Minutes of the meeting of the Confidentiality Advisory Group

28 April 2022 at HRA London, Skipton House

Present:

Name	
Dr Malcolm Booth	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr David Evans (absent for Items 3a & 3b)	CAG member
Dr Katie Harron	CAG member
Mr Tony Kane	CAG member
Professor Jennifer Kurinczuk (absent for Item 4a)	CAG member
Dr Harvey Marcovitch	CAG member
Mr Umar Sabat	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

1. Introduction, apologies and declarations of interest

Apologies from Mr Dan Roulstone from 11am onwards.

Mr David Evans declared a conflict of interest for items 3a and 3b and left the meeting for the duration of this discussion.

Mr Umar Sabat raised a potential conflict of interest with item 3b, noting that he worked as the Information Governance lead for some CCGs, and therefore may discuss local data flows to enable validation to happen. The CAG determined that this was not a true conflict of interest and Mr Sabat remained in the meeting for the duration of this discussion.

Professor Jenny Kurinczuk declared a conflict of interest for item 4a as the ASCEND PLUS study application has been submitted by the department she works in. Professor Kurinczuk left the meeting for the duration of this discussion.

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were discussed at the 24 March CAG meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **24 March 2022** meeting applications.

3. Annual Reviews

a. CAG 7-04(a)/2013 - Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs

Context

The current application has relied on Regulation 5 support since January 2014 to provide a legal basis for GP data and secondary care data (from NHS Digital) to be linked by "approved organisations". Doing so enables GPs to identify at risk patients and allows for targeted interventions to be made as early as possible (risk stratification).

In 2014 it was indicated that reliance on Regulation 5 support would be a temporary measure until new legislation was in place to provide an alternative legal basis. However this has not yet been possible with Regulation 5 support in place until 30 September 2022.

In October 2017, CAG clarified that support was not in effect for the purpose of population health management following a third party concern. Subsequently a third party raised a number of concerns on the use of data in the risk stratification activity that suggest the risk stratification activities are acting outside the scope of Regulation 5 support.

Because of this the 2021 annual review for this application was escalated for consideration at a full meeting of the CAG.

Confidentiality Advisory Group Advice

Broadly, there were concerns that the conditions of support set out in the non-compliance with conditions as set out in 2014 and that the third-party concerns indicate that the risk stratification activity is acting outside the scope of Regulation 5 support. As such it was agreed there was a risk to public confidence being undermined, and that GPs were at risk of inadvertently sharing of confidential patient information without a common law legal basis given the application is managed on behalf of GPs.

Given these issues CAG advised that a new application is submitted prior to 30 September 2022.

Compliance with conditions of support

The Regulation 5 support letter dated 23 January 2014 contained 11 conditions of support. Whilst some of these conditions were short term and met, a number of others were expected to be maintained for the duration of support. From the documentation provided there were three particular areas where CAG members did not have assurance that the condition of support is being met.

Whilst some CCGs/GPs may be locally complying with conditions members reiterated that any that do not comply with these conditions are breaching the terms of Regulation 5 support and as such will not have a legal basis to undertake risk stratification.

- **Detail on how right of patient objection will be managed.**

It was indicated that there had been no patient objections or public feedback had been reported and that patients are able to opt out locally if desired, as advised through local communications with patient groups and notices at practice level. Prior to the meeting the applicants were asked for further information on how the population is informed about risk stratification and provided an opportunity to opt-out, how this is communicated and how objections would be managed in practice.

In response NHS England indicated that responsibility for compliance to ensure that patient notification materials and local opt out information are in place rests with the data controllers, and that NHS England have not monitored the CCGs/GPs compliance with this.

A principle of CAG support is that patients are informed about the use of their data and have the opportunity to opt out of its use. Whilst appreciating that NHS England manage the application on behalf of CCGs/GPs, members agreed that the response provided did not provide sufficient detail for CAG to be assured that patients are made aware of the use of their data for risk stratification purposes and have the ability to opt out.

As part of the revised application, members requested that NHS England provide a clear communications plan for risk stratification that can be utilised by CCGs/GPs, with example patient notification materials provided. The communications plan should be proportionate to the scale of the disclosure, as it is understood that risk stratification encompasses all patients in England.

- **Risk stratification suppliers to meet the necessary security and assurance standards in place for all applications approved under Regulation 5, and to achieve compliance with all conditions established by the HSCIC (or relevant bodies) before information under this application can flow.**

It is DHSC policy that all entities operating under Regulation 5 support must achieve and maintain the relevant DSPT standard through NHS Digital verification of the self-assessed submission, as per standard application process guidance. Any legal entities that are not verified by NHS Digital are breaching the conditions of support and as such do not have a legal basis to undertake risk stratification.

Members noted that this issue has been raised a number times with NHS England. A review by the Confidentiality Advice Team identified five legal entities currently do not have their DSPT assurance verified by NHS Digital.

