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

13 March 2020

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice-Chair	1.a, 1.b, 2.a.
Ms Sophie Brannan	CAG Member	1.a.
Mr David Evans	CAG Member	1.a, 1.b.
Dr Katie Harron	CAG Member	1.b, 2.a
Mr Andrew Melville	CAG Member	2.a

Also in attendance:

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

1. New precedent set review applications – research

a. 20/CAG/0020 – Healthcare Usage of Bariatric/Metabolic Surgery

Context

Purpose of application

This application from King's College London set out the purpose of medical research that seeks to assess the overall long-term healthcare usage of bariatric and metabolic surgery.

Currently, less than 0.2% of patients who meet the NICE and international criteria for surgical treatment of obesity and Type 2 Diabetes undergo surgery in the UK. Widespread misperceptions about the relative risks of bariatric surgery may be a barrier to access to surgical treatment. No study has previously been conducted to compare the perioperative safety and long-term healthcare utilization of bariatric or metabolic surgery with those of other commonly performed elective surgical procedures.

The applicants will carry out a retrospective review of data from 100 consecutive patients who underwent bariatric surgery and other types of elective surgical interventions for benign diseases at King's College Hospital NHS Foundation Trust between February 2014 and March 2015. The outcomes of these patients will be compared with those of 700 consecutive patients who underwent other types of elective surgeries for benign diseases at the same Hospital. The applicants will examine the long-term rate of re-admissions and the related length of stay, emergency department attendances and GP encounters over a period of 5-year from the index surgery.

Data from NHS Digital on nationwide healthcare utilization will be obtained to ensure that accurate data on post-operative healthcare usage can be collected. This data would contain NHS numbers and would be anonymised by the applicants once

received and patient identifiers, NHS numbers, will be replaced by study specific identifiers.

A recommendation for class 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	800 patients who underwent surgery at King's College Hospital NHS Foundation Trust. This number is comprised of: • 100 consecutive patients who underwent bariatric surgery and other types of elective surgical interventions for benign diseases at King's College Hospital NHS Foundation Trust between February 2014 and March 2015. • 700 consecutive patients who underwent other types of elective surgeries for benign diseases at the same Hospital
Data sources	1. Electronic patient records at King's College Hospital NHS Foundation Trust 2. HES data at NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. Date of birth 5. Date of death

Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. 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 Group agreed that the application had a medical purpose and was in the public interest.

The remit of the CAG

The Group noted that in the response to the Confidentiality Advice Team's query regarding the data flows, the applicant had included the following statement, "Given that this will be a research study, the application was submitted to IRAS and has received preliminary approval pending CAG approval. It is the investigators' understanding that section 251 applies for non-research application."

Members advised that s251 support applied to both research and non-research applications and that, by submitting an application to the CAG, the applicants were seeking support under s251, which provided a legal basis for those outside of the direct care team to process confidential patient information without seeking consent from individual patients.

Data flows

The applicant stated that, once the local databases within King's College Hospital NHS Foundation Trust have been linked together, only the NHS numbers of patients would be shared with the research team. This information was repeated in the data flow diagram. Members requested clarification on whether the NHS number alone was needed for linkage to the HES data held by NHS Digital.

Members also noted that the data would be returned from NHS Digital to the research team with the NHS number still present and the study ID would only be applied at this point. The usual method is to apply the study ID prior to data being sent to NHS Digital so that NHS Digital receive both NHS number and study ID. NHS Digital then remove the NHS number before returning the linked data, meaning that support under s251 is no longer required from this point. The Group queried why this could not be done in this project.

Members noted that data on nationwide healthcare utilization will be obtained to ensure that accurate data on post-operative healthcare usage can be collected. This data would contain NHS numbers and would be anonymised by the applicants once received and patient identifiers, NHS numbers, will be replaced by study specific identifiers. What is the reason for the data to be transferred with identifiers, including NHS number, still present? NHSD is able to provide patient level data with all identifiers, including NHS number, removed.

NHS Digital provided the research team with patient's date of death, and members queried when this would be changed to year of death.

Members also asked if the date of birth was converted to age by the direct care team, prior to data being released to the research team.

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 study is retrospective and involves patients who have already undergone surgery at King's College Hospital NHS Foundation Trust. The applicants advise that it was not feasible to contact and seek consent from the 800 patients. Some patients may also have changed address and contact details. The Group accepted that it was not feasible to seek consent from individual patients.

