

## **Advisory Group for Data (AGD) – Meeting Minutes**

Thursday, 30<sup>th</sup> November 2023

09:30 – 15:20

*(Remote meeting via videoconference)*

<b>INDEPENDENT ADVISERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role:</b>
Paul Affleck (PA)	Specialist Ethics Adviser
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser (Items 7 and 9)
Kirsty Irvine (KI)	Chair ( <b>Presenter:</b> item 10.4)
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser (Items 7 and 9)
Miranda Winram (MW)	Lay Adviser (not in attendance for items 1, 2, 3 and part of item 4.1)
<b>NHS ENGLAND STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role / Area:</b>
Helen Buckels (HB)	SDE Service Team, Data and Analytics ( <b>Presenter:</b> item 10.1)
Michael Chapman (MC)	Data and Analytics Representative ( <b>Presenter:</b> item 10.1)
Garry Coleman (GC)	NHS England SIRO Representative ( <b>Presenter:</b> items 7, 9 and 10.6)
Andrew Martin (AM)	NHS England Data Protection Office Representative (Delegate for Jon Moore) ( <b>Presenter:</b> items 10.2 and 10.5)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative
Denise Pine (DP)	Applications Team, Data and Analytics ( <b>Observer:</b> items 2.1 and 2.2)

Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate ( <b>Presenter</b> : Item 8)
Emma Whale (EW)	Applications Team, Data & Analytics ( <b>Observer</b> : items 2.1 and 2.2)
Clare Wright (CW)	Applications Team, Data & Analytics ( <b>Observer</b> : item 2.3)
<b>INDEPENDENT ADVISERS NOT IN ATTENDANCE:</b>	
Claire Delaney-Pope (CDP)	Specialist Information Governance Adviser
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Jenny Westaway (JW)	Lay Adviser
<b>NHS ENGLAND STAFF NOT IN ATTENDANCE:</b>	
Jon Moore (JM)	NHS England Data Protection Office Representative

<b>1</b>	<p><b>Welcome and Introductions</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>• Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings;</li> <li>• The meeting will be minuted, with advice and minutes published;</li> <li>• 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.</li> <li>• Attendees would not be listed as “members” in minutes during the transitional period;</li> <li>• 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;</li> <li>• It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing.</li> </ul> <p>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.</p> <p>Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.</p>
<b>2</b>	<b>Review of previous AGD minutes:</b>

	The minutes of the 23 <sup>rd</sup> November 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.	
3	<p><b>Declaration of interests:</b></p> <p>Dr. Geoffrey Schrecker noted a previous working relationship with some staff involved with NIC-382794-T3L3M University of Oxford application when he was a member of the QResearch Advisory Board. It was agreed this did not preclude Dr. Schrecker from taking part in the discussion on this application, however it was agreed that he would not form part of the group's advice to the NHS England SIRO Representative.</p> <p>Dr. Imran Khan noted a potential conflict with NIC-382794-T3L3M-v8.2 University of Oxford, noting that he continues to be contracted by a direct competitor of EMIS, one of the collaborators in QResearch. It was agreed this did not preclude Dr. Khan from taking part in the discussion on this application.</p> <p>Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was noted that although PAG had reviewed the COVID-19 Therapeutics Programme Dataset – Briefing Presentation (in relation to NIC-382794-T3L3M), PAG had not specifically reviewed the linked application as the dataset had already flowed, it was therefore agreed this was not a conflict of interest.</p> <p>Dr. Jonathan Osborn noted that he had previously provided advice on an aspect of NIC-382794-T3L3M-v8.2 University of Oxford as part of his role in NHS Digital. It was agreed this did not preclude Dr. Osborn from taking part in the discussion on this application.</p>	
EXTERNAL DATA DISSEMINATION REQUESTS:		
4.1	<p><b>Reference Number:</b> NIC-63347-R8J2M-v5.17</p> <p><b>Applicant:</b> Royal College of Anaesthetists (RCoA)</p> <p><b>Application Title:</b> Perioperative Quality Improvement Programme (PQIP)</p> <p><b>Observers:</b> Denise Pine, Emma Whale</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 17<sup>th</sup> February 2022, 12<sup>th</sup> October 2017, 28<sup>th</sup> September 2017 and the 14<sup>th</sup> September 2017.</p> <p><b>Application:</b> This was a renewal, extension and amendment application.</p> <p>The purpose of the application is for a study to measure the rate of postoperative complications and other adverse outcomes after major inpatient surgery in England and Wales.</p> <p>The amendment was to add University College London (UCL) as a Data Controller.</p>	