Whilst these suppliers impact a minority of CCGs undertaking risk stratification it was noted by CAG members that until recently some larger risk stratification suppliers had not had their DSPT submissions verified by NHS Digital which placed a risk to significantly more CCGs.

As part of a resubmission it is expected that NHS England take steps to ensure that NHS Digital verifies DSPT submission for all risk stratification suppliers. It is suggested that this is undertaken as soon as the deadline for 2021/22 DPST submission passes on 30 June 2022 in preparation for a revised submission.

- **Submission of an annual review**

It is a standard condition of support that an annual review is provided every 12 months for the duration of support. It was noted that no annual review was provided between 2015-2020, and members were clear that moving forward an annual review should be submitted every 12 months.

Third party concerns

A number of concerns were raised by a third party that at least some CCGs are extending the use of risk stratification data to other purposes or using additional data flows as part of risk stratification.

Whilst some CCGs may be acting within scope of Regulation 5 support, CAG expressed their concern that risk stratification was acting outside the scope of support, and that the associated evidence provided indicate merit in these concerns. The annual review submission also stated "*CCGs using the data for their wider commissioning functions are not able to view identifiable data*" which indicated that risk stratification data is being used for wider commissioning purposes not supported under Regulation 5.

Members reiterated that any activities being undertaken outside the scope of Regulation 5 support (both flows and purposes) are done so without a clear common law basis. The revised application should, if necessary, include updated dataflows/purposes for consideration by the CAG.

Monitoring of CCG activities

Due to the above issues' members paid particular attention to the monitoring that NHS England undertakes of CCGs through use of a self-reported questionnaire.

As a result of the third party concerns a short narrative was requested to assure that the application operates in line with support. The response stated referred only to the audit responses as assurance that organisations were using the data in line with the supported

activities. Given the concerns raised the response did not provide assurance to CAG that risk stratification is being undertaken in line with Regulation 5 support, and that there are sufficient processes in place to monitor compliance.

Members were clear that the revised application should provide a comprehensive monitoring plan to assure CAG that processes are in place to ensure CCGs undertake risk stratification activities within the scope of support.

Exit Strategy

The application was initially supported in 2014 on the understanding that new regulations were being worked on to allow exit from reliance on Regulation 5 support. This support has subsequently been extended, currently due to end in September 2022.

There was uncertainty on the current work being undertaken to seek an alternative legal basis in the current annual review and CAG requested that a revised application provides information to demonstrate a clear exit strategy.

Public Interest and Patient and Public Involvement

CAG were unclear on the benefits that have been achieved on using substantial volumes of patient information for risk stratification. Members agreed that a revised application should provide demonstrable evidence of the benefits that risk stratification provides, with detail of the improved outcomes that have been achieved. Given the length of time that risk stratification has been ongoing members felt that demonstrating this should be achievable.

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.

It was however unclear what patient and public involvement activity has been undertaken in relation to risk stratification to demonstrate the public interest in the activity. As such, CAG requested evidence and outputs of recent public involvement as part of the revised application. This involvement should be proportionate to the scale of disclosure of data under risk stratification.

Change in legal entities

Members noted that it is expected CCGs will cease to be legal entities in July, to be replaced by Integrated Care Boards (ICBs). It was unclear how this change would impact on risk stratification and members asked for a revised application to take this into account.

Confidentiality Advisory Group advice conclusion

The CAG had a number of concerns that conditions of support are not being met, that the scope of activity has extended beyond which is supported, and that there is not adequate monitoring of local activities.

It was noted that third party concerns have been raised to other national organisations and it was agreed that CAG concerns will also be communicated to them.

CAG advised recommending continued support to the Secretary of State for Health and Social Care until 30 September 2022, subject to compliance with pre-existing standard conditions and, and the specific conditions of support as set out below.

Specific conditions of support

The CAG agreed that any request to extend support post 30 September 2022 should be done as part of a revised submission to be considered at a full CAG meeting.

The new application should address the following:

1. Clarity on the scope of support requested, both in terms of dataflows and purposes

2. Clear communication strategy with examples of patent notification materials

3. Detail on how local patient objection mechanisms will be managed, and clarity that the National Data Opt Out will be applied.

4. Evidence that risk stratification suppliers have had DSPT submissions verified by NHS Digital.

5. A comprehensive monitoring plan to ensure local activities remain within the scope of support

6. Detail, with anticipated timescales, of a clear exit strategy from Regulation 5 support

7. Demonstrable evidence of the improved outcomes and benefits that risk stratification has had to date.

8. Consideration whether change in legal entities from CCGs to ICBs impacts risk stratification and how.

Membership of the Committee

Mr David Evans registered a conflict of interest and left the meeting whilst this item was discussed.

b. CAG 7-07(a-c)/2013 - Invoice Validation applications

Context

The current application has relied on Regulation 5 support since November 2013 to provide a legal basis for data to flow to Clinical Commissioning Groups (CCGs) and Commissioning Support Units (CSUs), to enable the correct commissioner to be identified to allow payment for treatment (invoice validation).

