Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 5 May 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Martin Baker	Information Analysis & Statistics (Item 2.1)
Ian Bullard	Information Analysis & Statistics (Item 2.1)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 7.3)
Louise Dunn	Data Access Request Service (DARS) (**SAT Observer**: item 3.3) (Observer: item 7.2)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Items 5, 7.2)
Frances Hancox	Data Access Request Service (DARS) (Item 7.1)
Karen Myers	IGARD Secretariat
Danish Mahmood	Project Programmes & Portfolio Delivery (Item 2.1)
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 2.1 - 3.3)
Tania Palmariellodiviney	Data Access Request Services (DARS) (**SAT Observer**: item 2.1)
Frances Perry	Digi-Trials (Item 3.3)

Charlotte Skinner	Data Access Request Services (DARS) (Item 3.1)
Gemma Walker	Data Access Request Services (DARS) (**Observer**: item 3.2)
Joanna Warwick	Data Access Request Services (DARS) (Item 5)
Kimberley Watson	Data Access Request Service (DARS) (**SAT Observer**: item 3.1 - 3.2)
Anna Weaver	Data Access Request Service (DARS) (Item 3.2)
Vicki Williams	IGARD Secretariat
Amanda Young	Data Access Request Services (DARS) (**Observe**r: items 2.1 – 3.3)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) [NIC-420710-X0H1P], 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 agreed this did not preclude Dr. Khan from taking part in the discussions about this application, however it was agreed that he would not participate in making a recommendation about the application. Paul Affleck noted professional links to AIMES Management Service [NIC-406158-Q2J0X] but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Dr Maurice Smith noted professional links to AIMES Management Service [NIC-406158-Q2J0X] but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Paul Affleck noted he was a member of Ministry of Defence Research Ethics Committee (MODREC) (relevant to NIC-148024-P8GSC), but it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 28th April 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
2.1	Surgical Devices & Implants Data Set – Briefing Paper (Presenters: Ian Bullard / Martin Baker / Danish Mahmood)

	This briefing paper was to inform IGARD about the Surgical Devices and Implants Data Set (SDIDS) collected and processed by NHS Digital within a single system known as the Surgical Device and Implant Information System (SDIIS); which will be made available for customers to request through the Data Access and Request Service (DARS). The main aim of the collection of SDIDS is to improve patient safety so that patients can be traced in the event of a product recall or safety concern relating to a specific type of implant or treatment. Outcomes data collected will also be used to improve procedures offered to future patients and facilitate the national reporting of activity relating to any surgical device or implant across both the NHS and independent health care sector. SDIDS will support the improvement of patient safety in England only, by enabling analysis to facilitate surveillance of surgical devices and implants through linkage of component data modules e.g. Pelvic Floor Registry data. **Outcome:** IGARD welcomed the briefing paper and made the following high-level comments: 1. IGARD understand that the staged onboarding process of the four initial access partners will be subject to the DARS and IGARD route as per usual process. 2. IGARD strongly suggest that this new dataset is actively promoted to researchers as soon as possible (noting there is already research ongoing using NHS Digital data that would directly benefit from access to this dataset). IGARD understands that an Information Standards Notice (ISN) specifies the data capture and data quality required to assess if the dataset as suitable for wider use. 3. IGARD suggested updating the information within the public domain with an explanation of why data is only being collected from 2017 onwards and the plan for audit of data from 2010. 4. IGARD suggest that NHS Digital reviewed the published UK GDPR notice that covers this dataset, and ensure it reflects all likely future uses of the data, for example the current restriction on sending the data outside the UK would preclude a pharmaceutical company from sending safety data to a regulator in another jurisdiction. 5. IGARD noted positively the efforts made in explaining the alternate procedures that would form part of the dataset as it was important to note that members of the public who didn't receive a device or implant may still be captured by the dataset. 6. IGARD noted the plans and ongoing discussions to align with other datasets, for example, the Breast and Cosmetic Implant Registry. 7. IGARD noted the process plan to involve the devolved nations of the UK. IGARD welcomed the draft briefing paper and looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (either before or contemporaneously with any first of type applications received by IGARD).
3	**Data Applications**
3.1	Renal Registry: Linking the UK Renal Registry (UKRR) and Hospital Episode Statistics for research (Presenter: Charlotte Skinner) NIC-406158-Q2J0X-v0.17 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care and HES Outpatients data. This data is currently disseminated under NIC-94250-L8W8T. The purpose of the application is for research, namely to **1)** investigate risk factors (including the impact of renal treatment, morbidities and infections such as COVID-19) for clinical

