Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 3 November 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member (not in attendance for item 3.3)
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Associate Director, Deputy SIRO & Audit Services (Item 3.5)
Dave Cronin	Data Access Request Services (DARS SAT) (Item 3.5) (**SAT Observer**: Item 3.6)
Catherine Day	Data Access Request Services (DARS SAT) (Item 3.3)
Louise Dunn	Data Access Request Services (DARS SAT) (Item 5)
Duncan Easton	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.1 to 3.2)
Dan Goodwin	Data Access Request Services (DARS) (Items 3.1 to 3.2)
Frances Hancox	Data Access Request Services (DARS) (Item 7.1)
Tanmai Kalathurvadyer	Data Access Request Services (DARS) (**Observer:** items 3.1 to 3.4)
Mary Kisanga	Data Access Request Services (DARS SAT) (Item 5)
Dickie Langley	Privacy, Transparency, Ethics and Legal (PTEL) (Item 7.2)
Sara Lubbock	Data Access Request Services (DARS) (**Observer:** item 3.6)

Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (**Observer**: item 3.5)
Jodie Taylor-Brown	Data Access Request Services (DARS) (**Observer:** items 3.1 to 3.2)
Kimberley Watson	Data Access Request Services (DARS SAT) (**SAT Observer:** items 3.3 to 3.4)
Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Services (DARS) (Item 3.6)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Maria Clark noted that as part of her role as officer of the BMA as Vice Chair of its Patient Liaison Group, she had a professional link with NIC-148411-Q64H8. However, she noted no specific connections with the application, or the staff involved, and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 27th October 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	University College London (UCL): British Regional Heart Study (BRHS) (Presenter: Dan Goodwin) NIC-148411-Q64H8-v4.4 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registration (Deaths) data and Demographics data. It was also an amendment application to **1)** add Newcastle University as a joint Data Controller and Data Processor; **2)** to add an additional field 'General Practice Code' to the Demographics data set; and **3)** to remove Cause of Death Lines in the Civil Registration (Deaths) data set. The purpose of the application, is to enhance The British Regional Heart Study (BRHS) cohort study by obtaining more robust, detailed data on disease outcomes to research ways to prevent CVD, heart failure, dementia and disability in older ages. The researchers will link the NHS Digital data to pseudonymised data in the BRHS cohort study, which has been obtained (from the cohort) over the last 40 years; this includes mortality, cancer, postal questionnaire

	data completed by the participants, questionnaire data collected from General Practice and data collected during the physical assessments in 1978 -1980, 1998-2000 and 2010-2012. The data requested has been minimised to a cohort of approximately 8,000 individuals, currently aged 82-102 years~~.~~ NIC-148411-Q64H8 covers data supplied on the basis of s251 support. NIC-28591-H5Q3X (item 3.2) covers data supplied on the basis of consent. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 2nd August 2018. IGARD noted that NIC-28591-H5Q3X and relevant supporting documents had previously been presented at the IGARD meeting on the 28th June 2018; and had been discussed under 'Applications progressed via NHS Digital's Precedent route' on the 17th February 2022. IGARD noted that, prior to the meeting, an IGARD member had raised a query with NHS Digital, in respect of the information provided in section 3(b) (Additional Data Access Requested) that listed Cancer Registration Data, Civil Registration (Deaths) data and Demographics data for use in research; noting that the Patient Information Advisory Group (Health Research Authority Confidentiality Advisory Group's (HRA CAG) predecessor) (PIAG) gave permission under (PIAG 1-07(d)/2004) *"to collect CVD-related incident morbidity for prevention and the promotion of a disability-free life in older men aged over 65 years"* and under medical purposes only ticks 'preventive medicine', **not** 'medical research, approved by a research ethics committee'. IGARD noted that there was an amendment to receive Hospital Episode Statistics (HES), Diagnostic Imaging Dataset (DIDs) and the Mental Health Minimum Dataset (MHMDS) data but **not** cancer data; and queried if the purpose had been expanded to include research and if the scope had been extended to include cancer registration data. NHS Digital advised that the study was permitted to receive cancer data as part of their s60 support, which was then updated to s251 support. When the agreement was migrated from MRIS to the automated Cohort Management System the fields were mapped to the extract products in the new system (Demographics, Civil Registration Deaths and Cancer Registration data) so no extra data flowed as part of that change. NHS Digital noted that when the application was discussed at IGARD on the 2nd August 2018, the HRA CAG Annual Review which was provided as a supporting document, stated that the approval was to continue to receive cancer data, therefore it appeared that the scope had not changed. IGARD noted and thanked NHS Digital for the feedback on this issue, however, asked that written confirmation was provided from HRA CAG, for example in the form of an e-mail or similar, that the current s251 support maps to the processing outlined in the application; and that the written confirmation from HRA CAG was uploaded to NHS Digital's CRM system for future reference. IGARD noted that NIC-28591-H5Q3X (item 3.2) was linked to this application, and covered data supplied on the basis of consent; and asked that for transparency, section 5(a) of this application (Objective for Processing) was updated with further information of how the two cohorts and applications would work together, noting that this was currently unclear. IGARD noted the references throughout section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) to the involvement of the *"students"*, and asked that further clarification was provided, for example, were the students undergraduates or postgraduates, how many students etc. In addition, IGARD queried the difference between the *"students"* and the *"researchers"* referred to in section 1 and section 5; and asked that further clarification was provided on the difference between the two and that a distinction was provided.

	IGARD noted the technical terms within section 5(a) when referring to heart failure, for example *"reduced ejection heart failure and preserved ejection heart failure"*; and asked that these were removed and a more simplified reference was added, for example *"types of heart failure"*, or similar, in line with NHS Digital DARS Standard for Objective for Processing. IGARD queried the statement in section 5(b) (Processing Activities) to the study receiving *"GP record review - Morbidity data collected annually directly from participants GP"*; and noting that there was no information to support this; asked that section 5(b) was updated with clarification as to how the GP data would be collected, in line with NHS Digital DARS Standard for processing activities. IGARD noted the statement in section 5(b) *"There is no need to re-identify the patients from the pseudonymised dataset*"; and asked that for clarity, this was deleted given the application goes on to explain how re-identification is prevented. IGARD queried the statement in section 5(b) *"Data is downloaded securely from NHS Digital SEFT and provides data security during transmission (by using a 256-bit AES encryption mechanism)…"*; and asked that this was amended and replaced with less technical / restrictive wording, for example, *"appropriate encryption"* or similar; in line with NHS Digital DARS Standard for processing activities, or the text should be removed completely. IGARD noted the example given in section 5(c) (Specific Outputs Expected) with regard to developing initiatives *"Research from the BRHS has already been used to shape and change many policies on cardiovascular disease prevention, both nationally and internationally, for example, in developing initiatives for primary prevention of CVD and dementia in South East London"*; and asked that further clarification was provided on the initiatives developed in South East London and why this specific example was cited. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to move any outputs to section 5(c), and edited to only leave examples that reflect the benefits to the Health and Social Care System, in line with the NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD also noted that section 5(c) contained information more aligned with yielded benefits, for example, guidelines that have been influenced as a result of the study; and asked that this information was moved from section 5(c) to section 5(d) (iii) (Yielded Benefits). IGARD noted the yielded benefits in section 5(d) (iii) and, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, asked that this information was updated / amended to retain the details provided of two or three specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally. IGARD noted references in section 5(d) to the *"…management of people..."* and "*management of these patients*"; and asked that section 5(d) was updated to correctly refer to the *"condition"* being managed and not the people / patients. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions.

