Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 7th December

09:30 – 17:00

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser (items 5 and 6 only)
Claire Delaney-Pope (CDP)	Specialist Information Governance Adviser (not in attendance for items 4.6, 8, 9, 10, 10.1, 11.2 and 11.3)
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Kirsty Irvine (KI)	Chair
Jenny Westaway (JW)	Lay Adviser
Miranda Winram (MW)	Lay Adviser (part of item 7 only)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Laura Bellingham (LB)	Deputy Director, Data Access and Partnerships, Data and Analytics (**Presenter**: Items 5 and 6)
Vicky Byrne-Watts (VBW)	Assurance Team, Data and Analytics (**Observer:** item 4.1)
Garry Coleman (GC)	NHS England SIRO Representative (**Presenter**: items 8 and 9)
Dave Cronin (DC)	NHS England Data & Analytics Representative (Delegate for Michael Chapman) (**Presenter**: item 6)
Mujiba Ejaz (ME)	Applications Team, Data & Analytics (**Observer**: item 4.6)
Michael Goodson (MG)	Information Governance Lead, Genomics Unit, NHS England (**Presenter**: Item 7)
Dan Goodwin (DG)	Applications Team, Data & Analytics (**Observer**: item 4.2)

Andrew Martin (AM)	NHS England Data Protection Office Representative (Delegate for Jon Moore) (Presenter: items 11.1 and 11.2)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative
Frances Perry (FP)	Applications Team, Data & Analytics (**Observer**: item 4.3)
Deborah Porter (DP)	Deputy Director, Genomics Service Transformation, Genomics Unit, Specialised Commissioning, NHSE (**Presenter:** Item 7)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate (**Presenter:** item 10)
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Michael Chapman (MC)	Data and Analytics Representative
Jon Moore (JM)	NHS England Data Protection Office Representative

1	**Welcome and Introductions** The NHS England Senior Information Risk Owner (SIRO) Representative, noting the Advisory Group for Data (AGD) Terms of Reference (ToR) had not yet been agreed, proposed that: • Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings; • The meeting will be minuted, with advice and minutes published; • Attendees will include both independent advisers from outside NHS England and representatives from within NHS England. Attendees from NHS England include representatives covering the offices of the Data Protection Officer (DPO); the Caldicott Guardian; Data and Analytics; and the SIRO. • Attendees would not be listed as “members” in minutes during the transitional period; • NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting;

	• It was agreed to use the Data Access Service (DAS) Standards / Precedents in relation to applications for external data sharing. The attendees present at the meeting considered the proposal put forward by the NHS England SIRO Representative and, as no objections were raised, it was agreed that the meeting would proceed on this basis. Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.	
2	**Review of previous AGD minutes:** The minutes of the 30th November 2023 AGD meeting were reviewed in-meeting and subject to a number of amendments were agreed as an accurate record of the meeting; with the exception of paragraphs 4.2.9 and 4.2.10 which were reviewed out of committee by the AGD Chair, NHS England DPO representative and the NHS England Data and Analytics representative (delegate).	
3	**Declaration of interests:** Dr Robert French noted a professional link to the staff involved with NIC-420168-K4N1F (University of Bristol), but noted no specific connection with this application and it was agreed this was not a conflict of interest. Prof. Nicola Fear noted a professional link to NIC-420168-K4N1F (University of Bristol), but noted no specific connection with this application and it was agreed this was not a conflict of interest. Kirsty Irvine noted a personal link to Genomics England (item 10.1). It was agreed this did not preclude Kirsty taking part in the discussion about this item.	
EXTERNAL DATA DISSEMINATION REQUESTS:		
4.1	**Reference Number:** NIC-724508-B4V3Q-v0.2 **Applicant:** Queen Mary University London (QMUL) **Application Title:** PREDICT-PD - Identifying People at Risk of Parkinson's Disease and Neurodegenerative Disease in a United Kingdom Cohort **Observer:** Vicky Byrne-Watts **Application:** This was a new application. The purpose of the application is for a study which aims to identify individuals at risk of, or in the early stages of Parkinson's disease to facilitate early detection to enrol in programmes to delay progression. NHS England were seeking advice on the following point:	

1. Any advice or suggestions as to how the applicant can be more descriptive and informative about the data received from NHS England in their next newsletter to participants.

Should an application be approved by NHS England, further details would be made available within the Data Uses Register.

Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:

4.1.1 The group noted and thanked NHS England for the consent review provided as a supporting document; however advised that the document **did not** address the issue of those individuals / participants who had consented when the patient information materials gave dates for the end of the follow-up that have now passed. This does not align with follow-up continuing now. The group noted that the latest version of the consent materials indicates that follow-up will continue until April 2025 and that participants are asked to sign the latest consent form, each time they complete a survey as part of the study. It was therefore suggested that the applicant should engage with their patient and public involvement and engagement (PPIE) focus group to discuss whether they thought additional communications could be used to adequately inform participants that follow-up is continuing and, if so to formulate a communications plan.

In response to point 1 above:

4.1.2 The group noted in the internal application assessment form that NHS England had advised the applicant, that they would provide advice to them on possible content of the next iteration of the newsletter to send to participants; and suggested that in addition to the NHS England advice provided, the newsletter was also clear on the correct period of the follow-up; what data would be processed as part of this study; what the options were for withdrawing from the study which should contain at least **two** methods of contact for participants (post, telephone and / or e-mail); and other ways to communicate with the cohort such as via support groups.

4.1.3 The group noted that steps recommended should provide an opportunity for NHS England to ensure that the flow / processing of the data aligned with the consent provided.