	outcomes of adults and children with kidney disease; **2)** predict future outcomes for adults and children with kidney disease using novel statistical modelling methods on big datasets, including the impact of infections such as COVID-19 and changing underlying morbidities; **3)** understand trends and variations (geographical, socio-economic, ethnic, seasonal, time and by renal centre) in the care and outcomes of adults and children with kidney disease, including the impact of infections such as COVID-19 and changing underlying morbidities.; **4)** use patient reported measures, such as patient activation (PAM), patient reported outcome (PROM) and patient reported experience (PREM), to understand the impact of kidney disease on adults and children, taking into account morbidities; **5)** quantify the cost of kidney disease in adults and children, taking into account morbidities; and **6)** validate measures of risk factors, outcomes and treatment modalities using different data sources for adults and children with kidney disease. The study is relying on s251 of the NHS Act 2006, for the flow of contact details out of NHS Digital; and the cohort size for all patients (new and existing) is currently about 2.5 million. **Discussion:** IGARD noted and commended NHS Digital on the quality of the information provided within section 1 (Abstract) of the application, which supported the review of the application by Members. IGARD confirmed that they were of the view that the relevant s251 was broadly compatible with the processing outlined in the application. Separate to this application, NHS Digital advised IGARD that formal discussions were ongoing with the Health Research Authority Confidentiality Advisory Group (HRA CAG) in respect of the transition of Public Health England's (PHE) legal responsibilities to the UK Health Security Agency (UKHSA). IGARD queried purpose number five of the application outlined in section 5(a) (Objective for Processing) which was to *"Quantify the cost of kidney disease in adults and children…"*, and asked that further clarification was provided on this purpose, for example, was this the cost to patients' quality of life, financial costs to the health and care system etc, and that the purpose should be updated in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted the statement in section 5(a) in relation to the Acute Kidney Injury (AKI) that *"Participation of hospital laboratories is mandated by NHS England…"*, and asked that the language was updated to make clear that use of the national algorithm, standardising the definition of Acute Kidney Injury (AKI) was *"recommended"* and **not** *"mandated"*. IGARD noted the information in section 5(a) in relation to the expansion to the UKRR data collection, and asked that for transparency, this was updated to also include indicative numbers of the number of data subjects covered, in line with the NHS Digital DARS Standard for Objective for Processing. IGARD noted the Renal Association Patient Council and the excellent work undertaken in respect of transparency, and queried if there were plans for the UKRR Data Release Group to also have patient and public representation, and also queried if the Renal Registry Patient Council formed part of this Group. IGARD suggested that in either case an explanation was provided as to what was currently happening with regard to Patient and Public Involvement and Engagement, or what was planned in the future. **Outcome:** recommendation to approve The following amendments were requested:

