Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 10 December 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Nicola Bootland	Data Access Request Service (DARS)
JP Buckley	Privacy, Transparency and Ethics
Vicky Byrne-Watts	Data Access Request Service (DARS)
Garry Coleman	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS) (Observer: Item 4)
Gaynor Dalton	Privacy, Transparency and Ethics
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 3.1 – 3.4)
Jonathan Hope	Data Management
Frances Perry	Data Access Request Service (DARS) (Observer: Item 4)
Denise Pine	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat

Kimberley Watson	Data Access Request Service (DARS) (Observer: Item 4)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Nicola Fear noted a professional link with King's College London [NIC-207675-J4L7G] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 3rd December 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Paper**
2.1	<u>Cardiovascular Disease Prevention Audit (CVDPREVENT Audit) data collection – Briefing Paper (Presenters: Louise Dunn / Jonathan Hope / Nicola Bootland)</u> This briefing paper was to inform IGARD that NHS England have directed NHS Digital to collect and analyse data in connection with Cardiovascular Disease Prevention Audit (CVDPREVENT Audit). To deliver the audit, routinely recorded General Practice (GP) data will be extracted by NHS Digital via the GP Extraction Service (GPES) with an initial GPES extract containing historical information and then rolling three monthly extracts of routinely recorded GP data. The data will help clinicians to understand how well they are performing in the diagnosis and management of the six high-risk conditions for cardiovascular disease (CVD). The CVDPREVENT Audit is commissioned and delivered by several partners (Audit Partners), including NHS England and NHS Improvement (NHSE/I), Public Health England (PHE), the Healthcare Quality Improvement Partnership (HQIP) commissioned provider. It is anticipated that NHS Digital will only provide data to PHE, the only Audit Partner expected to request data from NHS Digital. The CVDPREVENT Audit is a new national primary care audit that will support the implementation of the NHS Long Term Plan, the annually negotiated General Medical Services contract and the national CVD Prevention programme. The aim of the audit is to support professionally led quality improvement, optimising diagnosis and treatment of high-risk conditions to prevent heart attacks and strokes at scale. The audit also aims to evaluate the national CVD Prevention programme and inform better decisions on its delivery. IGARD noted that the purpose of the audit was a really valuable and useful initiative with substantial benefits.

	Noting the limited nature of the direction, IGARD queried if this rich source of data could be placed within the Cardiovascular Trusted Research Environment (TRE); or, noting the previous discussion between IGARD and NHS Digital, if it could be added to the overarching NHS Digital Civil Registries data set. IGARD noted the different types of processing outlined for the three cohorts, and queried if there was any automated decision-making taking place. NHS Digital advised that it was their understanding that no automated decision making would take place. IGARD suggested that the Data Protection Impact Assessment (DPIA) was updated with further details and background as to why the conclusion had been reached there was no automated decision making in the creation of all the cohorts. IGARD queried what would happen, in the event that, data subjects that were originally identified as being part of cohort 3, whose data may not be required for any of the cohorts, following the processing and assessment; and what would happen to their data, and asked that the briefing paper was updated to provide further clarification. IGARD noted contradictory information within the briefing paper in respect of the National Data Opt-outs, and whether they would be applied, and asked that the briefing paper was updated to make it clear if National Data Opt-outs would be applied, and when; including, but not limited to, amending the contradictory footnote included within the briefing paper, relating to this issue. IGARD welcomed the briefing paper and looked forward to receiving a finalised briefing paper out of committee. Further details of the discussion will be noted in the published minutes. Key points to be addressed in the updated briefing paper and supporting documents: 1. To update the briefing note, to confirm if there will be any data subjects included within cohort 3 whose data may not be required after processing and assessment; and if so, to clarify what happens to their data. 2. To update the briefing note to make clear if and when the National Data Opt-out would be applied; and to amend the contradictory footnote within the briefing paper. 3. To update the DPIA to clarify why there is no automated decision making in the creation of all the cohorts.
3	**Data Applications**
3.1	<u>Public Health England: CVDPREVENT Audit (Presenter: Louise Dunn) NIC-395236-V3W9P</u> **Application:** This was a new application for access to pseudonymised Cardiovascular Disease Prevention Audit (CVD Prevent Audit) data. The purpose is for an audit, to support professionally led quality improvement, optimising diagnosis and treatment in these conditions to prevent heart attacks and strokes at scale. The audit will help clinicians to understand how well they are performing in the diagnosis and management of 6 high risk conditions for CVD. To deliver the audit, routinely recorded GP data about cardiovascular disease and the high-risk conditions that can cause cardiovascular disease, will be extracted by NHS Digital via GP Extraction Service (GPES). Data outputs from the audit will be available to all but will be targeted for use by health care economies including practices, primary care networks and CCGs. Information will also be generated to inform national policy and improvement work. Outputs will show variation in diagnosis and treatment across areas, provide new information on the occurrence and coexistence of CVD morbidities and also allow the impact of age, ethnicity and deprivation on CVD to be investigated. The adoption of the business rule set for CVDPREVENT at individual practice level will facilitate detailed case finding and quality improvement work within practices.

