Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

08 March 2018 at Skipton House, SE1 6LH

Present:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Dr Kambiz Boomla	Yes	
Ms Hannah Chambers	Yes	Lay
Dr Patrick Coyle	Yes	Vice Chair
Professor Barry Evans	Yes	
Dr Katie Harron	Yes	
Professor Jennifer Kurinczuk	Yes	
Dr Harvey Marcovitch	Yes	
Ms Clare Sanderson	Yes	Alternate Vice Chair
Mr Marc Taylor	Yes	
Ms Gillian Wells	Yes	Lay

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor
Mr Peter Lennon	Observer – Department of Health Ireland
Mr Kevin Conlon	Observer – Department of Health Ireland
Dr Teresa Maguire	Observer – Department of Health Ireland

Mr Stephen Robinson	HRA Corporate Secretary

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

Dr Katie Harron was welcomed back to the Group having been on an extended period of absence whilst working in Canada.

The Chair welcomed colleagues from the Department of Health Ireland to the Committee. Mr Peter Lennon, Mr Kevin Conlon and Dr Teresa Maguire were introduced to the Group and explained that they were in attendance to observer the CAG as it was the intention to establish an equivalent "section 251" system within Ireland.

Mr Stephen Robinson was welcomed to the CAG meeting. It was noted that Mr Robinson was in attendance in his capacity as appointed decision-maker for the Health Research Authority and was present for the research application business only.

Apologies for Absence

Mr Anthony Kane submitted apologies in advance of the meeting; however, there was no impact on quoracy or review allocations as notification was received in advance.

Declarations of Interest

- 17/CAG/0045 (Agenda Item 3.a.)

Ms Clare Sanderson declared a conflict of interest with the application in advance of the CAG meeting. Ms Sanderson has worked with the applicant providing IG guidance in relation to the project in her professional capacity. It was agreed in advance of the meeting that this presented a true conflict of interest. Ms Sanderson took leave of the CAG meeting during discussion of the item and had received no documentation in connection with the review in advance of the meeting.

- 17/CAG/0040 (Agenda Item 4.a.)

Professor William Bernal declared a conflict of interest with the application his employing Trust was involved in the proposal and he had discussed the submission in his professional capacity. It was agreed that this represented a true conflict of interest and Professor Bernal took leave of the meeting during discussion of the application.

It was also noted that Dr Murat Soncul, Alternate Vice Chair of the CAG, was employed by the South London and Maudsley NHS Foundation Trust, which was the applying organisation for the submission.

2. APPROVAL DECISIONS

The following decisions were taken in relations to the relevant CAG recommendations.

Secretary of State for Health and Social Care Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the 08 February 2018 meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 08 February 2018 meeting applications.

3. NEW APPLICATIONS – Non-Research

a. 18/CAG/0045 – Collaboration for Oncology Data in Europe: CODE

Context

Purpose of Application

This application from IQVIA set out the purpose of the non-research initiative, Collaboration for Oncology Data in Europe (CODE), supporting the creation of the Oncology Data Network (ODN) which involved the collation and analysis of data from Healthcare Providers (HCPs) on the use of anti-cancer medicines in clinical practice.

CODE, led by IQVIA, aims to expand the knowledge of anti-cancer medicines use, by supporting the development of a dedicated Oncology Data Network (ODN). The data collated will enable the oncology community to derive greater value from anti-cancer medicines for patients.

CODE includes working in partnership with healthcare professionals, industry, governments and patient groups to ensure that it is relevant and reflects the needs of the broader oncology community, and to ensure it works in a complementary way to existing sector initiatives.

The ODN Programme is initially being planned over 10 years and will involve the collection and processing of anti-cancer medicine use data from participating healthcare providers across selected European countries. Patient level data will be collected, then automatically and securely processed to render it anonymous before being transferred to IQVIA for management and delivery of information analyses results. Data will be mapped to common reference standards for diagnosis, anti-cancer drugs and regimens, and quality controlled in terms of accuracy and consistency.

