



Health Research
Authority

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

02 September 2022

Present:

Name	Role	Items
Dr Murat Soncul	CAG Alternate-Vice Chair	2a, 3a
Dr Katie Harron	CAG Member	2a
Dr Harvey Marcovitch	CAG Member	3a
Professor Sara Randall	CAG Member	2a
Ms Diana Robbins	CAG Member	3a

Also in attendance:

Name	Position (or reason for attending)
Mr Will Lyse	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Expressions of interest

No expressions of interest were declared.

2. New Precedent Set Review Applications – Research

a. **22/CAG/0122 - Radiotherapy for Oropharyngeal Cancer and impact on Neurocognition. Short title: ROC-ON**

Context

Purpose of application

This application from The University of Leeds set out the purpose of medical research of conducting a questionnaire study to evaluate the long term fatigue and neurocognitive impairment in patients who have received radiotherapy for oropharyngeal cancer. This application to CAG is only for contacting and inviting eligible patients to consent to the study.

Oropharyngeal cancer (OPC) is a type of head and neck cancer that develops in the oropharynx (the region in and near the tonsil). Patients treated with radiotherapy for OPC receive a low dose of radiotherapy to the base of the brain. This could lead to late effects including fatigue and neurocognitive deficits (in e.g., memory, language, processing speed and attention). Findings can help with better information provision, management and/or mitigation of late effects of radiotherapy. This study will help determine whether the base of the brain should be avoided when treating future head and neck cancer patients with radiotherapy and will encourage inclusion of neurocognitive function as a primary or secondary endpoint in future head and neck cancer radiotherapy trials.

Eligible patients will be identified by members of the direct care team at each site, this will include a check to ensure no invite is sent to a patient who has had OPC recurrence or is deceased. The National data opt out will be applied at this stage. A database at each site will be created containing patient name, address, NHS number and an allocated study number. This will remain on the NHS site servers. 's251' support is requested for members of the research team at each site, who are not members of the

direct care team, to invite participants by post to consent to complete a survey consisting of several validated questionnaires. Participants will also be invited to complete the Amsterdam Cognition Scan (ACS) online as a measure of neurocognition. A sample of participants will be asked to partake in semi-structured qualitative interviews. If the survey is not completed, after four weeks, then a reminder will be sent out.

A recommendation for class 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	<p>Adult Oropharyngeal cancer (OPC) patients, irradiated over the previous 10 years, ≥ 2 years after treatment, and remain disease free</p> <p>An invite to take part in the study will be sent out to around 1000 potential respondents.</p>
Data sources	<p>Pre existing clinical databases -</p> <ol style="list-style-type: none"> 1. Leeds Cancer Centre (Leeds Teaching Hospitals NHS Trust) 2. The Christie Hospital NHS Trust
Identifiers required for inviting patients to consent	<ol style="list-style-type: none"> 1. Names 2. addresses 3. NHS numbers
Identifiers required for analysis purposes	<ol style="list-style-type: none"> 1. N/A all data for analysis is collected with consent

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 agreed this application 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 applicants are seeking consent at the earliest opportunity, and it is not practicable for the direct care team to undertake the activity the applicant is seeking 's251' support for. Applicants have reasoned that it is not practicable for the direct care team to undertake the invitation process as it is not a practical or cost-efficient use of the direct clinical care teams' time to populate, print, staple, and stuff the envelopes with the personalised letters and surveys. Also, as the patients are a number of years out from their OPC diagnosis and treatment, their direct care clinician may no longer have any face-to-face contact with them. It is not possible for the direct care clinician to pre-contact individuals to tell them that researchers will be contacting them to invite them to join the study. The Members accepted these justifications.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to invite the patient to take part in the trial. It is not possible to invite eligible patients to take part without access to confidential patient information. The CAG accepted that using pseudonymous or anonymous information was not a practicable alternative.

'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 object 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.

Prior to the breach

In order to try to inform potential invitees that their identifiable information may be processed by someone outside of their direct clinical care team and to give them the option to opt out of this processing, the applicant has developed a study poster and twitter posts. The poster has an opt out option. The National data opt out will be applied by the direct care team before providing researchers the list of individuals to contact, and a study specific opt out mechanism has been developed for prior to receiving the invite, via poster at Trusts.

