Health Research Authority

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

14 February 2020

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice-Chair	1.a, 1.b, 1.c, 1.d.
Dr Lorna Fraser	CAG Member	1.a, 1.d.
Mr Myer Glickman	CAG Member	1.a, 1.b.
Dr Harvey Marcovitch	CAG Member	1.b, 1.c
Mr Marc Taylor	CAG Member	1.c, 1.d

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor

1. New precedent set review applications – research

a. 20/CAG/0007 – Professional work in austere healthcare in the UK – the case of physiotherapy

Context

Purpose of application

This application from the University of Nottingham set out the purpose of medical research that seeks to investigate how the physiotherapy healthcare profession, as a healthcare profession outside of medicine and nursing, responds to austerity measures and financial pressures in the National Health Service in the UK.

After the 2008 global financial crisis, widespread austerity measures were imposed across the public sector, including the NHS, in the UK. Research has been conducted in examining how medicine and nursing have adapted to austerity measures and financial pressures, but very little research has been done outside of these professions. The applicants had selected the physiotherapy profession to examine in this study in order to assess how different professions, which may have different resources, skills and abilities, respond to the challenges that austerity measures can provide.

This is a single centre, organisational, ethnographical study. The researcher will observe the practices within a physiotherapy department within an NHS organisation for 4-6 months. Physiotherapists will be observed in their normal working day and may also discuss their working life with the researcher. The physiotherapist may also be invited to take part in an interview, where they will be asked questions about their experience of working in the NHS during times of financial pressure. The researcher will not observe direct contact with patients, services users or relatives. Physiotherapists will be observed during team meetings, handover, interactions between members of the physiotherapy team, for example during prioritisation of caseload and allocation of workload, general presence in clinical areas and staff breaks. The observations will take place onsite at Nottingham University Hospitals NHS Trust in both inpatient and outpatient departments. This may include observations on general medical wards, specialist departments such as burns and

plastics and musculoskeletal outpatients. The researcher may be exposed to confidential patient information during these observations and support under Section 251 and its Regulations is sought to cover these incidental disclosures.

A recommendation for class 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 participants are 50 physiotherapists, recruited from Nottingham University Hospitals NHS Trust. No patients will be recruited into the research.
Data sources	No confidential patient information will be collected
Identifiers required for linkage purposes	No items of confidential patient information are required for data linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information are required for analysis purposes.

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 Sub-Committee noted that the application described a valid purpose of medical research, studying the clinical practice of a sample of physiotherapists, as representative of allied health professionals generally, in the context of constrained resources. Members also noted that there was a public interest in improving understanding of the functioning of healthcare services, the practices of allied health professionals in a hospital setting, and the effects austerity has had on those practices.

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 researcher would carry out observations of staff meetings, where confidential patient information may be discussed. The applicant advised that it would not be possible to gain consent from all patients who may be discussed during the staff meetings which the applicant observes. The Sub-Committee agreed that seeking consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicant advised that they will not record confidential patient information in the notes taken during observations. There was a possibility that confidential patient information may be disclosed in the audio recording of interviews. These will be transcribed by the applicant and any confidential patient information will be omitted from the transcription. The audio tapes will be destroyed after transcription. The Sub-Committee was satisfied by the process described.

‘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.

Posters will be displayed in all clinical observation areas advising patients, service users and visitors that a research study is taking place observing physiotherapists. The posters advised patients to contact the applicant or a member of staff if they wanted further information about the study or did not wish the researcher to observe physiotherapists in their vicinity. The applicant advised that the wishes of patients, service users and visitors who dissented would be respected.

The Sub-Committee reviewed the poster and asked that a phone number was provided in addition to the email. Members asked that the poster also mentioned the observation of staff meetings and professional conversations. The poster also needed to specifically state that information about individual patients will not be recorded and the academic supervisor’s name was included on the posters.

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 applicants had engaged with the engagement team at the research site in order to arrange a meeting with the patient participation group and patient representative to seek feedback and input on the design of the study and the presence of the researcher in the clinical environment.

A summary from the consultation with a patient representative was provided for review. The acceptability of the poster was discussed at this meeting.

The applicant also met with the head of patient and public involvement within the research site's Research and Innovation Team to discuss the study and review the study poster. Support for the study was verbally provided by this team lead. The CAG noted this and was satisfied by the information provided.