The HCP is responsible for existing primary data collection and use, i.e. direct care to patients, which is supported by their own electronic information systems. Only data which already exist in these systems will be collected for use by the ODN initiative, and no new data /information will be requested or collected from patients. Data collected for the ODN are classified as 'secondary data collection and use' and should not be used to support care decisions for individual patients although they will assist in the management of the oncology services through, for example, benchmarking clinical practice and assessing the update of new medicines.

IQVIA is submitting this application for Section 251 support for the extraction of data relating to patients receiving anti-cancer drugs and regimens so it can be pseudonymised ("Stage 1 De-identification") by the HCP, securely transferred to the trusted third party (TTP) and loaded into the ODN production platform (at the TTP) for anonymisation (Stage 2 De-identification), after which point it will be available to IQVIA.

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

Confidential Patient Information Requested

Cohort

All patients who receive anti-cancer medicines, in participating Health Care Providers, within England and Wales. If all HCPs in England subscribe to the ODN, this would equate to approximately 200,000 patients per annum.

The applicants stated that all patient identifiers would undergo a two-stage de-identification process. Before the data leaves the Health Care Professional's systems, to pass to the trusted third party acting as their data processor all direct identifiers are removed and replaced with a pseudonym: effectively the process can be considered to be pseudonymisation at source.

Confidentiality Advisory Group Advice

Members considered the application and supporting documentation which had been provided in connection with this proposal. It was acknowledged that the remit under which the CAG can advise is defined in section 251 of the NHS Act 2006 and its Regulations. At section 251(4), it is stated that the remit does not extend when there is a practicable alternative to processing confidential patient information without consent.

The Group acknowledged that the applicants had designed the project using a pseudonymised at source methodology. It was recognised that employing this type of methodology was an established practicable alternative to seeking support under the Regulations. The CAG agreed that, as set out by the applicants within the project documentation, there was a practicable alternative to enable this activity to proceed and as such, the remit under which the CAG can advise had fallen away.

As it was identified that there was no remit for the CAG to provide guidance in relation to this application, no wider consideration of the proposal was undertaken. It was commented that the applicants may benefit from seeking guidance from appropriate channels in order to establish patient and public involvement and engagement with the project and around the proposed patient notification materials which will support the project's communication strategy.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

4. NEW APPLICATIONS – Research

a. 18/CAG/0040 – eLIXIR, Early Lifecourse data Cross-Linkage in Research

Context

Purpose of Application

This application from the South London and Maudsley NHS Foundation Trust set out the purpose of medical research which aims establish a unique life course approach to mental and physical health disorders by combining maternal, infant and child clinical data into a single database. Approval is sought to link data from three Trusts: South London and Maudsley NHS Foundation Trust (SLAM), Guys and St Thomas NHS Foundation Trust (GSTT) and King's College Hospital NHS Foundation Trust (KCH) to create a data platform with linked mental healthcare and hospital records for pregnant women, infants and children.

The initial stage proposed in this application will involve a bringing together maternity data from Guys and St Thomas NHS Foundation Trust and King's College Hospital NHS Foundation Trust, neonatal/paediatric data from Guys and St Thomas NHS Foundation Trust and King's College Hospital NHS Foundation Trust and South London and Maudsley NHS Foundation Trust mental healthcare data.

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

Confidential Patient Information Requested

Cohort

- The population base is pregnant women and children receiving care from KCH and GSTT and people receiving mental health care from SLAM.
- This covers a catchment of around 600,000 residents predominantly residing in Lambeth and Southwark.

The following data items are required from the three Trusts in order to facilitate linkage and creation of the eLIXIR specific cohort. It is stated that the SLAM Clinical Data Linkage Service requires this data items as a minimum to ensure data linkage can be achieved:

- Name,
- NHS number,
- Hospital Number – this will be replaced with study-ID in database,
- Date of birth,
- Postcode,
- Full Address.

The following will be required as part of the research database for analysis:

- Sector-level postcode – translated into Lower Super Output Area or deprivation scoring for analysis,
- Sex,
- Ethnicity,
- Month and year of death.

Researchers would only receive access to a de-identified dataset for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined a medical purpose, through the establishment of a database to be used to facilitate medical research. The applicants had provided an overview of the areas within which proposed research would focus and it was acknowledged that as the resource aged; the data source would become richer and improve. Members were satisfied that the proposal was within the public interest.

