Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 14 July 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Observer: item 3.1) (Items 7.1 – 7.2)
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: Item 3.3)
Louise Dunn	Data Access Request Service (DARS) (Item 3.1) (**SAT Observer**: item 3.2)
Dan Goodwin	Data Access Request Services (DARS) (Observer: item 3.3)
Mary Kisanga	Data Access Request Services (DARS) (Observer: Item 3.1)
Shaista Majid	Data Access Request Services (DARS) (Item 3.4)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Items 7.1 – 7.2)
Tania Palmariellodiviney	Data Access Request Services (DARS) (**SAT Observer**: Item 3.4)
Gemma Walker	Data Access Request Services (DARS) (Observer: item 3.1)
James Watts	Data Access Request Service (DARS) (Observer: item 3.1)

Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Service (DARS) (Item 3.2)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Maria Clark noted professional links to the Royal College of Surgeons (NIC-656842-S5V7V), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Maria Clark noted professional links to NHS England (NIC-656842-S5V7V), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 7th July 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	NHS England and Healthcare Quality Improvement Partnership (HQIP): Gastro-Intestinal Cancer Audit Programme (GICAP) (ODR1819_260) (Presenter: Louise Dunn) NIC-656842-S5V7V 0.2 **Application:** This was a new application to NHS Digital (previously processed within Public Health England – reference no ODR1819_260) for identifiable National Disease Registration Service (NDRS) Cancer Registry, NDRS National Radiotherapy Dataset (RTDS), NDRS Rapid Cancer Registrations and NDRS Systemic Anti-Cancer Therapy Dataset (SACT). The National Gastrointestinal Cancer Audit Programme which comprises of National Bowel Cancer Audit (NBOCA) and the National Oesophago-Gastric Cancer Audit (NOGCA), is commissioned by HQIP on behalf of NHS England, as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The purpose of the application is to support the aims of NBOCA, which is to assess the quality of care received by patients with bowel cancer in England and Wales, providing those who commission, deliver and use services for people with colorectal cancer with high quality data on the process and outcomes of NHS care; and NOGCA who are aiming to assess the quality of care received by patients with oesophago-gastric cancer or oesophageal high-grade dysplasia (a pre-cancerous condition) in England and Wales. The cohort will consist of approximately 300,000 individuals who have been diagnosed with either Bowel or Oesophageal Cancer between the 1st April 2014 and the latest available data;