The CAG were content with the poster and the proposed twitter outputs and were pleased to see the opt out mechanisms available.

Post the breach of confidentiality

The patient will receive an invitation letter, and a Participant Information Sheet (PIS), which explains why they have been written to, however this is after the breach has occurred. The explanation in the cover letter about why they have been written to is fairly short and just says they have been identified by the clinical team rather than any mention of 's251' support, however this is much better explained in the updated PIS.

As part of feedback from the patient and public involvement undertaken, A PCOR RAG member advised the applicant to remove a part of the drafted text as they found it 'alarming'. The text removed stated "*We have been given specific permission to access your contact details under Section 251 of the NHS Act 2006. Section 251 enables the common law duty of confidentiality to be lifted to enable researchers to view confidential patient information to send study invitation letters.*" The member advised that the other information in the paragraph provides enough reassurance on its own'.

The remaining description of CAG reads; *'The Confidentiality Advisory Group of the Health Research Authority (CAG Reference [to be inserted after approval] has granted permission for members of the research team, authorised by your clinical team,'*

The CAG understood the feedback from the patient. The Members requested a small change to this wording to allow for slightly more accuracy in the description of the role of CAG, without all of the stark legal language. Namely changing 'permission' to 'support', and making sure its clear that the HRA are the decision maker on advice from the CAG. Please could the applicant update the sentence to something similar to the following? *'The Health Research Authority (after advice from the Confidentiality Advisory Group CAG) has provided support_to access your contact details specifically for the purposes of this research. Support was provided under Section 251 of the NHS Act 2006.'*

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 have consulted with several service-users regarding processing identifiable data (name, address, NHS number) to invite patients to join the study. Alternatives to this were discussed, but no other alternatives were found. It was important to service-users that all previous OPC patients in the Trusts got the opportunity to participate. By doing a large mail-out it ensures all patients, including those who do not attend the hospital regularly (as they are years on from treatment) get invited. All said that if they received the invite that they would be eager to take part.

The applicant has also presented the study at University of Leeds Radiotherapy Research Group presentation -The four attendees consisted of two cancer survivors, who have previously received radiotherapy and two lay members of public representing 'Use MY data' The group as a whole were very supportive of the study and believed the project was answering important questions that could improve the future of patient care. There were no specific concerns raised about research staff being involved in the recruitment process.

The study has been and will continue to be discussed three times a year at the Patient Outcome Centred Research (PCOR) Group Research Advisory Group (RAG) meetings. This group comprises around 30 members, compromised from a mix of cancer patients with various diagnoses and their carers. They are lay members of the public, with an interest in guiding and supporting the PCOR group's research.

The applicant has updated CAG as part of the query responses regarding review of the patient notification materials by patients. Both patients contacted reiterated that they saw no issue with the confidential information being accessed by researchers outside the direct care team, but encouraged them to be as transparent as possible about how data was accessed.

The CAG considered that the applicant has consulted with individuals who have experienced this cancer and treatment as well as other service users and user groups about the design of the study including accessing participants' names and addresses, without consent. The Members noted that this patient and public involvement undertaken is good, and they were content this fulfilled requirements.

Exit strategy

Support no longer required once the research team has finished inviting patients, and corresponding confidential patient information deleted. Invitations will be sent out in Leeds by November 2022 and in Manchester by January 2023. The key between contact details and a study ID is retained by the direct care team only for 5 years – therefore no 's251' required for this.

Once consent is obtained, 'Section 251' support under the Regulations is no longer required. Where consent is not obtained the anonymisation/deletion of identifiable data is the appropriate exit strategy, and this has been confirmed by the applicant in the query responses. Confidential patient information of those who opt out will be removed straight away. Non-responders confidential patient information will be removed 8 weeks after the reminder letter has been sent out (which is sent at 4 weeks). Therefore 's251' support required until approximately the end of February 2023 for Leeds, and end of April 2023 for Manchester. The list of invited and consented patients' names, addresses and NHS numbers will be destroyed at the end of the study (once analysis and write up is complete). However this will have been retained with consent as legal basis.

The CAG were content with the proposed exit strategy.