- **Use of anonymised/pseudonymised data**

Support is requested to allow the disclosure of confidential patient information from King's College Hospital NHS Foundation Trust to NHS Digital for data linkage to HES data. The Group agreed that the data linkage could not be undertaken in any other way.

'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 has been devised. The investigators plan to publish a communication about the study on the King's College Hospital Website, describing the methods and objectives. The communication will have the contact details of the PI and instructions for patients wishing not to be part of the study on how to opt out. The same communication will be available on leaflets and posted outside the surgical outpatient clinics for increased exposure and accessibility. A copy of this leaflet is attached. The leaflet text is very technical and may not be easily understood by the average reader. It should be discussed with patients at one of the Bariatric Surgery clinic monthly meetings.

The National Data Opt-Out will apply. The investigators will identify patients suitable for the study using local databases. This will be done by the direct care team. The NHS numbers are collected and then sent to NHS Digital. If any of the selected patients are part of the National Data Opt-Out, the direct care team will be informed, the respective patient's information will be discarded and will not be included in the analysis.

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 study design and patient selection had been made after discussions between the Chief Investigator, the research team and carers of patients from different specialties.

To date, no patient and public activity has been undertaken. Following the CAG advice feedback, the investigators are planning to involve patient and public around the application activity. The Bariatric surgery clinic hold a monthly discussion group that involves patients planned or considering bariatric surgery as well as patients who have already had surgery. This group welcomes any other member of the public interested in the discussion. The group aims at increasing awareness about the different perioperative stages of bariatric surgery. This group can serve as a suitable target for the proposed engagement.

The CAG agreed that patient and public involvement needed to be carried out. The issue of using data containing NHS number without consent must be discussed with this group. Feedback from at least one of the planned monthly discussion groups needed to be provided to the CAG.

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 whether the NHS number alone is sufficient for NHS Digital to conduct linkage to HES data.

2. Advise why the study ID cannot be applied prior to the data being shared to NHS Digital.

3. Advise why national data received from NHSD needs to contain identifiers including NHS number.

4. Clarify when patient's date of death will be changed to year of death.

5. Clarify whether patients' date of birth was converted to age by the direct care team, prior to data being released to the research team.

6. Give feedback from the consultation with Bariatric Surgery clinic monthly discussion group

7. The Patient Information Leaflet needs to be discussed at one of the Bariatric Surgery clinic monthly meetings, and revised in line with the feedback provided.

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 21 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: NHS Digital has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 10 June 2019.**

   - **Confirmed: King's College Hospital NHS Foundation 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/0021 – Breast reconstruction: investigating long-term clinical and cost-effectiveness in the National Mastectomy and Breast Reconstruction Audit cohort

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research that seeks to compare long-term clinical and cost-effectiveness of implant based and autologous breast reconstruction to help patients, health professionals and commissioners make more informed decisions about reconstructive breast surgery.

The majority of the 55,000 women diagnosed with breast cancer each year will be long-term cancer survivors but up to 40% will still require a mastectomy. Breast reconstruction is routinely taken in order to improve quality of life for patients. Decision-making for breast reconstruction is complex. Reconstruction can be performed using implants or the patient's own tissue from the back, abdomen or buttocks either at the time of mastectomy or at a later date, often after necessary cancer treatments have been completed. Each technique has different short-term risks and benefits, such as the duration of recovery, number and position of scars and surgical complications. Patients and surgeons need to balance these factors against the long-term outcomes of different procedures to make fully informed decisions about surgery. There is currently a shortage of evidence for patients and surgeons on which method of breast reconstruction after a mastectomy may be the best for patients in the long term. There is some evidence on the risks and benefits for each method of reconstruction during the next few years after the operation, but there is little evidence yet to say how patients will fare in the years further into the future.

The applicants will seek views from women who have undergone a mastectomy with and without breast reconstruction 10 years ago. Patients who underwent a mastectomy for breast cancer or a delayed breast reconstruction following a previous breast cancer diagnosis in an NHS setting between 1 January 2008 and 31 March 2009 will be identified within HES and data for this cohort extracted up until 31 March 2019. An up to date list of contact details for surviving patients will then be provided from National Cancer Registration and Analysis Service (NCRAS) via PHE. The research team at the University of Bristol will then contact the patients to invite them to complete questionnaires about their experience. Their involvement will then proceed on a consented basis.