	as well as any individuals who have received a diagnosis falling under a selection of ICD-10 codes but were not included in the cohort provided. The study is relying on s251 of the NHS Act 2006 to flow the data out of NHS Digital. NHS Digital noted that the data sharing agreement (DSA) was for a period of 12-months, and that this was in-line with previous PHE process, however advised that work was currently ongoing within NHS Digital to enable DSAs for data previously processed within PHE to have longer DSA timeframes, as deemed appropriate, and in-line with existing NHS Digital policy. **Discussion:** IGARD noted that the NDRS Cancer Registration Briefing Paper and the NDRS Cancer Registration: Non-Routine Collections Briefing Paper had previously been presented at the IGARD business as usual (BAU) meetings on the 7th April 2022 and 12th May 2022. IGARD welcomed the 'first of type' application and commended NHS Digital for the excellent work undertaken on this application to ensure it meets NHS Digital DARS Standards. IGARD noted the verbal update from NHS Digital in relation to the length of the DSA, and ongoing work within NHS Digital to permit longer DSAs where appropriate for data previously processed within PHE. IGARD advised that they supported NHS Digital's move to undertake all necessary work, to allow NDRS DSAs, to be longer than one-year, to enable regular data drops and minimise the burden on the applicant of applying for data every year. IGARD confirmed that they were of the view that the relevant s251 support was compatible with the processing outlined in the application. NHS Digital advised IGARD that NHS Digital's Production Team had a wealth of knowledge and experience, in respect of the very specific data fields within the NDRS datasets, and have worked closely with the applicant, to ensure that **only** appropriate data would be flowing for the specialised cancer projects, in line with NHS Digital DARS standard for data minimisation. IGARD noted and thanked NHS Digital for the verbal update and asked that a brief explanation of this was added to section 5(a) (Objective for Processing) for transparency. IGARD queried the statement in section 1 (Abstract) *"…the *RCS re-identifies the data when necessary"*, and were advised by NHS Digital that although the RCS do have the ability to re-identify the data, this was **not** permitted under this DSA. IGARD noted the verbal update from NHS Digital, and asked that for transparency, section 5(b) (Processing Activities) was updated to reflect this point. *Royal College of Surgeons (RCS) IGARD queried if, as well as being used to carry out the audit activity described in the application, if the data was also made available by HQIP for third parties to apply for other purposes via its data access requests programme. NHS Digital advised that the Data Controllers were **not** permitted to further disseminate NHS Digital data under this DSA, for example, via a sub-license; and that any further dissemination of the data, would be subject to a separate DSA being submitted to NHS Digital via the usual process, including, but not limited to, the appropriate Research Ethics Committee (REC) support in place where appropriate. IGARD queried what Opt-outs may be applicable for data subjects, noting that this was unclear within the application, and asked that this was clarified in section 5(b); along with further confirmation as to how the Opt-outs were applied to the flows of data. IGARD noted that there were issues with the transparency of the NDRS datasets to the public, for example, historical information in the public domain that needed updating; and it was agreed that NHS Digital would set up a meeting between the NDRS Engagement and

	Awareness Team and an IGARD member, to discuss transparency of the Registration Datasets. IGARD queried the statements relating to intellectual property in section 5(a) *"The data requested is to be used for the assessment of performance of services under contract to the HQIP…"*, and asked that as section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register, this was removed, since reference to intellectual property rights were not relevant / necessary to the DSA. IGARD noted the statement in section 5(a) *"The NHS Digital Clinical Audit and Registries Management Service (CARMS) is a data processor…"*; and asked that as section 5 forms NHS Digital's data uses register, this was removed as it was not relevant / necessary to include. IGARD noted the specific encryption methodology in section 5(b), and asked that this was removed, as it was not relevant / necessary to include. IGARD noted that section 5(b) was not currently clear that the data would be transferred using Secure Electronic File Transfer (SEFT), and asked that for transparency, this was updated accordingly to reflect the correct information. IGARD noted the importance of the audits and the information within the yielded benefits to reflect this, however asked that section 5(d) (Benefits) (iii) (Yielded Benefits) was updated further, to ensure all the yielded benefits were in line with NHS Digital DARS Standard for Expected Measurable Benefits. In addition, IGARD asked that the yielded benefits in section 5(d) (iii) were framed in terms of the clinical audit cycle, that is: standard, finding, intervention and the impact of the intervention on attaining the standard. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(b) to clarify that whilst the RCS does have the ability to re-identify the data, the DSA does **not** permit this. 2. To update section 5(a) with a brief explanation of the work undertaken by NHS Digital's Production Team to ensure that only appropriate data will be flowing, in line with NHS Digital DARS standard for data minimisation. 3. To update section 5(a) to reflect that the Data Controllers are not permitted to further disseminate NHS Digital data under this DSA, any further dissemination would be subject to a separate DSA, with appropriate REC support where appropriate. 4. As section 5 forms NHS Digital's data uses register: a) To remove the paragraph in section 5(a) *"The data requested is to be used for…"* since reference to intellectual property rights is not relevant. b) To remove the paragraph in section 5(a) *"The NHS Digital clinical audit and…"* as reference to NHS Digital being the Data Processor is not relevant. 5. In respect of the Opt-outs: a) To update section 5(b) to clarify the different Opt-outs that may be applicable; and, b) To confirm in section 5(b) how they are applied to the flows of data. 6. To remove the references in section 5(b) to the specific encryption methodology. 7. To update section 5b to clarify that the data is transferred using Secure Electronic File Transfer (SEFT). 8. In respect of the yielded benefits in section 5(d) (iii):