	1. To provide clarification on the reference to the *"…cost of kidney disease…"* in section 5(a), for example, is this the cost to patients' quality of life, to the health and care system etc. 2. To update section 5(a) to make clear that use of the algorithm, standardising the definition of AKI is *"recommended"* and not *"mandated"*. 3. To update the examples provided in section 5(a) of where the data collection has been expanded to also include indicative numbers of the number of data subjects covered. The following advice was given: 1. IGARD noted the Renal Association Patient Council and the excellent work undertaken in respect of transparency, and queried if there were plans for the UKRR Data Release Group to also have patient and public representation, and if the Renal Registry Patient Council forms part of this Group; and suggested that in either case an explanation was provided as to what was currently happening, or what was planned in the future.
3.2	<u>Office for National Statistics (ONS): ONS / NHS Digital TRE Public Health Asset (Presenter: Anna Weaver) NIC-420710-X0H1P-v2</u> **Application:** This was an extension application to permit the continuation of work by ONS to make an anonymised version of an existing dataset it holds, containing NHS Digital data (the Public Health Data Asset), available for use by approved researchers in its Trusted Research Environment (TRE). It was also an amendment application to **1)** update section 5 (Purpose / Methods / Outputs) throughout to reflect the request to include the Emergency Care Dataset (ECDS) and COVID-19 Vaccination Status data in the Public Health Research Database (PHRD), for approved users to access via ONS' Trusted Research Environment (TRE); **2)** to update section 1(c) (Data Processor(s)) and section 2 (Locations) to reflect that UKCloud Ltd have been processing data; **3)** to update section 2 to reflect the role of Equiniti Group a Data Processor; **4)** to update section 1(c) and section 2 to reflect the role of Crown Hosting Data Centre. ONS are requesting to use data, already disseminated (to ONS) under active NHS Digital Data Sharing Agreements (DSA) (NIC-175120-W5G2X and NIC-400304-S1P1B), to link to ONS 2011 Census data to create a new data asset. The data will be used to enrich the 2011 Census data with additional health characteristics. This new data asset will be referred to as the 'Public Health Data Asset'. The Public Health Research Database will be created from the Public Health Data Asset. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 17th December 2020 and 11th March 2021. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 10th March 2021 and that notes from this meeting had been attached to the IGARD BAU minutes from the 11th March 2021. IGARD noted that when this application was discussed at the IGARD BAU meeting on the 11th March 2021, they had requested that a special condition was inserted in section 6 (Special Conditions), that all GDPPR derived data shall be destroyed on the expiry of The Health Service Control of Patient Information (COPI) Regulations 2002, which at the time was the 30th September 2021. Noting that the expiry of the COPI Notice, was now the 30th June 2022, IGARD asked that, for transparency, section 5 was updated with an explanation that the use of the GDPPR data was continuing; the mechanism for the continued use of the GDPPR data,

	such as the legal basis; and the processes in place to provide oversight and assurance for the GDPPR data. In addition, noting that PAG previously thought they were providing comments on a time limited application under COPI, IGARD asked that NHS Digital provide an update to PAG on the ongoing status of this application and the use of the GDPPR data in the asset. IGARD queried the reference to, and reliance on, section 39(4)(i) of the Statistics and Registration Service Act 2007 (SRSA), which referred to personal data; noting the application asserts that the researchers were accessing functionally anonymous data and **not** personal data. IGARD noted that the first reference in the public facing section 5 to the Statistics and Registration Service Act did not include the acronym *"SRSA"*, and asked that this was updated accordingly. IGARD noted the ONS' helpful and detailed analysis supporting their position which had been provided as a supporting document, but, for completeness, IGARD reiterated previous advice that there was still a risk with regard to the concept of *"functionally anonymous"*; specifically, there was a risk that the assessments relating to whether the data in the hands of researchers was anonymous in terms of the UK General Data Protection Regulation (UK GDPR) may come down on the wrong side of ICO guidance, once this was finalised. IGARD made reference to the recent observation by the European Data Protection Board that *"anonymisation of personal data should be approached with caution in the context of scientific research."* IGARD queried the statement in section 10 (Sub-licensing) point b (iii) *"that data to be accessed within the Public Health Research Database by an approved researcher is **rendered anonymous**…"*; and asked that this was amended to *"functionally anonymous"*, noting that this was the term used throughout the remainder of the application. IGARD and NHS Digital had a lengthy discussion on the National Data Opt-out (NDO), noting that NHS Digital's privacy notice stated *"The National Data Opt Out does not apply to the health data we share with ONS for their own statistical purposes, as this purpose is exempt under the National Data Opt Out Policy"*; however the Public Health Research Database is for research and not ONS official statistics. IGARD suggested that ONS should update their privacy notice to make clear that Opt-outs have **not** been applied to the data populating the asset. In addition, IGARD noted a risk to NHS Digital in respect of transparency that was needed regarding the fact that the NDO has **not** been applied to the dataflows used to create the data asset; and whether the letter or the spirit of the NDO policy was being honoured, by allowing researchers to access data that had not had the NDO applied to the underpinning flows of data that populate the asset. IGARD queried the statement in section 5(b) (Processing Activities) *"ONS will also refer all applications for access to linked data…to NHSD for their consent under SRSA via an **information governance (IG) approvals process agreed with them** under the sub-licence agreed via this application"*; and asked that this was updated with a further explanation of what the IG process was, for example, by incorporating information within the relevant supporting document(s), and in line with NHS Digital DARS Standard for processing activities. IGARD asked that, as previously agreed, NHS Digital provide regular updates to IGARD on any sub-licenses issued through the joint NHS Digital and the ICO IG panel; and that for transparency, such updates would be noted in the IGARD minutes.