	NHS Digital advised IGARD that the *"audit partner"* referred to within the application had now been confirmed, and that the application would need updating to reflect this new information. **Discussion:** IGARD noted the updated from NHS Digital in respect of the *"audit partner"*, and supported the update to section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) reflecting this information. IGARD noted the references in section 1 and section 5(a) (Objective for Processing) to NHS England **and** NHS Improvement commissioning the audit, and queried if NHS Improvement should also be assessed as a joint Data Controller, along with NHS England and PHE. Citing the NHS Digital DARS Standard for Data Controllers / Data Processors, that if following the assessment that NHS Improvement **were** considered joint Data Controllers as borne out of the facts presented, IGARD asked that the application was updated throughout to reflect this; or if they were considered **not** to be joint Data Controllers, IGARD asked that the application was updated to remove references to NHS Improvement *"commissioning"* the work. IGARD queried the reference to PHE being the *"sole"* Data Controller in section 1(b) (Data Controller(s)) and asked that this was updated to correctly reflect the joint data controllership arrangements. IGARD noted the future organisational changes for PHE which were due to take place in 2021, and noted that this was prior to the end date of this Data Sharing Agreement (DSA), and asked what impact this may have on the joint data controllership arrangements outlined. IGARD suggested that NHS Digital liaise with their Data Security and Protection Toolkit (DSPT) Team, and determine whether extra protection was required, and if so, that the application be updated accordingly. IGARD noted that NHS England and PHE had cited two different General Data Protection Regulations (GDPR) Article 9 legal bases; and asked that section 1 and section 3 (Datasets Held / Requested) were updated with confirmation as to why the Data Controllers had different Article 9 legal bases; or that if the Data Controllers aligned their Article 9 legal bases, that the application was updated throughout to reflect this. IGARD queried what would happen in the event that data subjects that were originally identified as being part of cohort 3, whose data may not be required for any of the cohorts (following the processing and assessment) and what would happen to their data. IGARD asked that the application was updated to provide further clarification. IGARD queried the information in section 5(b) (Processing Activities) in relation to data access, in particular the statement *"They will, in effect, only be viewing the data which will physically remain within the Server environment"*, and asked that this was removed as it was not relevant. IGARD noted a number of acronyms in section 5(a) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"CVDPREVENT"*. IGARD noted the information with section 5(c) (Specific Outputs Expected) in relation to potential future use of the data, and the statement *"This will be subject to approval by the Independent Group Advising on Releases of Data (IGARD)"* and asked that this was amended to ensure it accurately reflected the advisory role of IGARD, and that the full name of IGARD was correct. IGARD noted the explanatory information relating to the NHS Long Term Plan within section 5(d) (Benefits), and suggested that this useful key information was moved and added to the beginning of section 5(a).

	IGARD queried contradictory information in section 5(d) that referred to identifying individuals with high-risk conditions; and noting that this is not reflected elsewhere in the application, asked that this was updated to ensure that it was clear that the outputs would support clinicians to only identify the *features* of at-risk patients, not actual individual patients. Due to the current COVID-19 pandemic, IGARD noted that PHE staff were home working and accessing the data via home computers; and asked that a special condition be inserted in section 6 (Special Conditions) that it was permissible, and that the relevant NHS Digital security advisor's standard wording was also inserted. IGARD noted that section 2 (Locations) contained the home addresses of staff members, and advised that although they understood the requirement to be transparent, this information should be removed to align with the NHS Digital DARS Standard for Processing and Storage Locations. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the data controllership: a) To assess whether NHS Improvement are a joint Data Controller, in light of the information provided in the application regarding joint commissioning with NHS England. b) If NHS Improvement **are** considered joint Data Controllers, to update the application throughout to reflect this. c) If NHS Improvement are **not** considered joint Data Controllers, to update the application throughout to remove references to them *"commissioning"* the work. The following amendments were requested: 1. In respect of the Article 9 legal bases: a) To update section 1 and section 3 with confirmation as to why the joint Data Controllers have stated different Article 9 legal bases. b) If the Data Controllers align their Article 9 legal bases, to update the application throughout to reflect this. 2. To update section 1 and section 5 to name the *"audit partner"* organisation. 3. To update section 1(b) to reflect the **joint** data controllership arrangements. 4. To amend section 5(b) to remove the sentence that starts *"They will, in effect, only be viewing the data…"*. 5. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example *"CVDPREVENT"*. 6. To provide a further explanation in section 5(b) outlining what happens to any data fields if they fall outside the 3 cohorts, for example: is the data deleted. 7. To amend the statement in section 5(c) relating to 'IGARD' to ensure it accurately reflects their advisory role and that the 'IGARD' name is correct. 8. To move the explanatory information relating to the NHS Long Term Plan from section 5(d) and add to the beginning of section 5(a). 9. To update section 5(d) to ensure that it is clear that the outputs will support clinicians to only identify the *features* of at-risk patients, not actual individual patients. 10. To remove the reference to a home address from section 2. 11. To update section 6, to insert a special condition that access via home computers and home working is permissible as per NHS Digital Security Advisor's standard wording. The following advice was given:

	1. IGARD suggested that NHS Digital liaise with their DSPT Team in relation to PHE's current DSPT and whether extra protection is required, in light of future organisational changes. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
3.2	<u>IQVIA Technology Services Ltd: HES data for IQVIA clinical trial site identification (Presenter: Denise Pine) NIC-210151-K9C7G</u> **Application:** This was an amendment application to 1) remove IQVIA Solutions UK Limited as a joint Data Controller, joint Data Processor and to amend the respective processing and storage locations to reflect this; 2) to update the application throughout to replace references to Solutions UK Limited with IQVIA Ltd and IQVIA Technology Services Ltd; and 3) to update the yielded benefits. The purpose of the application is to use pseudonymised Hospital Episodes Statistics (HES) data to analyse estimated patient populations at all hospitals in the UK; and compare these with similar estimates of patient populations in other countries in which IQVIA and its Affiliates undertake Clinical Trial Site Identification (CTSI) (using data sources specific to those countries). This information helps clients of IQVIA and its Affiliates to select suitable countries in which to recruit patients into clinical trials, in order to develop new medicines and treatments for patients. NHS Digital advised IGARD that following submission of the application for IGARD to review, the Data Sharing Agreement (DSA) end date had been updated from July 2022, to December 2021, and in alignment with other commercial applications. NHS Digital noted the statement in section 5(b) (Processing Activities) *"…and their Affiliates would identify which doctors work at the hospitals…"*, and advised that they believed this was incorrect, however this would be clarified with the applicant and removed as necessary. **Discussion:** IGARD noted and supported the update from NHS Digital, in respect of the update to the application that reflected the revised end date of December 2021. IGARD also agreed with NHS Digital that the statement in section 5(b) in respect of affiliates being able to identify Doctor's, appeared to be incorrect, and supported the removal of this. IGARD queried the reference in section 5(a) (Objective for Processing) to *"national (UK) data",* and asked that this was amended to correctly align with the territory of use in section 2(c) (Territory of Use), which stated *"England and Wales"*. IGARD queried the statement in section 5(b) *"It will not be possible to follow individual patient records through the workflow proposed in this section."*, and asked that this was removed as it was potentially misleading. IGARD asked that clarification was provided, as to what level of data the Data Controllers were receiving, the level of data the Affiliates were receiving, and the level of data clients and / or end users would be able to access. IGARD noted the reference within section 5(a) to IQVIA Technology Services Ltd Legitimate Interest Assessment, however, in the absence of this document, asked that further information was added to section 5(a), to expressly refer to IQVIA Technology Services Ltd's specific Legitimate Interests, and that this was linked to NHS Digital's DARS Objective for Processing Standard. In addition, IGARD also asked that section 5(d) (Benefits) was updated, to ensure that the benefits outlined, linked to IQVIA Technology Services Ltd Legitimate Interests noted in section 5(a) as per NHS Digital's DARS Benefits Standard.

	IGARD noted that the yielded benefits had been updated in section 5(d) (iii) (Yielded Benefits), and commended NHS Digital and the applicant for also including specific dates with this updated information. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to amend the reference to *"national (UK) data"* to align with the territory of use in section 2(c). 2. To remove the reference to *"…Affiliates would identify…"* in section 5(b). 3. In respect of section 5(b): a) To remove the second paragraph that starts *"It will not be possible to follow individual patient records…"*. b) To provide clarification as to what level of data the Data Controllers are receiving. c) To provide clarification as to what level of data the Affiliates are receiving. d) To provide clarification what level of data clients and end users will be able to access. 4. In respect of the Legitimate Interest Assessment: a) To update section 5(a) to ensure reference to the specific Legitimate Interests as linked to the processing as per NHS Digital's DARS Objective for Processing Standard. b) To update section 5(d) to ensure the benefits outlined, link to the Legitimate Interests noted in section 5(a) as per NHS Digital's DARS Benefits Standard.
3.3	<u>The Royal Wolverhampton NHS Trust: Request for HES mortality data link to NNRD for NIHR -HS & DR funded project Opti-Prem (Presenter: Vicky Byrne-Watts) NIC-125031-Z3D7S</u> **Application:** This was a new application for pseudonymised Civil Registrations and Hospital Episodes Statistics (HES) data, for the purpose of the 'Optimising neonatal service provision for preterm babies born between 27 and 31 weeks of gestation in England, using national data, qualitative research and economic analysis' (OptiPREM) study. The study seeks to establish best place of care for babies born between 27-31 weeks of gestation. The study data comes from an extraction of the National Neonatal Research Database (NNRD) on this specific age group for those born in England. As part of the work for the OptiPREM study, additional data is required beyond what is captured by the NNRD (who only captures information on babies while they are admitted to a neonatal unit). NHS Digital data will be used in a part of the OptiPREM project - Workstream 3. This workstream evaluates the cost of care for all preterm babies born between 27-31 weeks in England, up to the time they reach two years of age. It will look to see whether it is cost effective to be born and looked after in one of two types of neonatal units: a neonatal intensive care unit (NICU) or a local neonatal unit (LNU). It will assess whether this influences the longer-term cost of medical care up to two years of age. NHS Digital advised IGARD that the application had incorrect references to *"data access environment"*, and advised that these would need removing. **Discussion:** IGARD welcomed the application and noted the importance of the research. IGARD noted the update from NHS Digital in relation to the potentially misleading references within the application to *"data access environment"*, and supported the update to remove these. Citing the NHS Digital DARS Standard for Data Controllers / Data Processors, IGARD queried if an assessment had been made as to whether Imperial College London were a joint Data