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

**Outcome of discussion:** The group noted the importance of the research, however, were **not** supportive of the application **at this time** and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting:

**4.1.1** The independent advisers noted that, prior to the meeting, a query had been raised with NHS England, in respect of the period of follow-up of the cohort, for example, was the follow-up period more than four years post recruitment; and noted that the supporting documents provided contained conflicting information, and were unclear on this point.

**4.1.2** In addition, a query was also raised, prior to the meeting, as to whether the two patient and public representatives on the Study Management Team, as referred to in section 5(a) (Objective for Processing) of the application, had been asked whether they think those that have signed the consent forms would be surprised by the continuing flow / retention of follow up data.

**4.1.3** It was also noted that, prior to the meeting, the SIRO representative had raised a query with NHS England, in respect of the on-going recruitment and the patient information sheet provided as a supporting document, that indicates data will be provided for one year following surgery; and asked for clarification as to whether NHS England were only providing data according to that definition, for example, the data was either being minimised by the date; or the RCoA was providing new cohort details each month in which they add new people who have been recruited, and removed people for whom it is now one year beyond surgery. If neither of these options were being applied, the SIRO representative asked that confirmation was provided as to what data NHS England are currently providing, and whether consideration had been given of any changes in documentation from 2017, when it was first approved.

**4.1.4** NHS England advised that they had not yet had the opportunity to seek clarity on the queries raised (see points 4.1.1, 4.1.2 and 4.1.3 above) with the applicant, and were therefore unable to provide a response to the group. The group noted the verbal update and suggested that NHS England clarify these points with the applicant, and that the application and internal application assessment form were updated as may be necessary with the correct factual information.

**4.1.5** In respect of transparency, the independent advisers noted references in the transparency materials provided as supporting documents, to the data being “*kept for 30 years*” and suggested that the transparency materials should be updated to be clear that as well as retaining historical data, it would also involve obtaining ‘new’ data during this 30 year period (if that is the intention).

**4.1.6** The independent advisers noted that it was not currently clear what data had already flowed, and what data will flow in the future for a particular participant; and