In 2013 it was indicated that reliance on Regulation 5 support would be a temporary measure until new legislation was in place to provide an alternative legal basis. However this has not yet been possible with Regulation 5 support in place until 30 September 2022.

Confidentiality Advisory Group Advice

Compliance with conditions of support

The Regulation 5 support letter dated 22 November 2014 contained 12 conditions of support. Whilst many of these conditions were short term and met, some were expected to be maintained for the duration of support.

The principle area of non-compliance for this application was ensuring that Controlled Environments for Finance maintain adequate security assurances.

It is DHSC policy that all entities operating under Regulation 5 support must achieve and maintain the relevant DSPT standard through NHS Digital verification of the self-assessed submission, as per standard application process guidance. Any legal entities that are not verified by NHS Digital are breaching the conditions of support and as such do not have a legal basis to undertake invoice validation.

Members noted that this issue has been raised a number times with NHS England. A review by the Confidentiality Advice Team identified sixteen legal entities currently do not have their DSPT assurance verified by NHS Digital.

CAG agreed that NHS England should provide an updated report on the security assurances for the above organisations withing one month of this letter. It is expected that NHS England take steps to ensure that NHS Digital verifies DSPT submission for all controlled environments..

- **Submission of an annual review**

It is a standard condition of support that an annual review is provided every 12 months for the duration of support. It was noted that no annual review was provided between 2015-2020, and members were clear that moving forward an annual review should be submitted every 12 months.

Changes in NHS landscape

CAG noted that the commissioning landscape will be altered because of the upcoming change from CCGs to Integrated Care Boards (ICBs). It was unclear to members how this will impact invoice validation activities given the scope of the application and that a number of CCGs act as Controlled Environments for Finance.

As such, CAG asked for an indicative timeframe as to when the applicants will have clarity on any modifications to support that may be necessary with changes from CCGs to ICBs, within one month from the outcome letter being issues. Once the reorganisation is clear CAG will be requesting a revised application to be submitted to CAG.

Exit Strategy

The application was initially supported in 2013 on the understanding that new regulations were being worked on to allow exit from reliance on Regulation 5 support. This support has subsequently been extended, currently due to end in September 2022.

There was uncertainty on the current work being undertaken to seek an alternative legal basis in the current annual review and CAG requested further anticipated timescales for exiting support be provided as part of the resubmission.

Public Interest and Patient and Public Involvement

CAG discussed the public interest of the activity and were clear that the activity was necessary and needs to continue.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending continued support to The Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below

Specific conditions of support

Within one month from the date of the outcome:

1. Provide assurance that the organisations listed above have had their DSPT submissions assured by NHS Digital.

2. Give an anticipated timeframe for when clarity will be gained on how the change from CCGs to ICBs will impact the invoice validation application.

Following receipt of this information CAG will request a revised application within an agreed timeframe. This revised application should detail the steps to be taken to exit from support, and a timeframe as to when it is expected this will be achieved.

Membership of the Committee
Mr David Evans registered a conflict of interest and left the meeting whilst this item was discussed.

4. New applications

a. 22/CAG/0062 – ASCEND PLUS

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to determine whether use of Semaglutide can safely help to reduce cardiovascular problems in patients with Type 2 diabetes who have not previously had a heart attack or stroke.

People with type 2 diabetes mellitus (T2DM) are at twice the risk of suffering cardiovascular events, such as heart attacks and stroke, compared to those without diabetes. Previous large-scale randomised clinical trials conducted involving patients with T2DM who have, or are at a high risk of developing, cardiovascular disease have established that treatment with glucagon-like peptide-1 (GLP-1) receptor agonists reduced cardiovascular events. The treatments can also improve blood sugar control, reduce weight and blood pressure, and may also reduce deterioration in kidney function and the metabolic complications of T2DM. However, such treatments require regular injections and uptake of the treatments are low in the UK and globally. Oral Semaglutide is the first oral GLP-1 receptor agonist. Its effects on blood sugar, weight and blood pressure are similar to injectable GLP-1 receptor agonists. The trials conducted so far have involved patients with T2DM and existing cardiovascular disease, or who are at a high risk of developing cardiovascular disease. The applicants seek to conduct a trial to assess whether oral Semaglutide should be used in a broad range of people with T2DM at moderate to high cardiovascular risk.