It was recognised that the data collection for the project was currently localised between the participating three Trusts: South London and Maudsley NHS Foundation Trust, Guys and St Thomas NHS Foundation Trust and King's College Hospital NHS Foundation Trust. Members commented that it was likely that the data return would diminish as the study progressed as certainly a proportion of the patients included would relocate out of the area. The applicants would be required to consider this point and provide further information around how this would be managed at the time of first annual review.

Cohort

Further clarification was required around the patient cohort to be included within the database, as it was unclear from the documentation, whether it was the intention to continue adding to the database, i.e. the new birth cohort for each year that the database continues. Confirmation around this point was requested.

Members were also unclear whether it was the intention to include mothers within the cohort who were under 16 years old and what additional measures would be required to manage this cohort. Further information was required in relation to this point.

Practicable Alternatives

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

- Feasibility of consent

The applicants had stated that consent was not feasible for the project due to the number of patients to be included within the database, the potential for a consenting model to increase a sample bias and the requirement for a large case ascertainment. Members were supportive of the rationale provided and agreed that consent was not feasible for this project.

- Use of anonymised/pseudonymised data

The Group recognised that processing of confidential patient information was required to enable linkage between the various data sources, which could not be otherwise achieved.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The CAG was assured that the patient identifiers requested were appropriate and proportionate to the proposed activity. Members acknowledged that there was potential for linkage with wider data sources as the project progressed and were supportive of the retention of confidential patient information on this basis. It was noted that support was being recommended to the linkage of data held within the SLaM CRIS database together with BadgerNet maternity and neonatal data from GSTT and KCH only at this stage. Any wider linkage would need to be submitted as an amendment to the project for further consideration.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The project was currently funded for three years; however, it was identified that the applicants were anticipating this to be extended. Members acknowledged that, as such, the application was not clear around the proposed overall retention of confidential patient data, due to the possible longevity of the study.

The Group was content with the rationale that the project was likely to receive additional funding to extend the study duration; however, it was unclear what would happen to the study data if the additional funding was not received. It was agreed that an exit strategy for this eventuality would need to be considered by the applicants. Feedback would be required at the time of first annual review in connection with this item.

Management of the Database

Data collated with support under the Regulations must be used for ethically approved activities with an established medical purpose. The application had been submitted to the REC to seek generic approval for the use of the database within research, thus individual researchers who were seeking to use data extracted from the proposed database for their work were not required to seek individual ethical review of the proposed research project. The Group considered these points and agreed that the terms of reference for the database Oversight Committee should be revised to include an assessment of the ethics of proposals. It was further agreed that an assessment of the application should be undertaken to ensure it

fell within a medical purpose, as set out within section 251(12) of the NHS Act 2006, which was likely to be medical research.

The applicants had confirmed that all releases from the database would be anonymised prior to the data being provided to the applying researcher. It was recommended that the applicants consider applying the Information Commissioner's Office (ICO) Code of Practice on Anonymisation when releasing data. Further information would be required at the time of first annual review to explain how the database Oversight Committee was ensuring that all data releases were in line with this guidance.

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 an unconsented activity should go ahead.

The patient and public involvement and engagement activity which had been undertaken by SLaM was strong and supportive of the project and had been established to be ongoing with the project. Members were impressed by the work which had been undertaken in this area. It was acknowledged that further planned work was set out in the application, particularly with younger people and those with a focus on the maternity aspect of the project, and it was agreed that feedback would be required at the time of first annual review of the outcome of this additional activity. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members considered the patient information materials which had been provided to support the project and were largely satisfied with the documentation. It was commented that the posters should be revised to include information around patient opt-out. When offering dissenting options to patients, it was preferred that a number of communication modes are provided, i.e. telephone, email and postal. It was requested that the information leaflet for inclusion within the maternity packs be revised to include a header, to make clear that this was an information leaflet in relation to research.