	Noting the importance, scope and the long running nature of the study, IGARD suggested that there may be further benefit from the inclusion of COVID-19 data, for example, COVID-19 infection and vaccination data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews undertaken as necessary and as per process. In addition, IGARD suggested that if the application did add COVID-19 datasets to the data sharing agreement (DSA), that Health Research Authority Confidentiality Advisory Group (HRA CAG) should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG documentation to support this, were uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD also suggested that the applicant may wish to liaise with the funder of the study in respect of the additional COVID-19 limb to the study, which may, for example, look at possible links between CVD and COVID-19 infection and / or vaccination status. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the HRA CAG s251 support: a) To provide written confirmation from HRA CAG that the current s251 support maps to the processing outlined in the application; b) To upload the written confirmation from HRA CAG to NHS Digital's CRM system for future reference. The following amendments were requested: 1. To provide clarification in section 5(a) of how the two cohorts / applications work together. 2. In respect of the students / researchers referred to in the application: a) To update section 1 **and** section 5 to clarify the status of students; and, b) To update section 1 **and** section 5 to clarify the difference between the students and researchers. 3. To update section 5(a) to remove technical references when referring to heart failure, and replace with *"types of heart failure"* or similar. 4. To clarify in section 5(a) how the GP data will be collected. 5. To delete the statement in section 5(b) *"There is no need to re-identify the patients from the pseudonymised dataset.*" 6. To amend or remove the reference in section 5(b) *"256-bit AES encryption mechanism…"*; and replace with *"appropriate encryption"* or similar. 7. To provide further clarification on the reference in section 5(c) to the *"developing initiatives…in South East London"*. 8. In respect of section 5(d) and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To remove any specific outputs from section 5(d) and move to section 5(c); and, b) To remove any yielded benefits from section 5(c) and move to section 5(d) (iii). c) To update section 5(d) to ensure references to *"…management of people..."* and similar, are updated to refer to the *"condition"* being managed. d) Given the significant volume of data, to update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to either patients or the health and care system more generally.

	e) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 9. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. In respect of any additional COVID-19 datasets: a) Noting the importance, scope and the long running nature of the study, IGARD suggested that there may be further benefit from the inclusion of COVID-19 data, for example, COVID-19 infection and vaccination data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews undertaken as necessary and as per process. b) IGARD suggested that if the application did add COVID-19 datasets to the DSA, that HRA CAG should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG documentation to support this were uploaded to NHS Digital's CRM system for future reference. c) IGARD suggested that the applicant may wish to liaise with the funder of the study in respect of any additional COVID-19 limb to the study, which may, for example look at possible links between CVD and COVID-19 infection and / or vaccination status. It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair.
3.2	University College London (UCL): British Regional Heart Study (BRHS)- data linkage of established cohort to NHS Digital datasets (HES, MHMDS, DIDS) (Presenter: Dan Goodwin) NIC-28591-H5Q3X-v3.4 **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Emergency Care Data Set (ECDS), Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, HES Outpatients, Mental Health Services Data Set (MHSDS), Bridge file: Hospital Episode Statistics to DIDs and Bridge file: HES to Mental Health Minimum Data Set (MHMDS). It was also an amendment application to add Newcastle University as a joint Data Controller and Data Processor. The purpose of the application is to enhance The British Regional Heart Study (BRHS) cohort study by obtaining more robust, detailed data on disease outcomes to research ways to prevent CVD, heart failure, dementia and disability in older ages. The researchers will link the NHS Digital data to pseudonymised data in the BRHS cohort study, which has been obtained (from the cohort) over the last 40 years; this includes mortality, cancer, postal questionnaire data completed by the participants, questionnaire data collected from General Practice and data collected during the physical assessments in 1978 -1980, 1998-2000 and 2010-2012. Data will be restricted to 4,123 cohort participants who have provided consent to follow up. NIC-148411-Q64H8 (item 3.1) covers data supplied on the basis of s251 support. NIC-28591-H5Q3X covers data supplied on the basis of consent.

	NHS Digital advised IGARD that section 5(a) (Objective for Processing) was missing an objective that was reflected in the linked application NIC-148411-Q64H8; and confirmed that the application would be updated to ensure this was added to section 5(a). **Discussion:** IGARD noted that NIC-28591-H5Q3X and relevant supporting documents had previously been presented at the IGARD meeting on the 28th June 2018; and had been discussed under 'Applications progressed via NHS Digital's Precedent route' on the 17th February 2022. IGARD noted that NIC-148411-Q64H8 and relevant supporting documents had previously been presented at the IGARD meeting on the 2nd August 2018. IGARD noted the verbal update from NHS Digital in respect of the missing objective from section 5(a); and supported the update to the application to include the missing information. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted that NIC-148411-Q64H8 (item 3.1) was linked to this application and covered data supplied on the basis of s251 support; and asked that for transparency, section 5(a) of this application was updated with further information of how the two cohorts and applications would work together, noting that this was currently unclear. In addition, IGARD queried the difference between the *"students"* and the *"researchers"* referred to in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs); and asked that further clarification was provided on the difference between the two and that a distinction was provided. IGARD noted the technical terms within section 5(a) when referring to heart failure, for example *"reduced ejection heart failure and preserved ejection heart failure"*; and asked that these were removed and a more simplified reference was added, for example *"types of heart failure"*, or similar, in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted the statement in section 5(b) *"There is no need to re-identify the patients from the pseudonymised dataset*"; and asked that for clarity, this is deleted given the application goes on to explain how re-identification is prevented. IGARD queried the statement in section 5(b) *"Data is downloaded securely from NHS Digital SEFT and provides data security during transmission (by using a 256-bit AES encryption mechanism)…"*; and asked that this was amended or removed, and replaced with less technical / restrictive wording, for example, *"appropriate encryption"* or similar; in line with NHS Digital DARS Standard for processing activities. IGARD noted the example given in section 5(c) (Specific Outputs Expected) with regard to developing initiatives *"Research from the BRHS has already been used to shape and change many policies on cardiovascular disease prevention, both nationally and internationally, for example, in developing initiatives for primary prevention of CVD and dementia in South East London"*; and asked that further clarification was provided on the initiatives developed in South East London and why this specific example was cited. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to move any outputs to section 5(c), and edited to only leave examples that reflect the benefits to the Health and Social Care System, in line with the NHS Digital's DARS Standard for Expected Measurable Benefits.