	Processor, in light of the information outlined within the application in relation to their role, for example, *"the NNRD is hosted…within the Chelsea and Westminster Campus of Imperial College"*; and *"The team at NDAU working on the OptiPrem dataset…are substantive employees of NDAU, at Imperial College."*. IGARD therefore asked that the application was updated throughout to add Imperial College London as a joint Data Processor, if this should be borne out by the facts presented. IGARD also suggested that the application should be updated to remove reference to Chelsea and Westminster Hospital NHS Foundation Trust as Data Processor, depending on their level of access to the NHS Digital data on their servers, again, should this be borne out by the facts. IGARD queried the inconsistent information within the application in respect of the description of the cohort and that each description was subtly different; and asked that section 1 (Abstract), section 3(b) (Additional Data Access Requested) and section 5(b) (Processing Activities) were updated to ensure that the descriptions of the cohort were aligned, for example, the start date for the capture of the cohort, and that it reflected exactly what the applicant required for the study. IGARD noted the reference in section 5(a) (Objective for Processing) to *"desired babies"*, and noting the sensitivity of the study, asked that this was amended to more sensitively referred to "*cohort babies"* or *"cohort infants"*. In addition, IGARD also noted the references in section 5(a) to the study looking at the cost of care; and asked that this was amended to sensitively reflect that the study would consider aspects beyond the pure economic cost of NICU / LNU care, and was also ultimately designed to improve health outcomes for preterm infants, as per the benefits outlined in section 5(d) (Benefits). IGARD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) supporting documents that had been provided, referred to the *"Parent Advisory Panel"*; and asked that section 5 (Purpose / Methods / Outputs) was updated to reflect the involvement of this panel as outlined in the HRA CAG documentation. IGARD noted and endorsed the involvement of the national Charity for sick and preterm babies, BLISS, however suggested that the applicant may wish to raise a query via their Parent Advisory Panel, if there were significant regional variations in care for preterm babies which may also necessitate bespoke regional input. IGARD noted and commended the applicant for how the benefits were clearly outlined in section 5(d), and suggested that NHS Digital could use this as an exemplar for other applications. IGARD did however note that note that as the benefits were not yet known, asked that the applicant revise some of the language, for example, the definitive references to *"will"*. IGARD noted that the reference to the General Data Protection Regulations (GDPR) Article 9 legal basis within the applicant's privacy notice, included narrative from a different Article 9 legal basis, and suggested that this was reviewed and updated. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application throughout to add Imperial College London as a joint Data Processor. 2. To update the application throughout to remove references to *"data access environment"*.

	3. To ensure that the correct description of the cohort is aligned in section 1, section 3(b) and section 5(b) (especially the start date for the capture of the cohort) and that it reflects exactly what the applicant requires. 4. To update section 5(a): a) To amend the reference to *"desired babies"* to sensitively refer to *"cohort babies"* or *"cohort infants"*. b) To sensitively reflect that the study will consider aspects beyond the pure economic cost of NICU / LNU care and is also ultimately designed to improve health outcomes for preterm infants (as per the Benefits section 5(d)). 5. To update section 5 to reflect the involvement of the Parent Advisory Panel refenced within the HRA CAG documents. 6. To revise the language in section 5(d) to reflect that the exact benefits are not yet known; for example references to *"will"*. The following advice was given: 1. IGARD suggested that the application should be updated to remove reference to Chelsea and Westminster Hospital NHS Foundation Trust as Data Processor, depending on their level of access to the NHS Digital data on their servers. 2. IGARD noted that the reference to the Article 9 legal basis within the applicant's privacy notice, included narrative from a different Article 9 legal basis, and suggested that this was reviewed and updated. 3. IGARD noted and endorsed the involvement of BLISS, however suggested that the applicant may wish to raise a query via their Parent Advisory Panel, if there are significant regional variations in care for preterm babies which may also necessitate bespoke regional input.
3.4	<u>University College London: Evaluating protocols for identifying and managing patients with FH (Presenter: Catherine Day) NIC-300282-G9Q0Q</u> **Application:** This was an amendment application to 1) merge existing Data Sharing Agreements, NIC-300282-G9Q0Q and NIC-115405-P6X6Q as both DSAs are for the same purpose; 2) to remove UCL as a Data Controller; 3) to add the University of Nottingham and University of York as Data Controllers who also process data; 4) to add previously disseminated HES datasets under NIC-115405-P6X6Q to section 3a as data held; 5) to include the new Cohort Management and automated extract service products to replace future dissemination of the previously approved Medical Research Information Service (MRIS) products. The purpose is for a study to evaluate protocols for identifying and managing patients with Familial Hypercholesterolaemia (FH), an inherited condition that means their cholesterol levels are higher than normal from birth. The study team propose in this programme of research to evaluate treatment patterns and short- and long-term cardiovascular outcomes and the NHS costs of patients with FH. The outputs of this linkage request will result in providing the most accurate and up-to-date outcome of FH patients to date. The application was been previously considered on the 23rd July 2020 when IGARD had deferred pending: to cross reference the cohort numbers in the application and the supporting document's and ensure they are aligned. To provide clarification in section 5(a) and section 5(b) as to whether NHS Digital already holds the cohort data, or if UCL will be flowing the identifiable data into NHS Digital. To provide written confirmation that HRA CAG have been notified of the change in Data Controllership. To provide confirmation in section 1 and section 5 as to whether the various Principal Investigator organisations should also be considered as joint Data Controllers, and if so, to update the application accordingly. To confirm whether the