The Group acknowledged that the proposed database would include data on both mothers and children, who would be followed up for the duration of the project. The current communications strategy was focussed on the mothers within this cohort; however, it was recognised that the applicants would need to begin planning a communication strategy for the children in the cohort, who would in the future become adults. It was recognised that there was a considerable lead in time before this additional communication strategy would be required; however, Members agreed that the applicants would be required to provide feedback at the time of first annual review around how they intended to manage this point.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The applicants would be required to provide evidence of the favourable ethical opinion prior to the final recommendation of support for the activity being issued.

Additional Points

It was identified from the application that there was a supplementary biobank project, which would be operated on a fully consented basis and would run in parallel to the proposed research database. Members were unclear from the information provided whether it was the intention to link the samples stored in the biobank with the supplementary clinical information within the research database. It was agreed that confirmation was required from the applicants around this point.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for Further Information (Summary)

1. Confirm whether it is intended to continue adding to the database, by including the new birth cohort for each year which the project continues.
2. Clarify whether mothers aged under 16 and their children would be included within the database and whether there were any additional requirements to manage the inclusion of this patient cohort.
3. Revise the Terms of Reference for the database Oversight Committee to include the assessment of the ethics and medical purpose of proposed applications to data extracted from the database for a research proposal.
4. Patient Information Materials – the following revisions should be made to the documents:
    a. A number of means of communication should be offered to facilitate patient dissent, i.e. telephone, email, postal.
    b. A header should be added to the information leaflet, to ensure patients are aware that this is an information leaflet in relation to a research study,
    c. The study posters should be revised to include information around the patient objection mechanism.
5. Provide further information around the related biobank project and confirm whether there is the intention to provide linkage with the research database.

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, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Support is extended to the linkage of the South London and Maudsley NHS Foundation Trust CRIS dataset together with BadgerNet maternity and neonatal data sources from Guys and St Thomas NHS Foundation Trust and King's College Hospital NHS Foundation Trust only. Linkages with wider data sources would need to be submitted as an amendment for consideration.
2. A report is required at the time of first annual review to provide feedback on the following points:
    a. The applicants are asked to consider how potentially diminishing returns may impact on the quality of the database and what steps may be taken to mitigate against this,
    b. Clarification is required of the intended exit strategy for the project, should additional funding beyond the initial three year project not be received. Confirmation should be provided around how the destruction of confidential patient information would be handled in this circumstance,
    c. Provide an update around how the Oversight Committee is ensuring that all data releases conform to the ICO Code of Practice for Anonymisation,
    d. Provide an update at the on the outcomes of the additional patient and public involvement and engagement activity which was scheduled. It was noted that if the outcomes were negative that the CGA would take this into consideration when considering whether support can continue or if further action is required,

e. Planning should begin around a communication strategy for the children within the cohort, who become adults – feedback should be provided around progress made in this area for consideration by the CAG.

3. Favourable opinion from a Research Ethics Committee. **(Pending).**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – South London and Maudsley NHS Foundation Trust shows a reviewed grade of 91% satisfactory on Version 14, 2016/17).**

5. RESUBMITTED APPLICATIONS

a. 18/CAG/0049 (Resubmission 17/CAG/0197) – Yorkshire Bowel Scope Screening

Context

Purpose of Application

This application from University College London sets out the purpose of medical research which aims to investigate whether GP practice based interventions can help increase the uptake of bowel scope screening in Hull and other parts of Yorkshire. Over a six month period, individuals due to receive their NHS Bowel Scope Screening invitation (identified through GPs) will be randomly be assigned to one of three groups with attendance monitored and compared between groups:

1. Usual care: no contact from GPs.
2. Primer and self-referral letter: A letter advising of the future delivery of a BSS invitation will be sent by the individual's GP, along with a locally tailored leaflet explaining the test. If the practice receives notice that an individual did not attend their appointment, a letter highlighting the self-referral process will be sent.
3. Primer and patient navigation: As above, a letter and leaflet will be sent ahead of the NHS BSS invitation. If the practice receives notice that an individual did not attend their appointment, a call to the individual will be made. This call will aim to identify and address personal barriers to uptake and, if appropriate, help arrange a new appointment. If no telephone contact is possible, a self-referral letter will be sent.