	a) To update the yielded benefits in line with NHS Digital DARS Standard for Expected Measurable Benefits b) To update the yielded benefits to ensure these are framed in terms of the clinical audit cycle. The following advice was given: 1. IGARD supported NHS Digital's move to undertake all necessary work, to allow NDRS DSAs, to be longer than one-year, to enable regular data drops and minimise the burden on the applicant of applying for data every year. **ACTION:** NHS Digital to set up a meeting between the NDRS Engagement and Awareness Team and an IGARD member, to discuss transparency of the Registration Datasets.
3.2	University of Oxford: OPtimising Treatment for Mild Systolic hypertension in the Elderly: a randomised controlled trial (OPTiMISE) (Presenter: Clare Wright) NIC-459340-M8R2Rv0.11 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E) and HES Admitted Patient Care (APC). The purpose of the application is for a long-term follow-up study of participants enrolled into the OPTiMISE trial. Participants were enrolled into the OPTiMISE trial between April 2017 and September 2018 and underwent active follow-up until January 2019. The trial remains ongoing in passive follow-up (active participation from participants is no longer required). This study aims to examine the effect of antihypertensive deprescribing on adverse events including cardiovascular disease, death and falls in patients enrolled into the OPTiMISE trial. The findings of this work is hoped to establish the longer-term impact of antihypertensive deprescribing and inform clinical guidelines on the treatment of high blood pressure in older age adults. NHS Digital noted that prior to the meeting, an IGARD member had raised a query in respect of the cohort figure of 558 noted within section 5(a) (Objective for Processing). NHS Digital advised that 569 patients were randomised in the study, of which 11 originally withdrew from the study during the 12-week trial period, however only 4 withdrew consent for long term follow-up. NHS Digital advised that version 2.2 of the patient information sheet (PIS) had been sent to all participants who are still alive and are believed to have retained mental capacity apart from 62; the 62 participants are registered at GP practices, and that the applicant is currently waiting to hear back from the GPs as to individuals' vital status. NHS Digital advised that of those who have received version 2.2 of the PIS, only 2 participants had asked that they were withdrawn from the long-term follow-up. NHS Digital confirmed that at present, the final analysis cohort would comprise of **563 participants**, pending any further withdrawals from the 62 participants still to receive version 2.2 of the PIS. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted and thanked NHS Digital for the clarification in respect of the cohort numbers to date.