	IGARD suggested that section 5(c) (Specific Outputs Expected) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD queried the reference to a *technical"* breach in section 1 (Abstract) and asked that the word *"technical"* was removed, noting there was currently not a clear definition of what distinguishes a technical breach from a non-technical breach. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel nature of the access and the quantum of data. **Outcome:** recommendation to approve by a quorum of 4 members, with one GP Specialist member present not participating in making a recommendation on the application due to a potential conflict of interest. The following amendments were requested: 1. To provide an explanation in section 5: that the use of the GDPPR data is continuing, the mechanism for the continued use of the data, such as the legal basis, and the processes in place to provide oversight and assurance for this data. 2. To update section 5 to ensure the first reference to the Statistics and Registration Service Act also notes the acronym (SRSA). 3. To update the reference in section 5(b) to *"…information governance approvals process agreed with them…"*, to explain what the IG process is, for example, by incorporating information within the relevant supporting document(s). 4. To update point b (iii) in section 10, to amend the wording from *"rendered anonymous"* to *"functionally anonymous"*, using the term used throughout the remainder of the application. 5. To update section 5(c) to use a form of wording such as "*it is hoped* …", rather than "*it will*…". 6. To remove reference to the breach being *"technical"* in section 1. The following advice was given: 1. IGARD noted ONS' helpful and detailed analysis supporting their position but, for completeness, IGARD reiterated previous advice that there is still a risk with regard to the concept of *"functionally anonymous"*; specifically, there is a risk that the assessments relating to whether the data in the hands of researchers is anonymous in terms of UK GDPR may come down on the wrong side of ICO guidance, once this is finalised. IGARD made reference to the recent observation by the European Data Protection Board that *"anonymisation of personal data should be approached with caution in the context of scientific research."* 2. IGARD suggested that ONS should update their privacy notice to make clear that Opt-outs have **not** been applied to the data populating the asset. 3. IGARD suggested the reference to, and reliance on, section 39(4)(i) of the SRSA, which refers to personal data, was checked noting the application asserts that the researchers are accessing functionally anonymous data and **not** personal data. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel nature of the access and the quantum of data.

	5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel nature of the access and the quantum of data. **Risk Factors:** • Transparency is needed regarding the fact that the NDO has not been applied to the dataflows used to create the data asset. • Whether the letter or the spirit of the NDO policy is being honoured, by allowing researchers to access data that has not had the NDO applied to the underpinning flows of data that populate the asset. **ACTION:** NHS Digital to provide an update to PAG on the status of this application by 13th May 2022, and to confirm to the IGARD Secretariat that this action has been closed. **ACTION:** NHS Digital to provide regular updates to IGARD on any issued sub-licenses. Such updates will be noted in IGARD minutes for transparency.
3.3	Our Future Health: Our Future Health Recruitment Programme (Presenter: Frances Perry) NIC 414067-K8R6J-v0.2 **Application:** This was a new application for identifiable Demographics data. The purpose of the application is for a research programme to support people living healthier lives for longer through better prevention, earlier detection and improved treatment of diseases. The programme will aim to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early when outcomes are usually better. The programme aims to recruit up to 5 million adults from across the UK (from a variety of different recruitment routes including NHS Digital) to create a diverse and inclusive cohort of people who have consented to participate in the research. The aims of the research are to **1)** build a resource linking multiple sources of health and health-relevant information, including genetic data, on millions of people in the UK, to facilitate basic discovery research by academic and commercial researchers on early indicators of disease; **2)** to analyse the data in the resource to estimate personal disease risk information for participants, based on genetic and non-genetic information, and offer this estimated personal health information to participants who wish to receive it; **3)** to re-contact sub-groups of participants generally for additional samples, non-routine data and secondary studies over time; and **4)** to re-contact participants on a risk-stratified basis, specifically to enable secondary studies by academic and commercial researchers that is greatly enhanced by being able to identify highly enriched sub-populations / sub-cohorts of participants. The study is relying on s251 of the NHS Act 2006, for the flow of contact details out of NHS Digital. **Discussion:** IGARD noted and commended NHS Digital on the quality of the information provided within section 1 (Abstract) of the application, which supported the review of the application by Members. IGARD confirmed that they were of the view that the relevant s251 was broadly compatible with the processing outlined in the application. IGARD noted that some of the wording in the Pilot NHS DigiTrials Recruitment Support Services Direction 2021, seemed to be contradictory with the stated aims of the programme. Item 2.4.2 states the direction does not provide a legal basis to process data on behalf of NHS