	<p>suggested that this was clarified, and the application and internal application assessment form were updated as appropriate to reflect the correct information.</p> <p><b>4.1.7</b> The Data Protection Office (DPO) representative noted that the applicant's published privacy notice had <b>not</b> been updated since May 2018, and suggested that this was reviewed and updated, including, but not limited to, an update to reflect that UCL are a joint Data Controller.</p> <p><b>4.1.8</b> The independent advisers noted the reference on the applicant's website that The Health Foundation was funding the study; and suggested that this was reviewed and updated as may be necessary, noting that this did not align with the information in the application. If the website is correct in respect of The Health Foundation funding the study, then the independent advisers suggested that the application was reviewed and updated to reflect the correct information and align with the information on the website.</p> <p><b>4.1.9</b> The independent advisers queried the role of the 'National Institute of Academic Anaesthesia, Health Services Research Centre' (NIAA HSRC) as noted in the published privacy notice as a sponsor. Noting that the Director of Privacy, Transparency and Trust (PTT) (formerly Privacy, Transparency, Ethics and Legal (PTEL)), had confirmed to the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) in early 2021, that Health Research Authority (HRA) guidance states that study sponsors are automatically deemed Data Controllers and, if they are not, then NHS England should include a rebuttal statement in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) of the application detailing the analysis undertaken by NHS England that the study sponsor is not undertaking any data controllership activities, if supported by the facts.</p> <p><b>4.1.10</b> The independent advisers suggested that the application was reviewed and aligned with the information in the privacy notice / website, to ensure the role of <b>all</b> organisations involved with the study, were made clear in the application, including, but not limited to, any data controllership responsibilities, in line with <a href="#">NHS England's DARS Standard for Data Controllers</a>.</p> <p><b>4.1.11</b> Noting the plans for a 'research' dataset, the independent advisers advised that further information should be provided in the application as to what the current / future plans were (noting this was a five year data sharing agreement (DSA)), for example, how researchers will access / process this dataset, would this be via a sub-licensing model or other method.</p> <p><b>4.1.12</b> In respect of the 'consented' dataset and the Operating Procedure Codes Supplement (OPCS) derived dataset; it was suggested by the independent advisers that section 5 of the application was updated with further clarification of the relationship between the two datasets, and whether there are any issues around the identifiability of the OPCS data if linked with the 'consented' data; and if so, suggested that this was managed via a contractual undertaking, and that it was explicitly clear that there should be <b>no</b> re-identification undertaken.</p>	
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	<p><b>4.1.13</b> Noting that the group had <b>not</b> received the ‘full’ version of the protocol (the appendices were <b>not</b> included as supporting documents); the independent advisers queried whether the HRA Research Ethics Committee (HRA REC) had received the ‘full’ study protocol, which includes appendix 8 – “<i>List of eligible procedures</i>”; and queried whether HRA REC had considered how the OPCS code derived dataset was being handled.</p> <p><b>4.1.14</b> The independent advisers noted the statement in section 5(b) (Processing Activities) that “<i>The Data will contain no direct identifying data items but will contain a unique person ID which can be used to link the Data with other record level data already held by the recipient</i>”; and suggested that this was updated, noting that this was not factually correct for the second data linkage using OPCS codes.</p> <p><b>4.1.15</b> Noting the statement in section 5(b) “<i>The Data will not be transferred to any other location</i>”; the SIRO representative asked that this was updated to be clear / more specific as to what data is stored where.</p> <p><b>4.1.16</b> The SIRO representative also asked that section 5(b) was updated to be clear on the Cloud storage arrangements, for example, confirmation that there will be <b>no</b> external Cloud storage providers.</p> <p><b>4.1.17</b> The independent advisers suggested that section 3(c) (Additional Data Access Requested) of the application was updated to be clear that the patient objections were not being applied due to consent for one dataset <b>and</b> the data not being ‘confidential’ for the other dataset.</p> <p><b>4.1.18</b> The group noted and commended the applicant on some of the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits) of the application; however, suggested that this section was reviewed and any ‘outputs’ were moved to section 5(c) (Specific Outputs Expected) in line with <a href="#">NHS England’s DARS Standard for Expected Outcomes</a> and any ‘expected benefits’ were moved to section 5(d) (ii) (Expected Measurable Benefits to Health and / or Social Care) in line with <a href="#">NHS England’s DARS Standard for Expected Measurable Benefits</a>.</p> <p><b>4.1.19</b> It was also suggested by the independent advisers that the reference to “CQUIN” in section 5(d) was updated to ensure that acronyms were defined upon first use; and to provide further information as to what “CQUIN” is.</p> <p><b>4.1.20</b> The Data and Analytics Representative and SIRO representative suggested that this application be brought under a short term DSA to hold but not process the data whilst the issues highlighted above are resolved.</p>	
<b>4.2</b>	<p><b>Reference Number:</b> NIC-74625-S1Q8X-v2.6</p> <p><b>Applicant:</b> Cardiff University</p> <p><b>Application Title:</b> The LUCI Study: The long-term follow-up of urinary tract infection (UTI) in childhood</p>	



**Observers:** Denise Pine, Emma Whale

**Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 19<sup>th</sup> November 2020, 27<sup>th</sup> July 2017 and the 13<sup>th</sup> July 2017.