4.1.4 In addition, it was suggested that the applicant ensure that the current consent materials were future proofed to prevent any recurrence of a situation where the study wants to extend its end date beyond the date given in consent materials.

4.1.5 The independent statistician adviser also noted that in addition to the discussion of potential ways to upgrade their consent where it may be deficient, the applicants could further strengthen their case by explaining how the additional individuals would significantly improve the scientific outcomes of the study (and hence increase the public benefit).

4.1.6 The group also suggested that the applicant may wish to consider requesting a list clean, to ensure any outputs from the communication plan is sent to the correct individuals / participants.

In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:

4.1.7 The group welcomed the application and noted the importance of the study.

4.1.8 The independent advisers noted in the internal application assessment form that the funding for the study had first been allocated in 2011 at the start of the study and that the applicant had confirmed the project had become "*self-sufficient*" over the years, and queried whether ongoing funding would be an issue. NHS England advised that recent funding had been secured for the data linkage, and that it had been confirmed by the applicant that they were confident that ongoing funding for the study would be secured as and when required. The group noted the verbal update by NHS England.

4.1.9 The independent advisers queried the role of Guy's and St Thomas' NHS Hospitals Foundation Trust, noting that they had been referred to within the internal application assessment form as "*Guy's Hospital London*", but had not been referred to in the application; and commended NHS England on the questions asked of the applicant on this point. Based on this information, and the responses provided by the applicant, the group were content that the hospital were not considered a Data Controller or Data Processor.

4.1.10 Noting in the application that there were students working with the data from University College London (UCL) who were listed as a Data Processor; it was suggested by the independent advisers that NHS England clarify with the applicant that these student would **only** be carrying out data processing activities and not data controllership activities, and that this was made clear within the application. If it was deemed that the students from UCL were carrying out data controllership activities, then it was suggested that the application was updated to reflect that UCL were a Data Controller in line with NHS England's DAS Standard for Data Controllers.

4.1.11 The independent advisers queried the information in section 5(a) (Objective for Processing) of the application in respect of the timeframes stated; and suggested that this was reviewed and updated as appropriate to ensure that this reflected the correct information, for example, the year of recruitment, project start dates etc.

4.1.12 Noting the special condition in section 6 (Special Conditions) of the application in respect of honorary contracts, it was suggested that this updated to reflect that the applicant should ensure they keep NHS England appraised of **all** honorary contract holders, and that all the sufficient paperwork was in place for these individuals.

4.1.13 Separate to this application: it was suggested by the independent advisers that NHS England review the honorary contract special condition(s), to ensure that

	the applicant is aware that they need to agree the form of honorary contract in advance with NHS England. **ACTION:** NHS England Data and Analytics DAS Team to review the honorary contract special condition(s), to ensure that the applicant is aware that they need to agree the form of honorary contract in advance with NHS England. **4.1.14 Separate to this application:** it was suggested by the independent advisers that NHS England review the honorary contract special condition(s) to ensure that it covers all requirements from the applicant by NHS England. **ACTION:** NHS England Data and Analytics DAS Team to review the honorary contract special condition(s), to ensure that it covers all requirements from the applicant by NHS England.	DAS DAS
4.2	**Reference Number:** NIC-459523-C1N3K-v0.10 **Applicant:** University College London (UCL) **Application Title:** PDS Sampling for National Survey of Sexual Attitudes and Lifestyles (Natsal) **Observer:** Dan Goodwin **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 8th December 2022. **Application:** This was a new application. The purpose of the application is to support the sampling approach of 'Natsal-4', which is the recruitment of a representative survey sample aged 16-59 years, to ensure sufficient sample sizes among sub-groups of interest. The primary objective for processing data from the data under this Data Sharing Agreement (DSA) is to improve the efficiency of this sampling approach, by "enhancing" the Postcode Address File to rule out ('screen out') addresses with no eligible participants. In addition, the study will include a young person boost (16-29 year olds); this sample design will be implemented to ensure that the survey data include a sufficient number of interviews from these groups in order to carry out robust sub-group analyses. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The **majority** of the group were **not** supportive of the application until the following significant comments were addressed, and wished to draw to the attention of the SIRO the substantive points noted below. A **minority** of the group (one independent adviser) was supportive of the application in principle, if the additional work noted below was undertaken. **4.2.1** The independent advisers noted the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had raised a number of points / concerns	

	when the application was reviewed on the 8th December 2022 (please see appendix A); that **do not** appear to have been addressed, including, but not limited to, the significant safeguarding concerns raised. The independent advisers noted that **all** previous points / concerns remained outstanding and would need to be adequately addressed by the applicant and updated within the application, before the group could review this application further. **4.2.2** Noting that the study was already in progress, it was queried by the independent advisers whether the processing requested under this application was still required to achieve the aims and objectives of the study; and suggested that NHS England clarified this with the applicant, and that a justification was added to section 5(a) (Objective for Processing) of the application. **4.2.3** The Caldicott Guardian Team representative suggested that the applicant consider and address the impact on specific vulnerable groups, via an Equality and Health Inequalities Impact Assessment.	
4.3	**Reference Number:** NIC-302994-C2Q2Y-v9.4 **Applicant:** University of Oxford **Application Title:** ASCEND (A Study of Cardiovascular Events iN Diabetes) **Observer:** Frances Perry **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the Previously discussed at the IGARD BAU meetings on the 5th December 2019 and the 5th October 2017. The application and relevant supporting documents were previously presented / discussed at the DAAG meetings on the 27th September 2016 and the 6th September 2016. **Application:** This was an amendment and renewal application. The amendments are to **1)** request quarterly data flows changed to ad-hoc drops March 2024 and 2025 for original datasets; **2)** the additional datasets requested as a one-off data flow; **3)** the Medicine dispensed in Primary Care (NHSBSA data) from 2015 under the ad-hoc dissemination pattern of approximately March 2024 and March 2025; **4)** the addition of the final Annual Refresh file for HES APC and OP data for the year 2018/2019; **5)** a request for NHS England to link and extract the new additional datasets to be disseminated **a)** Mental Health and Learning Disabilities Data Set (MHLDDS) from 2014 to 2016 – one-off, **b)** Mental Health Minimum Data Set (MHMDS) from 2006 to 2014 – one-off, **c)** Mental Health Services Data Set (MHSDS) from 2017 – one-off, **d)** National Diabetes Audit (NDA) from 2005, **e)** Diagnostic Imaging Dataset (DIDS) from 2012; and **6)** to amend the territory of use changed from ‘England and Wales’ to ‘UK’.	