A recommendation for class 1, 2, 3, 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 who underwent a mastectomy for breast cancer or a delayed breast reconstruction following a previous breast cancer diagnosis in an NHS setting between 1 January 2008 and 31 March 2009. The applicants expect that 16212 patients will be included.
Data sources	1. HES and NCRAS data held by Public Health England
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Region of NHS care provider 3. 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 Group agreed that the application had a medical purpose and was within 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 seek to identify the required cohort and obtain up to date contact details. The Group accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information in order to make contact with eligible patients to seek consent for their participation. This could not be undertaken in any other way.

'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.

Patients will be contacted by the study team and asked to participate. Participation will then proceed on a consented basis.

The applicant provided a participant information leaflet v1.0, and invitation to participate letter v1.0. A study website would also be created and draft text was provided. This website could be used to register dissent for HES analyses, register consent for completing patient reported outcomes questionnaires, and to complete the questionnaires. The Group reviewed this information and requested the email address, telephone number and postal address were included in the website text in the paragraph describing dissent.

Awareness of the study would also be raised through engagement with the wider community via social media and the professional associations, the Association of Breast Surgery and British Association of Plastic Aesthetic and Reconstructive Surgeons.

Individuals who have dissented from the sharing of their NHS records with the GP practice will not be identified as eligible by NHS Digital or Public Health England. Patients will be contacted by the research team and are able to express dissent at that point.

The Group noted that the Information Leaflet stated that analysis would begin on or around the 1st of May and that patients wishing to opt-out would need to do so before then. Members expressed concern that the information would not be sent to patients in sufficient time for patients to opt-out and asked that patients were instead given a set timeframe from receiving the information leaflet within which dissent can be registered. Members suggested that patients were given a month to dissent.

The Group noted that the following statement was included in the protocol at paragraph 3.3.1, "Subsequent non-responders will be considered to have declined study participation for the PRO study but will be considered to have provided assent to their hospital records being accessed for the HES study in the absence of an opt-out instruction." Members advised that non-response cannot be interpreted as assent, it must be interpreted as dissent and cannot be a legal basis to access the HES records. S251 support was needed to provide a legal basis to access this information and the patient facing materials needed to be amended to make this clear.

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 application was discussed with two patient representatives, Trustees of Independent Cancer Patients Voice. They have been involved in designing the study and assessing the acceptability of study procedures, as well as developing patient information materials.

Both patient representatives have shared the study design and documents with their wider patient networks and obtained feedback regarding the design and conduct of the study. Locally in Bristol, patient focus groups involving women who have had mastectomy and reconstruction approximately 10 years ago have been held to discuss acceptability of the study procedures and quality of patient information.

Use of confidential patient information without consent was discussed with the patient representatives, who also sought feedback through their wider breast cancer patient networks, local patient focus groups and with the University of Bristol's Data Protection Officer. Feedback was supportive.

The Group noted the information provided and was satisfied that sufficient patient and public involvement had been 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 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 patient facing information documents need to be amended to explain that support under s251 is required to access HES data, should the patient not respond to the information leaflet opportunity to object.

2. Patients are to be given a month after receiving the patient information to respond to the applicants in order to register dissent.

3. The applicants' email address, telephone number and postal address were included in the website text in the paragraph describing dissent.

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 of Bristol – Bristol Medical School (by NHS Digital email dated 17 December 2019), Public Health England (by NHS Digital email dated 02 September**

2019) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON-RESEARCH

a. 20/CAG/0025 – SUPER (Southampton cardiac surgery Unit Performance Evaluation and Review project)

Context

Purpose of application

This application from the University Hospital Southampton NHS Foundation Trust set out the purpose of an evaluation of survival rates following cardiac surgery at Southampton General Hospital in order to improve performance and service provision in the Southampton cardiothoracic surgery unit.

This project involving unconsented processing will allow an updated and accurate analysis of mortality rates following cardiac surgery and identify any patterns in this cohort. The long-term survival data of patients after cardiac surgery will be considered for different surgical procedures in order to develop benchmarks and assess performance in the form of a local audit, in order to improve future performance and patient-related outcomes. Reflection on these findings will be translated into better management and improved service provision.

The applicants sought support for the disclosure of confidential patient information from University Hospital Southampton NHS Foundation Trust to NHS Digital for linkage to their survival database. The dataset disclosed from University Hospital Southampton NHS Foundation Trust to NHS Digital will contain confidential patient information for all living and deceased patients within the cohort. NHS Digital will return confidential patient information only for deceased patients.

