diversity of its practice and lack of, or limited, consensus on, appropriate metrics and benchmarks, systemic data collection indicative of effectiveness or quality of care is lacking in OMFS. This was highlighted in the 2018 OMFS Getting It Right First Time (GIRFT) report. In response to this report, the British Association of Oral and Maxillofacial Surgeons (BOAMS) has initiated the Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) project in order to undertake a series of audits to measure performance and quality of care at hospital, regional and national levels, assess disparities and encourage quality improvement.

In this application, support is sought for QOMS to undertake a programme of sub-specialty clinical audits under the QOMS umbrella. QOMS will also create registries, but support for these will be sought in a separate application. The audits will cover the following areas of OMFS practice: oral and dentoalveolar surgery, oncology & reconstruction, orthognathic, non-melanoma skin cancers, and trauma surgeries. The audits have already been developed and piloted using anonymous or consented data. The applicants are now extending the programme to include the processing of confidential patient information without consent. QOMS will collect data on pre-operative health status, details of the surgery performed, the principle healthcare professional responsible, and the development of recognised complications and outcomes. Clinical data will be collected and entered at hospital level by designated NHS staff at participating Trusts. The data will then be transferred via REDCap to the Barts Cancer Care (BCC) Safe Haven Environment, where the data will be checked for completeness and errors by the Designated Data Manager (DDM). The DDM will be the only member of the QOMS team who has access to confidential patient information. The DDM will prepare anonymised datasets to be used in analysis. The applicants advised that all UK NHS Trusts and Health Boards with an Oral and Maxillofacial Unit will be eligible to take part. This application sought support for the processing of confidential patient information generated within England and Wales, and appropriate support will be sought for the processing of information generated within Scotland and Northern Ireland.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All patients undergoing the selected OMFS procedures for the selected conditions in an NHS hospital within England and Wales. QOMS will be comprised of a series of audits, each with their own specific populations.
Data sources	1. All Trusts in England and Wales which have an Oral and Maxillofacial Unit.

Identifiers required for linkage purposes	1. NHS number 2. Hospital number 3. Sex 4. Date of birth
Identifiers required for analysis purposes	1. Sex 2. Age 3. Postcode

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. Members agreed that the application had a medical purpose and was in the public interest.

Scope

The CAG agreed that the size of the cohort was unclear. Up to 137 trusts would be approached, therefore it was likely that confidential patient information for a significant number of patients would be included. Members asked if the applicants could provide an estimation of the numbers that would be involved, or whether this could not be estimated until it was known how many trusts would take part.

The CAG also requested clarification on whether only oncology patients and those who underwent reconstruction would be included in the retrospective data collection.

The Group noted that the DDM would have access to the confidential patient information. Data from a large number of patients may need to be processed and the Group queried whether it was feasible for only one person to assess, clean and check the confidential patient information received.

Practicable alternatives

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

- **Feasibility of consent**

The applicant advised that data will be collected both retrospectively and prospectively for patients who have undergone procedures by OMFS surgeons nationally. The applicants anticipate that the sample size will vary between the different audits.

The procedures may have been performed electively, urgently or as emergencies, and it would not be possible to seek consent from patients in all circumstances. The applicants noted that seeking consent would increase the burden on the clinical care team. Six sites had participated in pilot study held between December 2019 and March 2020, for which consent was sought from patients, and feedback from this was that a requirement to seek consent would be a barrier to trusts' ability to take part in the programme.

Regarding the retrospective data collection, the applicants noted that a number of patients may have died and that it would not be possible to seek consent from this patient group.

The CAG noted that feedback from the trusts involved in the pilot had been that consent was not feasible. There was also a potential risk of bias, as the results of the audits will identify both trusts and surgeons who are outliers, which may mean that trusts and surgeons are less willing to take part. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicant advised that confidential patient information is required to enable QOMS to track patients to follow-up long-term outcomes and ensure clinically relevant information is linked to the correct patient.

QOMS will also endeavour to identify OMFS units with outlier performance. Confidential patient information will be needed to identify the primary source of the data in order to check the accuracy of the unit's data. The CAG agreed that confidential patient information was needed.

Justification of identifiers

The CAG noted that the patient information leaflet advised that patients' postcodes would be used for linkage, but the application stated that the postcodes would be used for analysis. Members were unsure whether the postcodes were required for either purpose and asked that the applicant provide more details on why patients' postcodes were required. The CAG also asked whether it was possible to convert postcodes to Lower Super Output Area, to reduce the potential identifiability of the data.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of 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 General Data Protection Regulation and Data Protection Act 2018.

Participating OMFS departments will be provided with a poster that can be shared with patients and displayed in their department. A patient information leaflet will be created for each audit. This leaflet will be sent out of participating units and displayed on the BAOMS website. The project's Privacy and Fair Processing Notice will be made available on the BAOMS website. The poster, sample information leaflet and Privacy and Fair Processing Notice were provided for review.