	The purpose of the application is for a research project, which aims to determine reliably whether low dose aspirin and/or supplementation with omega-3 fatty acids (FA), safely prevents cardiovascular events (such as heart attacks and strokes), and deaths in patients with diabetes, who have not previously been diagnosed with arterial disease. Aspirin is recommended for people with established arterial disease. However, since it also causes bleeding, the balance of benefits and possible harms were not clear in this group of people with diabetes. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: **4.3.1** The independent advisers noted the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had reviewed the application on the 5th October 2017, and had suggested that the applicant should commit to contacting those with whom they have lost touch, via their GP Practice in order that they receive a copy of the most up to date privacy notice and current newsletter. It was noted that this **did not** appear to have been undertaken, and concerns were raised that members of cohort, who consented on earlier versions of the consent materials but had not received the end of study patient information (SD 4.3) nor completed the end of study questionnaire (SD 3.2), may **not** be aware of the long-term follow-up and the consent was therefore **not** compatible with the long-term follow-up for these participants. **4.3.2** If this communication / engagement with the cohort had happened, the independent advisers suggested that the internal application assessment form and the application were updated with further clarification / transparency. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.3.3** The independent advisers noted the statement in section 5(a) (Objective for Processing) of the application *"…long-term follow-up is planned to continue until **at least** 2037…"*; and suggested that this was amended to align with the transparency and patient information materials that state that the long-term follow-up would be for up to 20 years, and therefore should state *"**until** 2037"*. If it was the intention of the applicant to do a follow-up beyond 2037, then it was suggested that the applicant start exploring / preparing for this now. **4.3.4** Noting the potential commercial benefit outlined in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application, it was suggested by the independent advisers that this was updated in line with NHS England's DAS Standard for Commercial Purpose to reflect that if it was determined that there was a benefit to patients from this research project, then this may also be a commercial benefits to the funders, noting that some of the funders are commercial	

	organisations who supply drugs being studied . It was suggested that this updated information also be replicated in section 5(a) for transparency. **4.3.5** The independent advisers noted that the standard special condition had been added to section 6 (Special Conditions) of the application, setting out the restraints of the Medicines dispensed in Primary Care (NHSBSA) data as per the NHS Business Services Authority (NHSBSA) medicines data Direction; however, noting that at the AGD meeting on the 2nd November 2023 (as part of the discussion for NIC-08472-V9S6K UK Biobank) and the 16th November 2023 (as part of the discussion for NIC-568980-P9W7B University of Edinburgh), the SIRO representative had advised that although the Direction did set out constraints of the use of data, it was not the only legal gateway that NHS England had to share data. It was therefore suggested that NHS England consider whether the NHSBSA special condition was required, dependant on which legal basis was being relied on for the processing of this data, and that the application was updated as may be appropriate. **4.3.6 Separate to the application:** the group reiterated the point made at the AGD meeting on the 16th November 2023 and the 2nd November 2023, that for transparency and public trust, NHS England should explore how this could be explained, since the public may take at face value the constraints as set out in a Direction and as published on the website, and may not envisage NHS England using other legal powers to set aside restrictions in a Direction. **4.3.7 Separate to the application:** Noting the NHS BSA presentation to the group on the 20th July 2023, and that the SIRO representative at AGD on the 24th August 2023 had noted that the Direction was being reviewed and would be presented back to the group in due course; the group also reiterated a request made at the AGD meeting on the 2nd November 2023 and the 16th November 2023, for a note setting out the work undertaken to reach the position set out in 4.3.5 above, alongside the work to review the Direction be presented to AGD as soon as practicable. In addition to the transparency and public trust points raised in 4.3.6, the group queried whether this view would have retrospective or prospective impact on other applications using this dataset, or indeed any other applications where there were restrictions on use or dissemination of data due to wording in Directions. **ACTION:** NHS England SIRO Representative to provide a note outlining the work undertaken to allow the applicant to use the data as outlined in the DSA, and to provide a copy of the work undertaken to review the Direction.	SIRO
4.4	**Reference Number:** NIC-635697-P0C5M-v1.2 **Applicant:** Office for Health Improvement and Disparities (OHID) **Application Title:** DHSC Data Sharing Agreement managed by OHID” **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meeting on the 3rd November 2022.	