A recommendation for class 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 cardiac surgery at Southampton General Hospital between 01/01/2000 and 01/07/2019. The applicants estimate that 21,200 patients will be included.
Data sources	3. Mortality data held by NHS Digital
Identifiers required for linkage purposes	2. Name 3. Date of birth 4. Hospital number 5. NHS number
Identifiers required for analysis purposes	4. Date of death

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 Group agreed that the application had a medical purpose and was in the public interest, but that further information was required on how performance will be improved and how the data will be analysed. Members also queried how this local audit would complement the National Audit of Cardiac Surgery.

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 only information for deceased patients would be sought from NHS Digital. Data for both living and deceased patients would be disclosed to NHS Digital from University Hospital Southampton NHS Foundation Trust, as the applicants did not know which patients in the cohort were deceased. The Group agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for NHS Digital to link data from University Hospital Southampton NHS Foundation Trust to the survival database within NHS Digital. This could not be undertaken in any other way.

'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 cohort of interest is deceased. However, the general population was informed by displaying flyers and holding open meetings, where they had the opportunity to raise objections and provide feedback.

Living patients of the cohort were invited to open meetings through flyers, where they were encouraged to express their opinion and object to being included in the study.

The Group advised that, as the support requested will include the transfer of data on the entire cohort from the local database to NHS Digital, living patients must be informed that they study is taking place and given the opportunity to dissent. Patient information leaflets should be made available and public notices displayed in appropriate clinics and on relevant websites, and these should include clear information on how patients can dissent from the inclusion of their data. The text of these will need to be provided to the CAG for review.

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 general population was involved in this review project through open meetings, where they were able to provide feedback regarding the project and express any objections. These meetings were held on the main cardiothoracic surgery ward (E3) at Southampton General Hospital.

Both living patients from the cohort and members of the general public were invited to attend these open meetings through flyers and posters. The patient pamphlet used was provided with the application. These flyers and posters were displayed within the cardiothoracic wards and department. The open meetings were held by the project co-ordinator, who presented the aims of the study, including the methods through which these could be achieved, including this application and disclosure of patient identifiers for linkage to NHS Digital. Although there was no formal written feedback, patients and the general public were encouraged to express their opinions. They were also given the opportunity to object to being included in the study. There were no objections received, only positive feedback supporting this study.

The Group requested that further information on the public meetings was provided. This needed to include information on how many attended and the questions asked. Members queried whether the issue of processing confidential patient information without consent had been discussed during these meetings.

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. Provide further information on how performance will be improved and how data will be analysed.

2. Clarify how this local audit will complement the National Audit of Cardiac Surgery.

3. A patient notification strategy for living patients needs to be created. Patient information leaflets should be made available and public notices displayed in appropriate clinics and on relevant websites, and these should include clear information on how patients can dissent from the inclusion of their data. The text of these is to be provided to the CAG for review.

4. Provide further information on what was discussed at the public meetings. This needs to include information on how many attended and the questions asked. It also needs to be clarified whether the issue of processing confidential patient information without consent had been discussed during these meetings.

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. 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 Hospital Southampton NHS Foundation Trust (by NHS Digital email dated 29 November 2019) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

Security assurance requirements

It is the policy position of the Department of Health and Social Care (DHSC) in England that all approved applications seeking 'section 251 support' to process confidential patient information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the relevant Data Security and Protection Toolkit (DSPT). All organisations that are processing confidential patient information under this support must have completed a DSPT submission, and NHS Digital must have reviewed the self-assessment.

There is an agreed bespoke process in place, specifically for applicants seeking 'section 251 support', where the IG Delivery Team at NHS Digital will review the relevant DPST submission and confirm to CAG that the submission meets the 'Standards Met' threshold. An organisational self-assessment does not provide sufficient evidence; the submission must be independently reviewed by NHS Digital.

To enable NHS Digital to confirm to CAG that the relevant DSPT submission has achieved 'Standards Met', applicants must ensure that the relevant organisations have competed a DSPT submission and submitted their self-assessment(s) through the usual process. At this stage, the applicant must email the Exeter Helpdesk via exeter.helpdesk@nhs.net and provide this CAG reference number, the organisational names and references that require review, and ask NHS Digital to review the DSPT submissions due to a CAG application. Once reviewed, NHS Digital will confirm to CAG by email that the submission has met the required level.

Please note that even if the outstanding clarifications are satisfactorily addressed, a final outcome letter will not be issued until evidence of adequate security assurance is provided as per the process above. Applicants are strongly encouraged to progress this element as soon as possible.