**Application:** This was an extension and amendment application.

Cardiff University have previously conducted two large studies of acutely ill children less than five years old in primary care; the purpose of the application is for a study, that links data from these cohort studies, with routine hospital admission data giving a rich dataset of detailed symptoms and signs, including urinalysis, of acutely ill children presenting to general practice linked with outcomes including hospital admission.

The amendment is to permit the archiving of data previously disseminated under this data sharing agreement (DSA).

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 **at this time** and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting:

**4.2.1** The group noted that this was an 'archiving' application, and discussed whether this was the correct description of the proposed processing. NHS England advised that the study team are wanting to retain the data to answer any queries regarding publishing results, but also to allow them to secure funding to proceed with further research, and that funding was currently only available for archiving; and that it was unclear at the current time whether further funding could be secured. NHS England noted that if further funding was secured, the study team are intending to amend / expand the objective for processing in the data sharing agreement (DSA). The group noted and thanked NHS England for the verbal update and suggested that the application was amended to reflect that this was for 'archiving' **and** 'to hold the data but not otherwise process to enable further research' (until funding has been secured and the agreement has been updated).

**4.2.2** In addition, the independent advisers noted that this DSA was for five years; and suggested that NHS England should consider whether this was appropriate when funding had **not** been secured.

**4.2.3** The group noted the information in the internal application assessment form that National Data Opt-outs (NDO) had not been applied when the data was originally disseminated in 2017 by NHS Digital, and that Cardiff University may have received data on individuals who had registered a Type 2 opt-out. However, the group noted that a study specific opt-out had been offered. It was suggested that NHS England review the original s251 conditions of support provided by the Health Research Authority Confidentiality Advisory Group (HRA CAG). If it was determined





	<ul style="list-style-type: none"> <li>Contemporaneous interpretation was therefore that opt-outs would not be applied in this scenario since the information released was pseudonymised and not personal confidential information.</li> <li>Following introduction of the NDO on 25<sup>th</sup> May 2018, it was clarified via policy that this scenario was in scope of the NDO since the data use (pseudonymisation) was covered by the s251 support and therefore this scenario would now have NDO applied. Therefore the approach was in line with policy at the time.</li> </ul> <p><b>4.2.10 Subsequent to the meeting:</b> NHS England noted that this information had <b>not</b> been provided to the group as part of the review; and advised that further work would be undertaken internally to ensure incorrect information was not shared with AGD at future meetings.</p> <p><b>Action:</b> The Data Access Service (formerly DARS) to undertake further work to ensure that incorrect information was not shared at future AGD meetings</p>	DC
4.3	<p><b>Reference Number:</b> NIC-382794-T3L3M-v8.2</p> <p><b>Applicant:</b> University of Oxford</p> <p><b>Application Title:</b> QResearch-Oxford Data Linkage Project</p> <p><b>SAT Observer:</b> Clare Wright</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 21<sup>st</sup> September 2023.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 17<sup>th</sup> November 2022, 11<sup>th</sup> August 2022, 16<sup>th</sup> June 2022, 7<sup>th</sup> April 2022 and the 3<sup>rd</sup> March 2022.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the</p> <p>Previously discussed at the COVID-19 response meetings on the 2<sup>nd</sup> March 2021, 19<sup>th</sup> January 2021 and the 12<sup>th</sup> January 2021.</p> <p>The 'COVID-19 Therapeutics Programme Dataset – Briefing Presentation' was discussed at the IGARD business as usual (BAU) meeting on the on 4<sup>th</sup> August 2022. IGARD also noted that the Briefing Presentation only had also been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 27<sup>th</sup> April 2022 (see Appendix B); and that the notes clearly stated that a review of this application was not required by PAG.</p> <p><b>Linked applications:</b> This application is linked to NIC-656839-K5V9L.</p> <p><b>Application:</b> This was a renewal application.</p> <p>The purpose of the application is for a linked research database (QResearch linked database) for the following reasons: <b>1)</b> for use by the University of Oxford for specific</p>	

research purposes; **2)** for use by the University of Nottingham for ongoing research studies; and **3)** onward sharing to UK universities via a sublicensing agreement.

