Minutes of the meeting of the Confidentiality Advisory Group

06 February 2020 at HRA London, Skipton House

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr William Bernal	Yes	CAG Alternative Vice-Chair
Dr Malcolm Booth	Yes	CAG Member
Ms Sophie Brannan	Yes	CAG Member
Dr Patrick Coyle	Yes	CAG Vice-Chair
Mr Tony Kane	Yes	CAG Member
Dr Harvey Marcovitch	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Mr Marc Taylor	Yes	CAG Member
Ms Gillian Wells	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Ms Lindsey Peggs	Senior Confidentiality Advisor

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **05 December 2019** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **05 December 2019** meeting applications.

3. Consideration items

a. Discussion on future linkage application with Chief Data Officer and Deputy Director of Digital Innovation Hub: PIONEER Health Data Research Hub for Acute Care. Supported by Health Data Research UK (HDR-UK).

b. Request to waive National Data Opt-Out – HQIP/NHS England commissioned audits – two test cases
    i. Discussion with HQIP representatives
    ii. CAG advice to non-research decision-maker

4. New applications – Research

a. 20/CAG/0009 – The Cambridge Cohort: a breast screening population mammography database

Context

Purpose of application

This application from the University of Cambridge sets out the purpose of creating a research database, containing mammographic images to be used as a resource for the development, testing and creation of artificial intelligence algorithms.

All women aged 50 – 70 years who attended breast screening at the Cambridge Breast Screening Programme, part of the National Health Service Breast Screening Programme (NHSBSP) conducted by Public Health England, between 2011/2012 and 2021/2022 from whom a mammogram was acquired at either mobile or static units will be included.

The mammographic screening image for each patient and corresponding clinical, radiological and histopathological information, already stored in patients records at the Cambridge University Hospitals NHS Foundation Trust, will be extracted. This will include information from Picture Archiving and Communication System (PACS), Electronic Health Records (EHR) and National Breast Screening System (NBSS) and Breast Screening Select (BSS). Support under s251 is required as the staff undertaking the processing of confidential patient information will be research staff, who are not members of the direct care team.

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

Confidential patient information requested

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

Cohort	All women aged between 50 – 70 years who attended breast screening at the Cambridge Breast Screening Programme, part of the National Health Service Breast Screening Programme (NHSBSP) conducted by Public Health England, between 2011/2012 and 2021/2022 from whom a mammogram was acquired at either mobile or static units.
Data sources	Electronic Health and paper medical records at Cambridge University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	NHS Number Hospital ID number Date of birth
Identifiers required for analysis purposes	Gender Year of birth

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.

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 explained that it was not feasible to seek consent due to the size of the cohort. Also, a disclosure of confidential patient information would be required in order for the applicants to obtain up to date contact details for patients.

Members agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to extract and link data from Picture Archiving and Communication System (PACS), Electronic Health Records (EHR) and National Breast Screening System (NBSS) and Breast Screening Select (BSS) within Cambridge University Hospitals NHS Foundation Trust.

Exit Strategy

The applicant confirmed that no items of confidential patient information would be stored in the research database disclosed to the applicants at the University of

Cambridge. Patients' date of birth was converted to their year of birth, so that patients age when the screening mammogram was taken could be calculated.

within the Trial Database.

The group noted the intention to retain the Key Database with identifiers for 15 years. Members queried the intentions for doing so, including the possibility of further research studies/linkage being undertaken. Where this is the case the group wished to remind applicants that it will be necessary to submit a further application or submit an amendment for this to happen.

'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.

Whilst the applicant explained that an objection mechanism would be advertised on the departmental website as part of the lay summary with opt out details, members queried the notification mechanism. The lay summary provided in the application was noted but the application did not refer to any other form of notification, such as posters within the Trust. Members queries whether the lay summary was the text to be used on the website, and whether it will be available in other formats.

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 explained that the lay summary had been reviewed by 7 members of the Cambridge University Hospitals NHS Foundation Trust's patient and public involvement panel. Feedback was also obtained from a patient representative from Independent Cancer Patient Voices (ICPV). Suggestions and comments were incorporated into the application where necessary. Feedback from these discussions was provided.

Members queried whether any of the Trust's patient and public involvement panel were Breast Cancer patients, thought that a wider consultation, involving a breast cancer charity should be considered. Queries were also raised on whether the participants in the patient and public involvement panel were specifically asked opinions regarding undertaking these activities without consent. It appeared so from the responses, but a list of the questions asked was requested by the group.

The group also queried if there be any lay members on the Database Access Committee and suggested that there should be if not.

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. Provide clarification on the intention retain the Key Database with identifiers for 15 years

2. Confirm whether the lay summary provided is the text to be used as a website notification, and whether it will be used in any other formats. If other formats will be used, please supply these to the group.