	DigiTrials customers. However, IGARD advised that, taken in the round with the specification document, it did appear to provide a legal gateway for the processing outlined in the application. IGARD suggested that any future Direction is checked to ensure any potential ambiguity is addressed. IGARD discussed the potential bias resulting from sectors of society not forming part of the cohort, and suggested that the applicant should address this by; referring to the lessons learnt from recent cohort study exercises, for example, the autism genetics project; Spectrum 10K - Common Variant Genetics of Autism and Autistic Traits (GWAS) and expanding on the references within the consent materials to providing information to *"insurance companies",* for example by reference to industry standards, noting that they may be updated from time to time, such as code-on-genetic-testing-and-insurance-final.pdf (abi.org.uk). In addition, IGARD suggested that the researchers were made aware of, if not already, of the latest developments and current issues in respect of the UK General Data Protection Regulation (UK GDPR) and Genomics data. IGARD noted the benefits in section 5(d) (Benefits), however, asked that further information was provided, on **how** it was envisaged that the selection and recruitment process would help improve representation for those groups traditionally under-represented in health research, noting, amongst other features, that consent must be given electronically, and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD suggested that in order to address concerns about cohort members losing capacity to consent in the future, the applicant could take robust forward-looking consent now, to ensure a continued legal gateway into the future and avoid the need to obtain future consultee advice or having to utilise another mechanism. IGARD discussed Opt-outs, both service specific and the National Data Opt-out (NDO); and noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) on occasion require reference to the NDO in cohort gathering exercises; and suggested that reference to the NDO was advisable within the contact materials, in a way that did not cause confusion. IGARD queried the UK Research and Innovation (UKRI) UKRI Life Sciences Industrial Strategy funding information in section 5(a) (Objective for Processing), and asked that this was updated, to acknowledge the immediate benefit, including, but not limited to, being positively associated with a high-profile project, and in line with NHS Digital DARS Standard for Commercial Purpose. In addition, IGARD noted that the funding information in section 5(a) also stated that there would be *"Development of Accreditation process for Founding members to apply for accreditation of their own Trusted Research Environments (TRE's)"* and asked that this was removed as NHS Digital had indicated it was no longer the plan, and instead be replaced with an explanation as to how data would be accessed. IGARD noted the various Boards referred to in section 5(a), and asked that further clarity was provided as to which Boards had patient and public involvement and engagement (PPIE) representatives; and if any boards did not have PPIE representatives, suggested that further consideration was given, as whether PPIE representatives could usefully contribute; and in line with HRA guidance on Public Involvement. IGARD noted the statement in section 5(b) (Processing Activities) *"In order to mitigate the risk of individuals being invited by more than one recruitment route…"*, and asked that this was

amended to make clear that the mitigation referred to individuals responding more than once rather than being contacted more than once.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel nature of the application.