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. The poster is to be revised as follows;

    a. A phone number is to be provided in addition to the email contact.

    b. The poster needs to mention the observation of staff meetings and professional conversations. The poster also needs to specifically state that information about individual patients will not be recorded

    c. The academic supervisor's name needs to be included.

2. Clarify that the lawful basis relied on for the processing of personal data is: Article 6(1)(e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

3. Clarify that the lawful basis relied on for the processing of special category data is Article (9)(2)(j) Processing is necessary for scientific research purposes in accordance with Article 89(1).

Once received, the information will be reviewed 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 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 14 January 2020.**

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: Nottingham University Hospitals NHS Trust - 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.

b. 20/CAG/0008 – Patterns of Adult Food Allergy (PAFA-Stage 1)

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to determine how common food allergies are in adulthood in a UK based population.

Many people in the UK suffer from food allergies and intolerances, which cause problems for them when choosing what to eat, buying food and eating outside of the home. Food allergies are well-recognised in children, but many adults are also affected. The applicants seek to establish how many adults in the UK have food allergies and intolerances. The applicants will conduct a community survey of adults aged 18-70 who live in Greater Manchester, Isle of Wight and Southampton to find out their experiences of symptoms related to eating food, excluding food poisoning. The study locations have been chosen in order to be representative of populations within the UK and to allow the applicants to collect food allergy information from a diverse range of ethnic groups.

Volunteers will be invited to take part in the questionnaire through their local GP surgeries. The GP surgeries involved in the study will send a letter to potential participants informing them about the study, along with the Participant Information Sheet and a paper copy of the questionnaire with a paid reply envelope. This will be posted to potential participants using contact information held in GP records through an outsourced mailing company. Patients can respond online, by post, or telephone. This is outside the scope of the support sought. Additionally, a group of participants from a previous Food Standards Agency sponsored food allergy study, Food Allergy

and Intolerance Research (FAIR), will be invited to complete a modified version of the community survey. Support under s251 is sought to re-contact these patients. The FAIR data is held by the Isle of Wight NHS Trust. As the FAIR study concluded some years ago, patient contact details may not be up to date, therefore support is sought for the research team at the Isle of Wight NHS Trust to access the Summary Care Records, via the NHS Spine, in order to obtain correct contact details. FAIR participants will then be invited into the study by the Isle of Wight NHS Trust research staff, using the same methodology as used for the Community Survey.

The questionnaire responses will be transferred to REDCap, a secure, online, research platform. Participants will be identifiable only by their unique identification number (UID), linked to their questionnaire response. Participants will also be invited to indicate their interest in receiving further information about a planned allergy assessment. The results of the questionnaires will be used to identify cases and controls for confirmation of food allergy, which will take place in a planned second stage of this research project.

A recommendation for class 1,3 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	2,300 participants in the FAIR study would be invited, and the applicants anticipate that responses would be received from 1,165. 35,000 patients between 18 and 70 years of age will be invited to participate in the survey. 12300 patients are expected to be included in total.

Data sources	1. FAIR study cohort data, held at Isle of Wight NHS Trust 2. Summary Care Record, accessed via NHS Spine
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID Number 4. Date of birth 5. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – district level 2. Gender

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 Sub-Committee noted that the application had a valid medical research purpose in determining how common food allergies are in adulthood in a UK-based population. This is in the public interest, as providing an advance in medical knowledge on the subject of common food allergies, which could benefit people with those conditions.

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 FAIR study concluded some years ago, therefore access to confidential patient information is required in order for the research team to obtain up-to-date contact information from the Summary Care Record, and then make contact with patients to seek consent. The Sub-Committee noted that it was not possible for the applicants to make contact with the FAIR study participants in advance, as this would require the disclosure of confidential patient information for which support is sought.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order for the research team to obtain up to date contact information and make contact with participants in the FAIR study. Members accepted that this could not be undertaken in any other way.

Exit strategy

Patients in the FAIR study will be contacted and consent sought. Their participation will then proceed on a consented basis. The contact details obtained would be destroyed after 12 months. The CAG raised no queries regarding the exit strategy.