	IGARD also noted that section 5(c) contained information more aligned with yielded benefits, for example, guidelines that have been influenced as a result of the study; and asked that this information was moved from section 5(c) to section 5(d) (iii) (Yielded Benefits). IGARD noted the yielded benefits in section 5(d) (iii) and, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, asked that this information was updated / amended to retain the details provided of two or three specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally. IGARD noted references in section 5(d) to the *"…management of people..."* and "*management of these patients*"; and asked that section 5(d) was updated to correctly refer to the *"condition"* being managed and not the people / patients. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…" where appropriate. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. Noting the importance, scope and the long running nature of the study, IGARD suggested that there may be further benefit from the inclusion of COVID-19 data, for example, COVID-19 infection and vaccination data. IGARD advised that they would be supportive of the applicant receiving COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews undertaken as necessary and as per process. IGARD therefore suggested that the applicant consult with a group of cohort members (more than 3 but less than 7) in respect of any addition of the COVID-19 datasets to the DSA; to seek their views of the addition of the COVID-19 limb of the study and if this was a good / expected use of the patient data. IGARD also suggested that the applicant may wish to liaise with the funder of the study in respect of any additional COVID-19 limb to the study, and whether funding was available to support this important area of work, which may, for example look at possible links between CVD and COVID-19 infection and / or vaccination status. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to add the missing objective (as per NHS Digital's verbal update). 2. To provide clarification in section 5(a) of how the two cohorts / applications work together. 3. To update section 1 **and** section 5 to clarify the difference between the students and researchers. 4. To update section 5(a) to remove technical references when referring to heart failure, and replace with *"types of heart failure"* or similar. 5. To delete the statement in section 5(b) "There is no need to re-identify the patients from the pseudonymised dataset." 6. To amend or remove the reference in section 5(b) *"256-bit AES encryption mechanism…"*; and replace with *"appropriate encryption"* or similar.

	7. To provide further clarification on the reference in section 5(c) to the *"developing initiatives…in South East London"*. 8. In respect of section 5(d) and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To remove any specific outputs from section 5(d) and move to section 5(c); and, b) To remove any yielded benefits from section 5(c) and move to section 5(d) (iii). c) To update section 5(d) to ensure references to *"…management of people..."* and similar, are updated to refer to the *"condition"* being managed. d) Given the significant volume of data, to update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to either patients or the health and care system more generally. e) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" where appropriate. 9. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. In respect of any additional COVID-19 datasets: a) Noting the importance, scope and the long running nature of the study, IGARD suggested that there may be further benefit from the inclusion of COVID-19 data, for example, COVID-19 infection and vaccination data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews undertaken as necessary and as per process. b) IGARD suggested that the applicant consulted with a group of cohort members in respect of adding any COVID-19 datasets to the DSA. c) IGARD suggested that the applicant may wish to liaise with the funder of the study in respect any additional COVID-19 limb to the study, which may, for example look at possible links between CVD and COVID-19 infection and / or vaccination status.
3.3	UK Health Security Agency (UKHSA) / Public Health England (PHE): D1.1 - UK Health Security Agency (UKHSA) Single Data Sharing Agreement (Presenter: Catherine Day) NIC-343380-H5Q9K-v16.6 **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Community Services Data Set (CSDS), Emergency Care Data Set (ECDS), Health Survey for England, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES-ID to MPS-ID HES Outpatients, Mental Health Services Data Set (MHSDS) v5.0, National Diabetes Audit (NDA), Primary Care Mortality Data; **and** identifiable Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19, NHS 111 Online Dataset, ECDS, Maternity Services Data Set, Secondary Uses Service (SUS+) Payment by Results (PbR) data, SUS plus - Admitted Patient Care (beta version), Hospital Episode Statistics Accident and Emergency (HES A&E), HES APC, HES Critical Care, HES Outpatients, Escriva Registration (Deaths) bridge.

	It was also an amendment to request identifiable Covid-19 UK Non-hospital Antigen Testing Results (pillar 2); Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3) and Secondary Uses Service Payment By Results Spells data. UKHSA is responsible for preventing, detecting, analysing, responding to and leading partnerships to protect the UK from communicable diseases and other threats to public health. It is a direct provider of health protection services as well as a processor of data and information for public health purposes that do not involve direct interaction with patients and the public. The successful fulfilment of its remit depends on its ability to process data on the health of patients and the public, and on the social, economic and environmental factors that determine health. Some of the data UKHSA uses it collects directly, but it also depends on timely access to other sources of health data, such as the healthcare activity data collected at a national level by NHS Digital. A separate data sharing agreement (DSA) NIC-635697-P0C5M (Item 3.4) will list all the data sets that are processed exclusively by the Department of Health and Social Care (DHSC) / Office for Health Improvement and Disparities (OHID). **Discussion:** IGARD noted that a briefing paper relating to this application was discussed at the IGARD meeting on the 23rd June 2022. IGARD noted that the application had previously been discussed under 'Applications progressed via NHS Digital's Precedent route' on the 16th December 2021. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 27th July 2021. IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 3rd June 2021. IGARD noted that prior to the meeting, an IGARD Specialist member had raised a query with NHS Digital, in respect of the information in section 1 (Abstract) and section 5(a) (Objective for Processing), that identified three conditions under Article 9 the UK General Data Protection Regulation (UK GDPR) and noted that only two were referred to in section 3 (Datasets Held / Requested). IGARD asked for clarity that the application be updated as to how the datasets would be used under each Article 9 condition. NHS Digital advised that the application set out the public health purpose for each of the datasets and for all purposes Article 9(2)(i) was relied upon by UKHSA to carry out their processing activities; and that the purposes reflected the UKHSA health protection remit from the government. It also included responding to the COVID-19 public health emergency, infectious disease surveillance and control, syndromic surveillance, vaccination safety and efficacy monitoring, environmental hazards monitoring, monitoring and reporting at national, regional, and local levels to inform and guide responses to health protection threats. NHS Digital advised that Article 9(2)(h) and Article 9(2)(j) would be removed from section 3 and elsewhere in the application. IGARD noted the verbal update from NHS Digital and supported the update to the application to ensure the correct Article 9 condition was referred to. Prior to the meeting, an IGARD Specialist member had raised a query with NHS Digital, in respect of the statement in section 1 *"This DSA recognises the specific legal gateway provided to UKHSA under Section 60 of the Health and Social Care Act 2001, as re-enacted by Section 251 of the National Health Service Act 2006"*; noting the information in some of the supporting documents provided related to entities that now form part of NHS Digital; and therefore queried what s251 support UKHSA had for the flow of data under this data sharing agreement (DSA). NHS Digital advised IGARD that the supporting documents referred to had been