	application relates only to the s251 cohort or if there is also a consented cohort, due to the discrepancy between the application and supporting documents. To update section 5(a) and section 5(b) to clarify the flow of NHS Digital data to the University of Nottingham and / or the University of York. To clarify the reference in section 5(b) to the "UK" territory of use. To provide more examples of measurable and yielded benefits within section 5(d) (iii) of the application and with a clear timescale for outputs. To update section 4 to ensure the privacy notice is GDPR compliant and meets NHS Digital's Standard. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made; and commended both NHS Digital and the applicant in addressing the previous deferral points. In respect of the previous deferral point, to ensure the privacy notice was General Data Protection Regulation (GDPR) compliant; IGARD noted that the updated privacy notice(s) was not clear on the role of the University of York; and asked that this was updated to expressly reflect their role as a joint Data Controller. In addition, IGARD also asked that the list of collaborators within the privacy notice(s) was updated to remove the reference to the University of York, given their role as a joint Data Controller. IGARD noted that section 1 (Abstract) referred to the University of Nottingham being the **main** Data Controller; and asked that this potentially misleading reference to "**main**" was removed. IGARD also discussed the previous deferral point in relation to cross referencing and aligning the cohort numbers in the application and the supporting documents, and queried the revised figures in the application, and were advised by NHS Digital that there had been a subsequential amendment to extend the s251 support to the consented cohort, and that the stated 3553 figure was correct. IGARD queried the role of University College London (UCL), noting that the application stated they were a Data Processor, on the basis that they continued to hold the mortality data disseminated under NIC-115405-P6X6Q. IGARD queried if this was an accurate reflection of the current situation under this application and borne out of the facts presented, noting that if that were the case they would be acting under the direction of a Data Controller and would not be making decisions on the purpose(s) of how the data was used. NHS Digital advised that they had discussed this with the applicant and were satisifed with their view that UCL were not a joint Data Controller. IGARD noted the update from NHS Digital and citing the NHS Digital DARS Standard for Data Controllers / Data Processors asked that justification was provided in section 5(a) (Objective for Processing) as to why UCL were continuing to hold the data and how it related to the processing outlined in this Data Sharing Agreement (DSA). In additional how UCL was under the instruction of one or both of the Data Controllers. IGARD also noted the reference in section 5(a) to UCL being a *"Data Guardian"* and asked that this potentially misleading statement was removed. In addition, IGARD also asked that confirmation was provided as to whether the purpose of this application permitted UCL to retain the data, which they had received under application NIC-115405-P6X6Q. IGARD also noted that section 3(b) (Additional Data Access Requested) did not reflect the data previously held by UCL under NIC-115405-P6X6Q, and asked that this was updated accordingly. IGARD noted that section 1 contained a helpful definition summary of Simon Broome Registry, and asked that this also replicated in the public facing section 5(a). In addition, given the public interest and importance of the outputs, IGARD suggested that UCL may wish to consider

	making information publicly available generally (for example on their website) with regard to the Simon Broome Registry. IGARD suggested that on renewal a detailed analysis of the outputs and benefits should be provided, and as per NHS Digital's DARS Benefit Standard. **Outcome:** recommendation to approve subject to the following condition: 1. In respects of UCL: a) To provide a justification in section 5(a) why UCL (listed as a Data Processor) are continuing to hold the data and how it relates to the processing outlined in this agreement and how UCL is under the instruction of one or both of the Data Controllers. b) To confirm whether the purpose of this application permits UCL to retain the data which they received under application NIC-115405-P6X6Q. c) To remove reference to UCL being a *"Data Guardian"* in section 5(a). The following amendments were requested: 1. To update section 3(a) to reflect the data previously held by UCL under NIC-115405-P6X6Q. 2. In respect of the data controllership: a) To ensure the privacy notice is updated to expressly reflect the role of the University of York as a joint Data Controller. b) To update the list of collaborators within the privacy notice(s), to remove the reference to the University of York. c) To update section 1 to remove the reference to the University of Nottingham being the **main** Data Controller. 3. To update section 5(a) with the helpful definition summary of Simon Broome Registry contained in the abstract. The following advice was given: 1. IGARD suggested that on renewal a detailed analysis of the outputs and benefits should be provided (as per NHS Digital's DARS Benefit Standard). 2. Given the public interest and importance of the outputs, IGARD suggested that UCL may consider making information publicly available with regard to the Simon Broome Registry. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
4	<u>Office of National Statistics and NHS Digital Public Health Trusted Research Environment (TRE) (Presenters: Garry Coleman / Gaynor Dalton / JP Buckley)</u> This briefing paper was to inform IGARD that Health Data Research UK (HDR UK) have commissioned a piece of work to link datasets between the TRE's of the other UK nations, to harmonize data access processes. NHS Digital advised that there is a strong drive to move to *"TRE by default"* and reduce / remove extracts, and that the Realignment of data access processes would support easier TRE access. There would also be clarity over status of data in TRE when accessed by researchers.