Support under the Regulations is required to facilitate groups two and three as the additional patient contacts which are detailed in these two options will involve sharing confidential patient information outside the direct care team without consent.

A recommendation for class 1, 2, 5 and 6 support was requested to cover activities as described within the application.

Confidential Patient Information Requested

Cohort

1. Patients aged between 55 years and 21 days and 55 years and 48 days at the time they are enrolled in the study, who are registered with a GP practice participating in the trial.
2. Patients will be excluded from inclusion in the study if they:
   a. Have had their large bowel removed.
   b. Have a stoma bag to collect their stool.
   c. Are currently being treated for inflammatory bowel disease (i.e. ulcerative colitis, Crohn's disease, etc.).
   d. Are awaiting heart surgery or who have had heart surgery in the last three months.
   e. Have been diagnosed with cancer (any type) in the last 12 months.
   f. Are registered on their GPs clinical system as a type II objector/opt out.

The following items of confidential patient information are requested from the patient's GP record:

- Full name – to enable intervention materials to be sent,
- Full Address – to enable intervention materials to be sent,
- NHS Number – to facilitate linkage via NHS Digital,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

The CAG recognised that this application was a resubmission of 17/CAG/0197, which had originally been considered at the meeting held on 24 November 2017. The application was issued with a deferred outcome, pending further information. The applicants had provided a written response to this request for information, together with a revised application for review.

Public Interest

The CAG had established at the initial review that the application defined a medical purpose through medical research. Members were satisfied at this point that there was a public interest in the overall activity due to the potential to increase the uptake of bowel screening by using the trial intervention methods.

Scope of Support

Within the revised documentation, the applicants had confirmed that support under the Regulations was required for the following activities: disclosure of confidential patient information from participating GP practices to MailaDoc, the online mailing company supporting the project, access to confidential patient information by the research nurse and research assistant supporting the project, to enable management of the study database and navigation intervention and the disclosure of NHS Numbers from participating P practices to NHS Digital in order to follow-up participants via the bowel cancer screening system. Members received the clarification and were content to provide a recommendation of support for the application activity on this basis.

Practicable Alternatives

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

- Feasibility of consent

The CAG had confirmed as part of the initial review that consent was not feasible for the project and no further consideration was undertaken in this area.

- Use of anonymised/pseudonymised data

The Group had confirmed during the initial review that the project could not proceed without access to confidential patient information and no further consideration was undertaken in this area.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The CAG was assured during the initial review that the identifiers which had been requested were appropriate to undertake the application activity. The applicant had been asked to seek assurance from NHS Digital that they were able to undertake the proposed linkage on NHS Number alone. Evidence was provided as part of the resubmission documentation from NHS Digital that this was possible in this instance. It was understood that, as the

providence of the NHS numbers was known for this proposal, this was not to be considered as setting a precedent for future applications to undertake linkage via NHS Digital.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicants had stated that support under the Regulations would be required for a maximum period of 13 months, at which point analysis would be undertaken on a pseudonymised dataset. The third party mailing company which was involved in issuing intervention materials to patients would only retain confidential patient information for a maximum of 30 days, at which point it would be deleted. The CAG was assured by the processes during the initial review and no further issues were raised.

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 an unconsented activity should go ahead.

The applicants had provided the outcome of two patient and public engagement events in relation to the project. It was acknowledged that the first workshop were generally supportive of the activity progressing as per the proposed methodology. The second workshop raised significant concerns around the use of the third-party mailing company to undertake the mailings for the intervention. Further engagement had been undertaken with four members of the Patient and Public Involvement Panel which was managed by the NIHR CLAHHRC North Thames, who also voiced similar concerns around the use of the mailing company.

Following the patient and public engagement, the applicants acted on the feedback provided in order to improve the patient notification materials to support the project, in order to incorporate feedback received. The applicants had named the mailing company within the patient facing materials and provided assurance that the company was approved for use by Public Health England. The materials also directed patients to the company's website to enable the interested reader to check the credentials of the organisation.