	Linked applications: This application is linked to NIC-343380-H5Q9K. **Application:** This was an amendment application. The amendments are to **1)** add Department of Health and Social Care (DHSC) mortality surveillance and disparities work programme to the purpose; **2)** the addition of an additional purpose under the Drug and Alcohol work programme to now include 'DHSC Drug and Alcohol work programme – drug and alcohol related'; **3)** the addition of identifiable fields to the Mental Health Services Data Set (MHSDS) dataset; and **4)** the addition of Mental Health and Young People dataset. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were **not** supportive of the application until the following significant comments were addressed, and wished to draw to the attention of the SIRO the following substantive points: **4.4.1** The independent advisers noted the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had reviewed the application on the 3rd November 2022, and that a number of points from this review had **not** been addressed, including, but not limited to, being specific as to which limb of Regulation 3 of The Health Service (Control of Patient Information) Regulations 2002 (COPI) was applicable in each instance and suggested that the application was reviewed and updated throughout to reflect this information. In addition that section 5 (Purpose / Methods / Outputs) of the application was updated with clarification that research was **not** being undertaken, noting that this would **not** be permitted under Regulation 3 of COPI. **4.4.2** It was noted by the independent advisers that they were supportive of the proposed use of the data; however noted that the application as currently presented, would present issues if audited by the Secretary of State for Health and Social Care, as outlined / permitted in the COPI Regulations. **4.4.3** It was noted by the independent advisers that where Regulation 3 COPI is being relied on, National Data Opt-outs (NDO) do not apply to the disclosure of confidential patient information if being used to protect public health (*When does a national data opt-out not apply? – NHS Digital*); whereas NDOs do apply when, for example, processing activities are under s251. Independent advisers noted that this was an additional reason to examine carefully whether proposed processing could rely on Regulation 3 in order to ensure that the NDO was applied consistently across comparable projects. **4.4.4** Noting that the UK Health Security Agency (UKHSA) was listed as a Data Processor, the independent advisers queried if they should also be considered a Data Controller; and suggested that NHS England explore this was the applicant in line with NHS England's DAS Standard for Data Controllers, and that the internal application assessment form and the application were updated as required.	

	4.4.5 The independent advisers noted that the internal application assessment form stated that ethical approval was **not** required due to the datasets shared being requested by DHSC to support its statutory remit and function. Noting that as part of the review of NIC-463165-H3R4K (DHSC) on the 5th October 2023, the *"DHSC Ethics Team"* had been referred to, the independent advisers queried whether that ethics team had reviewed this application; and if not, suggested that the applicant engage with them, in line with NHS England's DAS Standard for Ethical Approval. **4.4.6** Noting the statement in section 5(a) (Objective for Processing) *"under circumstances which may fall outside of the applicable COPI regulations. DHSC will act as a Data Processor…when cohorts of individuals from one dataset need to be matched to other individual level datasets supplied…"*; the independent advisers suggested that further detail was provided, or the information was removed from the application if not relevant. **4.4.7** The independent advisers queried the reference to the UKHSA *"data lake"* in section 5(a), where data previously held by Public Health Engand is stored; and it was suggested by the Data Protection Office representative that this was amended to correctly refer to the *"Enterprise Data and Analytics Platform"* (EDAP) if this transition has now been made, or the wording amended so as not to restrict processing in the data lake if that is not the long-term intention. **4.4.8** The independent advisers noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits); and noting the volume of data flowing, suggested that this should be updated further to include further information on the yielded benefits to date, in line with NHS England's DAS Standard for Expected Measurable Benefits. **4.4.9** The independent advisers noted and commended the work undertaken by the applicant and NHS England's DAS on the content of section 5(a) which clearly outlines the different projects, and the data processed for each one.	
4.5	**Reference Number:** NIC-692602-Q6P4F-v0.5 **Applicant:** Neo Health Hub **Application Title:** Medicines dispensed in Primary Care NHS Business Services Authority data **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meetings on the 17th August 2023 and the 25th May 2023. **Application:** This was a new application. The purpose of the application is for NeoHealthHub Limited to access NHS England data for the purpose of providing services to the NHS, healthcare charity organisations and NeoHealthHub Limited's private organisation clients in the health sector.	

	Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the 6-month time-limited application and wished to draw to the attention of the SIRO the following substantive comments: **4.5.1** The group noted that the NHS Business Services Authority (NHSBSA) Information Asset Owner (IAO) had been approached for a view on the latest version of the application and supporting documents to ensure they were content that the purpose of the study aligned with the NHSBSA Medicines Data Direction 2019. The group noted that a response had **not** yet been received and so they were therefore unable to opine on this point. **4.5.2** The independent advisers noted the importance of the IAO response to ensure that the latest version of the application and supporting documents aligned with the parameters of the Direction, i.e. the processing was for safety and efficacy of medicines; and suggested that the internal application assessment form and application were updated as may be necessary, once a response had been received. **4.5.3** The independent advisers noted that the standard special condition had been added to section 6 (Special Conditions) of the application, setting out the restraints of the Medicines dispensed in Primary Care (NHSBSA) data as per the NHS Business Services Authority (NHSBSA) medicines data Direction; however, noting that at the AGD meeting on the 2nd November 2023 (as part of the discussion for NIC-08472-V9S6K UK Biobank) and the 16th November 2023 (as part of the discussion for NIC-568980-P9W7B University of Edinburgh), the SIRO representative had advised that although the Direction did set out constraints of the use of data, it was not the only legal gateway that NHS England had to share data. It was therefore suggested that NHS England consider whether the NHSBSA special condition was required, dependant on which legal basis was being relied on for the processing of this data, and that the application was updated as may be appropriate. **4.5.4 Separate to the application:** the group reiterated the point made at the AGD meeting on the 16th November 2023 and the 2nd November 2023, that for transparency and public trust, NHS England should explore how this could be explained, since the public may take at face value the constraints as set out in a Direction and as published on the website, and may not envisage NHS England using other legal powers to set aside restrictions in a Direction. **4.5.5 Separate to the application:** Noting the NHS BSA presentation to the group on the 20th July 2023, and that the SIRO representative at AGD on the 24th August 2023 had noted that the Direction was being reviewed and would be presented back to the group in due course; the group also reiterated a request made at the AGD meeting on the 2nd November 2023 and the 16th November 2023, for a note setting out the work undertaken to reach the position set out in 4.5.3 above, alongside the	