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** In respect of transparency, the independent advisers noted that it was **not** clear that Type 1 opt-outs would **not** be upheld for this flow of data; and it was suggested that the applicant should make this explicitly clear within the application.

**4.3.2** In addition, it was noted that there was an incorrect statement on the applicant's website, that the National Data Opt-out (NDO) would be effective in removing the data of individuals from the QResearch database; and suggested that this was amended to reflect the correct / factual information, or that the factually incorrect statement be removed from the website.

**4.3.3** The independent advisers also suggested that the applicant ensure that it was clear that **only** the QResearch opt-out will be effective in preventing an individual's GP data flowing into the QResearch database.

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

**4.3.4** The independent advisers queried whether the datasets were minimised to 'Egton Medical Information Systems' (EMIS) patients or patients of a practice using the EMIS electronic health record system, or all citizens; and noting that the internal application assessment form suggested that if it was **all** citizens, that this was clarified in the internal application assessment form and section 5 (Purpose / Methods / Outputs) of the application.

**4.3.5** The independent advisers queried the content of the special conditions in section 6 (Special Conditions) relating to "*remote access*" and "*data released for COVID-19*"; and suggested that these were reviewed to ensure the current / correct text was reflected.

**4.3.6** Noting the special condition in section 10 (Sub-licensing) that stated "...*which must be maintained under change control*...", it was suggested by the group that this was removed and updated to be explicit that any changes to the sub-licensing arrangements must be agreed in writing in advance with NHS England, and that NHS England should be provided with a tracked version copy of any updated documents.

**4.3.7** The group suggested that NHS England review the transparency of the QResearch Science Committee, including, but not limited to, transparency on the activities undertaken by the QResearch Science Committee and the information available to the public, for example published meeting minutes.

	<p><b>4.3.8</b> Noting the statement in section 5(a) (Objective for Processing) “<i>The Q-Research linked database also holds data from the UK Teratology Service...</i>”; the independent advisers suggested that further clarification was provided as to what processing was undertaken with that dataset; and to outlined the outputs and benefits from this processing in section 5(c) (Specific Outputs Expected) in line with <a href="#">NHS England’s DARS Standard for Expected Outcomes</a> and section 5(d) (Benefits) in line with <a href="#">NHS England’s DARS Standard for Expected Measurable Benefits</a>.</p> <p><b>4.3.9</b> The independent advisers noted that the website referred to the data as being “<i>anonymised</i>” and that this did not align with the internal application assessment form and the application that describes the data as being “<i>pseudonymised</i>”; and suggested that the website as updated to reflect the correct information.</p> <p><b>4.3.10</b> The group noted the information on the data controllership for this application outlined in the internal application assessment form; and advised that they were in agreement with NHS England’s analysis / conclusion.</p> <p><b>4.3.11</b> The independent advisers noted that there appeared to be some text missing from the bottom of section 5(a), and suggested that NHS England review this and amend / update as may be necessary to ensure all the information is correctly noted.</p> <p><b>4.3.12 Separate to the application:</b> the independent advisers suggested that as OpenSAFELY develops, NHS England should keep a view on the data disseminations and consider whether they were <b>all</b> necessary to achieve the stated research aims.</p> <p><b>4.3.13</b> In addition, it was suggested that NHS England consider if there was an inconsistency of approach between QResearch and OpenSAFELY and how they handle GP data, for example, in relation to how opt-outs and objections should be applied.</p>	
<b>EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL</b>		
5.1	<p><b>Reference Number:</b> NIC-60714-M4T1M-v5.2</p> <p><b>Applicant:</b> University Hospital Southampton NHS Foundation Trust (FT)</p> <p><b>Application Title:</b> FLuid Optimisation in Emergency LAParotomy (FLO-ELA) trial</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented / discussed at the IGARD meetings on the 14<sup>th</sup> June 2018, 10<sup>th</sup> May 2018 and the 8<sup>th</sup> March 2018.</p> <p>The SIRO approval was for six-month extension.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this.</p> <p>The group thanked NHS England for the written update and made the following observations on the documentation provided:</p>	