The applicant advised that all patients will have a right of access to the data about them held by QOMS and an opt-out procedure is described on the QOMS patient information leaflet and website. The right to be forgotten also forms part of that.

In England, prior to data being uploaded, it will be the participating trust's responsibility to check the patient details against the National Data Opt-Out register. Furthermore, in every country, if a patient decides not to have their data in QOMS, they will need to inform their

clinical team or the QOMS Project Team. If dissent is registered prior to data entry, the local team will not enter any data and will keep a record of the patient's decision. If the data collection had already taken place, the DDM would delete the record from the database.

The Group asked that the poster was amended to provide further details on the purpose of the application and an explanation on how patients could opt-out of the inclusion of their data. This included clarifying why patients' postcodes were collected. Patients were provided with an email contact to register dissent. Members asked that a telephone number was provided as well. The CAG also asked that the applicant screen the information leaflet for spelling and grammatical issues.

The CAG requested further information on where the patient information material would be available and whether it would be included on suitable websites, such as Saving Faces.

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 the unconsented activity should go ahead.

The applicant advised that the QOMS project has been designed and implemented with the participation of two lay representatives, who regularly attend the project Steering Committee meetings. The lay representatives have provided comments on the public-facing documents and will undertake further reviews of these documents as the project continues. The applicants noted that they intended to seek further specialty/audit-specific patient and public involvement/engagement in the near future, using online questionnaires and focus groups to determine the views of patients. Patient groups will also be accessed through Saving Faces and specialty groups.

The Group observed that the activity undertaken so far was focused on patient involvement rather than engagement. It was unclear whether the specific question of the use of confidential patient information without consent had been discussed. Members asked that the questionnaires used during the patient and public involvement were provided to the CAG for review, alongside plans for more detailed patient and public involvement. These plans also needed to explain what actions will be taken should those participating in the activity respond unfavourably to the processing of confidential patient information without consent, or other issues are raised. Feedback from the further public and patient involvement carried out would need to be submitted to the CAG within 6 months of support being issued, and further feedback given in annual reports to the CAG.

Exit strategy

Confidential patient information will be retained for 4 years from the end of follow-up. The applicant advised that the timeframe for the collection of follow-up data will vary between individual audits. The data collected would be used in 6 audits, however members noted that it may be used in a greater number of audits. The application also contained references to the retention of confidential patient information for 9 years.

The Group requested that further clarification was provided on how long confidential patient information would be retained. Members asked if the confidential patient information would be anonymised once the follow-up of patients was completed and requested a timescale for this.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Secretary of State for Health and Social Care that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Further clarification of the scope of the support requested is needed:

    a. Provide an estimation of the numbers involved. If an estimation cannot be given, please advise whether this is because the number cannot be estimated until it is known how many trusts will take part.

    b. Clarify if only oncology patients and patients who underwent reconstruction will be included in the retrospective data collection.

2. Clarify if only the Designated Data Manager will have access to the confidential patient information received in order to assess, clean and check, and whether it is feasible for only one person to do this.

3. Confirm whether patients' postcodes are required for linkage and/or analysis. Also, please confirm whether the full postcode is needed, or if the postcodes can be converted to Lower Super Output Area.

4. Further details need to be provided on where the patient notification materials will be displayed and whether this will include displaying information on suitable websites, such as Saving Faces.

5. The patient information poster needs to be amended to include further details on the purpose of the application, including clarifying why patients' postcodes will be collected, and an explanation on how patients could opt-out of the inclusion of their data.

6. The patient information leaflet needs to be amended as follows:

    a. Further details on the purpose of the application needs to be included, including clarifying why patients' postcodes will be collected.

    b. An explanation of how patients can opt-out of the inclusion of their data needs to be included. A telephone number should be provided, alongside the email address, for patients to register dissent.

    c. The leaflet needs to be screened for potential inaccuracies, spelling and grammatical issues.

7. Further information needs to be provided regarding patient and public involvement, as follows:

    a. The questionnaires used in the patient and public involvement that has already taken place need to be provided.

    b. Plans for more detailed patient and public involvement, particularly around the specific issue of the processing of confidential patient information without consent, need to be created and submitted to the CAG. These plans also needed to explain what actions will be taken should those participating in the activity respond unfavourably to the processing of confidential patient information without consent, or other issues are raised.

8. The Group requested that further clarification was provided on how long confidential patient information would be retained. Members asked if the confidential patient information would be anonymised once the follow-up of patients was completed and requested a timescale for this.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Feedback from the further public and patient involvement carried out will need to be submitted to the CAG within 6 months of support being issued, and further feedback given in annual reports to the CAG.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed – Barts CR-UK Centre, Queen Mary University of London has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 03 March 2020).**

Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

Declarations of Interest

There were no declarations of interest.

6. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date