	IGARD confirmed that they were of the view that the consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD noted in section 5(a) that the pseudonymised primary care data for the study, would be collected via the Oxford Royal College of General Practitioners (RCGP) Clinical Informatics Digital Hub (ORCHID). Noting that it was unclear within the application, IGARD queried if the GP practices joining the ORCHID database, and subsequently the data uploaded to the ORCHID database, was the data for the **entire** GP practice population, and asked that written confirmation was provided. In addition, IGARD asked that written confirmation was provided, that the appropriate transparency was in place to cover this, including, but not limited to, in the GP practice(s) and / or their website(s). IGARD also queried whether patients from those GP practices who were **not** members of the ORCHID database, could be usefully followed up, without access to the information held in the ORCHID database; and asked that section 5(a) was updated with further clarity. In addition, IGARD asked that clarity was provided in section 5(a), whether for patients from those GP practices who were **not** members of the ORCHID database, the flows of NHS Digital data in respect of those patients was appropriate. IGARD noted the linkage of consented OPTiMISE trial patients, to data held in ORCHID, and queried how this can be done without identifying patients in the ORCHID database, noting the ORCHID database was **not** identifiable data; and asked that for transparency, further clarity was provided in section 5(a). IGARD noted a reputational risk to NHS Digital in respect of the linkage to NHS Digital data if there was insufficient transparency relating to the data to which it was linked. IGARD queried if the data was truly pseudonymised, if the Study Team held the identifiers. NHS Digital advised that the Study Team **only** had access to the pseudonymised data, and had no access to identifiers; however, noted that the identifiers were stored securely and separately from the main study database, within the University of Oxford. IGARD noted the verbal update from NHS Digital, and asked that for transparency, further clarity was added to section 5(b) (Processing Activities), on the controls in place to ensure there was no re-identification of the data subjects by those accessing the data. IGARD noted the statement in the 'data minimisation' column in section 3(b) (Additional Data Access Requested) *"The minimal number of fields required…"*; and asked that this was updated to remove the incorrect reference to *"minimal"* and replace with *"minimum".* IGARD noted the statement in section 5(a) *"This study showed that deprescribing can be successfully achieved in two thirds of patients with no short-term impact on blood pressure control, quality of life or serious adverse events."* , and asked that a publicly available web link or Harvard reference for a journal / book to the reference was provided, in order for the public to read the relevant background information. IGARD suggested that NHS Digital may wish to audit this DSA, particularly with respect to transparency for the data to which NHS Digital data is being linked. IGARD advised that this application would be suitable for NHS Digital's Precedent route including the Senior Information Risk Owner (SIRO) route, if all qualifying NHS Digital's Data Access Request Services (DARS) Standards were met. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the ORCHID database:

	a) To provide written confirmation that for the GP practices joining the ORCHID database the data uploaded to the ORCHID database is the data for the entire GP practice population; and, b) To provide written confirmation that the appropriate transparency is in place to cover this, including (but not limited to) in the GP practice and / or their website; and, c) To clarify in section 5(a) whether patients from those GP practices who are **not** members of the ORCHID database, can be usefully followed up, without access to the information held in the ORCHID database; and, d) To clarify in section 5(a) whether for patients from those GP practices who are **not** members of the ORCHID database the flows of NHS Digital data in respect of those patients is appropriate; and, e) To explain in section 5(a) the linkage of consented OPTiMISE trial patients, to data held in ORCHID, to explain how this can be done without identifying patients in the ORCHID database, noting the ORCHID database is **not** identifiable data. The following amendments were requested: 1. To update section 5(b) to provide clarity on the controls in place to ensure there is no re-identification of the data subjects by those accessing the data. 2. To update section 3(b) to remove the reference to *"minimal"* and replace with *"minimum".* 3. To provide a publicly available web link or Harvard reference for a journal / book to the reference to *"This study showed that deprescribing can be successfully achieved in two thirds of patients with no short-term impact on blood pressure control, quality of life or serious adverse events."* in order for the public to read the relevant background information. The following advice was given: 1. IGARD suggested that NHS Digital may wish to audit this DSA, with particular reference to transparency around the data to which NHS Digital data is being linked. 2. IGARD advised that this application would be suitable for NHS Digital's Precedent route including the SIRO route, if all qualifying NHS Digital's DARS Standards are met. **Risk Area:** There is a reputational risk to NHS Digital in respect of the linkage to NHS Digital data if there is insufficient transparency relating to the data to which it is linked. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	University College London (UCL): Childhood outcomes after perinatal brain injury (Data flowing to ONS) (Presenter: Dan Goodwin) NIC-342322-Q1N7Mv1.3 **Application:** This was an amendment application to add Imperial College London as a joint Data Controller. For this study, NHS Digital data will be disseminated for three cohorts of children under this Data Sharing Agreement (DSA) to create an overarching cohort by NHS Digital. Additional identifiable demographics data is also requested for three cohorts under the connected DSA NIC-475526-F3Z5H, to allow linkage to the National Pupil Database (NPD) at the Department for Education, allowing University College London (UCL) to explore long term health and educational outcomes. The purpose of this application is for a study comparing health and educational outcomes in children with perinatal brain injury; and will consist of two matched control groups, **1)** a preterm