Outcome: recommendation to approve

The following amendments were requested:

1. To update section 5(d) to provide further information on **how** it is envisaged that the selection and recruitment process will help improve representation for those groups traditionally under-represented in health research, noting, amongst other features, that consent must be given electronically.
2. To update the UKRI Life Sciences Industrial Strategy funding information in section 5(a), to acknowledge the immediate benefit to commercial partners, including (but not limited to) being positively associated with a high-profile project, and in line with NHS Digital DARS Standard for Commercial Purpose.
3. In respect of PPIE:
   a) To clarify in section 5(a) which Boards have PPIE representatives; and
   b) If any boards do not have PPIE representatives, to give further consideration if PPIE representatives could usefully contribute.
4. To amend section 5(b) to make clear that the mitigation refers to individuals responding more than once rather than being contacted more than once.
5. To remove the statement in section 5(a) *"…accreditation of their own Trusted Research Environments (TRE's)"* , and explain how data will be accessed.

The following advice was given:

1. IGARD noted that some of the wording in the Pilot NHS DigiTrials Recruitment Support Services Direction 2021 seemed to be contradictory with the stated aims of the programme; however, taken in the round with the specification document, does appear to provide a legal gateway. IGARD suggested that any future Direction is checked to ensure any potential ambiguity is addressed.
2. IGARD suggested that in order to address concerns about cohort members losing capacity to consent in the future, the applicant could take robust forward-looking consent now, to ensure a continued legal gateway into the future and avoid the need to obtain consultee advice or utilise another mechanism.
3. IGARD discussed Opt-outs, both service specific and NDO; and noted that HRA CAG on occasion required reference to the NDO for cohort gathering exercises, suggested that reference to the NDO was advisable within the contact materials, in a way that does not cause confusion or deter potential participants.
4. IGARD suggested that the applicant should address issues that may result in any unrepresentative cohort by:
   a) Referring to the lessons learnt from recent cohort study exercises, for example, the autism genetics project; Spectrum 10K - Common Variant Genetics of Autism and Autistic Traits (GWAS). and
   b) expanding on the references within the consent materials to providing information to *"insurance companies",* for example by reference to industry standards (as they may be updated from time to time) such as code-on-genetic-testing-and-insurance-final.pdf (abi.org.uk),

	c) taking note of the latest developments and current issues in respect of UK GDPR and Genomics data. 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel nature of the application. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel nature of the application.
4	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).
4.1	NIC-604851-W0M3S-v1.2 GRAIL Bio UK Ltd (No Presenter) The purpose of this application is to carry out follow-up analysis based on a cohort of patients who are being recruited to a clinical trial called 'NHS-Galleri'. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 13th January 2022. IGARD noted that on the 25th April 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement, to five years in length. IGARD noted and thanked NHS Digital for the written update, and noted that at the IGARD BAU meeting on the 13th January 2022, they had recommended for approval for 1-year; and had been unable to recommend for approval a three-year DSA, until such time the NHS Digital DARS Standard(s) had been updated. In addition, IGARD drew the applicant and NHS Digital to the advice previously given and significant risk factor outlined at the BAU meeting on the 13th January 2022. IGARD asked that the next iteration of the DSA should be brought to a future IGARD BAU meeting.
4.2	NIC-15814-C6W9R Monitor (No Presenter) The purpose of this application was to request data for the NHS Trust Development Agency, NHS England / NHS Improvement, and Monitor as joint Data Controllers for use to support the delivery of statutory functions and support improvement and / or oversight of Trusts. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 17th March 2022. IGARD noted that on the 29th April 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an urgent release of Patient Level Information and Costing System (PLICS) data under this Data Sharing Agreement. IGARD noted and thanked NHS Digital for the written update and supported the confirmation from NHS Digital, that the next iteration of the DSA, with the PLICS dataset included, would be brought to a future IGARD BAU meeting.
5	Oversight & Assurance

IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital.

- **NIC-148024-P8GSC-V3.3 Ministry of Defence (SIRO Precedent)**

  IGARD noted that the application had SIRO approval under precedent until November 2022, however the application had been extended to February 2023, with no explanation given in section 1 (Abstract) as to the additional three-month extension to the twelve-month SIRO approval.