3. Supply the list of questions used in the Patient and Public Involvement and Engagement event.

4. Consider a wider patient consultation to include the involvement breast cancer charity.

5. Consider having lay members on the Database Access Committee, if not already in place.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 3 April 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 – Cambridge University Hospitals NHS Foundation Trust has a confirmed 'Standards**

Met' grade on DSPT submission 2018/19 by NHS Digital DSPT Tracker checked 17 March 2020).

b. 20/CAG/0002 Investigating the incidence of radiation-related cancer following endovascular aortic aneurysm repair compared to open aneurysm repair

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to determine whether radiation exposure during X-ray guided endovascular aortic report and follow-up lead to an increased risk of cancer.

Patients undergoing X-ray guided endovascular aortic aneurysm repair are exposed to a dose of radiation during their initial operation and then during annual follow-up CT scans. Those who have their aneurysms repairs by an open approach instead are not exposed to this dose of radiation during surgery or follow-up. The applicants will compare the incidence of cancer between these two groups to determine whether this radiation exposure increases the risk of malignancy.

Support is sought to link data from the Hospital Episode Statistics (HES) database with the National Cancer Registration and Analysis Service (NCRAS) registry. Patients undergoing aortic aneurysm repair either by an open approach (OAR) or endovascular approach (EVAR) will be identified by NHS Digital from the Hospital Episode Statistics (HES) dataset. A list of the remaining patient NHS numbers, dates of birth and a unique pseudonymised ID will be transferred to Public Health England (PHE) by secure electronic transfer agreed between NHS Digital and PHE. At PHE, the National Cancer Registration and Analysis Service (NCRAS) will perform a look up on the cancer registry using deterministic matching based on NHS number and date of birth. This process will identify which patients developed cancer after their procedure. Follow-up on NCRAS will continue to December 2020 such that any patients from the original HES dataset who have a diagnosis of a primary tumour as per future NCRAS data releases can be included in the analysis. PHE will then send the cancer data

including date of diagnosis, type and stage of cancer to King's College London (KCL) in a depersonalised format. NHS digital will also send the demographic and operative details to KCL in a depersonalised format linked by the pseudonymised ID.

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

Confidential patient information requested

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

Cohort	40,170 patients, aged 50 years and over, who underwent elective open abdominal aortic aneurysm repair or EVAR between January 2000 and December 2016.
Data sources	HES data held by NHS Digital NCRAS data held by Public Health England
Identifiers required for linkage purposes	NHS number Date of birth
Identifiers required for analysis purposes	Date of birth 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 was satisfied that the application had a clear medical purpose and was in the public interest.

Scope

Most areas of the protocol and application refer to the lower age limit being 50 years of age. However, question 16 of the IRAS form lists the lower ager limit as 40 years of age. The group requested clarification on the lower age limit of the study.

Practicable alternatives

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

- **Feasibility of consent**

The applicant advised that it was not feasible to seek consent, due to the number of participants involved. Members were content and agreed that consent was not feasible

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link HES data with data from NCRAS. A pseudonymised dataset was then disclosed to the applicants. The CAG accepted that this could not be undertaken in any other way.

Justification of identifiers

The group noted that the applicants were retaining date of birth following linkage, and sough justification why this was required. Members suggested that date of birth should not be retained, and that age at diagnosis could be recorded instead.

Data Flows

It is understood that NHS Digital will send a de-identified dataset to King's College London, and that this includes some demographics that were identifiable (for example date of death). The group requested clarification on what identifiers are sent from NHS Digital to King's College London.

Exit strategy

Members understood that the initial linkage process is a one off but it appeared that King's College London will continue to link to NCRAS data until Dec 2020, and so it was assumed that Public Health England will be holding onto Confidential Patient Information for this period. The group requested clarification on how long Public Health England is processing Confidential Patient Information and when the identifiers are destroyed. It was noted that Q52 of the application form indicates that personal data will be stored for over 3 years.

'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.

No project specific patient notification and dissent process provide. The National Opt-Out would be applied by NHS Digital to the cohort of patients identified via HES. Patients who had opted-out would be removed at this stage and their data would not be sent to PHE for linkage to NCRAS.

The group discussed this and felt a form of patient notification should be in place for the study. Members asked for the applicants to provide the committee with the notification to be used (including details on how to opt out), as well as provide details of where this notification will be placed, or for the applicants to provide a strong justification as to why patient notification is not able to be done.

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's Patient and Public Involvement and Engagement work was noted. However, it was not clear if patients were explicitly asked for a view on the use of confidential patient information without consent. Members agreed that the applicant should provide the views of at least two patients on the use of confidential patient information without consent.