	IGARD queried why the combination of data in the TRE would be "anonymous" to the researchers in terms of General Data Protection Regulation (GDPR) and asked that a copy of ONS analysis was provided. IGARD also asked that NHS Digital provided an assessment of the ONS analysis, either in support or offering a counter view. IGARD noted that the Information Commissioner's Office (ICO) Code on Anonymisation was dated, and noted as under review on the ICO website, and referenced further guidance on the topic for example the Article 29 Working Party position and recent suggestions from the UK Anonymisation Network (UKAN). IGARD acknowledged that privacy notices were being developed and noted that the essence of the joint data controllership agreements, between ONS and NHS Digital, should also be made available to data subjects for transparency. IGARD queried what governance arrangements were in place, with regard to this model of working, for example the role (if any) of the National Statistician's Data Ethics Advisory Committee; and asked NHS Digital to provided details about the relevant governance arrangements with regard to this model of working, governance over which researchers would have access to the TRE and what controls over data access will be in place within the TRE. IGARD queried the breadth and detail of data and time periods of the data, for example, whether the TRE would contain all Census data, or Census data from 2011, and asked that further information was provided, for example, what postcode details would be available. IGARD welcomed the presentation and made the following key points: 1. To provide a copy of the ONS analysis as to why the combination of data in the TRE will be anonymous to the researchers in terms of GDPR (not just anonymised). 2. NHS Digital to provide an assessment of the ONS analysis, either in support or offering a counter view. IGARD noted that the ICO Code on Anonymisation was dated (and noted as under review on the ICO website) and referenced further guidance on the topic for example the Article 29 Working Party position and recent suggestions from UKAN. 3. IGARD acknowledged that privacy notices were being developed and noted that the essence of the joint data controllership agreements (between ONS and NHS Digital) should also be made available to data subjects for transparency. 4. NHS Digital to provide detail about the relevant governance arrangements with regard to this model of working, governance over which researchers would have access to the TRE and what controls over data access will be in place within the TRE. 5. To provide further information on the breadth and detail of data and time periods of the data, for example, will the TRE contain all Census data, or Census data from 2011.
5	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-207675-J4L7G King's College London • NIC-243790-Y8K8C Carnall Farrar Ltd • NIC-55950-Y5Y2Y Queen Mary's University of London • NIC-363464-J4F8N The King's Fund IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report.

	Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
6	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 8th December 2020 can be found attached to these minutes as Appendix B.
7	<u>AOB:</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 04/12/20

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-196263-J9Q7Z	University College London	08/10/2020	1. In respect of the control cohort: a) To provide a clear written justification for the size of the control cohort in relation to the size of the study cohort. b) To justify and align the volume of data requested with NHS Digital's DARS Data Minimisation Standard and generally accepted research principles. 2. In respect of the IG advice: a) To provide a copy of the IG advice confirming the legal bases. b) To ensure that the IG advice is uploaded to NHS Digital's CRM system.	IGARD members	Quorum of IGARD members	None
NIC-391959-Q3C3G -	University Hospitals of Derby and Burton NHS Foundation Trust	12/11/2020	1. In respect of deferral point 2: a. To provide further justification of how the code sets for conditions with biological plausibility to a COVID outcome are assessed, and how the determination is made. b. To ensure this aligns with NHS Digital DARS Standard for Data Minimisation.	IGARD Deputy Chair	IGARD Chair, under Chair's Authority (In the absence of the IGARD Deputy Chair)	None

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action (addition of Liaison Financial Service and Cloud storage):

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-55752-D6X5Y NHS Herts Valleys

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 8th December 2020

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Vicky Byrne-Watts (DARS)
	Dave Cronin (DARS)
	Louise Dunn (DARS)
	Mujiba Ejaz (DARS - observer)
	James Gray (DARS)
	Karen Myers (IGARD Secretariat)
	Heather Pinches (DARS)
	Charlotte Skinner (DARS – observer)
	Bethan Thomas (DARS)
	Kimberley Watson (DARS)
	Vicki Williams (IGARD Secretariat)
In attendance (External):	Andy Boyd (AB - University of Bristol – item 2.3 only)
	Emma Turner (ET – University of Bristol – item 2.3 only)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	<u>Novavax Vaccine study (NIC number unknown)</u> **Background:** This was a verbal briefing for a new application for the Novavax vaccine study cohort of approximately 50,000 consented participants across the UK who, as part of the study, had been given three bar coded self-test kits and instructed that should they show any

	symptoms, that they complete the test kit and return as per usual process for a positive or negative test to be ascertained. NHS Digital were being asked to be a trusted 3rd party to link the cohort details to the study ID and provide a pseudonymised dataset back to Novavax. NHS Digital noted that work was ongoing across all four devolved nations. The following observations were made on the verbal briefing only. **IGARD Observations:** IGARD members noted the importance of the study and vaccine trial being undertaken, and that it was vitally important that Novavax could receive pseudonymised data to match the self-reported information from cohort members with NHS Digital pillar 2 test data. IGARD members noted that although this was a consented cohort, the applicant was relying on the National Health Service Control of Patient Information Regulations 2002 (COPI), which IGARD accepted was appropriate given the wording of the consent materials (that did not explicitly address potential flow of data to and from NHS Digital). IGARD noted that COPI only applies to England and Wales and also suggested that a sunset clause should be inserted in section 6 of the application due to the time-limited nature of the relevant notice issued under COPI. IGARD members therefore suggested that whilst using COPI, the applicant should take the opportunity to inform the cohort of any possible long-term follow up (since there appeared to be none outlined); listing NHS Digital and other potential data sources or processors; and including reference to possible data linkage that may be part of any future processing. Noting that the parent company of both the Data Controller and Data Processor were based in the USA, that appropriate security assurance was in place and aligned to COPI for the involvement of an additional processor, and that an assessment had been undertaken with regard to Article 46 of GDPR. IGARD members noted the update from NHS Digital on this particularly urgent application of vital importance and supported NHS Digital's assessment that the application would be approved under the DARS SIRO precedent.
2.2	<u>NIC-393650-B7J6F Department of Health (DoE) / Ipsos Market and Opinion Research International (MORI)</u> **Background:** This was a verbal update to an application presentation at the COVID-19 response meeting on the 4th August 2020. The application from the Department of Health and Imperial College London had originally requested record level identifiable demographic data to flow to Ipsos MORI to support the REACT1 study (Real-time Assessment of Community Transmission 1). The application had been amended to push back the Data Sharing Agreement (DSA) end date to 31/03/2021; to add three additional drops of demographic data before 31/03/2021; to add Ipsos MORI sub-contracted suppliers to the agreement as Data Processors; and to add detail in section 5(a) as to the involvement of the Ipsos MORI sub-contractor, Questback, as this had been omitted from previous DSAs. In addition, NHS Digital noted that Ipsos MORI had a data processing location in Germany and that a special condition had been inserted in section 6 stating that "I*psos MORI must provide NHS Digital with the data processing contract between Questback (Germany) and Imperial*