	shared in error and had now been retired from this DSA as supporting documents, noting they were only relevant to Public Health England (PHE). NHS Digital confirmed that UKHSA had approval from the Secretary of State for Health and Social Care to process confidential patient information for the purposes of diagnosing, recognising trends, controlling and preventing, and monitoring and managing communicable diseases and other risks to public health under section 60 of the Health and Social Care Act 2001, as re-enacted by section 251 of the National Health Service Act 2006, and, as a body listed under regulation 3(3), regulation 3(1) of the Health Service (Control of Patient Information) Regulations 2002 (COPI). Approvals to process confidential patient information under regulation 3, except regulation 3(4), are authorised by UKHSA itself on behalf of the Secretary of State for Health and Social Care and not subject to advice from the Health Research Authority's Confidentiality Advisory Group (HRA CAG), noting the remit of HRA CAG was restricted to advising the HRA and Secretary of State on requests to process confidential patient information under regulations 2, 3(4) and 5 only. IGARD noted and thanked NHS Digital for the verbal update, and asked that the application was updated throughout, to reflect that Regulation 3 of COPI was being relied on for the processing of confidential data. In addition, IGARD asked that the application was updated throughout to provide further details of the specific Regulation for processing, for example, in respect of the identifying Maternity Services Data Set, this may be Regulation 3(i)(d)(iii) for the delivery, efficacy and safety of immunisation programmes, due to the processing being in relation to the efficacy of the vaccination programmes. IGARD noted the objectives for processing in section 5(a), however asked that these were reviewed and updated / amended as appropriate to ensure that all processing was directly related to Regulation 3(1) of COPI, and in line with NHS Digital DARS Standard for Objective for Processing. In addition, IGARD asked that all outputs in section 5(c) (Specific Outputs Expected) **and** benefits in section 5(d) (Benefits); were reviewed and updated / amended as appropriate to ensure they were directly related to Regulation 3(1) of COPI, in line with NHS Digital DARS Standard for Expected Outcomes and NHS Digital DARS Standard for Expected Measurable Benefits. Noting that the public facing section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register, IGARD asked that for transparency, a statement was added to the beginning of section 5(a), explaining the purpose of requesting confidential data **and** why pseudonymised data cannot be used. IGARD noted that the identifiable data was flowing under Regulation 3; however queried the statement in section 3(c) (Patient Objections) *"For purposes that require the processing of confidential patient information but for which the legal basis is not provided by Regulation 3, national data opt-outs are applied by UKHSA"*, which implied that not everything was covered by Regulation 3 and NHS Digital may need to apply opt-outs. NHS Digital advised that the statement referred to would need removing from section 3(c), noting that this was historical and no longer applied; and that opt-outs were **not** applied as all of UKHSA's activity with identifiable data was covered by Regulation 3. IGARD noted the verbal update from NHS Digital and supported the update to the application to amend section 3(c) to reflect the opt-outs would **not** be applied. IGARD asked that for transparency, section 5 was updated with clarification that research was **not** being undertaken with identifying data. IGARD suggested that if any research was being

	undertaken with identifiable data, that the applicant would need to obtain s251 support from HRA CAG for the processing of this data. IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was the "*UK*"; however, in line with current published NHS Digital DARS Standard for Territory of Use, suggested that this was reviewed and updated / amended as appropriate because COPI was **only** applicable in England and Wales. **Separate to this application:** IGARD were concerned that NHS Digital DARS Standard Territory of Use was in use by DARS as a finalised version with regard to changing the territory of use on all applications to "*UK*", when IGARD had not returned their comments on the DARS Standard (returned on 3/11/22) and had significant issues with the use of "*UK*" rather than "*England and Wales*". IGARD could not see any analysis for the reason for the removal of the "*England and Wales*" option, which was concerning as that geographical level aligned (amongst other things) to various legislation and policy that refers to England and Wales (not Scotland and Northern Ireland), transparency notices, DPNs, regulations, HRA CAG support is for England and Wales etc. IGARD suggested that until the DARS Standard had been discussed and finalised, that DARS should continue to use "*England and Wales*" where applicable. IGARD noted that the Memorandum of Understanding (MOU) that predated the DSA between NHS Digital and PHE had been provided as a supporting document; and advised that key information from the MOU had not been copied across to the DSA. IGARD asked that the MOU was reviewed and, where applicable, appropriate sections were replicated in the DSA, including, but not limited to, clause 4.4, in respect of the onward sharing on data, and the mitigating protections in the appendices to the MOU. IGARD noted that prior to the meeting, an IGARD Specialist member had noted the statement in section 5(a) *"Data from these linked reference data sets may be shared by UKHSA with third parties in the form of identifiable or de-personalised extracts"*, and had queried whether there was a public Register of Dissemination. NHS Digital advised that work was currently underway within UKHSA to prepare a consolidated register of disseminations of personally identifiable or de-personalised data to third parties. IGARD noted and thanked NHS Digital for the verbal update provided, and asked that section 5 was updated with an indicative timeframe of when the Register of Dissemination will be published, for example, within three months. In addition, IGARD also asked that a special condition was added to section 6 (Special Conditions) clarifying the timeframe for the publication of the Register of Dissemination, in line with NHS Digital DARS Standard for Special Conditions. IGARD noted that the COVID-19 datasets in the DSA, for example Covid-19 UK Non-hospital Antigen Testing Results (pillar 2); Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3), were restricted to COVID-19 related research only; and asked that in line with NHS Digital DARS Standard for Special Conditions that a special condition outlining any restrictions were inserted in section 6, i.e. processing **must** be for the purpose of COVID-19 related research **only**. IGARD asked that in line with NHS Digital DARS Standard for Special Conditions, a special condition was inserted in section 6, that, following the signing of the DSA, a detailed annual review was scheduled in twelve-months. The relevant supporting documents should be provided by the applicant to NHS Digital during the calendar month preceding the Annual Review Date and these documents should be uploaded to NHS Digital's customer relationship management (CRM) system for future reference.

	IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, asked that this information was updated / amended to retain the details provided of two or three specific yielded benefits accrued to date with the identifiable data, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally; noting the large volume of data being processed. IGARD noted that legal advice had been sought from NHS Digital's Privacy, Transparency, Ethics and Legal (PTEL) in respect of the data controllership and data processing arrangements; and asked that this was uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD queried whether the ethnicity data derived from the GP data may provide more accurate and complete information for this important processing; and that IGARD would be supportive of the inclusion of this dataset in the DSA, however noted the required steps before this data could flow, for example, the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) and IGARD. 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 quantum and identifiability of the data; and the transparency. **Outcome:** recommendation to approve for 1-year The following amendments were requested: 1. In respect of the legal basis: a) To update the application throughout, to reflect that Regulation 3 of COPI is being relied on for the processing of confidential data; and, b) To update the application throughout to provide further details of the specific Regulations for processing. c) To update the application throughout to ensure that only the correct / relevant UK GDPR Article 9 condition was referred to. 2. In respect of processing, outcomes and benefits: a) To update section 5(a) to ensure that **all** the outputs are directly related to Regulation 3(1) of COPI. b) To update section 5(c) to ensure that **all** the outputs are directly related to Regulation 3(1) of COPI. c) To update section 5(d) to ensure that **all** the benefits are directly related to Regulation 3(1) of COPI. 3. To update section 5 to confirm that research is **not** being undertaken with identifying data. 4. To add a statement at the beginning of section 5(a) explaining the purpose of requesting confidential data **and** why pseudonymised data cannot be used. 5. To update section 3(c) to clarify that opt-outs will **not** apply. 6. To update the application with the appropriate sections of the MOU, for example, in respect of onward sharing of data. 7. To review the territory of use in section 2(c) and amend as appropriate.

	8. To update section 5 with clarification of when the Register of Dissemination will be published. 9. In respect of section 6 and in line with NHS Digital DARS Standard for Special Conditions: a) To add a special condition in section 6 clarifying the timeframe for the publication of the Register of Dissemination. b) To insert a special condition in section 6, that, following the signing of the DSA, a detailed annual review was scheduled in twelve-months. The relevant supporting documents should be provided by the applicant to NHS Digital during the calendar month preceding the Annual Review Date. These documents should be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. c) To insert a special condition in section 6 outlining the restrictions on the COVID-19 datasets, i.e. processing must be for the purpose of COVID-19 related research **only**. d) To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. 10. Given the significant volume of data, to update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to either patients or the health and care system more generally, in line with NHS Digital DARS Standard for Expected Measurable Benefits. The following advice was given: 1. IGARD suggested that if in future any research is being planned with identifiable data, that the applicant obtain s251 support from HRA CAG, and the DSA is updated and goes through the relevant approvals process. 2. IGARD queried whether the ethnicity data derived from the GP data may provide more accurate and complete information for this important processing; and that IGARD would be supportive of the inclusion of this dataset in the DSA, however noted the steps required before this data could flow, for example, PAG and IGARD. 3. IGARD noted that legal advice had been sought from NHS Digital's PTEL in respect of the data controllership and data processing arrangements; and asked that this was uploaded to NHS Digital's CRM system for future reference. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the quantum and identifiability of the data; and the transparency. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the quantum and identifiability of the data; and the transparency.
3.4	Office for Health Improvement and Disparities (OHID): DHSC Data Sharing Agreement managed by OHID (Presenter: Catherine Day) NIC-635697-P0C5M **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS), Health Survey for England, Hospital Episode Statistics Accident and Emergency (HES A&E), HES:Civil Registration (Deaths) bridge, HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Improving Access to Psychological Therapies Data Set_v1.5, Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), National Diabetes Audit (NDA), Primary Care Mortality Data, Community Services

	Data Set (CSDS), Improving Access to Psychological Therapies (IAPT) Data Set_v1.5, Maternity Services Data Set (MSDS) v1.5, National Child Measurement Programme, Personal Social Services Survey of Adult Carers, Sexual and Reproductive Health Services Activity Data Set; **and** identifiable ECDS, HES A&E, HES APC, HES Critical Care, HES Outpatients and Health Survey for England. DHSC is now a direct provider of health improvement services to patients and the public in England. The successful fulfilment of its remit depends on its ability to process data on the health status of patients and the public, and on the social, economic and environmental factors that determine health. Some of the data it uses it collects directly, but DHSC also depends on appropriate and timely access to other sources of health and care data, such as the health status and healthcare provider activity data collected at a national level by NHS Digital. NIC-343380-H5Q9K (Item 3.3) contains some of the datasets (also listed under this DSA) that are disseminated to UKHSA and then onwardly transferred to the Department for Health and Social Care (DHSC) to process for the purposes outlined in this DSA. **Discussion:** IGARD noted that a briefing paper relating to NIC-343380-H5Q9K was discussed at the IGARD meeting on the 23rd June 2022. IGARD noted that NIC-343380-H5Q9K had previously been discussed under 'Applications progressed via NHS Digital's Precedent route' on the 16th December 2021. IGARD noted that aspects of NIC-343380-H5Q9K had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 27th July 2021. IGARD noted that NIC-343380-H5Q9K and relevant supporting documents had previously been presented at the IGARD meeting on the 3rd June 2021. IGARD noted that the application identified three Article 9 conditions of the UK General Data Protection Regulation (UK GDPR) and asked for clarity that the application be updated as to how the datasets would be used under each condition. NHS Digital advised that Article 9(2)(h) and Article 9(2)(j) would be removed from section 3 and elsewhere in the application. IGARD noted the verbal update from NHS Digital and supported the update to the application to ensure the correct Article 9 condition was referred to. IGARD noted the objectives for processing in section 5(a), however asked that these were reviewed and updated / amended as appropriate to ensure that all processing of identifiable data was directly related to Regulation 3(1) of COPI, in line with NHS Digital DARS Standard for Objective for Processing. In addition, IGARD asked that all outputs in section 5(c) (Specific Outputs Expected) **and** benefits in section 5(d) (Benefits); were reviewed and updated / amended as appropriate to ensure they were directly related to Regulation 3(1) of COPI, in line with NHS Digital DARS Standard for Expected Outcomes and NHS Digital DARS Standard for Expected Measurable Benefits. Noting that the public facing section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register, IGARD asked that for transparency, a statement was added to the beginning of section 5(a), explaining the purpose of requesting confidential data **and** why pseudonymised data cannot be used. IGARD noted that the identifiable data was flowing under Regulation 3; however queried the statement in section 3(c) (Patient Objections) *"For purposes that require the processing of confidential patient information but for which the legal basis is not provided by Regulation 3, national data opt-outs are applied by DHSC"*, which implied that not everything was covered