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. Confirm the lower age limit of participants in the study.

2. Confirm that age at diagnosis, rather than date of birth is retained, or provide justification why date of birth is required to be kept.

3. Provide clarification on what identifiers are sent from NHS Digital to King's College London.

4. Supply clarification on how long Public Health England is processing Confidential Patient Information, and when the identifiers are destroyed.

5. Provide the group with patient notification materials, which include details of how to opt out, or provide justification why these should not be used.

6. Offer the views of at least two patients on the use of confidential patient information 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 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 15 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 (by NHS Digital email dated 10 June 2019) and National Cancer Registration and Analysis Services (Public Health England) (NHS Digital DSPT tracker checked 16 March 2020) have confirmed 'Standards Met' grade on DSPT 2018/19).**

It is currently unclear whether the applicant's department at King's College London has appropriate DSPT assurance from NHS Digital. Applicants instructed to follow process to confirm security assurances.

c. 20/CAG/0012 - A Retrospective Cohort Study of Treatment Outcomes Among Adult Patients with Refractory or Relapsed Follicular Lymphoma

Context

Purpose of application

This application from King's College Hospital NHS Foundation Trust set out the purpose of medical research which aims to estimate the Complete Response Rate (CRR) in adult patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) treated with standard therapies.

Non-Hodgkin's Lymphoma (NHL) is a type of blood cancer that originates in the lymphatic system. There are various sub types of NHL, one of which includes Follicular Lymphoma (FL). Approximately 20% of all NHL and 60% of indolent NHL cases are Follicular Lymphoma (FL). FL is a disease considered treatable, but not curable with current therapeutic options. Patients with FL who relapse (when the disease comes back after treatment) or who are refractory (when the disease does not respond to treatment) to chemotherapy and other non-chemotherapy treatments are rare, and

their prognosis is poor. Whilst recently approved drugs show evidence of efficacy, their use is limited by severe side effects. There is therefore a high unmet need for newer treatments with novel mechanisms of action to offer potentially curative options for these patients. Tisagenlecleucel is a cellular immunotherapy that uses autologous blood cells that have been genetically modified. Preliminary data indicates a good response in FL patients. The applicants plan to conduct a retrospective study in order to provide a historical cohort for a planned clinical trial. It is not feasible to include a placebo-controlled arm in the trial, hence this design has been chosen.

The applicants will conduct a retrospective medical record review of a patient cohort with Follicular Lymphoma. Suitable patients will be identified using a controller data extraction from the participating Trust's electronic medical records, using a technique called 'Cogstack.' Cogstack will identify suitable patients and provide a proportion of the clinical data required. The applicants will then review each potential patient. Patients deemed unsuitable at this point will be deleted from the report. The applicants will complete an eligibility worksheet for suitable patients. A unique study ID will be assigned and non-identifiable data will be entered into the Electronic Data Capture System. The patients' unique study ID, name and hospital number will be entered into a password-protected document. Once all data queries have been resolved by the research site, the pseudo-link document will also be destroyed and there will be no identifiable data retained by sites at the end of the study.

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

Confidential patient information requested

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

Cohort	Data will be collected from patients from multiple oncology centres with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) treated between 1998 and 2019

Data sources	Electronic and paper patient records held at King's College Hospital NHS Foundation Trust and Guy's and St Thomas' Hospital
Identifiers required for linkage purposes	Name NHS Number Hospital ID Number GP Registration Date of birth Date of death Postcode
Identifiers required for analysis purposes	Gender Year of birth Month and year of death

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 clear medical purpose and was in the public interest though noted the following concerns regarding the commercial involvement.

Members noted that the application lists a number of people associated with the study that are employed by Novartis but there is no mention of the involvement of the organisation in the study.

The group also noted that the protocol and the anonymised data generated by the study will be owned by Novartis, but the protocol makes clear that no Novartis drug of interest is being studied.

As such, members requested clarity on the role of Novartis in this study and their possible uses of the data generated by the study (for example use as a comparator for studies of a new product in the future). This is required in order to ensure that the patient/public confidence is maintained.

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 patients in the cohort had a poor prognosis and it was unlikely that many patients diagnosed between 1998 and 2019 would still be alive. The applicants did not think it feasible to contact the families. King's College Hospital NHS Foundation Trust and Guy's and St Thomas' Hospital are referral centres for patients with FL and patients would have been referred back to their local hospital once they had progressed.

The committee agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to check that patients identified via Cogstack were suitable for inclusion in the study and to link data from patient records within the hospitals.

Members agreed that access to confidential patient information was required to undertake this study. However, the group wished for confirmation that any confidential patient information relating to patients not accepted into the study is destroyed at the earliest possible moment or anonymised if required for control purposes.