The Group considered the outcomes of the patient and public engagement activity and commended the applicants on the candid report which had been provided from the workshops. Use of third-party organisations to undertake mailing tasks was common-place within the NHS and there was established precedence in recommending support for this type of activity. Members recognised the steps which the applicants had taken to allay the concerns voiced in connection with the use of a mailing company and were satisfied that no further action was required here. It was noted that, in providing detail around the involvement of a third-party mailing company to patients as part of the wider communications strategy for the project, those individuals with a strong objection to this would be able to register dissent to their involvement in the project.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Following feedback from the patient and public involvement, the applicants had amended the communications strategy for the project. A revised poster was provided for consideration, which was now supplemented with an information leaflet comprised of detail from the study website. The applicants had confirmed that within the revised information materials, they had tried to make clear that any objection which was raised was in connection to the research project only, not the national screening programme.

It was confirmed that type two opt-outs would be applied prior to any data extraction from the GP practices, to ensure that patients who had registered this opt-out were not included in the research study.

The applicants advised that, whilst it was previously proposed that a statement would be added to the primer letter intervention regarding opting out of receiving further information from the GP practice, it had subsequently been decided that this was not appropriate. The applicants explained that at this stage in the project, the patient's personal details would already have been provided to MailaDoc in order for the primer letter to have been delivered. It was also noted that the applicants wanted to keep the content of this letter brief and focused on the introduction of BSS. Incorporating the option to opt-out may cause confusion as the next delivery to patients will be from the NHS Bowel Cancer Screening Programme, not the GP practice as part of the research intervention.

Members received the revised communication materials and proposed strategy from the applicants and it was agreed that these addressed the previous concerns which had been raised. It was acknowledged that the involvement of the third party mailing company had been clearly explained in the documentation. No further issues were raised in this area.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for MailaDoc Ltd. had been published in respect of version 14 (2016/17) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The applicants had confirmed that the revised information materials would be submitted for consideration by the REC as a substantial amendment. It was noted that evidence of the favourable ethical opinion for the amendment was required prior to the final recommendation of support being issued for the study.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for Further Information

1. Provide a copy of the favourable ethical opinion for the substantial amendment (revised patient information materials).
2. Confirmation of the IG Toolkit assurance for MailaDoc Ltd.

Once received, the information will be reviewed by a Member of the Confidentiality Advice Team in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – project received a favourable opinion on 05/12/2017. Pending for substantial amendment).**

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending).**

6. AMENDMENTS – Revised Applications

a. 18/CAG/0050 (Resubmission of 15/CAG/0195) – The DESIGN Trial

Context

Purpose of Application

This application from King's College London and Guy's & St Thomas' NHS Foundation Trust set out the purpose to transfer the data controllership arrangements for the application activity currently supported under 15/CAG/0195, from University College London's Comprehensive Clinical Trials Unit. The change was brought about due to a change in trial sponsorship.

The application activity previously supported under reference 15/CAG/0195 set out the purpose of medical research into the Growth Assessment Programme (GAP), which aimed to improve the identification of small babies by considering maternal characteristics such as size and ethnicity when assessing growth.

Hospitals are randomised, rather than individual women who will receive the care allocated to their hospital avoiding contamination of the intervention. All maternity units in the trial will introduce the GAP programme eventually, but one group will use GAP immediately, while the other group will delay implementation of GAP. The time before the introduction of GAP in the delayed arm means the applicant can compare maternity units using GAP with those continuing with usual care.

A recommendation for class 1, 3 and 6 support was requested to enable the activity specified in the application.

Confidential Patient Information Requested

Data on few secondary outcomes, such as clinical detection of SGA and compliance assessment, are not routinely available in the hospital systems. To collect this data the research team will need to review notes of all women delivering children within the 13 hospital sites (which are classed as the participants) to extract the anonymised data required for analysis.

Confidentiality Advisory Group Advice

The CAG acknowledged that the application activity was currently supported; however, due to the change in data controller for the project, a revised application form was required to evidence these changes. It was acknowledged that the review of this revised submission had been escalated for full CAG consideration as the applicants had also requested a change to the study methodology in relation to the anonymisation process of the confidential patient information accessed in the study.