	<p><b>5.1.1</b> The independent advisers noted a number of issues flagged within the SIRO approval form provided as a supporting document; and suggested that NHS England should consider undertaking an audit of this data sharing agreement (DSA).</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
<b>5.2</b>	<p><b>Reference Number:</b> NIC-302604-S7H2N-v3.5</p> <p><b>Applicant:</b> Imperial College London (ICL)</p> <p><b>Application Title:</b> MR735 - Anglo-Scandinavian Cardiac Outcomes Trial</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented / discussed at the IGARD meetings on the 21<sup>st</sup> November 2019 and the 20<sup>th</sup> September 2018.</p> <p>Previously discussed at the IGARD BAU meetings on:</p> <p>The SIRO approval was for six-month extension to hold but not process the data.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this.</p> <p>The group thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p><b>5.2.1</b> The independent advisers noted a number of issues flagged within the SIRO approval form provided as a supporting document; and suggested that NHS England should consider undertaking an audit of this data sharing agreement (DSA).</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
<b>5.3</b>	<p><b>Reference Number:</b> NIC-12784-R8W7V-v15.1</p> <p><b>Applicant:</b> Genomics England</p> <p><b>Application Title:</b> Genomics England: Use of data within the National Genomics Research Library (NGRL)</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented / discussed at the AGD meeting on the 17<sup>th</sup> August 2023.</p> <p>The application and relevant supporting documents had previously been presented / discussed at the IGARD meetings on the 28<sup>th</sup> April 2022, 13<sup>th</sup> August 2020, 7<sup>th</sup> February 2019 and the 13<sup>th</sup> April 2017.</p> <p>The application and relevant supporting documents had previously been presented / discussed at the DAAG meetings on the 20<sup>th</sup> December 2016, 6<sup>th</sup> December 2016, 1<sup>st</sup> November 2016, 5<sup>th</sup> April 2016 and the 15<sup>th</sup> March 2016.</p> <p>The SIRO approval was for six-month renewal to hold but not process the data, with a request for the application to be brought back to a future AGD meeting.</p>	

	<p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this.</p> <p>The group thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p><b>5.3.1</b> The independent advisers suggested future incorporation of the Generations Study will require careful consideration, noting that newborns cannot provide consent and their data could be used for decades to come.</p> <p><b>5.3.2</b> The independent advisers noted that Genomics England’s register of approved projects does not name the institution for each approved application; and suggested that for transparency, particularly regarding commercial applicants, this was reviewed and checked for consistency with other similar sub-licensing applications.</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
<b>AGD Operations</b>		
<b>6</b>	<p><b>Statutory Guidance</b></p> <p>The independent advisers again noted the reference to reviewing materials in accordance with “<i>a clearly understood risk management framework</i>” within the published <a href="#">Statutory Guidance</a> and advised that they were <b>not</b> 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 26<sup>th</sup> June 2023, and was answered by Lord Markham on the 5<sup>th</sup> July 2023: <a href="#">Written questions, answers and statements – UK Parliament</a>.</p> <p>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 DARS 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 “...<i>using a clearly understood risk management framework, precedent approaches and standards that requests must meet...</i>”, suggested that the risk management framework is <b>separate</b> to the DARS 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 23<sup>rd</sup> November 2023, and noted that plans for this work were in train.</p> <p>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.</p> <p><b>ACTION:</b> NHS England SIRO representative to provide a written response addressed to AGD with further clarity on the risk management framework.</p>	GC