Exit strategy

The data would be extracted via Cogstack as a one-off extraction. Once suitable patients had been identified and the required data entered in the study Electronic Data Capture system, then the Cogstack report containing items of confidential patient information would be deleted. The pseudonymised link file would be kept until the final database was confirmed. The link file would then be destroyed.

The group were content with 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.

Members noted that no patient notification or details of an opt out mechanism had been provided. Whilst mortality will be high within the patient cohort the group felt that there should be some form of notice within the public domain, which should include details of an opt out mechanism. As well as the cohort for the study, there will also be a number of patients whose identifiable confidential information will be revealed by CogStack who will ultimately be excluded. Their right to confidentiality must also 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 explained that a summary of the design and objectives of the study was discussed with a Follicular Lymphoma patient at King's College Hospital. Feedback from this was supportive. Members felt that consultation with one patient was inadequate and thought there would be a suitable patient group associated with KCH that could be consulted. The group requested further Patient and Public Involvement and Engagement to be undertaken.

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. Provide clarity on the role of Novartis in this research study.

2. Describe the possible future uses of the data generated from this research study.

3. Provide a patient notification to be used for this study, as well as details where the patient notification will be place. The notification should include clear details on how patients can opt out.

4. Undertake further Patient and Public Involvement and Engagement with a group relevant to this study, which should include discussion on the use of confidential patient information without consent.

5. Confirm that any confidential patient information relating to patients not accepted into the study is destroyed at the earliest possible moment or anonymised if required for control purposes

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 04 February 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: The NHS Digital DSPT review for King's College Hospital NHS Foundation Trust (checked 17/03/2020) and Guy's and St Thomas' Hospital NHS Foundation Trust (check (13/05/2020) were confirmed as 'Standards Met' on the NHS DSPT Tracker**

d. 20/CAG/0014 - Obstetrics and Perinatal Outcomes in relation to various stages of assisted reproductive technology treatment

Context

Purpose of application

This application from the Shropshire and Mid Wales Fertility Centre set out the purpose of medical research that seeks to investigate whether the early maternal clinical conditions, embryonic development and culture environment affect the maternal and neonatal outcomes of assisted reproductive technology treatment.

During assisted reproductive technology treatment, patients receive hormonal injections to maximise the number of eggs produced during treatment, this is termed 'controlled ovarian stimulation'. However, some patients overrespond and develop Ovarian Hyperstimulation Syndrome (OHSS) and can become very unwell as fluid accumulates in the abdominal cavity and in severe cases in lung and heart spaces (pleural and pericardial effusion). Traditionally, embryos are returned to the uterine cavity on day 3. Recent studies have shown the outcomes may be more promising when embryos are transferred on day 5, the blastocyst stage. Most embryos develop into blastocyst on day 5, but there are some slower developing embryos and only become blastocyst on day 6. Embryos are traditionally kept in incubators and evaluated daily for their development. The introduction of embryoscope allows minimal interruption of the early embryonic environment.

The applicants will collect and examine retrospective data obtained from the Mid Wales and Shropshire Fertility unit and Human Fertilisation and Embryology Authority (HFEA), to compare groups of patients who used embryoscope versus those who did not and will evaluate if the group with embryoscope has a better treatment and perinatal outcome. The applicants are seeking support to obtain data from the Mid Wales and Shropshire Fertility Unit for patients who developed severe and critical OHSS over a 10-year period. OHSS is rare, and the applicant is also seeking support to obtain additional data from the HFEA for patients nationally who were reported to the HFEA as developing OHSS. Patients demographics, treatment protocols and outcomes will be obtained from the HFEA database and compared against a matched cohort of patients who underwent in vitro fertilisation (IVF) but not develop OHSS.

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

Confidential patient information requested

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

Cohort	1000 patients who received IVF. Three groups will be evaluated; Patients who developed severe OHSS over the last 5 years – estimated as 200 patients Patients who had blastocyst transfer on day 5 and day 6 – estimated to be 480 patients on day 5 and 180 on day 6

	Patients who used embryoscope in the Mid Wales and Shropshire Fertility unit from 2016 onwards – estimated to be 220 patients
Data sources	Electronic Health records held within the Human Fertilisation and Embryology Authority records Electronic and paper patient records at Mid Wales and Shropshire Fertility Unit
Identifiers required for linkage purposes	NHS Number 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 agreed that the application had a medical purpose and 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**

Only retrospective data will be processed. All patients who received fertility treatment signed a 'consent to disclosure' HFEA form, agreeing to use of their data in non-contact research.