	by Regulation 3 and NHS Digital may need to apply opt-outs. NHS Digital advised that the statement referred to would need removing from section 3(c), noting that this was historical and no longer applied; and that opt-outs were **not** applied as all of the activity with identifiable data was covered by Regulation 3. IGARD noted the verbal update from NHS Digital and supported the update to the application to amend section 3(c) to reflect the opt-outs would not be applied. IGARD asked that for transparency, section 5 was updated with clarification that research was **not** being undertaken with identifying data. IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was the "*UK*"; however, in line with the current published NHS Digital DARS Standard for Territory of Use, suggested that this was reviewed and updated / amended as appropriate because COPI was **only** applicable in England and Wales. **Separate to this application:** IGARD were concerned that NHS Digital DARS Standard Territory of Use was in use by DARS as a finalised version with regard to changing the territory of use on all applications to "*UK*", when IGARD had not returned their comments on the DARS Standard (returned on 3/11/22) and had significant issues with the use of "*UK*" rather than "*England and Wales*". IGARD could not see any analysis for the reason for the removal of the "*England and Wales*" option, which was concerning as that geographical level aligned (amongst other things) to various legislation and policy that refers to England and Wales (not Scotland and Northern Ireland), transparency notices, DPNs, regulations, HRA CAG support is for England and Wales etc. IGARD suggested that until the DARS Standard had been discussed and finalised, that DARS should continue to use "*England and Wales*" where applicable. IGARD noted that the Memorandum of Understanding (MOU) that predated the DSA between NHS Digital and PHE had been provided as a supporting document; and advised that key information from the MOU had not been copied across to the DSA. IGARD asked that the MOU was reviewed and, where applicable, appropriate sections were replicated in the DSA. IGARD asked that in line with NHS Digital DARS Standard for Special Conditions, a special condition was inserted in section 6, that, following the signing of the DSA, a detailed annual review was scheduled in twelve-months. The relevant supporting documents should be provided by the applicant to NHS Digital during the calendar month preceding the Annual Review Date and these documents should be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD asked that a special condition was inserted in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, asked that this information was updated / amended to retain the details provided of two or three specific yielded benefits accrued to date with the identifiable data, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally; noting the large volume of data being processed. In addition, IGARD noted the statement in section 5(d) (iii) *"The benefits arising from DHSC's data processing are manifest in the improvements to population health and wellbeing across England"*; and suggested that this was updated to state *"The DHSC aims to achieve*

	improvements to population health and wellbeing across England, by processing the data as set out in this agreement, as follows…". IGARD noted the reference to "*Caldicott Guardian"* in section 5(a) and asked that this was updated to also include the organisation of the Caldicott Guardian, since it was not clear. IGARD queried the statement in section 5(a) *"Enabling GPs to prescribe optimally, thus improving health outcomes"*; and queried if this could be achieved, and asked that it was either updated with further information or removed. IGARD noted the reference to *"NHS Clinical Commissioning Groups (CCGs)"* in section 5(b) (Processing Activities)and asked that this was updated to correctly reference *"Integrated Care Boards (ICBs)"*, noting that ICBs replaced CCGs on the 1st July 2022. IGARD queried the statement in section 5(a) "*DHSC is now a direct provider of health improvement services to patients and the public in England*"; and asked that section 5(a) was updated to confirming that there will be **no** processing for the purpose of direct care under this DSA. 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 quantum and identifiability of the data; and the transparency. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the legal basis: a) To update the application throughout, to reflect that Regulation 3 of COPI is being relied on for the processing of confidential data; and, b) To update the application throughout to provide further details of the specific Regulations for processing. c) To update the application throughout to ensure that only the correct / relevant UK GDPR Article 9 condition was referred to. 2. In respect of processing, outcomes and benefits: a) To update section 5(a) to ensure that **all** the outputs are directly related to Regulation 3(1) of COPI. b) To update section 5(c) to ensure that **all** the outputs are directly related to Regulation 3(1) of COPI. c) To update section 5(d) to ensure that **all** the benefits are directly related to Regulation 3(1) of COPI. 3. To update section 5 to confirm that research is **not** being undertaken with identifying data. 4. To add a statement at the beginning of section 5(a) explaining the purpose of requesting confidential data **and** why pseudonymised data cannot be used. 5. To update section 3(c) to clarify that opt-outs will **not** apply. 6. To update the application with the appropriate sections of the MOU. 7. To review the territory of use in section 2(c) and amend as appropriate. 8. In respect of section 6 and in line with NHS Digital DARS Standard for Special Conditions: a) To insert a special condition in section 6, that, following the signing of the DSA, a detailed annual review is scheduled in twelve-months. The relevant supporting documents should be provided by the applicant to NHS Digital during the calendar

	month preceding the Annual Review Date. These documents should be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. b) To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. 9. Given the significant volume of data, to update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to either patients or the health and care system more generally, in line with NHS Digital DARS Standard for Expected Measurable Benefits. 10. To update the statement in section 5(d) (iii) "*"The benefits arising from DHSC's data processing…".* 11. To update the reference in section 5(a) to *"Caldicott Guardian"* to also provide an organisation. 12. To amend / update the statement in section 5(a) *"Enabling GPs to prescribe optimally, thus improving health outcomes"*. 13. To update section 5(b) to remove reference to "*CCG*" and replace with "*ICB*". 14. To clarify in section 5(a) that there will be no processing for the purpose of direct care under this DSA. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the quantum and identifiability of the data; and the transparency. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the quantum and identifiability of the data; and the transparency.
3.5	Office for National Statistics (ONS): How immunity to SARS-CoV-2 affects future use of NHS resources and mortality (Presenter: Garry Coleman / Dave Cronin) NIC-599458-Y5Y8X-v0.5 **Application:** This was a new application for Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients. This application is a joint request from the Office for National Statistics (ONS) COVID-19 Infection Study (CIS) Analysis Team and the University of Oxford, that will permit the ONS to re-use pseudonymised subsets of the HES and GDPPR to link to data from the CIS. ONS plan to use their Secure Research Service (SRS) to give the University of Oxford, and other researchers following standard approval processes, access to this data as part of the research dataset in line with the research ethics committee approvals for the CIS. The re-use of this data will allow the linkage of information from these health sources, for CIS participants only, to the data collected from them by the CIS itself; thereby enabling the joint research team to answer important policy-relevant research questions and assist in the achievement of one of the CIS's exploratory research objectives to "assess how immunity to SARS-CoV-2, and having had SARS-CoV-2 infection, affects future use of NHS resources, development of specific conditions, and mortality".