NHS Digital will identify potentially eligible patients. The National Data Opt-Out will be applied, as well as a study specific opt-out. NHS Digital will also undertake a vital status check and obtain up-to-date addresses. The data linkages undertaken at NHS Digital will be carried out under Directions, in line with the Pilot NHS DigiTrials Recruitment Support Services Direction 2021. Support is required to disclose the dataset, containing confidential patient information,

will be disclosed to Paragon Customer Communications. Paragon generate the invitation letter with patients NHS numbers securely encoded into the Replay Form and then send the invitation letters and information sheets to patients. Patients wishing to take part then send the Reply Form to the study team in Oxford. The patients' participation will then proceed on a consented basis.

A recommendation for class 3, 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.

Cohort	Patients aged 55 years and over diagnosed with Type 2 diabetes.
Data sources	1. NHS Digital held datasets: a. Hospital Episode Statistics Admitted Patient Care b. NHS BSA Medicines Dataset c. Personal Demographics Service Dataset
Identifiers required for linkage purposes	1. Name 2. NHS number 3. GP registration 4. Date of birth 5. Postcode – unit level
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Postcode – unit level 4. 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.

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Scope

Following their initial submission of the application, the applicants had made significant changes to the recruitment methodology. The data linkages undertaken at NHS Digital will be carried out under Directions, in line with the Pilot NHS DigiTrials Recruitment Support Services Direction 2021. Therefore, support under s251 is only required for the disclosure of confidential patient information from NHS Digital to Paragon Customer Communications to facilitate the sending of the invitations. The University of Oxford would only process confidential patient information after patients had consented.

The CAG noted that a large amount of confidential patient information will be processed after patients had consented. The data collected for the study would also be retained for 25 years after the study had finished. As this processing will take place after consent, this was outside the CAG remit, however members recommended that the applicant check with NHS Digital that their standards have been met and that they are satisfied that the consent taken is sufficient, to minimise the likelihood for potential amendments or resubmissions to the CAG in future.

Practicable alternatives

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

- **Feasibility of consent**

The applicants seek to include 20,000 patients in the study. The size of the cohort meant that alternatives were not practicable. The applicants noted that open advertisement for volunteers using posters and advertising in previous studies has led to a low response rate. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Paragon Customer Communications require access to confidential patient information in order to facilitate the sending of invitation letters to eligible patients. The CAG agreed that the recruitment could not feasibly be undertaken in any other way.

Justification of identifiers

The CAG noted that patients' ethnicity was not collected and queried whether it should be. Members agreed that this came under the scope of the REC review rather than CAG, as this data was not required to identify and contact patients, but recommended that

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants advised that it would be difficult to publicise the study via posters or notices in waiting rooms. Information will be hosted on the study website and other relevant websites, such as the National Institute for Health Research (NIHR) Be Part of Research website. In addition, NHS Digital will create a study specific page on their website.

A maximum of two contact attempts would be made. If patients do not respond to the first invitation letter, a further invitation letter may be sent.

The applicant provided the Invitation Letter, Reply Form and Initial Invitation Letter. These documents don't clearly advise patients that they can dissent from further contact. Patients contacted will be asked to return the reply form. A maximum of two contact attempts would be made.

The National Data Opt-Out will be applied by NHS Digital before the confidential patient information is released to Paragon Customer Communications. The

applicants will also work with NHS DigiTrials to provide a study specific opt-out, similar to that set up for NHS Galleri (21/CAG/0056).

The CAG reviewed the provided documents and agreed that the patient facing materials were well written and easy to understand. However, members agreed some changes were required. The Initial Invitation Letter needed to advise patients that they could request not to be contacted again and give telephone, postal and email contacts to do so. The patient information leaflet also needed to explain the role of DigiTrials and how confidential patient information was processed to identify and contact patients.

The patient facing materials also described that no hospital or clinic visits will be required for the study. This should say that no additional hospital or clinic visits are required.

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 provided a PPI report. This report explained that two lay members had been recruited to the Trial Steering Committee. A series of six patient and public focus groups had been held between June and October 2021. A summary of the individual groups, the materials considered, and the impact was provided.

In the CAT advice form the applicants explained that the proposed data flow, including use of a third-party supplier to facilitate the sending of invitation letters, had been discussed at two “Research for the Future” focus groups. The applicants state that there was no concern from focus group participants about the use of a third-party mailing house. However, no detailed feedback from these discussions had been provided.

A Trial Steering Committee had been set up, which included two lay members. Members of the public also had input into the creating of the patient facing information.

The patient and public involvement activity conducted so far had included discussion of the previous data flow. The CAG noted that that the revised data flow was less disclosive than the previous flow but agreed that patient and public involvement needed to be conducted to discuss the revised data flow and use of NHS DigiTrials. The use of confidential patient information without consent also needed to be explicitly discussed.

Exit strategy

Paragon Customer Communications will destroy the personal data about potentially eligible participants 30 days after mailing the invitation letter.