There are frequent references in the IRAS form to all IVF patients having completed a 'consent to disclosure HFEA form', in which they have previously consented to non-contact research. At Section 30 it is stated that prior consent has been obtained and the consent to disclosure form appears to be the basis for this assertion. If prior consent has been obtained from all the patients involved, then a separate legal basis already exists and there is no need for the applicant to seek Section 251 exemption. Indeed, if an alternative legal basis exists, it is not possible to provide Section 251 support. However, question 15-2 indicates that the consent form does not provide a legal basis for this study. It is recommended that advice is sought from HFEA to clarify the status of the consent to disclosure form, and the legal basis to access the data. If an application is still required, it is also recommended that the IRAS form is revised in the light of the HFEA information, not least with regard to any justification why consent for this particular research study is not feasible. Any future application should be clear on why s251 support is with explanation why the consent to disclosure form cannot be used as a legal basis.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data from the HFEA with patient data at Mid Wales and Shropshire Fertility Unit. Once the data linkage has been performed, confidential patient information will be deleted, and anonymised data only used for analysis.

The group were content that confidential patient information is required as part of this study

- **Retention of identifiable data**

The answer to Q52 of the application form indicates that personal identifiable information will be kept for over three years. In any future application please consider whether this is correct. If this is correct, further justification for the length of storage of personal identifiable information would need to be provided.

'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 has not provided any patient notification materials, based on the that fact that only patients who consented to use of their data would be included in this study. As well, no dissent mechanism is discussed as it is assumed that the HFEA consent is sufficient.

Members felt that this was not satisfactory and, if a future s251 application is required, requested both a patient notification to be provided, which should include details of an opt-out mechanism.

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 has not undertaken any patient and public involvement and engagement, nor provided any justification for this.

The group felt that Patient and Public Involvement and Engagement is important to be able to further demonstrate the public interest. If a future application is required Patient and Public Involvement and Engagement should be undertaken with a relevant patient group, ensuring the use of confidential patient information without consent is discussed.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information to be provided

The following points should be taken into consideration for any future application.

1. Provide confirmation from HFEA that non-contact research consent form cannot be used as a legal basis, with a justification for this decision, as well as providing the HFEA non-contact research consent form.

2. Detail a clear justification why consent for this research study is not feasible.

3. Confirm the response to Q52 (regarding retention of personal identifiable information) is correct, providing further justification if so.

4. Provide patient notification materials as well as details on where they will be placed. Any patient notification material should include details on how to opt out.

5. Undertake Patient and Public Involvement and Engagement with a relevant patient group, ensuring the use of confidential patient information without consent is discussed.

6. Ensure NHS Digital can provide assurances that the organisation DSPT Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. Further details on how to do this are below.

Once received the information will be reviewed initially by a sub-committee of all Members present at this initial review, prior to consideration at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

e. 20/CAG/0015 - Clinical outcome modelling of rapid dynamics in acute stroke with joint-detail, remote, body motion analysis

Context

Purpose of application

This application from King's College Hospital NHS Foundation Trust set out the purpose of medical research which aims to capture high-resolution joint-level motor function in acute stroke and correlate it with clinical outcome measures and neuroimaging.

Stroke is characterised by rapid changes over time and marked variability in outcomes. Patients may improve or deteriorate within minutes, and optimal treatment requires both detailed characterisation of the patient's clinical picture and its pattern of change over time. The most important aspect of the patient's clinical picture, body movement, remains poorly documented, quantified subjectively and at infrequent intervals in the patient's clinical evolution. Artificial intelligence, combined with high-performance computing, has enabled the automatic extraction of a patient's skeletal frame, down

to major joints, delivered simply, safely and inexpensively, without the use of body worn markers. The skeletal frame is extracted in real time, ensuring no video data, from which patients can be identified, to be stored or transmitted by the device. The prototype motion categorisation system, MoCat, will be used to study the rapid dynamics of acute stroke. Changes in motor deficit over time will be quantified, so that the relationship between the trajectories and the clinical outcomes can be examined and predictive models developed to support clinical management.

The applicants will conduct a prospective observational study, in which patients admitted to the stroke unit will be monitored using the MoCat motion capture device for the length of their acute admission. All patients admitted to the unit will be eligible for the study. Following the patient's discharge, the motion capture data will be linked to the clinical outcome data of interest and routinely collected clinical data obtained via the hospital electronic medical records and picture archiving and communication system (PACS). On completion of linkage, the data will be pseudonymised, and allocated a unique study identifier.

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

Confidential patient information requested

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

Cohort	1000 patients aged over 18 years admitted to the stroke unit of King's College Hospital NHS Foundation Trust with a possible diagnosis of acute stroke.
Data sources	Electronic Health records held within King's College Hospital NHS Foundation Trust
Identifiers required for linkage purposes	Hospital number Date of birth

	NHS number
Identifiers required for analysis purposes	Date of birth Gender 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 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.