	work to review the Direction be presented to AGD as soon as practicable. In addition to the transparency and public trust points raised in 4.5.4, the group queried whether this view would have retrospective or prospective impact on other applications using this dataset, or indeed any other applications where there were restrictions on use or dissemination of data due to wording in Directions. **ACTION:** NHS England SIRO Representative to provide a note outlining the work undertaken to allow the applicant to use the data as outlined in the DSA, and to provide a copy of the work undertaken to review the Direction. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.5.6** The independent advisers noted that there were various UK General Data Protection Regulation (UK GDPR) Article 9 legal bases cited in the application and the internal application assessment form; and suggested that these were reviewed and updated / aligned as may be appropriate. **4.5.7** The independent advisers noted in the internal application assessment form that five years of historical data were requested; and suggested that this was also reflected in section 3(b) (Additional Data Access Requested) and section 5 (Purpose / Methods / Outputs) of the application. **4.5.8** The independent advisers noted the helpful content of the Legitimate Interest Assessment (LIA) provided as a supporting document; and suggested that this was used to update section 5(a) (Objective for Processing) of the application, to be clearer on the purpose of the application, in line with NHS England's DAS Standard for Objective for Processing. **4.5.9** Noting the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) in relation to an internal assessment being undertaken to confirm whether the commercial benefit accruing to the commercial organisation is proportionate to the benefit to health and social care *"NeoHealthHub will also seek external review by a **current member of the NHS** who holds a relevant position…to ascertain the relevance of the project and the balance of benefit to the health and social care sector, patients and the commercial benefit to the private sector"*; it was suggested by the independent advisers that further clarification was provided as to who this may be, what their role is and that they would not otherwise have an interest in the proposed processing. **4.5.10** The independent advisers suggested that section 5 of the application and internal application assessment form were updated to be clear that the applicant **cannot** currently process the data within NHS England's Secure Data Environment (SDE) and that this will be done via data extracts. **4.5.11** The independent advisers suggested that NHS England may wish to add this application to the AGD forward plan.	SIRO

4.6	**Reference Number:** NIC-420168-K4N1F **Applicant:** University of Bristol **Application Title:** University of Bristol - Longitudinal Linkage Collaboration **Observer:** Mujiba Ejaz **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 16th March 2023. The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 7th July 2022, 23rd June 2022, 5th May 2022, 4th March 2021, 4th February 2021 and the 21st January 2021. The application and relevant supporting documents were previously presented / discussed at the IGARD-NHS Digital COVID-19 response meetings on the 5th October 2021, 27th April 2021, 15th April 2021, 16th March 2021, 28th January 2021, 12th January 2021, 17th December 2020 and the 8th December 2020. The application was presented to the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 10th March 2021 and the 16th December 2021. NHS England were seeking advice on the following point: 1. The process flow and whether AGD are supportive of the University of Bristol using this process model to progress with the UK Longitudinal Linkage Collaboration (UK LLC) under consent. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were **not** offering support on the application as requested by NHS England, and made the following observations on the documentation provided as part of the review: In response to point 1 above: **4.6.1** The group noted that they were broadly supportive of the proposal to move the UK LLC from a COVID-19 service to a more general research service. **4.6.2** The independent advisers noted a risk to NHS England that the approach outlined meant that its own staff and the AGD would **not** be carrying out individual consent reviews as would normally be the case for applications to Data Access Service (DAS) and instead NHS England would be relying on reviews and assurance being carried out by the UK Longitudinal LLC; but advised that the risks did appear to have been acknowledged and mitigated. **4.6.3** The independent advisers noted that when they reviewed the application on the 16th March 2023, they had advised that the consent analysis should hone in on any potentially conflicting statements in the original consent forms / participant	

	information sheets, and that the UK LLC study team had created a consent analysis flow that requires the study teams to evaluate their consent materials. As part of feedback from the applicant on this point, it was noted that *"the relevant patient and public involvement and engagement (PPIE) panels are involved **where applicable**"*. The independent advisers suggested that the applicant ensure they undertake PPIE with the relevant panel related to the study cohort involved; and that the reference to "*where applicable*" was updated to state that PPIE will be undertaken, unless there is a specific / justifiable reason not to. **4.6.4** In addition, it was noted as part of the feedback from the applicant that *"there are no restrictive statements in the consent materials…including the information sheet and consent form"*; and it was suggested by the group that this was amended to refer to the following (or similar): *"LPS confirm there are no statements in consent materials or other information provided to cohort members that conflict with the proposed processing in the LPS. For instance, this might include statements around the following non-exhaustive list of topics:* • *What onward sharing will or will not take place* • *The involvement of any other organisations* • *What linkage would take place* • *What the length of the study and/or follow up would be* • *The purpose(s) or the study"* **4.6.5** Noting the incorrect use of *"i.e."* (id est (that is)) within the feedback document, it was suggested that these were reviewed and amended where appropriate to state *"for example"*. **4.6.6** The independent advisers noted "*step 7*" in the 'proposed NHS England consent review process (version 1)' document, which was to update the fair processing notice; and suggested that the applicant should consider starting this step earlier in the process. **4.6.7** The independent advisers queried how the UK LLC will document all of the steps outlined in the 'proposed NHS England consent review process (version 1)' document; and suggested that applicant consider this further for audit / future reference, for example, what was done at each stage and the process. **4.6.8** The independent advisers queried if there was anything NHS England could do to support the corrective actions, for example, a list clean to help provide updated fair processing materials to those lost to follow up.	
5	**Q&A following the presentation at the AGD meeting on the 23rd November 2023 (Presenter: Laura Bellingham)**	