	<p>down NHS England's precedent route and suggested that NHS England may wish to consider adding oversight activity to AGD's programme of work.</p> <p>The SIRO representative discussed with the group a number of possible options for oversight activity, and AGD's role with supporting this process.</p> <p>The SIRO representative requested that an AGD independent adviser was involved with further discussions on this subject out of committee; and advised that a further update / discussion would be held with the group in due course to progress this area of work.</p> <p><b>ACTION:</b> AGD Secretariat to liaise with independent advisers to seek a suitable volunteer to engage with the SIRO representative out of committee on the oversight and assurance activity, and AGD's role with supporting this process.</p> <p><b>ACTION:</b> The SIRO representative to provide further feedback at a future meeting with regard to the oversight and assurance activity, and AGD's role with supporting this process; following out of committee engagement with an independent adviser.</p>	<p>VW / KM</p> <p>GC</p>
<b>Any Other Business</b>		
<b>10.1</b>	<p><b>Secure Data Environment (SDE) update (Presenter: Helen Buckels / Michael Chapman)</b></p> <p>The group were provided with a verbal update / slides in the meeting of the latest information in respect of NHS England's SDE; and were advised that applications for access to the SDE would be presented to the group in the coming weeks / months for review / advice.</p> <p>The group were also asked to review and provide comments on version 7 of the delegated access policy document; and that the deadline for this feedback was the 6<sup>th</sup> December 2023.</p> <p>The group noted and thanked NHS England for the update.</p> <p>In addition, the group discussed the approach to reviewing applications for access to the SDE; and suggested that a further discussion on this at a future AGD meeting.</p> <p><b>ACTION:</b> AGD Secretariat to add to the AGD forward plan a discussion with regard to the approach to reviewing applications for access to the SDE.</p>	
<b>10.2</b>	<p><b>Information Commissioner's Office (ICO) Transparency in health and social care draft guidance consultation (Presenter: Andrew Martin)</b></p> <p>Andrew advised the group that NHS England were in the process of preparing a response to the ICO, on the Transparency in health and social care draft guidance <a href="#">consultation</a>; and advised that NHS England would welcome feedback from AGD as part of this collective feedback.</p> <p>It was agreed that the document would be shared with the group (via the AGD Secretariat) and that comments would be collated and discussed at the AGD meeting on the 14<sup>th</sup> December 2023; and final comments shared with NHS England by the 18<sup>th</sup> December 2023.</p>	

	<p>It was noted that if preferred, individuals can respond directly to the ICO on an ‘individual’ capacity and not as a member of or on behalf of AGD.</p>
<b>10.3</b>	<p><b>Cost Recovery Collection, Processing and Dissemination of overseas visitor and UK Patient-Level Data Directions</b></p> <p>The independent advisers noted that they had requested that colleagues from the Department of Health and Social Care / NHS England attend an AGD meeting to discuss issues raised by an <a href="#">article</a> published in The Guardian; and that this had been cancelled by NHS England. The independent advisers asked that (i) an explanation was provided as to why this had been cancelled, and (ii) whether this could be rescheduled. The SIRO representative noted the requests and advised that further clarification would be provided in due course.</p> <p><b>Action:</b> The SIRO Representative took an action to respond to AGD on these two queries.</p>
<b>10.4</b>	<p><b>AGD Chair engagement with Health Research Authority Confidentiality Advisory Group (HRA CAG) / National Data Guardian (Presenter: Kirsty Irvine)</b></p> <p>The AGD Chair provided feedback to the group with regard to her meeting with Dr. Tony Calland, the Chair of the Health Research Authority Confidentiality Advisory Group (HRA CAG) and Dr. Nicola Byrne, the National Data Guardian for health and adult social care in England, on Tuesday 28<sup>th</sup> November 2023, as part of their regular engagement.</p>
<b>10.5</b>	<p><b>Legal basis for dissemination guidance (Presenter: Andrew Martin)</b></p> <p>The Data Protection Office (DPO) representative advised the group that following previous discussions, including at the AGD meeting on the 17<sup>th</sup> August 2023, there was ongoing work to obtain and share the legal basis for dissemination guidance with the group; and that either the legal basis for dissemination guidance, or a further update, would be provided to the group in due course.</p>
<b>10.6</b>	<p><b>NHS England Genomics Unit (Presenter: Garry Coleman)</b></p> <p>The SIRO representative noted that colleagues from NHS England’s Genomics Unit would be attending the AGD meeting on the 7<sup>th</sup> December to seek advice from the group on a number of areas.</p>
<p><b>Meeting Closure</b></p> <p>As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.</p>	