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. Please provide the favourable opinion from the REC, as per standard condition of support below

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. Please update the PIS with the terminology surrounding CAG support, and provide for CAG review within one month of the date support provided.
2. Favourable opinion from a Research Ethics Committee. **Pending**
3. 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**

The NHS Digital 21/22 DSPT reviews for **Leeds Cancer Centre (Leeds Teaching Hospitals NHS Trust)** and **The Christie Hospital NHS Trust** were confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 09 September 2022)

3. New Precedent Set Review Applications – Non-Research

a. 22/CAG/0128 - Stroke Patient Reported Experience Measures (PREMS) Survey 2022

Context

Purpose of application

This non-research application submitted by The Stroke Association, as joint data controllers with NHS England, sets out the purpose of conducting the 2022 Stroke Patient Reported Experience Measures (PREMS) Survey.

The purpose of the Stroke PREMS survey is to undertake a national survey which captures the patient experience of stroke care, and to use the survey findings to inform quality improvement activity at local, regional, and national level – in line with the NHS's statutory responsibility for quality improvement. No such patient experience tool or data exists at a national level, and yet this is part of the Stroke Long Term Plan ambitions for England. The survey will support nationally recognised aims of:

- Improving the quality and standard of stroke care and rehabilitation across England.
- Supporting a shift in focus towards measuring patient reported experience measures.
- Placing the experience of people affected by Stroke at the heart of Stroke services.
- Ensuring that Stroke patient experience measurement becomes a regular feature and key driver for improving and learning from patients to improve the services experienced by them.

There are approximately 80,000 strokes per year. Some patients will require inpatient stroke rehabilitation, but for the majority of patients, rehabilitation will take place in the community. The intention is to use the patient-reported data to better understand patients experiences across the entire stroke pathway, from emergency admissions, acute stroke unit stay, community or inpatient rehabilitation and life after stroke services. The outcome aims to enable further improvements to improve the experience,

and hopefully outcomes, for stroke survivors.

's251' support is requested to allow Trusts to disclose confidential patient information to Quality Health for the purposes of undertaking a postal questionnaire survey. Quality Health will contact patients by post. Patients will be sent a survey pack initially. This will include the survey itself, cover letter and language leaflet. A first reminder will be sent 5 weeks after the survey to non-responders only. A second reminder and another copy of the survey will be sent 4 weeks later to non-responders only. If patients opt-out of the survey they will not receive further letters or communication. Questionnaires are sent back to Quality Health, and this is taken as implied consent to take part. Quality Health undertake analyses, and provide anonymous outputs to the Stroke Association.

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	Adult stroke survivors (aged 18+) who have experienced a confirmed Stroke and were admitted to an NHS England stroke service within the last 4-8 months Maximum estimated number of patients contacted; 27,712
Data sources	3. NHS Patient Administration System (PAS) from participating Trusts
Identifiers required for patient invitation purposes	4. NHS number, 5. Name, 6. Address including postcode, 7. Sex, 8. Ethnicity, 9. Date of birth,

	10. ICD10 code, 11. Date of stroke, 12. Specialty code, 13. Treating NHS Trust, 14. NHS Trust of residence or commissioning board.
Identifiers required for analysis purposes	2. Date of birth – modified to age 3. Ethnicity 4. Gender This would be effectively anonymous, and additionally analysis undertaken with consent as the legal basis

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.

The CAG agreed that this was an important medical purpose which 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 applicants are gaining implied consent at the earliest possible time point. To avoid a breach of confidentiality, the direct care team would send out the survey, however the

applicants reason that this is not practicable either and that this methodology will provide;

- Minimal workload implication for over-stretched stroke clinicians on busy stroke units, still impacted by Covid – which would impact on participation levels, and therefore the number of surveys issued
- this provides the most robust methodological approach, where the results will be valid, with the least number of concerned about coverage, representativeness, and bias (including no selection bias)
- Geographical coverage impacting on ability to benchmark and undertake quality improvement activity

This is further detailed in the application and the reasoning aligns with the reasoning provided for the national surveys. The CAG were content with the justification for not taking consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to invite participants to complete a questionnaire. Survey contractors require confidential patient information in order to send questionnaires to selected patients. The CAG were content that this could not be undertaken with less identifiable information.

‘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 object 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.