'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 applicant explained that the Isle of Wight NHS Trust had worked with the David Hyde Asthma and Allergy Research Centre to host a website which provided information about the historic FAIR cohort. An information leaflet had been provided through the FAIR study webpages and the University of Manchester main PAFA project website, which are currently in development. The information leaflet will also be made available on the PAFA project and David Hyde Asthma and Allergy Research Centre websites. The PAFA study will also be advertised on the Food Standards Agency website. Patients will be approached for consent and are able to express dissent at this point. No wider publicity campaigns are planned. The Sub-Committee was satisfied with the plans for patient notification.

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 acceptability of the study design has been assessed by the Project Steering Committee and by the Anaphylaxis Campaign. They felt that this approach was acceptable as the last contact with these participants was many years ago and the contact information held by the Isle of Wight NHS Trust may need to be updated.

The PAFA-Stage 1 study documentation, the IRAS application, protocol, information leaflet, questionnaire, study invitation letter, for both FAIR cohort follow-up and the community survey have been reviewed by the Project Steering Committee (PSC), which included individuals from different backgrounds: academics, clinicians, statisticians, informaticians, research commissioners (Food Standards Agency) and patient support group (Anaphylaxis Campaign). The Anaphylaxis Campaign group provided lay review by patients of the PAFA-Stage 1 questionnaires and information leaflet to ensure these documents were easy for study participants to read and understand. The Sub-Committee was satisfied by the patient and public involvement and engagement carried out.

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 actions required to meet the specific conditions of support where indicated, within one month.

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. **Pending.**

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. **Pending for the Isle of Wight NHS Trust.**

Once received, the information will be reviewed 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 outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

c. 20/CAG/0013 – Correlates of cognitive changes in epilepsy

Context

Purpose of application

This application from University College London set out the purpose of medical research that seeks to determine whether cognitive changes can be predicted following treatments of epilepsy by either medication or surgery.

The quality of life of patients with epilepsy is not limited to the seizures they suffer, but extends to psychological issues, including cognitive difficulties and co-morbidities such as depression. These cognitive issues are primarily related to memory and language-related issues, impacting on their personal lives. The applicants seek to assess the role of these cognitive impairments on patients' lives and investigate the factors that may drive these issues. Two main treatments given with the aim of stopping seizures are anti-epileptic medication and surgical intervention. The applicants will use existing clinical and non-clinical data to assess which patient-related factors are associated with cognitive changes over time, in order to determine which factors can predict decline.

Support is sought for the applicant, who is not a member of the direct care team, to access confidential patient information, including clinical examinations, MRI, EEG, neuropsychology and treatments, for patients treated at the National Hospital for Neurology and Neurosurgery.

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	Patients aged between 18 and 75 years of age, who were treated for their epilepsy by a physician at, or affiliated with, the National Hospital for Neurology and Neurosurgery. 2000 patients will be included.
Data sources	1. Electronic patient records at the National Hospital for Neurology and Neurosurgery
Identifiers required for linkage purposes	1. Hospital ID number 2. Date of birth
Identifiers required for analysis purposes	1. Gender No other identifiers will be retained for analysis purposes.

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 was satisfied that the activity proposed was in the public interest.

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 the study was retrospective and there was no risk of harm to patients. 2000 patients would be included and it would be impractical to contact all patients to seek consent. The CAG raised no queries on this aspect of the application.

- **Use of anonymised/pseudonymised data**

The applicant requires access to confidential patient information in order to extract an anonymised dataset for analysis. The applicant explained that the direct care team extracted and pseudonymised the data where possible, which was the case for neuropsychological data and the details of any neurosurgical treatment carried out under UCLH. Summaries of the clinical history, medications taken and treatment response will be abstracted from the Hospital clinical record by the Epilepsy surgery coordinator and epilepsy database manager, and then pseudo-anonymised with a code number.

The applicant advised that it was not feasible for the current care team to abstract data from the clinical record or for consultant radiologists to extract the MRI data from PACS, as they have no capacity in their job plans to do this and, for patients seen years ago, many of the consultants are no longer working at UCLH.

The Group noted that the proposed roles of the various clinicians and researchers involved in anonymising and pseudonymising the data were not well-described. The information given in the IRAS form was that the final dataset would be anonymised,

however the anonymisation stage was not clearly described. The data flow diagram referred to pseudonymisation, but it was not clear when the keys would be destroyed and how the keys were kept secure and separate from the identifiable or pseudonymised datasets.