Members agreed that the study had a medical purpose and 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.

- **Minimising flows of identifiable information**

The group noted that the research team intended to retain date of birth and date of death for analysis purposes but referred to this data as being pseudonymised. Members were concerned about this as the data is not pseudonymised, given the identifiers retained. If these identifiers are to be retained in an identifiable format

members agreed that further justification would be required, as well as an absolute assurance that if it is retained it will not be released to others without a proper legal basis.

- **Feasibility of consent**

Members discussed the feasibility of consent. Whilst noting the applicant's opinion that this consent would introduce bias, the group's view was that the argument for not seeking consent had not been properly justified and required further information on the reasons for not seeking consent.

Participant cohort and Mental Capacity Act

The group had uncertainties of the cohort to be studied. Whilst it was noted the application indicated that those who lack capacity would not be included, the group wished for further clarification on the cohort to be included, and whether the applicant had fully considered the provisions of the Mental Capacity Act, and whether a legal basis can be provided through this route.

Members noted that the application refers to a retrospective and prospective cohort. The group requested further information on the number of participants whose data will be retrospective, how many prospective and if there will be any controls. Members also requested further information on how retrospective participants will be identified, and which dates they will be selected from.

'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 response to Q15-3 in the application states *'We are therefore exploring options for the provision of additional material to inform patients*.' Members requested sight of the patient notification material, with preference for it to be provided as a poster with appropriate wording for that medium, a leaflet with more detail, and on appropriate websites. All materials would need to prominently detail the right to object, with details on how this can be done.

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 group noted that two patient and public engagement (PPE) activities were held at King's College Hospital NHS Foundation Trust. However, members requested details on how many people attended these meetings and what questions those present were asked to consider. It would be useful to provide the demographic of those attending and how well this matched the demographic of those likely to be subjects of the study.

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 as to why date of birth and date of death should be retained for analysis.

2. Assurance that any identifiers retained would not be released to others without a proper legal basis.

3. Confirm whether participants who lack capacity would be included in this study.

4. Clarify whether the provisions of the Mental Capacity Act have been considered, and justify why a legal basis cannot be provided through this legislation.

5. Confirm how many participants will be selected retrospectively and prospectively, and whether there are any controls.

6. Clarify how retrospective patients will be identified, and between which dates these patients will be selected.

7. Provide all patient facing materials to be used, ensuring the right to object features prominently.

8. Confirm how many people attended the engagement events and the questions asked of them, as well as provide information on how the demographics of these people match the patient cohort of the study.

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 27 April 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: 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.

f. 20/CAG/0018 - Protocol for hospital-based, test-negative case–control studies to measure seasonal influenza vaccine effectiveness against influenza laboratory-confirmed SARI hospitalisation among the elderly across the European Union and European Economic Area Member States

Context

Purpose of application

This application from Public Health England sets out the purpose of medical research which aims to evaluate the effectiveness of influenza vaccination in hospitalised adults over the age of 65 years, during the 2019/20 and 2020/21 influenza seasons.

Influenza viruses undergo frequent changes and therefore, the influenza vaccine is reformulated each year and annual re-vaccination is recommended. In recent years a range of enhanced vaccines, designed to improve vaccine effectiveness, have been developed. In order to understand how well vaccination protects individuals against disease and to compare different vaccines it is important to understand their effectiveness.

All patients admitted during the 2019/20 and 2020/2021 influenza seasons with respiratory samples tested for influenza will have their medical records reviewed by the study nurse against inclusion/exclusion criteria for eligibility. Of eligible patients, those with a test result positive for influenza will be cases, and those with a test result negative for influenza will be controls. The study nurse will collect data on eligible patients including medical and vaccination history, and laboratory results. As well Medical history will be collected through hospital medical records. Any information that is not available within hospital records will be collected through GP records including vaccination history. The

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

Confidential patient information requested

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

Cohort	Adults over the age of 65 years, hospitalised with severe acute respiratory infection during the 2019/20 and

	2020/21 influenza seasons. Cases and controls will be collected, based on whether patient tested positive or negative for influenza.
Data sources	Laboratory records at University Hospitals Birmingham NHS Foundation Trust (Heartlands Hospital) Medical records at University Hospitals Birmingham NHS Foundation Trust (Heartlands Hospital) GP-held medical records
Identifiers required for linkage purposes	Name Date of birth NHS number Hospital number GP registration data Postcode
Identifiers required for analysis purposes	None

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 there is a strong public interest because of risk to the target population, cost to and burden on health services, and lack of consensus about most effective use of vaccination

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**

It was noted the retrospective design of the study and the fact that most patients will have been discharged, make consent impracticable. Members agreed that consent was not feasible in this study.