Prior to the breach of confidentiality

A dissent flyer will be provided to participating trusts, associated with a poster to be displayed. A local opt out option is included on both. These currently do not specify

dates for the cohort, and the applicant has confirmed this will be added when confirmed. The dissent posters will be displayed on stroke units and in clinics for a minimum of 28 days and the dissent flyers will be included with appointment letters for clinics, and can be given out at appointments in both clinics and by community therapy teams. Each Trust will be requested to display dissent information on their website and to encourage social media posts to raise awareness. This is in line with other national surveys.

Further information will be available on the SA website page referenced on the posters. Applicants tried to keep the information on the posters and flyers simple and accessible, given that some stroke survivors may have cognitive impairments as a result of their stroke. The website content has been provided for review. Applicants plan to suggest to Trusts that they share a digital image of the poster and/or flyer, as this contains accessible information and references the SA website.

The CAG were broadly happy with the proposed notification methodology, however there were a few inaccuracies that are required to be corrected before support can be recommended. This webpage has slightly inaccurate wording under the header 'The Stroke Associations lawful basis'. The wording should be amended to reflect that 's251' 'support' rather than 'approval', has been 'recommended' rather than 'granted', by the 'Secretary of State for Health and Social Care following advice from the Confidentiality Advisory Group (CAG), who are an independent advisory group which includes lay representation. ' rather than the 'CAG at the HRA'. You can then remove the final line in that section, as it does not read well – *'the approval also provides the reassurance as it is an independent review of the purposes and governance arrangements for the survey'*.

On a separate note, the applicant has titled the HRA the 'Health Research Agency' rather than its actual title the 'Health Research Authority', however this is a moot point, as all references to the HRA should be removed as this is non research, and the decision maker is the Secretary of State for Health and Social Care.

The third paragraph should also be amended to something similar to; 'Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') is the legal basis under common law'.

There will be opportunities both before the survey is sent out and during the fieldwork

for any patients to opt out, as well as the opportunity to opt out later on being included in the survey covering letter. A local opt out option is available, and the applicants have confirmed the National Data Opt Out will be applied.

The CAG were content with all the opt out opportunities, however there appears to be an incorrect statement on both the flyer and poster stating '*If you have previously opted out of national surveys, your information will not be disclosed by your Trust.*' The CAG noted that this is likely not possible, (or appropriate), and that the applicant must be referring to the National Data Opt Out. Please correct both the flyer and the poster, and any other materials to remove this line, and instead state '*if you have opted out via the National Data Opt Out, your information will not be disclosed by your Trust*')

After the breach of confidentiality – information sent to patients:

The applicant has provided all of the material sent out to patients for review including a cover letter, the survey front page, the survey (not yet formatted), and the first and second reminder letters. These reference what data has been shared by whom and the legal basis for doing so. These have been cognitively tested as part of the unconsented activity process, and the language has been chosen for accessibility purposes and to keep the reading level to a minimum, given cognitive impairments experienced by some stroke survivors.

The CAG were broadly happy with these materials, although noted some inaccuracies regarding CAG, similar to those described in the above section.

The cover letter has a couple of sections that require alterations; In the section headed 'Will my personal details be safe?' the cover letter states; '*The data sharing arrangement has been independently reviewed and approved by the Confidentiality Advisory Group (CAG) at the Health Research Agency (HRA)*'. This should be altered to something similar to '*The data sharing arrangement has been supported by the Secretary of State for Health and Social Care, following advice from the Confidentiality Advisory Group (CAG), an independent advisory Group which includes lay representation*'

The cover letter also has a section headed 'What is the legal basis for sharing my details?' which states *'Section 251 approval has been given by the Confidentiality Advisory Group at the Health Research Agency ahead of any personal information being shared by NHS trusts. This allows your details to be shared without your consent. Regulation 5 of the 2002 Control of patient Information Regulations provide a lawful basis for confidential patient information to be processed for medical purposes'* Which should be altered to something similar to; *"Section 251' support has been provided by the Secretary of State for Health and Social Care, following advice from the Confidentiality Advisory Group (CAG), ahead of any personal information being shared by NHS trusts. This allows your details to be shared without your consent. Regulation 5 of the 2002 Control of patient Information Regulations provide a lawful basis under common law, for confidential patient information to be processed for medical purposes'*

The survey front page also has a slightly incorrect statement – *'That your personal contact information can be held and used by NHS England, and organisations acting under its instructions.'* However, it isn't held by NSH E - only by Quality Health. This should be altered to reflect that it is only Quality Health who hold personal contact information.