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, the applicant is required to respond to all requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The patient notification materials need to be revised as follows:

    a. The Initial Invitation Letter needs to advise patients that they can request not to be contacted again and give telephone, postal and email contacts to do so.

    b. The patient information leaflet needs to explain the role of DigiTrials and how confidential patient information was processed to identify and contact patients.

    c. The patient facing materials need to be revised to state that no additional hospital or clinic visits are required, rather than no hospital or clinic visits are required.

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. Further patient and public involvement activity needs to be conducted to discuss the revised data flow and use of NHS DigiTrials. The use of confidential patient information without consent also needs to be explicitly discussed and feedback provided. This feedback needs to be provided within three months of the issuing of the final outcome letter.

2. Favourable opinion from a Research Ethics Committee. **Pending.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

Confirmed:-

The NHS Digital 2020/21 DSPT review for NHS Digital was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 April 2022).

Pending:-

The NHS Digital 2020/21 DSPT review for Paragon Customer Communications is pending.

b. 22/CAG/0059 – Whitehall II – The Stress and Health Study

Context

Purpose of application

This application from University College London set out the resubmission of the Stress and Health Study (Whitehall II), which was originally started in 1985 to advance knowledge of the

effects of social circumstances on health and the biological pathways by which they operate, with a particular focus on cardiovascular disease.

Life expectancy has doubled in the last century, which has led to increasing median age in the UK. Understanding the specific morbidities which are more common at higher ages is a key societal and scientific priority. Increasingly, research suggests that it is midlife levels of risk factors that are important for health outcomes in old age. The W-II research design, which involves repeat measures of both risk factors and functioning starting in midlife, is ideally suited to allow the identification of the best targets of preventing these age-related conditions. Measures included blood pressure, blood sugar, blood lipid levels, height, weight, cardiovascular tests, walking speed, lung function, questions about diet, and five tests of mental functioning.

All participants were initially recruited in 1985 and have been followed up with clinical screenings at 3-5 years intervals. Patients were consented at recruitment and re-consented at each of the 13 phases via questionnaires and clinical assessments. The study database is held at the University College London Data Safe Haven (UCL DSH). In 2014, support was given to allow the applicants to disclose confidential patient information to NHS Digital and SAIL to link to death certificates, cancer registrations, HES data and MHMDS data. In 2016 an amendment was supported to extend support to access of Diagnostic Imaging Data for this cohort, via NHS Digital. Support was required as NHS Digital had determined that the consent in place did not cover the proposed data linkages.

The application was originally supported in 2014, under reference CR2/2014. This study had previously accessed data under the NHS Central Register (ECC 2-04(c)/2010) application. When the applicants submitted their 2021 annual review, they were asked to submit a refreshed application as the previous application had been made on a bespoke application form and important information was missing.

A recommendation for class 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers.

Cohort	5253 participants who were recruited into the Whitehall II study in 1985. The applicants anticipate that around 4900 participants will take part in phase 13.
Data sources	1. The following datasets, provided by NHS Digital and SAIL: a. HES APC (1989-2019) b. HES Outpatients (2003-2015) c. HES A&E (2009-2019) d. Mental Health Minimum Data Set (2006-2015) e. Mental Health and Learning Disabilities Data Set (2014-2016)

	f. Mental Health Services Data Set (2017-2018) g. Diagnostic Imaging Dataset with Bridge file (2012-2018) h. MRIS - Members and Postings Reports (2017-2018) i. MRIS - Cohort Event Notification Report (Historical 1987-2020) j. MRIS - Cause of Death Report (Historical 1987-2020) k. Demographics (latest available) l. Civil Registrations - Deaths (latest available) m. Cancer Registration Date (latest available) n. COVID-19 data sets CHESS(SARI-WATCH) and SGSS
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Date of death 5. Postcode – unit level
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode – unit level 5. Gender 6. Occupation 7. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application was in the public interest and had a clear medical purpose.

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**

Participants in Whitehall II were consented when they were recruited in 1985. NHS Digital have since determined that the consent in place does not extend to the proposed data linkages to datasets they hold. The applicants therefore applied for support under s251 in 2014.

In the answer to Q31-1, the applicants explained that patients still participating have been re-consented at each phase. As recruitment took place in 1985, the applicants advised that they have not been able to update consent for those no longer participating.

In their answers to the CAT advice form, the applicants stated that they have not sought to obtain updated consent from those still actively participating and requested that support continued for all participants. This includes those who are still actively participating, as well as patients who have died, been lost to follow up or no longer respond to contact attempts.

10,308 participants were originally included in the study. Around 5,000 are participating in Phase 13 (taking place in 2019-22). The applicants advised that most participants are too old, tired, unwell or sick to respond or undergo the clinical examinations and that not consenting to these activities does not mean that they would object to the data linkages to NHS Digital.

The applicants also noted the risk of bias and the potential impact on the study as the ongoing Wellcome Trust funded research programme examines proteins measured in 1997-1999 as predictors of later-life Alzheimer's disease. Attempting to re-consent patients, if non-response was considered to be dissent, may mean that patients with cognitive impairments are removed from the study.