	The group noted that Laura had attended the AGD meeting on the 23rd November 2023 to provide the group with an update on some recent internal changes within the Data Access and Partnerships sub-directorate; and to outline the roles and responsibilities of the work area. In addition, Laura had provided a brief overview of advice that they would be seeking from the group over the coming months. It was agreed on the 23rd November 2023 that the group would have the opportunity for a Q&A session with Laura following the meeting on the 23rd November 2023 (originally scheduled for the 30th November 2023). The group raised a number of queries with Laura on the update provided at the 23rd November 2023; and it was noted that any further updates would be shared with the group in due course. The group thanked Laura for attending the meeting and providing further clarification on the outstanding queries.	
6	**NHS England Precedents and Standards (Presenters: Laura Bellingham and Dave Cronin)** The group noted that, prior to the meeting, they had been provided with a draft proposal for the approval process for data sharing agreements (DSA) extensions and renewals. NHS England requested that the group provide feedback on the initial principles, aims and purposes etc. The group had a lengthy discussion on the information provided, and focussed on a number of issues, including, but not limited to, how to maintain public trust and confidence, public expectations, checks and balances, risks and how to mitigate them, whether the proposed process would be the same for all types of applicants, and the benefits of the proposed process to applicants and NHS England. It was noted that the SIRO representative and Deputy Director, Data Access and Partnerships would discuss this further outside of the meeting, and that an updated draft proposal would be presented to the group at a future meeting. **ACTION:** The Deputy Director, Data Access and Partnerships and SIRO representative to update the draft proposal and present / discuss with the group at a future AGD meeting. The group thanked NHS England for providing them with a draft proposal and looked forward to further discussions on this at future AGD meetings.	LB / GC
7	**NHS England Genomics Services: advice on data release (Presenters: Deborah Porter, Michael Goodson)**	

	NHS England's Genomics Unit attended and wished to receive advice on whether the appropriate assurances and legal basis exist to release data from the Genomics England (GEL) Data Warehouse (which feeds the Trusted Research Environment (TRE)) to the Institute of Cancer Research, for the purposes of the research study 'Stratified Medicine Paediatrics' (SMPaeds) - a study looking at genetic changes in children's cancer'. The organisation's SaaS platform and bioinformatics tooling are not supportable within the GEL TRE, and therefore the data must be exported. Patients will have been dual consented, into the SMPaeds Study and by GEL for their data to be used for research purposes. This research is vital to childhood and teenage/young-adult (TYA) cancer patients who experience a relapse of their cancer as the aims/benefits are: **1)** to establish a comprehensive clinical pathway for the submission of childhood cancer biologic samples to analysis using leading diagnostic technology platforms; **2)** to collect clinical data on disease progression, response to therapy, treatments assigned and outcomes in relapse patients; **3)** to collect, analyse, and share diagnostic and research data to clinicians and researchers seeking to advance treatment and research in childhood cancers, and; **4)** to develop advanced diagnostic technologies to discover new biologic mechanisms and treatment targets important in these cancers. NHS England's Genomics Unit were seeking advice on the following specific queries: 1. Would AGD agree with the view of NHS England that AGD, in line with its terms of reference, could act as the Data Access Group (as referenced in the DSA Variation) to consider proposals from Genomics England to share data with approved cohorts in line with the established procedure set out in the data sharing agreement (DSA) Variation? 2. If so, would the advice provided include consideration of commercial aspects of data sharing proposals in line with the Value Sharing Framework? 3. Will the AGD require representation / membership from a member of the NHS England Genomics Unit, and if so in what role (e.g.: as a standing member or co-opted as required)? **Outcome of the discussion:** In response to point 1 above: **7.1** The group advised that in line with its current **draft** Terms of Reference AGD could act as the Data Access Group to consider proposals from Genomics England to share data with approved cohorts in line with the established procedure set out in the DSA Variation. In response to point 2 above: **7.2** The group noted that they were able to provide advice on commercial aspects of data use, noting that this was part of their current remit with AGD business as usual	

	work; and could be done in line with the Value Sharing Framework, as well as NHS England's DAS Standard for Commercial Purpose and the National Data Guardian (NDG) guidance on benefits. **7.3** It was noted that the Data and Analytics Representative would undertake a review of the Value Sharing Framework and provide further details to the group as to how this will be applied by AGD when reviewing proposals from Genomics England. In response to point 3 above: **7.4** The group noted it would be beneficial to have a representative from the NHS England Genomics Unit, who could take the place of the NHS England Data & Analytics representative when considering proposals from NHS England Genomics Unit, and to ensure quoracy was in line with the draft AGD Terms of Reference, that the Data & Analytics representative / delegate would become an 'observer' for those discussions, to allow the NHS England Genomics Unit colleague to be the NHS England representative. The NHS England Genomics Unit colleague would **not** be an observer for any other items on the AGD agenda and would attend the meeting for the relevant Genomics-related matter(s) only. **7.5** In addition, the SIRO representative advised that further discussions would take place out of committee to agree how this process can be made transparent to the public. **7.6** The group advised that if full advice on the SMPaeds project was desired, they would usually review the original consent materials. The group had reviewed the GEL consent, but the other study consent materials were not provided as part of the pack; NHS England's Genomic Unit advised that they could provide those additional consent materials (including an update as to how the transition from parental to young person consent would be handled) to ensure a full review of the SMPaeds project. The group emphasised that they would welcome relevant staff to a future AGD meeting to support that review. **7.7** The group noted and thanked NHS England's Genomic Unit for attending the meeting; and looked forward to future discussions on how to progress this area of work.	
AGD Operations		
8	**Statutory Guidance** The independent advisers again noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were **not** aware of an agreed risk management framework, and requested that NHS England provide further information/ clarity on this, noting this topic had been raised by Lord Hunt in the House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements – UK Parliament.	