Change to Anonymisation Methodology

The anonymisation process is currently undertaken by clinical staff at the study sites. As part of the revised application, the applicants are seeking support to enable a member of the research team to attend the hospital sites in order to undertake the data extraction and linkage process and pseudonymise the records to be extracted. Previously support was only extended to the requirement for a clinical member of the research team to access the records of women who delivered a SGA (small for gestational age) child; however the change in methodology requested that support was extended to the records of all women delivering children within the 13 hospital sites (which are classed as the participants).

The applicants explained that the process of anonymising the patient data locally was complex and as such, it was not time efficient to request a clinician at each site to undertake this task. It was further noted that the

system was not reliable and likely to cause inconsistencies in the data reported, which could lead to errors in the research conclusions. The CAG was assured by the rationale provided by the applicants and was content to recommend support to the revised data processing arrangements. It was acknowledged that the applicants had requested a further change to the methodology to enable patient medical records to be accessed by either the research midwife or clinical fellow. The Group was content to recommend support to this change.

Members considered the revised patient notification materials which had been submitted alongside the revised application. Whilst the documents included only minor revisions in line with the amendments to the project, and had previously been supported for use, it was commented that the documentation could be improved by making the information in relation to opt-out clearer. It was agreed that this would be added as a recommendation to the outcome, but would not be mandated as a condition of support.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. All pre-existing conditions of support related to 15/CAG/0195 remain applicable.
2. The pre-existing annual review cycle remains applicable, with the next annual review to be received 4 weeks before 09/05/2018, and then on an annual basis to this schedule.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Guy's and St Thomas' NHS Foundation Trust shows a reviewed satisfactory grade on Version 14, 2016/17).**
4. Favourable Opinion from a NHS Research Ethics Committee. **(Confirmed – Favourable Opinion 12 January 2018 – support had been ongoing for the project since 20 November 2015).**

Recommendation:

1. It was recommended that the patient notification materials (posters and information leaflet) be revised to make the information around the patient's right to opt-out clearer and more prominent in the document.

7. MINUTES OF THE MEETING HELD ON 08 FEBRUARY 2018

The minutes of the meeting held on 08 February 2018 were agreed as an accurate record of proceedings, with no amendments raised with the content of the document; however, some minor typographical issues were noted for correction.

The following additional information was reported in relation to the recommendations given at the CAG meeting held on 25 January 2018. It was reported that this additional information had been included within the minutes of the 08 February 2018 CAG meeting, to ensure that this was could be published in a timely fashion.

<u>Secretary of State for Health and Social Care Approval Decisions</u>

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the **25 January 2018** meeting applications.

In relation to reference PIAG 03(a)/2001 'National Cancer Registration and Analysis Service (NCRAS) Annual Review' submitted by Public Health England, the SofS agreed with the majority of the CAG advice

provided in relation to this annual review. The SofS decided that the following should be strengthened as part of the conditions of continuing support:

1. CAG advised there should be consistency and clarity of language between internal standard operating procedures and public facing information, particularly in relation to the PHE list of disclosures and references to identifiability. The CAG did not specify a time period for completion; the SofS decided this must take place immediately.

2. CAG had advised that the patient information leaflet did not provide sufficient clarity of the different processing purposes that were taking place under the COPI Regulations, and this should be revised in line with advice and reported against at time of annual review. The SofS decided this must take place far sooner and should be fully revised by May 2018 as this would also support transparency requirements under the GDPR.

3. The SofS has decided that the CAG should be provided with a copy of the revised leaflet immediately to ensure it is sufficient for COPI Regulation support purposes.

CAG minutes dated 25 January 2018 were updated post-ratification in light of the SofS decision and re-published to reflect the original CAG advice and the additions made by the SofS.

8. CAG CHAIR REPORT – JANUARY 2018

The Chair's report for January 2018 was received and considered at the meeting.

9. ANY OTHER BUSINESS

The Group discussed possible future educational items which would be recorded by the Confidentiality Advice Team for further investigation.

A high-level overview on the progress with CAG Member recruitment was provided for information purposes.

The Confidentiality Advice Team reminded Members to submit any expense claims in a timely fashion as the financial year end approached.

The Chair thanked Members for their time and consideration and the meeting was concluded.