The applicants advised that they could discuss re-wording the consent from with NHS Digital before Phase 14 begins. This would mean those actively participating were consented to the NHS Digital data linkages. S251 would still be required for participants unable to respond or participate in Phase 14 and those lost to follow-up. Reliance upon regular up-to-date consent and the inevitable loss of follow-up data through non-response would make reliable longitudinal epidemiological research with repeat follow-ups impossible in the UK.

The outcome letter from the 2014 review requested that efforts were made to inform participants about the data linkages, but did not specifically state that consent needed to be sought. The applicants had cited a potential risk of bias or the loss of patients, as patients may be too unwell to consent, and this was accepted. However, the CAG felt that consent needed to be explicitly sought for the data linkages from patients in the following circumstances:

- Patients who were still actively responding - once it is clear that they are still responding.
- The patient group that have the capacity to consent to the visits which are required as part of the study.

Both groups would be able to consent (or object) to the data linkages so consent should be sought from them during any visit or after they have responded.

The CAG agreed that patients who did not respond to requests for consent to the data linkage needed to be removed from the study. The invitation letter sent out to all participants should inform patients of the linkages and how to opt-out, but should not specifically seek consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for NHS Digital and SAIL to undertake linkages of patients in the Whitehall II cohort to datasets they hold. The CAG agreed that this could not be undertaken in any other way.

- **'Patient Notification' and mechanism for managing dissent**

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Participants in Whitehall II are sent newsletters between the collection phases. The newsletters sent during Phases 12 and 13 contained the following text, "In addition to the collection of questionnaire and clinical data, a crucial aspect of the study is the identification and verification of illnesses and health status, even after incapacity or death. This is achieved by securely linking with electronic health data such as cancer and death registrations, hospital records and mental health data. The linkage has been approved by NHS Digital under a very robust and safe system of provision of health data for research purposes." The newsletter was provided. The newsletter contained contact details should participants have queries, but did not mention withdrawal from the study or the ability to dissent to data linkages to NHS Digital.

The applicants will not attempt to contact patients who have withdrawn from the study. The Initial Contact Letter and Home Visit Initial Contact Letter provides contact details should participants have queries, but do not mention withdrawing from the research.

The CAG noted that the contact letter sent to patients for the current phase did not mention the data linkages to NHS Digital. Members also noted that the information on the website directed patients to the Type 2 National Data Opt-Out.

Members agreed that the participant notification and information materials needed to explain the data linkages to NHS Digital and advise how participants could opt-out of the use of their data for this purpose specifically.

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.

No patient and public involvement was described. The answers given to the relevant questions in the IRAS form did not describe patient and public involvement and the answer given on the CAT Advice Form describes patient notification activity rather than patient and public involvement.

The CAG agreed that further patient and public involvement needed to be undertaken around the use of confidential patient information without consent as described in the application. Feedback needed to be provided to the CAG.

Exit strategy

Core Whitehall II staff only will be able to access patients dates of birth and death. These staff will be tasked with contacting participants and managing linkage to e-RCHD. Once these two activities have ceased, the data items will converted to age and age at death.

Natcen will delete the confidential patient information used to contact participants once Whitehall II staff have checked the data collected from the last of the scheduled home visits. The last home visit is anticipated to take place in December 2022 and the applicants have allocated 3-4 weeks to check and verity the data sent by Natcen. Natcen should delete the confidential patient information they hold by February 2023.

REC Favourable Opinion

The CAG noted that the protocol was dated 2019 and did not describe the linkages. Members requested confirmation that the REC were aware of the data linkages to NHS Digital and have given a favourable opinion to this activity.

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 specific and standard conditions of support as set out below.

Specific conditions of support

1. Previous application CR2/2014 will be expired from the date of this letter, and replaced with 22/CAG/0059.

2. Consent needs to be explicitly sought for the data linkages from patients who are still actively responding. Provide feedback to the CAG within one month from the date of this letter.

3. The invitation letter sent out to all participants needs to inform patients of the linkages to NHS Digital and how to opt-out, but should not specifically seek consent. Provide feedback to the CAG within one month from the date of this letter.

4. The participant notification and information materials need to explain the data linkages to NHS Digital and advise how participants can opt-out of the use of their data for this purpose specifically. Telephone, postal and email contacts need to be provided for patients to register an opt-out. Provide feedback to the CAG within one month from the date of this letter.

5. Patient and public involvement needs to be undertaken around the use of confidential patient information without consent as described in the application. Feedback needs to be provided to the CAG, within two months from the date of this letter.

6. Provide confirmation that the REC are aware of the data linkages to NHS Digital and have given a favourable opinion to this activity. Provide feedback to the CAG within one month from the date of this letter.