	The NHS England SIRO Representative had provided further clarity on the risk management framework via email to the group, which confirmed that NHS England were asking the interim data advisory group to use the NHS England DAS Standards and Precedents model to assess the risk factors in relation to items presented to the interim data advisory group for advice; however the independent advisers noted that the wording in the in the statutory guidance "…*using a clearly understood risk management framework, precedent approaches and standards that requests must meet*…", suggested that the risk management framework is **separate** to the DAS Standards and Precedents, and asked that this be clarified by NHS England. The group noted that the Deputy Director, Data Access and Partnerships, Data and Analytics attended the meeting on the 23rd November 2023, and noted that plans for this work were in train. It had been noted previously that an Oversight and Assurance Programme of applications that had not be subject to AGD review could form part of this Risk Management Framework. **ACTION:** NHS England SIRO representative to provide a written response addressed to AGD with further clarity on the risk management framework.	GC
9	**AGD Terms of Reference (ToR)** The independent advisers noted that six months had passed since the Statutory Guidance had been published, requiring a ToR to be agreed and published. Following the update by Jackie Gray, Director of Privacy, Transparency and Trust (PTT) (formerly Privacy, Transparency, Ethics and Legal (PTEL)) at the AGD meeting on the 16th November 2023, it was noted that the group had received the updated draft ToR on Wednesday 22nd November 2023; and that a stakeholder workshop, including representatives from AGD and AGD Secretariat, took place on Monday 27th November to discuss the draft ToR and any further suggested updates and amendments. The SIRO representative advised that following the workshop, a further iteration of the draft ToR would be reviewed / updated by the Director of PTT; and that further outcomes from this review, including comments accepted / rejected would be shared with AGD in due course. The SIRO representative noted a previous request from the independent advisers, that a 'final draft' of the ToR be shared with AGD prior to this document being submitted to the NHS England Board / subcommittee of the Board; and advised that this document would be circulated on Friday 8th December 2023. **ACTION:** The SIRO representative to provide outcomes from the review of the updated draft ToR following the workshop on the 27th November 2023.	GC

	ACTION: The SIRO representative to provide a copy of the final draft of the ToR prior to this document being submitted to the NHS England Board / subcommittee of the Board. In addition, the group reiterated that they looked forward to further information on the timeline for progressing the ToR, including when this would be considered by the NHS England Board / subcommittee of the Board. **ACTION:** The SIRO representative to provide further information to the group on the timeline for progressing the draft ToR, including when this would be considered by the NHS England Board / subcommittee of the Board, following the workshop on the 27th November 2023.	GC GC
10	**Standard Operating Procedures (SOPs)** The ongoing forward plan of work for creating Standard Operating Procedures was discussed and noted that although this could not progress further without sight of the final ToR, there would be further discussion in January 2024 of a work plan to progress and finalise the AGD SOPs, in line with the progression of the AGD ToR.	To note
Any Other Business		
11.1	**Legal basis for dissemination guidance (Presenter: Andrew Martin)** The Data Protection Office (DPO) representative noted that following previous discussions, including at the AGD meetings on the 30th November 2023 and 17th August 2023, the legal basis for dissemination guidance had been shared with the group prior to the meeting. It was noted that this was a 'working document' and would be updated as and when required to ensure that it contained the latest / most relevant information. The group thanked the DPO representative for sharing the document, and requested that future iterations were shared as early as possible. **ACTION:** The DPO representative to share future iterations of the legal basis for dissemination guidance as soon as available.	
11.2	**NIC-74625-S1Q8X and Data Protection Office (DPO) processes and procedures following a suspected breach (Presenter: Andrew Martin)** The DPO representative noted that at the meeting on the 30th November 2023, as part of the review of NIC-74625-S1Q8X (Cardiff University), the group has suggested that NHS England escalate to the NHS England DPO, a possible issue with opt-outs not having been applied. The group were advised that following the meeting on the 30th November 2023, this had been escalated to the DPO as per the advice; and that work was currently underway to review this and to either action as may be appropriate; or that the incident was closed if it was concluded that all processes at the time had been duly followed. The DPO representative noted that he would provide a further update on this in due course.	

	In addition, the DPO representative noted a further action from the 30th November 2023 meeting, to arrange a learning session at a future AGD meeting, to provide the group with further information on the DPO processes and procedures following a suspected breach; and advised that this would be done at an AGD meeting in January 2024. The group noted the updates from the DPO representative and looked for an update in due course on the DPO review of NIC-74625-S1Q8X; and the learning session in January 2024. **ACTION**: The DPO Representative to provide an update in due course on the DPO review of NIC-74625-S1Q8X **ACTION:** The DPO Representative / AGD Secretariat to schedule a learning session in January 2024
11.3	**Prof. Nicola Fear** Both independent advisers and NHS England representatives noted that this was Prof. Nicola Fear's final business as usual (BAU) meeting, but that she would continue to support NHS England on bespoke project work; and wished to extend their sincere thanks for her significant contribution since joining IGARD on the 1st February 2017, and as part of AGD.
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.	

Appendix A – Extract from ratified IGARD Minutes: 8th December 2022

University College London (UCL): PDS Sampling for National Survey of Sexual Attitudes and Lifestyles (Natsal) (Presenter: Dan Goodwin) NIC-459523-C1N3K-v0.10

Application: This was a new application for identifiable Demographics and Hospital Episode Statistics Admitted Patient Care (HES APC) data.