- **Use of anonymised/pseudonymised data**

Whilst understanding that the inclusion and exclusion criteria are complex, members queried whether it was possible to extract data using automated processing of laboratory, medical and GP-held records, which would enable a holding organisation to provide pseudonymised data. The group requested justification that data collection cannot be undertaken using automated processes.

Justification of identifiers

The application form (Q28) indicates that all clinical data will be held in an anonymised database. However, members noted the list of data items provide in appendix 2 of the protocol, which will be collected in the CRF. The group commented that the first data items are potentially disclosive and would not render the CRF as anonymised. Justification was sought for keeping potentially identifiable items, such as date of birth, date of death, hospital ward, as well as other specific dates. Members also queried, if these are justified, whether these could be held in a separate database to enable the clinical data to be anonymised. This was especially relevant given it is understood this dataset will be sent outside the UK for analysis.

Exit Strategy

Given the details above regarding the data items kept in the CRF, it was felt that the study did not have a clear exit strategy from using confidential patient information. The group required further details on how the applicant intends to move away from using confidential patient information without consent.

'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.

It was noted that there was no information provided on patient notification. Members discussed and agreed that the study should undertake some form of patient notification, for example posters in the Trust, at local GPs, or on a study website. Little information was provided in the form of how patients can opt, other than respecting the national data op tout.

The group request patient notification materials to be provided, which should include information on how patients can opt out. Details should also be provided on where the notification will be placed.

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.

Members were concerned that the application indicates no Patient and Public Involvement and Engagement, and so there is no evidence provided to the group that patients are happy with transfer and pooling of rich potentially disclosive data set. The group requests some Patient and Public Involvement and Engagement to be undertaken with a relevant patient group. This should include specific questions around using confidential patient information without consent, in the context of this study.

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. Undertake Patient and Public Involvement and Engagement to be undertaken with a relevant patient group. This should include specific questions around using confidential patient information without consent, in the context of this study. The outcomes should be provided to the CAG.

2. Provide justification that data collection cannot be undertaken using automated processes.

3. Detail why potentially identifiable items, such as date of birth, date of death, hospital ward, as well as other specific dates are required in the CRF. if these are justified, provide detail on whether these could be held in a separate database to enable the clinical data to be anonymised.

4. Provide further details showing how the study will move away from using confidential patient information without consent.

5. Provide patient notification materials, which should include information on how patients can opt out.

6. Give detail on where the patient notification materials will be placed.

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. **The NHS Digital DSPT review for University Hospitals Birmingham NHS Foundation Trust organisation was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 14/05//2020).**

5. New precedent set – Non-research

a. 20/CAG/0016 – 2020 Maternity Survey

Context

Purpose of application

This application from the Care Quality Commission set out the purpose of service evaluation which will be achieved through a patient survey in order to build up a national picture of women's experiences of maternity care.

Support under Section 251 and its Regulations is sought for the transfer of confidential patient information from participating Trusts to the Survey Co-ordination Centre for Existing Methods (SCCEM), to enable the facilitation of the survey invitation process. The methodology for the 2020 survey is unchanged from the 2019 survey. The applicants received support under Section 251 in 2019 to allow the transfer of full postcodes or sample members and trust-held antenatal and postnatal attribution information on sample members from trusts directly to the Survey Co-ordination Centre for Existing Methods. Support was also given for the sharing of this data with approved contractors by the SCCEM, which enabled them to provide an extra level of data insight to trusts.

This will be the eighth maternity survey carried out to date and forms part of the NHS Patient Survey Programme (NPSP). Preparations for the survey will begin in March 2020, with fieldwork expected to commence from the end of April 2020. 126 trusts are expected to be involved. All trusts will draw a sample of patients according to set criteria and follow standardised materials and procedures for all stages of the survey. The current model for the NPSP is a devolved model where participating trusts can either undertake the implementation of the survey themselves or they can appoint one of the approved contractors from the CQC framework. The flow of data and what is processed will vary depending on whether a trust undertakes the survey themselves or not. If a Trust undertakes the survey themselves, the SCCEM is the main centre for assisting and supporting the trusts. SCCEM will issue sampling materials for a trust to use to draw their sample correctly, send the sample for deceased checks and how to submit an anonymised file for checking. For trusts using an approved contractor, the SCCEM will also remain as the main centre for assisting trusts, however the main

liaison will happen between the SCCEM and the approved contractor. The applicants anticipate that most trusts will opt to use an approved contractor.