7. Favourable opinion from a Research Ethics Committee. **Confirmed** (Previous Whitehall II application was under REC 16/SS/0003, Scotland A REC, The home visit leaflet refers to IRAS 142374, which relates to REC 85/0938. The applicants advised that they had used IRAS project 158963 for this refreshed application to CAG due to the age of their original REC application, and Favourable Opinion for 158963 was provided 02 February 2016)

8. 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 **2020/21** DSPT reviews for **University College London – School of Life and Medical Sciences, SAIL Databank within Swansea University and Natcen Social Research** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 05 May 2022).

c. 22/CAG/0066 – A pragmatic trial of an Artificial intelligence DRiven appOInTment maNagEment SyStem

Context

Purpose of application

This application from London South Bank University set out the purpose of medical research that seeks to investigate whether use of the DrDoctor appointment managing system increases the efficiency of patient appointments without compromising patient outcomes.

Managing out-patient appointments is a challenge to healthcare providers and patients, as missed appointments can lead to missed treatments and wasted capacity. Technology for improving attendance, such as DrDoctor, has been developed. This uses Artificial Intelligence to address the issues. The applicants are seeking to evaluate the efficiency of the DrDoctor technology. The technology has three main elements; a Did-Not-Attend (DNA) system which predicts how likely it is that patients will attend, a linked appointments system, which monitors the impact of appointment changes in one care pathway on other pathways, and a decision support tool which recommends the appointment type and urgency of appointment to clinical staff, based on the patient provided information.

Patients will be sampled from a single intervention site, Nottingham University Hospital Trust and a single comparator site, Imperial College Healthcare NHS Trust London. Participating NHS Trusts will disclose confidential patient information to London South Bank University (LSBU) and held within the UKFAST Secure Cloud Data Storage. Confidential patient information, containing hospital patient ID, will also be disclosed to LSBU from DrDoctor. The DrDoctor data and data from hospital trusts will be combined. LSBU will create a unique identifier and the dataset for analysis will be pseudonymised using this identifier. A separate dataset, containing confidential patient information, will be retained until the data linkages and cross references are complete. There will be three data disclosures, one pre-covid, one pre-deployment of DrDoctor and post-deployment. The two datasets will then be combined, and all items of confidential patient information removed.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers.

Cohort	Patients aged 18 years and over attending renal, ophthalmology, oncology outpatient appointments at Nottingham University Hospital Trust (intervention site) and Imperial College Healthcare NHS Trust (the comparator site). Patients will be eligible for inclusion in the analysis if they enter the service within one of the sampling periods (pre-COVID, pre deployment and 3 months post final deployment). • Pre-COVID = 1st May 2019

	• Pre-deployment = 1st May 2022 • Post-deployment = 1st April 2023 The applicants anticipate that 500,000 patients will be included in the cohort where confidential patient information will be processed without consent.
Data sources	1. Patient data supplied by participating trusts 2. Patient data provided by the DrDoctor Patient Engagement Platform,
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID number 3. Date of birth 4. Postcode – District Level
Identifiers required for analysis purposes	1. Postcode – District Level 2. Gender 3. Occupation 4. Ethnicity
Additional information	After data linkage, patients date of birth will be converted to age by year.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Legal basis

Article 22 of the UK GDPR has additional rules to protect individuals if solely automated decision-making is carried out that has a legal or similarly significant effect on them. GDPR is strict around use of special category data and processing described in Article 22(1) can only be carried out if explicit consent is in place for individuals or the processing is necessary for reasons of substantial public interest.

The activity proposed in the application may fall under Article 22 if decisions about patient care are made solely by automated means without any human involvement and members queried whether this was the case. If so, the applicants needed to provide details on the legal basis under which DrDoctor is operating, taking Article 22 into account.

Scope of support

The CAG noted a lack of clarity over whether confidential patient information was disclosed to DrDoctor, as a separate organisation, or whether DrDoctor was software that sat on the systems of participating trusts, meaning that no confidential patient information left the trusts to flow to DrDoctor. Members asked the applicants to clarify.

If confidential patient information was disclosed to DrDoctor, members queried whether support under s251 was required for this disclosure or whether another legal basis was in place, i.e. if the disclosure to DrDoctor happened as part of routine care, separate to the research application.

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**

Consent will be sought from patients in the survey cohort.

The applicants advised that the size of the data collection cohort, 500,000 patients, meant that consent was not feasible.

The applicants noted that some patients were approached to take part in the survey. Although the breach in the common law duty of confidentiality would already have taken place, this still presented an opportunity to seek consent. When approached for the survey, patients must also be informed of the use of their data and given the opportunity to remove their information.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link the DrDoctor supplementary data to data supplied by participating NHS Trusts. The CAG agreed that this could not be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and

mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

An advert was provided, which included an email contact for the study team, should patients have queries or wish to dissent. An information sheet was provided for patients in the survey cohort.