  IGARD noted that the application had a number of high risks identified by DARS: the purpose section does not provide sufficient detail as to: the activities undertaken; the Common Law Duty of Confidence, and ethical approval. A number of medium risks had been identified by DARS: seven NHS DARS Standards were not met (Data Minimisation, Objective for Processing, Processing Activities, Expected Measurable Benefits, Yielded Benefits, Ethical Approval and Duty of Confidentiality).

  IGARD reiterated their previous advice when it had been part of O&A on the 26th November 2020 and advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the fact that there had been no previous independent IGARD / DAAG review and that seven NHS Digital DARS Standards were not met.

  IGARD reiterated that they had still not seen the risk matrix and scoring, and which had not been included as a supporting document because it had not been labelled as an *"SD"*.

- **NIC-148322-TMFVQ-v8.2 University of Oxford (Simple Amendment)**

  IGARD noted that the transparency action plan had not been provided to IGARD, since its recommendation to approve the application on the 13th May 2021 and had not been provided as part of the OOC consideration on 21st October 2021. IGARD were unclear of the decision reached not to have IGARD review the progress on the communication plan, noting that the last newsletter published on the EPIC website was from 2020, noting that their recommendation to approve and support was based on the implementation of the action plan.

  IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent to check on the progress of the action plan.

- **NIC-15741-J6Y4L-V3.1 Queen Mary University of London (Class Action: risk assessed DSA Extension)**

  IGARD noted that the previous DSA had expired on the 31st July 2020 however there was no explanation or narrative in section 1 (Abstract) as to why the application had been out of agreement for such a period of time.
  IGARD noted that a number of medium risks had been identified by DARS: four NHS DARS Standards were not met (expected outcomes, expected measurable benefits, duty of confidentiality and transparency (fair processing), also issues with data controllership (the applicant had confirmed that since PHE had been dissolved that NHS England and NHS Improvement had become joint Data Controllers), the Common Law Duty of Confidentiality (some evidence relating to HRA CAG s251 remains outstanding), and

	actions plans / special conditions (the privacy notice has been partially updated but does not state the retention period or data processing periods). IGARD reiterated that they had still not seen the risk matrix and scoring, and which had not been included as a supporting document because it had not been labelled as an *"SD"*. IGARD reiterated previous advice that NHS Improvement cannot sign documents in its own right since it is not a legal entity and is made up of NHS TDA and Monitor. IGARD noted that the applicant had reused NHS England's DPA registration, which was incorrect. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the fact that four NHS Digital DARS Standards were not met, and the action plan had not been completed. • **NIC-29827-Q8Z7Q-v4.4 University of Oxford (Extension & Renewal)** IGARD noted that the Yielded Benefits did not meet the NHS Digital DARS Standard for Expected Measurable Benefits and that NHS Digital should check that the yielded benefits against the expected benefits. • **NIC-351722-W7D4N-v13.2 CRAB Clinical Informatics (Extension & Renewal)** IGARD noted that the Yielded Benefits did not meet the NHS Digital DARS Standard for Expected Measurable Benefits and that NHS Digital should check that the yielded benefits against the expected benefits, noting that the Yielded Benefits were outlined clear on the company's website. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the commercial aspect of the application, and that including this extension it would be four years between independent reviews. • **NIC-381078-Y9C5K-v7.2 HDRUK (Simple Amendment)** IGARD reiterated their previous advice when it had been recommended for approval on the 29th July 2021 and advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the novel nature of the TRE and how the data controllership agreement is progressing • **NIC-72626-V4P9B-v3.4 Nottingham University Hospitals NHS Trust (Extension & Renewal / Simple Amendment)** IGARD noted contradictory statements in section 1 (Abstract): not adding to the cohort **and "***Recruitment commenced on 14/02/2012 and is still on-going*" and suggested that this should be clarified as soon as possible. • **NIC-86954-Y0R2N-v6.2 University College London (Extensions & Renewals)** IGARD noted that a significant risk had been identified for NIC 420168-K4N1F University of Bristol when discussed at the CV19 response meeting on the 12th January 2021, and noted this significant aspect was feeding into the Trusted Research Environment, which was not mentioned. IGARD noted that the extension and renewal was for three years, however there was no mention within the DSA of the additional use of data and in line with the NHS Digital DARS Standards.