The CAG noted that some, or perhaps many of the patients will have impairments - fine motor problems which makes form-filling dependent on another person or cognitive impairments that mean a carer might have to interpret questions to make sure they are understood. The questionnaire itself does recognise this by stating:

'1. In what role are you filling in this survey?

o I am a stroke survivor

o I am a carer or friend or family member of a stroke survivor

o Other (please specify)

If you are filling this survey in on behalf of someone else, please make sure all answers do NOT come from your own point of view, but from the point of view of the person you are helping.'

However, there is no reference in the initial invitation letter to the possibility that it might be opened (or read) by a relative/carers, so that the reminder that only the patient's views are relevant, even though they might need assistance completing it, might reasonably

be stated here also. Indeed it might increase uptake of the invitation if such third parties realise from the start that they may have a role to play. The CAG suggest that this should also be incorporated into the cover letter and any reminder letters.

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 Stroke Association surveyed their Involvement community and previous cognitive testing volunteers, to test the acceptability of the lack of consent and feedback on the content of the covering letter. 21 volunteers responded in total, of which:

- 18 responded that they would be happy to receive the survey
- 18 responded that they would be happy for their information to be shared for the purposes of sending the survey
- 18 responded that they would be comfortable with the personal details being shared for reporting and analysis purposes
- 17 responded that the cover letter gave enough information about how to opt out of the survey, and from receiving further surveys.
- 16 responded that the cover letter reassured them that their details would be kept safe and their responses would be anonymous.

The respondents who gave a negative or 'not sure' response were contacted and their concerns were discussed, leading to some changes in the covering letter. 1 respondent felt that they would not reply to any postal surveys no matter what their origin or reassurances.

Other Patient and public involvement has been undertaken on the survey content, and other elements of the application, and this is detailed in the query responses.

The CAG commented that the patient and public involvement is mostly helpful in terms of contribution to the format of the questionnaire and the participants' majority view that they would be happy to complete such a questionnaire. However confirmation has not yet been provided about who the 21 respondents were and whether they represented the cohort. Confirmation has also not been provided regarding exactly what information the respondents were shown regarding the method of obtaining confidential patient information without consent, and it is unclear if individuals were asked whether they have any concerns. The CAG would therefore like to see some more detail surrounding this specific point.

Exit strategy

The exit strategy is anonymisation. Confidential Patient Information will be destroyed by Quality Health within 3 months of the close of the project. The applicant now plans to delay the fieldwork, to enable more time for communication to Stroke Networks and the project will now close in July 2023. Therefore, applicants are requesting 'S251' support until October 2023. The CAG were content with the proposed exit strategy.

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 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, within one month.

Request for further information

1. Please provide the formal letter of support from the Caldicott Guardian equivalent of the submitting organisation.
2. Ensure the website text is updated for accuracy as per this letter, and provide an updated version back to CAG.
3. Please ensure the flyer and the poster are updated regarding the inaccurate comment about having previously opted out of national surveys, when this should read national Data opt Out, and provide updated versions back to CAG.
4. Please ensure the cover letter is updated for accuracy with the points in this letter, and provide an updated version back to CAG.
5. Please later the front page of the survey to make it clear that NHS England do not hold contact information, and this is only referring to Quality Health, and provide an updated version back to CAG.
6. Please ensure consistency and clarity in the cover/invitation letter, and any reminder letters regarding the possibility that third parties such as relatives and

carers may have opened this letter on the patients behalf, and may have a further role to play, and provide updated versions back to CAG.

7. Please provide more detail surrounding the patient and public involvement activity surrounding the use of confidential patient information without consent, including who the 21 respondents were to ensure they are representative of the cohort, what was covered, and what were the views on use of confidential patient data without consent.

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 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. 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:**

The NHS Digital **21/22** DSPT review for **Quality Health** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 September 2022)

<i>Minutes signed off as accurate by correspondence from</i>		
Signed – Officers of CAG		Date
<i>Dr Murat Soncul, CAG Alternate Vice-Chair</i>		<i>27 September 2022</i>
Signed – Confidentiality Advice Team		Date
<i>Caroline Watchurst, HRA Confidentiality Advisor</i>		<i>22 September 2022</i>