	control group (before 34 weeks gestation) and **2)** a term control group (after 34 weeks gestation); providing the most complete picture of how children's lives are affected by perinatal brain injury. Reducing the number of infants with perinatal brain injury is a current governmental priority. Over 3,000 infants suffer a perinatal brain injury in England every year and in 2015 the Department of Health and Social Care (DHSC) declared a national ambition to halve the rates of perinatal brain injury by 2030. The proposed matched cohort includes approximately 130,384 infants. The maximum proposed follow up would be twelve years, and the minimum follow up of one year; and would include a total of 833,183-person follow-up years. The study is relying on s251 of the NHS Act 2006, for the flow of data into NHS Digital. NHS Digital noted that section 7 (Ethics Approval) would need amending to correctly reflect that supporting document (SD) 6.1 was version 1.6 and not 1.5. Noting that the DSA was for more than a one-year period, NHS Digital advised that a standard special condition would need adding to section 6 (Special Conditions), in respect of the DARS annual confirmation report that would need completing by the applicant. NHS Digital advised IGARD that they had noted that condition 1 of the Health Research Authority Confidentiality Advisory Group (HRA CAG) condition of support, in relation to continuing patient and public engagement, did not align with the recent annual review submitted and approved by HRA CAG. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 30th September 2021. IGARD noted that the connecting application NIC-475526-F3Z5H had been presented at the IGARD BAU meeting on the 30th September 2021. IGARD noted and supported the verbal update from NHS Digital in respect of the update to section 7, to reflect the correct version number of SD1.6. IGARD also noted and supported the verbal update from NHS Digital in respect of the special condition that would be added to section 6, in relation to the annual confirmation report process. IGARD confirmed that they were of the view that the relevant s251 support was compatible with the processing outlined in the application. IGARD noted the verbal update provided by NHS Digital in respect of the HRA CAG condition of support relating to engagement. Noting that the annual report submitted by the applicant had been accepted and processed by HRA CAG, IGARD suggested that NHS Digital liaised with HRA CAG to confirm that there were no concerns with further engagement. IGARD noted that they had previously asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which subsection of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. NHS Digital's Privacy, Transparency & Ethics (PTE) attended the IGARD BAU meeting on the 7th July 2022, and suggested that the legal basis for NHS Digital to disseminate pseudonymised data to universities under s261 was likely to be: s261(5)(d). IGARD asked that section 3 (Datasets Held / Requested) be updated with the most appropriate s261 subsection, in line with the .

	IGARD noted the language in section 5(b) (Processing Activities), and noting this forms NHS Digital's data uses register, suggested that it was updated to ensure that it was written in a language suitable for a lay reader, including, but not limited to, amending the reference from *"autism spectrum disorders"* to *"autism spectrum condition"*. and that further sensitive consideration was given to the patient audience and how this type of language could be perceived. 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 large quantity of data flowing and the HRA CAG query with regard to further engagement. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3(b) with the s261 legal basis for NHS Digital to disseminate data. 2. To amend section 7 to reflect the correct version of SD 6.1 (as per the verbal update from NHS Digital). 3. To update section 6 with NHS Digital's special condition with regard to the annual confirmation report (as per the verbal update from NHS Digital). 4. To update section 5(b) to ensure it is written in a language suitable for a lay reader and that sensitive consideration is given to the patient audience, including (but not limited to) amending the reference from *"autism spectrum disorders"* to *"autism spectrum condition"*. The following advice was given: 1. IGARD noted the verbal update provided by NHS Digital in respect of the HRA CAG condition of support relating to engagement. Noting that the annual report submitted by the applicant had been accepted and processed by HRA CAG, IGARD suggested that NHS Digital liaised with HRA CAG to confirm that there were no concerns with further engagement. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the large quantity of data flowing and the HRA CAG query with regard to further engagement. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the large quantity of data flowing and the HRA CAG query with regard to further engagement.
3.4	King's College Hospital NHS Foundation Trust: **PRE**gnancy-associated progression of chronic kidney **DI**sease: development of a **C**linical predictive **T**ool (PREDICT): The National Registry of Rare Kidney Diseases (RaDaR), UK Renal Registry (UKRR), Hospital Episode Statistics (HES), and Maternity Services Data Set (MSDS) Linkage (Presenter: Shaista Majid) NIC-324170-J4P1Jv1.5 **Application:** This was an amendment application to **1)** add additional years of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) from 1997/98 - 1999/00, a further 3 years, in addition to receiving the already approved HES APC data from 2000/01 -2020/21 latest available; and **2)** to add the HES APC 'EPITYPE' and 'DIAD_NN' fields to ensure that comorbidities of the women are captured in the data. The study team have established unique research collaborations to develop a prediction tool for pregnancy-associated progression of Chronic Kidney Disease (CKD) using data from approximately 60,000 women. The prediction calculator will allow women, their families and