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	Service users who had a live birth in January or February 2020, and were aged 16 years and over at the time of delivery. Trusts are instructed to sample all eligible service users in February 2020. If this is fewer than 300 records they are asked to sample back from the last date in January to the beginning of January or until they reach 350 records (in order to achieve a sample of 300 post-DBS checks).
Data sources	126 participating trusts
Identifiers required for linkage purposes	A unique identifier code Title First name Surname Address fields Full postcode

Identifiers required for analysis purposes	A **sample file** is used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn. It will also be used to enable the identification of service users who received antenatal and postnatal care directly from the trust. This file contains: A unique identifier code Gender Mother's year of birth Mother's ethnic group Day of delivery Month of delivery Year of delivery Time of delivery (for multiple births, this will be the time that the last baby is born) Number of babies born at delivery Place of birth: NHS site code Actual delivery place CCG code Mother's full postcode (or postcode sector if approval for the additional element is not granted) An **attribution file** which includes the sample file fields above and additional information relating to the provision of antenatal care or postnatal community care as follows:

	Antenatal provider information Postnatal provider information Full postcodes to which the trust provides maternity services (ONLY if using the postcode method to complete the antenatal and postnatal provider information). Submission of an attribution file is optional for trusts though the majority of trusts choose to submit this information (in 2019, 118 out of 126 trusts chose to do so).

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 noted that there was a strong public interest. The results of the survey would be used to monitor the use of services and assist Trusts in planning and making improvements.

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 provided three central arguments as to why seeking consent for this survey would be impracticable.

If consent needed to be sought, then individual Trusts would be required to arrange their own mailing to patients, which would remove the benefits of the Trust employing a specialist contractor.

There was a risk that a systematic and damaging bias would be introduced in response rates by changing the nature of the survey from an opt-out system to an opt-in system. Trusts, the CQC, the Department of Health and Social Care and NHS England require that accurate measurements are collected in order to assess the quality and impact of their services and policies, and act upon the results to improve the experience of patients. Unreliable data may lead those conducting the analysis to conclude that they could not say whether a policy or initiative was working. There was also a risk that policies that were working would be stopped because the data provided were inaccurate and did not demonstrate the improvement.

Requiring staff within Trusts to seek prior consent would place an additional burden on staff Given the often extremely busy nature of services, it could be viewed as an unrealistic burden on staff to seek prior consent for this survey if service users were asked during the labour and birth stages. The Group noted the information given and was satisfied that seeking prior consent was not feasible.

- **Use of anonymised/pseudonymised data**

Processing of confidential patient information is required to enable the surveys to be sent to the correct patients. The Group accepted that this could not be done 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.

Participating Trusts are required to display posters in their site locations during the full sample period, running between January and February 2020, in order to inform service users that they may be sent a questionnaire. These posters will include contact details for service users to contact the trust with queries or to request dissent.

Trusts will be required to keep a record of any objections and requests to dissent they have received. It is up to the individual Trusts to determine the best way of keeping this record. The applicants anticipated that most Trusts would use a flag on the electronic records system and will have a data field specifically about whether the service user is happy for their details to be used for purposes other than direct care. Other Trusts will keep a separate record which is cross-referenced against the eligible population before the final sample file is drawn.

The Group reviewed this information and the posters that had been provided for review, and was satisfied that appropriate patient notification and dissent procedures were in place.

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 this survey employs methodology broadly similar to that used in the NHS Patient Survey Programme previously.

There was a substantial redevelopment undertaken on the survey content for the 2019 iteration. This redevelopment focussed on two particular work streams; consultation with key stakeholders, and in-depth face to face interviews with recent mothers. The interviews focussed on understanding their priorities for maternity care and experience of recently using the services to enable us to determine what key aspects of experience needed to be measured within the survey itself.

An advisory group was held to discuss the findings and recommendations for the survey content. Following agreement of the questionnaire content, cognitive testing was undertaken with recent mothers to ensure that the questions being asked are easy to understand and measure what they are designed to evaluate.

Following substantial redevelopment of the survey for the 2019 iteration, development for 2020 will be more focused. An advisory group attended by different stakeholders was held in November 2019 to discuss the content of the survey. Following agreement of the questionnaire content, cognitive testing will be completed in mid-January 2020 with recent mothers to ensure that the questions being asked are easy to understand and measure what they are designed to evaluate. The Group reviewed the above information and patient feedback provided, and was satisfied that appropriate patient and public involvement and engagement had been conducted.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support as set out below.

Specific conditions of support

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: Patient Perspective (by NHS Digital email 30 July 2019), Picker Institute Europe (by NHS Digital email 17 July 2019) and Quality Health (by NHS Digital email dated 23 July 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

6. Chair's Report

A report from the Chairman was received for February 2020

7. Office Report

A report from the office was received for February 2020

8. Minutes of the meeting held on 05 December 2019

The minutes were received and agreed as an accurate record of proceedings.

9. Any other business

No other business was raised.

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

Signed – Chair Date

Signed – Confidentiality Advice Team Date