	College London that they have in place for any processing of data in Germany continuing after the transition period of 31st December 2020." The following observations were made on the verbal briefing only. **IGARD Observations:** IGARD members noted that they had raised the issue of the processing location in Germany when last presented to the COVID-19 response meeting on the 4th August an reiterated their point that the application set out how Ipsos MORI, as a processor of confidential patient information, satisfied the requirement in Regulation 7(2) COPI and whether or not reliance on COPI meant there was any geographical restriction on confidential patient information being transferred to Ipsos MORI in Germany. IGARD members also noted that the purpose of the application had expanded significantly since last presented and that Ipsos MORI would be receiving 57 million partial records (the population of England) and noting the NHS Digital DARS Standard for Data Minimisation asked why NHS Digital was not minimising the data before forwarding the partial records to Ipsos MORI (for example by using their filtering criteria), since they only required 850,000 full records per additional data drop. A clear justification of this approach should be provided in section 5 of the application. Noting that the study would be approaching citizens aged 5 years and over, the consent materials should be stratified accordingly and to cover the differing age ranges and understanding of children per age bracket and that further consideration should be given as to how Ipsos MORI were complying with GDPR considerations with regard to handling children's data. IGARD members noted that members of the public may think of Ipsos MORI as a purely marketing organisation, and noting the update from NHS Digital with regard to the low take up rate and complaints received thus far, that further consideration be given as to whether the information being received by members of the public was fully effective (for example by engaging with members of the public to gauge feedback). In addition, thought could be given to monitoring over the time period the number of complaints being received, noting the reputational risk and damage that could be caused during the pandemic. NHS Digital noted that while the application would proceed via the SIRO precedent a further update on points raised would be provided at a future COVID-19 response meeting.
2.3	<u>NIC 420168-K4N1F University of Bristol</u> **Background:** this was a briefing and education session update from the University of Bristol with regard to their longitudinal linkage collaboration. The collaboration aims to combine a number of longitudinal studies into one dataset to form a unique asset which will add value to the understanding of COVID-19 and answer questions relating to COVID-19 via a Trusted Research Environment (TRE) for longitudinal populations studies linked to health and routine records. **IGARD Observations:** IGARD members thanked the University of Bristol for their insightful presentation and noted that that the application and relevant supporting documents would be presented to a future business as usual (BAU) meeting.

	To support any future application, IGARD members noted that supporting documentation should include a copy of the formal information governance (IG) advice from NHS Digital's Privacy, Transparency and Ethics (PTE) Directorate (formerly Information Governance Directorate); that the application be clear as to who was/were the Data Controller/s under the agreement, citing the NHS Digital DARS Standard for Data Controllers / Data Processors, and that this should be borne out by the facts presented; that it be clearly set out in the application how any international users would access the TRE or outputs from the TRE and the type of data they would have access to; to understand more about the approved researcher programme and to detail the approach in section 5 of an application. Noting that each longitudinal study had its own legal basis for processing the data and consent materials of varying scope, IGARD suggested that DARS consider design a supporting document outlining the differing Data Controllers, scope of consent, extent of contact with the cohort, any s251 support and varying legal bases for ease of reference. In summary, IGARD Members noted that they were supportive of the concept and offered additional support to NHS Digital and the applicant out of committee in order to help progress this innovative collaboration.
2.4	NIC-402417-N9Z5W UCL Partners **Background:** This was a brief verbal update to the update received on the COVID-19 response meeting 6th October,13th October, 10th November and 1st December 2020 with regard to the NHS Digital Cancer Trusted Research Environment (TRE) and an application from UCL Partners to access the Cancer TRE. The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** NHS Digital noted that further discussions were being undertaken between all parties involved in the Cancer TRE which was supporting the work being undertaken to scope specific applications. IGARD members thanked NHS Digital for the update and looked forward to receiving more information in due course.
2.5	NIC-411785-Z6X7M NHS England **Background:** this was a new draft application from NHS England with regard to Rapid Diagnostic Centres (RDCs) which are being rolled out nationally as an important part of a broader strategy to deliver faster and earlier diagnosis and improved patient experience. Whilst RDCs will be established for patient with symptoms that could indicate cancer, most patients seen by an RDC will not have cancer. NHS England has commissioned Ipsos Market and Opinion Research International (MORI) to undertake the evaluation of the work, who in turn have commissioned York Health Economics Consortium and the Strategy Unit hosted by Midlands and Lancashire Commissioning Support Unit (CSU) to undertake different elements of the programme. A strategy document outlining the analytical questions being answered for each element of the programme will be maintained by NHS England and will be a "live document", published and maintained by NHS England over the 3 year programme.