	The outcomes of the research will be used by the Government and other advisory committees to guide ongoing decision making about the optimal policy response to the pandemic, and the longer-term consequences of COVID-19 infection on health more broadly. As such, the increase in the study's ability to answer important questions about the pandemic that would result from the integration of the HES and GDPPR will improve public health, help the NHS to plan for the future, for example in terms of increased incidence of specific health conditions following COVID-19, and potentially save lives. **Discussion:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted the importance of the research. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 14th December 2021. IGARD noted that the ONS and the University of Oxford were seeking permission to link participants' data, to obtain past medical information from 2016 up until 15 years after they 'stop taking part in the study', following the date of the final home visit. NHS Digital advised that they were seeking IGARD's view on a possible approach of permitting data to flow for three-years following the study; and then for ONS to seek either a reconsent / s251 for anyone that, at that point, is no longer participating actively in the Study, for example, not attending any follow-up sessions and not responding to surveys etc. IGARD noted that the original consent **only** permitted linkage of data for one year after the person's last visit. IGARD discussed whether the common law duty of confidentiality was met for linkage beyond one year. Applying the NHS Digital DARS Standard for Duty of Confidentiality, drafted with HRA CAG, IGARD concluded the common law duty of confidentiality was not met and could not be addressed via offering an opt-out in subsequent communication. IGARD, in accordance with the Schedule to that Standard, suggested NHS Digital consult HRA CAG . IGARD noted a risk to NHS Digital, that proceeding would deviate from the NHS Digital DARS Standard for Duty of Confidentiality Standard and may be contrary to the expectations of the data subjects who consented to the original data use. IGARD also cautioned NHS Digital against using forms of wording supporting the processing, suggesting there was a basis in consent, such as "*grounds for consent*". IGARD queried the content of the original consent forms, which were **not** included as part of the meeting pack but are available online, and asked that these were provided as supporting documents at the next IGARD review to support the discussion. IGARD noted that the Caldicott Guardian may support a public interest argument, given the potential public benefit of the research. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. The Common Law Duty of Confidentiality is not satisfied via consent (applying the NHS Digital DARS Standard for Duty of Confidentiality, drafted with HRA CAG input) and in accordance with the Schedule to that Standard; and suggested that the next step is for NHS Digital to speak to HRA CAG. 2. NHS Digital DARS Standard has not been met; and the data processing is incompatible with the consent, due to explicit exclusion which cannot be met via offering an opt out communication. 3. To provide original consent forms as supporting documents at the next IGARD review.

	4. If NHS Digital are minded to support the application, IGARD suggest that the Caldicott Guardian could consider a public interest argument. 5. A three-year period is not supported by consent or the reasonable expectations of data subjects. **Risk Factor:** proceeding would deviate from the NHS Digital DARS Standard for Duty of Confidentiality Standard and may be contrary to the expectations of the data subjects who consented to the original data use.
3.6	University of Oxford: EXTEND Study: Needs-Assessed Care for Early Psychosis (Presenter: Clare Wright) NIC-474674-R3F7S-v0.6 **Application:** This was a new application for pseudonymised Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care, Bridge file: HES to Mental Health Minimum Data Set (MHMDS), Civil Registration (Deaths), Emergency Care Data Set (ECDS), and Mental Health Services Data Set (MHSDS). The purpose of the application is for a study to investigate the impact of alternative durations of Early Intervention in Psychosis (EIP) care on service users' health outcomes. This will include understanding and contextualising the existing variations in the duration of EIP care provided and service user outcomes, and estimating the cost-effectiveness of an alternative, flexible, needs-assessed EIP service. The study team proposes to create and analyse a pseudonymised dataset linking routine health service data from NHS Digital, to a clinical audit dataset held by the Royal College of Psychiatrists (National Clinical Audit of Psychosis-NCAP). NHS Digital advised IGARD that there was information within section 5(d) (Benefits) relating to patient and public involvement and engagement (PPIE); and confirmed that this would be moved to section 5(a) (Objective for Processing). NHS Digital noted that section 2(c) (Territory of Use) stated that the territory of use was *"England and Wales"*; and advised that this was incorrect, and would be updated to state *"UK"*. **Discussion:** IGARD noted the verbal updates from NHS Digital, and supported the updates to the application to move the PPIE information from section 5(d) to section 5(a); but did not support the update to section 2(c) to reflect that the territory of use was the *"UK"* and asked that this remain as *"England and Wales"*. **Separate to this application:** IGARD were concerned that NHS Digital DARS Standard Territory of Use was in use by DARS as a finalised version with regard to changing the territory of use on all applications to "*UK*", when IGARD had not returned their comments on the DARS Standard (returned on 3/11/22) and had significant issues with the use of "*UK*" rather than "*England and Wales*". IGARD could not see any analysis for the reason for the removal of the "*England and Wales*" option, which was concerning as that geographical level aligned (amongst other things) to various legislation and policy that refers to England and Wales (not Scotland and Northern Ireland), transparency notices, DPNs, regulations, HRA CAG support is for England and Wales etc. IGARD suggested that until the DARS Standard had been discussed and finalised, that DARS should continue to use "*England and Wales*" where applicable. IGARD noted that section 5(a) referred to both the Chief Investigator from the University of Oxford, and the Manchester Metropolitan University (MMU) professor who is the Co-chief Investigator; and asked that further clarity was added to section 5(a) outlining the different roles and responsibilities of the Chief Investigators.