Cohort

Further information around the cohort to be included in the application is required. The time period over which data will be collected is unclear and the protocol refers to data being available from 1990. The CAG asked the applicant to clarify if data collected from 1990 onwards would be used.

'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 applicant advised that, following the official start of the study, an announcement would be made at one of the regular patient and public engagement meetings, held as part of the Brain Buddy UK initiative. An information flyer will also be created and made available at the information stand in the epilepsy clinics, which is manned by a Charity volunteer. An announcement will also be made on the BrainBuddyUK and UCL department websites of this study.

The Sub-Committee noted this information and determined that the text of project specific patient notification needs to be seen by CAG and be available before the start of the study. In addition to being available in clinics it should be placed on appropriate web sites. It must include a dissent mechanism that includes contact points by telephone, email and standard mail.

The Group asked whether the National Data Opt Out would be respected.

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 results and ideas for next steps in the research programme were discussed with individuals with epilepsy that is not controlled by medication or have had epilepsy surgery. This group, 'BrainBuddyUK', meets regularly with the epilepsy neurologists, neurosurgeons and psychologists at the National Hospital for Neurology and Neurosurgery, and was made it clear that difficulties with language and memory are a major problem for this patient group, who are supportive of the development of improved medical and surgical treatments.

The applicant gave a presentation of the study goals at the announcement event to the Epilepsy Research UK grant, which funded part of this research. The audience at this public event was primarily individuals with epilepsy and their carers, who gave positive feedback on the aims of the study.

The Sub-Committee reviewed the information provided and noted that, although patient and public involvement and engagement had been undertaken more detail was needed regarding the membership of the National Hospital for Neurology and Neurosurgery patient support and self-help group.

Also, it was unclear from the information provided whether the specific issue of the processing of confidential patient information by those outside of the direct care team without consent being sought from individual patients had been discussed. Feedback from patient and public involvement around this specific issue needed to be provided.

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. Clarification of the period of time covered by the collected data needs to be provided.

2. A clear explanation on how the keys will be kept secure and separate from the identifiable or pseudonymised datasets, and when the keys will be destroyed, needs to be provided.

3. A stronger patient notification and dissent mechanism needs to be created and supplied for review. This needs to include project specific objection.

4. Clarify whether the National Data Opt Out will be respected.

5. More detail is required regarding the membership of the National Hospital for Neurology and Neurosurgery patient support and self-help group.

6. Clarify whether the specific issue of the processing confidential patient information by those outside of the direct care team without consent being sought from individual patients had been discussed during patient and public involvement and provide feedback from this discussion.

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. **Pending.**

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 College London Hospitals NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 30 August 2019.**

d. 20/CAG/0017 - Effectiveness of differing psychotherapies offered in a specialist psychotherapy service – a benchmarking study

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research that seeks to determine how effective and durable psychotherapy is for patients presenting for specialist tertiary care psychotherapy.

Tertiary level psychotherapy services, often regional centres, cater for particularly complex and enduring presentations. This is because patients using these services have been non-responsive to interventions offered in Primary and Secondary care. Little research evidence is available regarding the effectiveness of tertiary care psychotherapy services and is therefore under-represented with regards to evidence compared to primary and secondary services. The applicants will carry out an in-depth statistical analysis of a pre-existing routine outcome data-set collected by a Specialist Psychotherapy Service (SPS) at Sheffield Health and Social Care NHS Foundation Trust, to collect evidence for local tertiary care services to establish how tertiary care services compare to existing benchmarks set by randomised controlled trials.

Patients accessing the SPS are invited to complete an outcome measure, the OQ-45, at the start of treatment, monthly, at the end of treatment and as follow-up from psychotherapy at the SPS. The changes in the questionnaire score will be used as an indicator of the effectiveness of an intervention. Patient outcomes data, along with other relevant demographic information, age, gender, employment status, is routinely recorded within an electronic database. Patients who indicate they do not wish to share their clinical records for health purposes, or decline questionnaire participation, are omitted from this process. The applicants will use this dataset for analysis. They will also request individual electronic patient records in order to extract additional information on medication use, previous psychological therapy input, diagnosis, carecluster. The dataset will be imported into the service outcomes database. Support is sought as the student investigator, who is not part of the direct care team, will carry out the anonymisation of the dataset, before it is exported to the University of Sheffield through the data-gatekeeper identified for this study. Following verification that data is fully anonymised, data will be forwarded to the research team for data analysis.