	partners and health care professionals to input relevant data (e.g. severity of kidney disease, presence of high blood pressure) and the tool will estimate the chance of kidney function loss as result of pregnancy. Out of the 60,000 women provided in the cohort to NHS Digital, it is estimated that between approximately 750 and 6,000 cohort members will be identified as pregnant. The study is relying on s251 of the NHS Act 2006 to flow the data in and out of NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 21st January 2021. IGARD confirmed that they were of the view that the relevant s251 support was compatible with the processing outlined in the application. IGARD queried why, noting the volume of historical data already requested by the applicant, a further three-years of data was required, in addition to the data already requested. NHS Digital advised that following the review of the application by IGARD in 2021, the applicant and NHS Digital's Production Team had agreed that volume of data previously requested was not sufficient, and the additional three-years was required to increase the cohort number to further support the outcomes of the study, ideally to 3,000 women, although this is an estimate. In addition, NHS Digital noted that no data had flowed to the applicant to date. IGARD noted the verbal update from NHS Digital, and asked that section 5(a) (Objective for Processing) was updated, with additional explanation as to why the additional three-years of data had been added to the data sharing agreement (DSA), for example, following internal discussions with NHS Digital's Production Team. In addition, IGARD noted the verbal update from NHS Digital in respect of the issues encountered by the applicant in identifying the correct volume of data required, and suggested that NHS Digital should look at how they can further support applicants to clarify at an earlier stage of the process the correct volume of data to sufficiently support the objectives for processing, in line with NHS Digital DARS standard for data minimisation. IGARD queried the statement in section 5(b) (Processing Activities) *"The Renal Association will send NHS Digital one file of cohort data from the Rare Renal Disease Registry (RaDaR) and UK Renal Registry (UKRR) including the identifiers"*; and asked that further clarity was provided on this, including, but not limited to, how this data would be kept separate from the NHS Digital data. IGARD asked that as section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register, section 5(b) **and** section 5(d) (Benefits) were amended throughout, so technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example in respect of the encryption of data and equations. IGARD advised that this application would be suitable for NHS Digital's Precedent including the Senior Information Risk Owner (SIRO) Precedent route if all qualifying NHS Digital's Data Access Request Services (DARS) Standards are met. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) with additional explanation as to why the additional three-years of data has been added to the DSA, for example, internal discussions with NHS Digital's Production Team.