	The following observations were made on the basis of the draft application only. **IGARD Observations:** IGARD members noted this was valuable and useful work. Noting the application was to be presented to a future business as usual (BAU) meeting, IGARD members suggested that DARS ensure that the draft application was updated to reflect: • Data Controllership: citing the NHS Digital DARS Standard for Data Controllers / Data Processors, and that this should be borne out by the facts presented • Further consideration be given to the governance arrangements • To delineate this approach to that of Cancer Alliances and any interplay between the two programmes • To include further background to where and how the RDCs fit into a broader programme of work or if these are a new development IGARD members noted the update from NHS Digital and that the application was to be presented to the IGARD business as usual (BAU) Meeting on Thursday, 21st January 2021. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.
2.6	<u>NIC-388794-Z9P3J Office for National Statistics (ONS)</u> **Background:** this was an update to an application previously presented to the COVID-19 response meetings on the 14th July, 28th July, 8th September and 15th September, and application previously discussed at the IGARD business as usual (BAU) Meeting on the 9th July and 16th July 2020. ONS have requested to extend access to the Trusted Research Environment (TRE) to enable continuation of their work and until ONS are in a position where it could undertake the work using the data within its own systems; and to access two additional datasets of the COVID-19 Second Generation Surveillance System (SGSS) and COVID-19 UK Non-Hospital antigen testing results (pillar 2) service types. **IGARD Observations:** IGARD members noted the update from NHS Digital and that the application was to be presented to the IGARD BAU Meeting on Thursday, 17th December. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.
2.7	<u>Briefing Paper - CVD Prevention Audit data collection</u> **Background:** this was a business as usual (BAU) briefing paper which outlined the Cardiovascular Disease Prevention Audit (CVDPREVENT Audit) data collection. The data will help clinicians to understand how well they are performing in the diagnosis and management of the six high risk conditions for CVD. **IGARD Observations:** IGARD Members noted this was a BAU briefing paper.

	IGARD members noted the update from NHS Digital and that the application was to be presented to the IGARD business as usual (BAU) Meeting on Thursday, 10th December. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.
2.8	<u>NIC-372791-X0H3Q NHS Blood & Transplant</u> **Background:** this was an update to an application previously discussed at the COVID-19 response meetings on the 28th July, 18th August and 10th November 2020, and application previously discussed at the IGARD business as usual (BAU) Meeting on 27th August 2020. The application had been updated to include Pillar 3 data to enable NHS Blood & Transplant (NHSBT) to get data on those with positive antigen tests and now antibody test and the addition of email address as a way to contact people. NHS Digital noted that NHSBT had completed a PECR assessment and that NHS Digital's Privacy, Transparency and Ethics (PTE) Directorate (formerly Information Governance Directorate) had reviewed and were content. NHS Digital noted that the application would be proceeding via the SIRO precedent route. **IGARD Observations:** IGARD members queried if the consent materials had been reviewed in terms of an express statement about use of the email address or any contradiction to what NHSBT were asking for in terms of the provision of an email address. By way of example, it was unknown if participants had provided their email address for the sole reason of provision of a test result. Any email to participants should clearly set out how a participant could opt out of receiving any further emails (and ideally also other forms of communications, such as by phone). In addition, IGARD cautioned the applicant from contacting people multiple times via multiple means to ensure a balance between people finding out about the study and unduly disturbing people, since that may increase the likelihood of complaints, which in turn may have a detrimental effect on the uptake (and the public perception of use of NHS Digital-held data generally). IGARD members noted the update from NHS Digital and supported NHS Digital's assessment that the application would be approved under the DARS SIRO precedent.
2.9	<u>NIC-13906-G0F3F PHIN</u> **Background:** this was an update to an application previously discussed at the IGARD business as usual (BAU) Meeting on 2nd July 2020. The amendment application is to allow PHIN to publish an analysis showing the extent and nature of the shift of NHS funded care from the NHS to private sector as a result of COVID-19. The amendment proposal has been reviewed by NHS Digital's Chief Statistician who was content with the publication providing the data have disclosure control applied to them. NHS Digital noted that the application would be proceeding via the SIRO precedent route. IGARD Observations: Noting the amendments made, IGARD suggested that section 5 should be updated to give a clear rationale for the analysis and how it would inform and benefit health or health research, since it was not clear within the application.

	In addition, and noting this was outside of the scope of IGARD's Terms of Reference to comment on an applicant's research, IGARD suggested that the applicant may wish to also consider the displacement effect of the pandemic where patients had elected to self-fund private treatment to avoid longer NHS waiting times, since that behaviour may mask the full impact of the pandemic on the NHS waiting lists. NHS Digital queried the legal basis cited by the applicant. IGARD noted it was for the applicant to ensure they were compliant with their legal basis, but that NHS Digital should ensure that the application processing clearly maps to the scope of the Competition & Markets Authority (CMA) Order. IGARD members noted the update from NHS Digital with regard to the amendments that had been made to the application following its last review, and would also support this going via the NHS Digital SIRO precedent.
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.