	IGARD suggested that a review of all linked application to University of Bristol's TRE be undertaken by NHS Digital. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the linked nature of this application and that NHS Digital should ensure that all linked TRE applications are brought to the same IGARD BAU meeting for discussion (those seeking recommendation and those included as a SD for information so that they can be seen in the round). IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was January 2022. IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to February 2022: NHS Digital Data Uses Register - NHS Digital.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: Adult Psychiatric Morbidity Survey (APMS) Population Health Survey Precedent (Presenter: Frances Hancox) NHS Digital attended the meeting to discuss the above Precedent, following comments / feedback provided by IGARD members in February 2022. NHS Digital noted that only two applications had progressed under the Precedent to date, noting that some had progressed under SIRO and picked up as part of oversight and assurance. It was agreed that a future discussion be pencilled in for the first week in November 2022 to review the precedent again.
7.2	Update on the National Disease Registration Service (NDRS) service go live into Secure Data Access (Presenter: Liz Gaffney) The Head of Data Access, Data Access Request Service (DARS) attended the meeting to provide IGARD with a verbal update on the changes to the NDRS service. NHS Digital confirmed that work was ongoing to align the services as they are onboarded to DARS and that there was no requirement to stand up any additional IGARD BAU Meetings in the next 12 months or so in addition to the Thursday meeting, to deal with any "backlog", since NHS Digital will operate a 12-month grace period through extension letters to allow applicants time to meet the NHS Digital DARS Standards. NHS Digital expect new applications to progress through the DARS process to meet the NHS Digital DARS Standards and IGARD Assurance, and this would be managed through the current processes in place. IGARD noted the content of the verbal update and thanked the Head of Data Access for attending the meeting.

7.3	<u>CCG / ICS applications</u> Garry Coleman, NHS Digital SIRO, attended IGARD to give members a verbal update on the latest wording in CCG / ICS applications with regard to sub-licencing and their accountability for their Data Processors. IGARD noted the content of the verbal update and thanked the NHS Digital SIRO for attending the meeting.
7.4	<u>Process for referral to the NDG or HRA CAG</u> IGARD noted that they had been provided with a draft copy of the NHS Digital resolution path process for proceeding with GP Data applications that IGARD had not recommended for approval. IGARD committed to providing comments to NHS Digital on the draft process document by the end of May 2022. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 29/04/22

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-374190-D0N1M	Genomics England	16/12/2021	1. In respect of the consent: a. To provide a written analysis of the 100,000 Genomes Project consent assessment which establishes there is appropriate legal basis through consent for the use of the data as a control group for this research. b. To upload a copy of the written analysis to NHS Digital's CRM. 2. In respect of the territory of use: a. Noting that the special condition section 6 notes that users of the data must be physically based in the UK, and that SGSS / CHSS datasets are UK use only, to provide confirmation that those requirements from the disbanded PHE still apply. b. To notify the SIRO that there may have been a breach of the DSA in relation to the access of data from outside the permitted territory of use. c. To update or delete the special condition in section 6, as may be	IGARD members	Quorum of IGARD members	None

			necessary, to reflect any current restrictions on the use of CHSS / SGSS data.			
NIC-414909-M5W6W	University of Oxford	31/03/2022	1. In respect of the Pharmacy 2U direct marketing database: a) To provide written confirmation that Pharmacy 2U will **not** include any individuals taking part in this trial on their direct marketing database, unless they have consented to be part of the database. b) To upload the written confirmation to NHS Digital's CRM system for future reference.	IGARD *Members*	Quorum of IGARD Members	*IGARD comments*: We would suggest that NHS Digital clarifies that the study participants will **not** receive any marketing contact in any form - as "not receive marketing emails" would not, for example, preclude receiving marketing material in the post. We were trying to ensure there would be **no contact** unless the individuals were introduced to the commercial companies by other means/were existing customers/consented to receiving marketing info via a route other than participation in the study. We note that these actions mitigate the risk factor.

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

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None