Information about the study will be displayed on targeted NHS websites. The applicants will also contact relevant charities and ask that they display the advert.

The applicants noted that, during patient and public involvement, concerns had been raised about how patients with learning disabilities, cognitive impairment or lack of digital access will be informed. Posters would also be placed in the outpatient departments at participating trusts. Leaflets will also be distributed via clinicians.

This process will be started 4 weeks before the data collection commences, although patients will be informed that they can opt-out any time after data collection has commenced. The CAG noted that patients would no longer be able to opt-out once the dataset had been anonymised, as patients could no longer be identified and removed. The timescale for opt-out needed to be made clear and patients informed of the date after which they will no longer be able to opt-out.

The patient notification materials needed revision to give further details on DrDoctor and the purpose of the research. The Opt-out advert advises that "The evaluation team (based at London South Bank University) has permission from the Health Research Authority to access your health records." This should be revised and the following wording was suggested, "The application was reviewed by the HRA Confidentiality Advisory Group who recommended to the HRA Decision Maker that support was given under Regulation 5 of the Control of Patient Information Regulations to allow the applicants to process confidential patient information without consent."

Participating NHS trusts will ensure that the National Data Opt-Out will be applied. Further updates every 6 months during the project lifecycle will check for additional patients who have opted out and their data will be removed from the study. Participating trusts will also ensure that patient records are checked for evidence of existing dissent.

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.

A PPI group was consulted about the acceptability of the approach of using confidential patient information without patient consent to gain their feedback. Minutes from this focus group meeting were provided (CAG - discussion with PPI group edited 300322). The PPI Group was formed of seven people; four with lived experience of kidney disease (one young male of south Asian heritage, one older white male, one middle-aged woman of African heritage, one middle-aged white British woman) and three with lived experience of cancer (one older white male, one

middle-aged white male and one male carer of South Asian heritage). A meeting was held with this PPI Group in October 2021, which focused specifically on the CAG application.

The CAG noted that the responses given by participants during the patient and public involvement activity were difficult to understand. Members asked that further patient and public involvement was undertaken specifically around the use of confidential patient information without consent and feedback from this provided to the CAG.

Exit strategy

The applicants advised that, once the data linkages are complete, and the data has been transferred into the master record and verified, then the NHS numbers will be deleted. Patients' date of birth will also be converted to age in years. The dataset will then no longer be identifiable.

The CAG requested clarification on how long confidential patient information would be retained in identifiable form and when the dataset would be anonymised.

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, the applicant is required to 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. Details need to be provided on the legal basis under which DrDoctor is operating, taking Article 22 of UK GDPR into account.
2. Clarify whether confidential patient information is disclosed to DrDoctor as a separate organisation, or whether DrDoctor is software that sits on the systems of participating trusts, meaning that no confidential patient information left the trusts to flow to DrDoctor.
3. If confidential patient information is disclosed to DrDoctor, clarify whether support under s251 is required for this disclosure or whether another legal basis is in place.

4. Patients approached to take part in the survey must also be informed of the use of their data and given the opportunity to remove their information.
5. The patient notification materials need to be revised as follows;
    a. The timescale for opt-out needs to be made clear and patients informed of the date after which they will no longer be able to opt-out.
    b. Further details need to be provided on DrDoctor and the purpose of the research.
    c. The statement “The evaluation team (based at London South Bank University) has permission from the Health Research Authority to access your health records” in the Opt-Out adverts needs to be revised and the following wording was suggested, “The application was reviewed by the HRA Confidentiality Advisory Group who recommended to the HRA Decision Maker that support was given under Regulation 5 of the Control of Patient Information Regulations to allow the applicants to process confidential patient information without consent.”
6. Further patient and public involvement needs to be undertaken specifically around the use of confidential patient information without consent and feedback from this provided to the CAG.
7. Clarify how long confidential patient information will be retained in identifiable form and when the dataset would be anonymised.

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

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:** Favourable Opinion issued 01 April 2022.

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 **2020/21** DSPT reviews for Nottingham University Hospitals NHS Trust, Imperial College Healthcare NHS Trust and UFAST were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 May 2022).

   Pending:-

   The NHS Digital **2020/21** DSPT reviews for London South Bank University and DrDoctor Patient Engagement Platform are **pending**.

5. Minutes of the meeting held on 24 March 2022

The minutes of the meeting held on 24 March 2022 were not reviewed as an outcome is pending.

6. Any other business

No other business was raised.

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

Minutes signed off as accurate by correspondence from:-

Signed – Officers of CAG	Date
Dr Patrick Coyle, CAG Vice Chair	*07 June 2022*
Ms Clare Sanderson, CAG Alternate Vice Chair	*09 June 2022*

Signed – Confidentiality Advice Team	Date
Ms Laura Gordon, Confidentiality Advisory Group Assistant	*01 June 2022*