	IGARD noted that this data sharing agreement (DSA) was for the purpose of a workstream that was part of a larger programme; however, noting that this was not clear within the application, asked that section 5(a) was updated with further clarity, in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted the references in section 5(d) to *"system"*, for example *"…help the system to better understand the health and care needs of populations"*; and asked that this was updated to refer to *"health and social care system"*. NHS Digital noted the reference in section 5(d) to "*national health system"* and advised that this would be updated to correctly refer to *"National Health Service"*. IGARD noted the verbal update from NHS Digital and supported the amendment to section 5(d). IGARD noted that the NHS Digital citation special condition had been added in section 6 (Special Conditions), however asked that this was updated to also include the relevant quotation marks, for example *"this work uses data provided by patients and collected by the NHS as part of their care and support"*. **Outcome:** recommendation to approve The following amendments were requested: 1. To move the PPIE information from section 5(d) to section 5(a) (as per verbal update from NHS Digital). 2. To provide further clarity in section 5(a) on the Chief Investigator(s) roles. 3. To update section 5(a) to clarify that the workstream under this DSA is part of larger programme. 4. To amend the reference in section 5(d) from *"national health system"* to *"National Health Service"*. 5. To amend the references in section 5(d) from *"system"* to *"health and social care system"*. 6. To amend the NHS Digital citation special condition in section 6, to include the relevant quotation marks.
4 **4.1**	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). King's College London: The National Early Inflammatory Arthritis Audit Data Linkage Request (No Presenter) NIC-199726-F4V3C The purpose of this application, was for an audit looking to improve the quality of care for people living with inflammatory arthritis by assessing the performance of rheumatology units against NICE Quality Standards. There is compelling evidence that early intensive treatment greatly improves the outcome of these disabling diseases, which predominantly affect people of working age. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 7th March 2019 where IGARD were unable to recommend for approval. IGARD noted that on the 26th October 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a six-month extension to the Data Sharing Agreement (DSA). IGARD noted and thanked NHS Digital for the written update, however queried the end date of the extension which noted August 2023, noting that it was a six-month extension.

	In addition, IGARD asked that for future reference, the full history of the previous IGARD review was noted in section 1, including a copy of the minute extract and how the points raised had been addressed. IGARD asked that the next iteration of the DSA should be brought to a future IGARD meeting.
5	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. **Public Health England (PHE) migrated applications** IGARD queried if the updated briefing document National Disease Registration Service (NDRS) Congenital Anomalies Data Sets – Briefing Paper (tabled at IGARD 20 October 2022) was available. NHS Digital agreed to follow this up with the relevant personnel and table the updated briefing note, which could then be appended to a future set of IGARD minutes. Data sharing agreements (DSA) were novated from PHE following its cessation in 2021, concerning the National Disease Registry Service (NDRS). To manage these active DSAs DARS has added a record to the NHS Digital customer relationship management (CRM) system capturing at a high level some basic information on the controllers and purpose. This information was taken from the documentation available to DARS. The key purpose of this was to ensure that DARS had an active record of each novated agreement in CRM, which also allows DARS to trigger the automated DSA expire emails to applicants, capture correspondence with data controllers in one place, store all documents associated with the DSA and act as a "skeleton" application ready for the data controller to work on whilst they meet DARS Standards, should they wish to retain the data beyond the current DSA end date. The DSA which the controller holds for the continued access and processing of data, remains that which was novated from PHE until such time as it comes up for renewal. This further session between IGARD and DARS follows on from initial discussion at the 13th October 2022 meeting under oversight and assurance. • **NIC-656819-F7Q2C-v0.2 (PHE Migrated) University of Cambridge (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. • **NIC-656858-Y9D0P-v0.2 (PHE Migrated) University of Leeds (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. • **NIC-656869-N1K3D-v0.2 (PHE Migrated) University of Southampton (Precedent: N/A)**

	IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. • **NIC-656745-T4C2C-v0.2 (PHE Migrated) UK Biobank (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. • **NIC-656864-X5H4L-v0.2 (PHE Migrated) Health IQ Ltd (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. • **NIC-656874-T3L9D-v0.2 (PHE Migrated) University College London (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. • **NIC-656838-J7H7S-v0.2 (PHE Migrated) Imperial College London) (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. • **NIC-656866-V3H6X-v0.2 (PHE Migrated) Health IQ Ltd (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period.

	• **NIC-656882-D2N4G-v0.2 (PHE Migrated) Health IQ Ltd (Precedent: N/A)** IGARD noted a number issues and queries which were raised at today's meeting (*Please refer to the three advice points below, which may / may not be applicable to this application). DARS noted that prior to the expiry of the DSA, they will work with the data controller to bring the application, previously issued by PHE, up to the published NHS Digital Standards should they wish to continue to hold and process the data for a further period. * IGARD noted the following advice points may / may not be applicable to PHE migrated applications and any other linked briefing notes that could be tabled and published for transparency: 1. IGARD advised that where protocols specifically refer to pseudonymised data agreements should acknowledge that is the case. Where this is the case appropriate GDPR legal bases need to be cited. 2. IGARD advised that applicants should ensure that their transparency materials are appropriate and up to date including GDPR compliant privacy notices where necessary. 3. IGARD advised that where data flow has conditions set by various RECs that DARS check, or ask the application to confirm, those conditions are met. The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response. 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. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
6	COVID-19 update *No items discussed*
7 **7.1** **7.2**	AOB: Adult Psychiatric Morbidity Survey (APMS) Population Health Survey Precedent (Presenter: Frances Hancox) NHS Digital attended the meeting to discuss the APMS Precedent, following comments / feedback provided by IGARD members in February 2022; and following the discussion at the IGARD meeting on the 5th May 2022. IGARD thanked NHS Digital for attending the meeting to provide a verbal update, and suggested a couple of minor amendments to the APMS Precedent. IGARD thanks NHS Digital for attending and it was agreed that a further discussion would take place at a future IGARD meeting. Data Safe Haven (Presenter: Dickie Langley)

	NHS Digital attended the meeting to provide IGARD with a verbal update on the Data Safe Haven, including the ongoing work and current position around the NHS England / NHS Digital merger. IGARD noted and thanked NHS Digital for attending the meeting; and advised that they were able to support NHS Digital with the ongoing work on the Data Safe Haven when required; and stressed the benefits of early engagement on this area of work.
7.3	<u>GP Data for Planning & Research (GPDPR)</u> IGARD noted that NHS Digital were due to attend the meeting to discuss GPDPR; however NHS Digital had advised IGARD (via the IGARD Secretariat), that this would need to be held at a later date, due to ongoing discussions with the new Health and Social Care Ministerial Team. IGARD noted the update and looked forward to holding this important discussion as soon as possible and before the end of the year. 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 27/10/22

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-08472-V9S6K-v15.3	UK Biobank	08/09/2022	1. In respect of the COVID-19 datasets: a) To insert a special condition in section 6 outlining the restrictions on the COVID-19 datasets, i.e. processing must be for the purpose of COVID-19 related research **only**; and, b) To update section 5(a) with a brief reference to the restrictions on the COVID-19 datasets as per the special condition. c) To update section 5(a) with confirmation as to how Biobank UK has, to date, restricted access to the COVID-19 datasets for COVID-19 related research only.	IGARD members	Quorum of IGARD members	*N/A*

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