	2. As section 5 forms NHS Digital's data uses register, to amend section 5(b) **and** section 5(d) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example in respect of the encryption of data and equations. 3. To provide further clarity in section 5(b) on the linkage of *"…one file of cohort data from the Rare Renal Disease Registry (RaDaR) and UK Renal Registry (UKRR)…"*, including (but not limited to) how this data will be kept separate from the NHS Digital data. The following advice was given: 1. IGARD advised that this application would be suitable for NHS Digital's Precedent including the SIRO Precedent route if all qualifying NHS Digital's DARS Standards are met. **Separate to this application:** IGARD noted the verbal update from NHS Digital in respect of the issues encountered by the applicant in identifying the correct volume of data required, and suggested that NHS Digital should look at how they can further support applicants to clarify at an earlier stage of the process the correct volume of data to sufficiently support the objectives for processing, in line with NHS Digital DARS standard for data minimisation.
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). *No items discussed.*
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. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. 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 May 2022. IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: Common Law Duty of Confidentiality (CLDoC) / pseudonymised data (Garry Coleman / Jonathan Osborne) NHS Digital's Associate Director / Senior Information Risk Owner (SIRO) and the Deputy Caldicott Guardian attended the meeting, to provide an update, and the advice they will subsequently seek from NHS Digital's Legal Department, with regard to pseudonymised data;

	and whether such advice needs to consider whether additional controls provided by the Data Controllers (e.g. fortress) might change that advice, which was in response to queries IGARD had raised in-meeting on numerous applications with regard to CLDoC. Currently data is controlled via a data sharing agreement / data sharing framework contract, which clearly articulates how data is processed, i.e. that data should not be re-identified etc; however this delineates between the differing risk factors, for example if the pseudonymised data has a *"wrapper"* or if the organisation has local patient identifiers etc. IGARD suggested that any scenarios put forward for advice to NHS Digital's Legal Department, should have specific questions underpinning, so that a clear answer could be provided as to what the conditions were for someone to rely on the common law legal basis. NHS Digital noted their thanks to IGARD for raising the query. IGARD thanked NHS Digital for the verbal update and looked forward to receiving further information in due course, alongside a copy of the update draft scenarios and draft questions.
7.2	Guardian Article & NHS Digital (Garry Coleman / Jonathan Osborn) IGARD welcomed the brief verbal discussion with regard to the Guardian article, with NHS Digital's Associate Director / Senior Information Risk Owner (SIRO) and the Deputy Caldicott Guardian. IGARD noted the proactive work that NHS Digital do with regard to audit breaches, but suggested that NHS Digital may wish to be more proactive in publicising the outputs of audit activities, for example, a quarterly press release to outline the work undertaken. NHS Digital noted that IGARD minutes continue to be important for public transparency since they outline audit breaches for applications. IGARD suggested that the Caldicott Guardian discuss these points with the NHS Digital Communications Team as part of the Caldicott Guardian's role around public trust.
7.3	The Health Service Control of Patient Information (COPI) Regulations 2022 IGARD noted that the Coronavirus (COVID-19 Notice under Regulation 3(4) of the Health Service (Control of Patient Information) (COPI) Regulations 2002 had been extended to the 31st October 2022 for those who demonstrate effective compliance by carrying out the required processing using the OpenSAFELY platform for COVID-19 purposes only. There was no further business raised, the Deputy 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 08/07/22

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-136916-B7D5C-v2	University College London (UCL)	26/05/2022	1. In respect of the amendment to add The Health Foundation as a Data Processor: a) To provide written confirmation that NHS Digital are content that adding The Health Foundation as a Data Processor is the most appropriate route; or, b) To provide written confirmation that a secondment or other honorary contract for the individual from The Health Foundation to UCL is more appropriate; and, c) In either case to make a clear statement why the individual will not be carrying out data controllership activities, in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts; and, d) To update the application as necessary throughout, reflecting the above.	IGARD Chair	IGARD Chair	The condition is no longer relevant as The Health Foundation is no longer carrying out any processing activities, be that via a data processing agreement or via an employee on an honorary contract: **On those facts, I am content that the condition (and its limbs) can be set aside** Please make the necessary amendments and for completeness (and to be prudent) insert a clear statement that the individual on the Honorary Contract will, in due course, be acting on the instructions of the applicant and not carrying out data controllership activities for the Health Foundation. I do not need to

						see the wording again and would be happy for a senior manager to support Dan to sign off the wording.

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