The purpose of the application, is to permit The National Surveys of Sexual Attitudes and Lifestyles (Natsal) team, to utilise the data for sampling the next Natsal iteration. The project is led by UCL, and is managed by a multi-disciplinary team of researchers from UCL, the London School of Hygiene & Tropical Medicine (LSHTM), the University of Glasgow, Orebro University Hospital and the National Centre for Social Research (NatCen).

The Natsal Surveys are large, probability-sample bio-behavioural surveys, representative of the British population. The primary objective for processing the data is to recruit a representative survey sample aged 16-59 years and to ensure sufficient sample sizes among sub-groups of interest for the fourth Natsal. The team plan to include a young person 'boost' (16 - 29-year-olds) and an ethnic minority 'boost'; this sample design will be implemented to ensure that the survey data include a sufficient number of interviews from these groups in order to carry out robust sub-group analyses.

Whilst in previous Natsals the target population were identified solely using the Postcode Address File (PAF), with doorstep screening to establish participant eligibility, the Natsal team would now like to use the NHS Digital data to help establish the eligibility of the address-based sample selected from PAF.

The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital.

NHS Digital advised IGARD that following an update from the Privacy, Transparency, Ethics and Legal (PTEL) Team; the application would be amended to remove reference to *"s261(7)"* and instead cite s261(5)(d) of the Health and Social Care Act 2012, as the legal basis for NHS Digital to disseminate the data.

Discussion: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

IGARD noted the verbal update from NHS Digital, in respect of the update from PTEL on the s261 legal basis; and asked that the relevant updates were made to the application to ensure the correct legal basis was cited.

IGARD noted the potential risk, distress or harm to individuals of the proposed approach including, but not limited to, the steps an individual has to take to stop a

home visit; and that this *'opt out'* mechanism was **not** in line with other health research where NHS Digital data was being used in recruitment. IGARD were very concerned with regard to the safeguarding of individuals, noting that many of those being approached may be classed as vulnerable. For example, a safeguarding concern could arise if a family member, partner or other associate observed that the data subject had been selected for the doorstep approach and made an incorrect inference about the reason for this – for example the data subject had made use of sexual health services and that was why they had been selected for this survey on sexual attitudes and lifestyles. IGARD was concerned for the potential for this to put some of the individuals approached to take part at risk.

IGARD also suggested that careful consideration was given to specific sensitivities of the data subjects, including, but not limited to, the age of the data subjects.

IGARD noted that the study had received Health Research Authority Confidentiality Advisory Group (HRA CAG) support and a positive HRA Research Ethics Committee (REC) opinion. IGARD suggested the sensitive subject of the study, and the invasive approach to obtain consent, may require further ethical consideration. IGARD had not been provided with all the documentation provided to HRA CAG and HRA REC and was unclear if the potential issues were fully communicated to and discussed by the HRA CAG and the HRA REC. IGARD further observed that it was within the IGARD Terms of Reference to raise ethical and safeguarding considerations at this stage to ensure that all the issues had been appropriately considered, and from the perspective of NHS Digital.

IGARD suggested that extensive patient and public involvement and engagement (PPIE) and potentially consultation with sources of expertise such as domestic violence charities was undertaken, i.e. in respect of the vulnerable age group of the cohort, the home visits and actively having to stop these.

IGARD noted the significant volume of data flowing and the sensitive nature of the data being processed (including children and young adults). IGARD therefore recommended that the applicant carry out a Data Protection Impact Assessment (DPIA) **before** processing commences in line with Article 35 of UK General Data Protection Regulation (UK GDPR). A copy of the DPIA should also be uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD noted the potentially emotive / coercive language in the patient information materials, including, but not limited to *"We can't give your place to anyone else"*; and suggested that this was reviewed and amended as appropriate to amend the tone / language used.

IGARD also suggested that the patient information materials were updated, to explicitly refer to the HRA CAG support, and to provide a further explanation as to how they were selected for approach to the study.

IGARD suggested that NHS Digital should formally seek the view of the Caldicott Guardian on whether it is ethical and appropriate to use data to support such recruitment methods.

IGARD suggested that this application would **not** be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the sensitive nature of the study and novel method of recruitment.

Outcome: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

1. To update the application throughout with the correct legal basis (as per the verbal update from NHS Digital).
2. IGARD noted the potential risk, distress or harm of the proposed approach including (but not limited to) the active steps required to be taken to stop a home visit and that this *'opt out'* mechanism for an unsolicited home visit was **not** in line with other health research where NHS Digital data was being used in recruitment.
3. IGARD suggested that careful consideration was given to specific sensitivities and safeguarding of the data subjects, including, but not limited to the age of the data subjects.
4. Noting the HRA CAG and HRA REC support for the study, IGARD suggested that this may need further discussion, due to the sensitive subject of the study and the recruitment process.
5. IGARD suggested that extensive PPIE was undertaken, i.e. in respect of the vulnerable age group of the cohort, the home visits and actively having to stop these.
6. IGARD suggested that the applicant carries out a DPIA **before** processing commences in line with Article 35 of UK GDPR.
7. IGARD suggested that the potentially emotive / coercive language in the patient information materials is reviewed / amended.
8. IGARD suggested that the HRA CAG support was explicitly referred to in the patient information materials explaining how they were selected for approach.
9. IGARD suggested that NHS Digital should formally seek the view of the Caldicott Guardian on whether it is ethical and appropriate to use data to support such recruitment methods.
10. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the sensitive nature of the study and method of recruitment.