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	Patients aged between 18 and 80, who have attended a specialist psychotherapy service. The applicants anticipate that 1000 patients will be included.
Data sources	1. Electronic patient records at Sheffield Health and Social Care NHS Foundation Trust 2. The outcomes evaluation database at Sheffield Health and Social Care NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth
Identifiers required for analysis purposes	No identifiers will be retained for analysis purposes

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 noted the clear medical purpose and public interest in the application.

Scope of Support

By way of overview, the remit under which the CAG can advise is defined in s251 of the NHS Act 2006 and its Regulations, which enables the common law duty of confidentiality to be temporarily lifted so that confidential patient information can be processed for specific purposes, without seeking consent from the individual patient, and without the controller being in breach of this common law duty.

The Sub-Committee reviewed the information provided and determined that the flow of data was not clear. Members asked that a data flow diagram was provided, clarifying the "NHS Electronic records' which will be accessed. Members also queried whether primary care data would be included and whether the data source used was complete enough to provide the required information.

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 would not be practicable to collect consent. The study was a retrospective review of previously collected data and patients were given the opportunity to opt-out of the use of their records in research when the data was collected during routine care.

The applicant explained that omitting patients who may not have consented for data to be used for research purposes would provide significant bias to the sample, inaccurate effect sizes, and a sample size that is not large enough for meaningful statistical analysis. The Group accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicant requires access to confidential patient information in order to extract an anonymised dataset for analysis.

The applicant advised that it was not feasible for a member of the direct care team to access the confidential patient information and extract an anonymised dataset due to the time constraints of the application and resources within the clinical care team. The Sub-Committee raised no queries on this aspect of the application.

Exit Strategy

The applicant will access patient records in order to extract an anonymised dataset. The Sub-Committee observed that the student would check that the dataset was anonymised before it was transferred to the University of Sheffield, where the anonymisation would be checked again. Members asked that a member of staff within the NHS checked the anonymisation prior to transfer to the University of Sheffield.

'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 applicants explained that the confidential patient information required was obtained retrospectively and that patients had already been discharged from the service. No other means for patients to provide dissent had been put in place.

The Sub-Committee agreed that a patient notification and dissent mechanism needed to be created. A poster offering an opt out is to be displayed in the Sheffield service for a period of 4-6 weeks before data extraction takes place. The poster needs to

contain information on how patients can register their dissent. Notices should also be placed on appropriate websites.

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 research team had determined not to conduct patient and public involvement, due to a concern that any activity carried out would not be meaningful.

Staff working in the host service were considered to be stakeholders in the project. The applicant sought feedback from therapists in the service regarding the questions that they would like the proposed analysis to answer, however no feedback was received. No further patient and public involvement and engagement activity was planned.

The Sub-Committee determined that patient and public involvement must be undertaken to explore the views of patients around the use of their confidential patient information. The Group suggested contacting a mental health charity, such as MIND, to facilitate this. Feedback from the patient and public involvement is to be provided to the CAG for review. Details should be provided around the format of the activity, the demographics of those involved and the information which was provided together with an overview of the feedback which was provided.

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. Members asked that a data flow diagram was provided, clarifying the “NHS Electronic records’ which will be accessed. Members also queried whether primary care data would be included and whether the data source used was complete enough to provide the required information.

2. patient and public involvement must be undertaken to explore the views of patients around the use of their confidential patient information. The Group suggested contacting a mental health charity, such as MIND, to facilitate this. Feedback from the patient and public involvement is to be provided to the CAG for review. Details should be provided around the format of the activity, the demographics of those involved and the information which was provided together with an overview of the feedback which was provided.

3. A poster offering an opt out is to be displayed in the Sheffield service for a period of 4-6 weeks before data extraction takes place. The poster needs to contain information on how patients can register their dissent. Notices should also be placed on appropriate websites.

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 17 January 2020.**

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. **Pending for Sheffield Health and Social Care NHS Foundation Trust.**

Signed – Officers of CAG	Date

Signed – Confidentiality Advice Team	Date