Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 6 May 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Nicola Bootland	Data Access Request Service (DARS) (Observer: item 2.1)
Vicky Byrne-Watts	Data Access Request Service (DARS)
Jon Coolican	DSCRO North West
Louise Dunn	Data Access Request Service (DARS) (Observer: item 3.3)
Liz Gaffney	Data Access Request Service (DARS)
Vicki Hartley	Data Access Request Service (DARS)
Jonathan Hope	Data Management
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Dave Roberts	Information Analysis and Statistic
Vicki Williams	IGARD Secretariat
Tom Wright	Data Services for Commissioners (DSfC)

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 29th April 2021 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 Papers**
2.1	<u>COVID-19 Ethnic Category Data Set (v0.3) Briefing Paper (Presenter: Jonathan Hope)</u> The briefing paper was to inform IGARD about a small stand-alone data set known as the COVID-19 Ethnic Category Data Set. This data set was created using ethnic category data from the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (COVID-19) (GDPPR) and Hospital Episode Statistics (HES). Ethnic category data is combined and 'cleaned' as part of the linkage process to create the best derived versions of fields. These fields will be made available for customers to request via the COVID-19 Ethnic Category Data Set. This data set will be made available for secondary uses in other areas where data relating to ethnic category is useful for the purposes of COVID-19 planning and research. Although outside of the scope of this briefing, this data will also be used for the following purposes; 1. Publication on the NHS Digital website of anonymised CCG level management info with small number suppression applied from the COVID-19 HES combined ethnic category analysis showing coverage and breakdowns by ethnic category for each CCG. This publication will complement efforts being made by CCGs and NHS England to improve ethnic category data coverage. 2. Added to the private dashboard release to the Ministry of Housing, Communities and and Local Government (MHCLG). A breakdown of Shielded patient list by Ethnic Category to allow them to ensure equality in the delivery of support packages to Shielded patients. IGARD noted that section 9 of the briefing paper, the legal bases for the processing, stated that the UK General Data Protection Regulation (GDPR) Article 9(2)(g) would be used for processing, as it was necessary for reasons of substantial public interest; and advised that as outlined in the Information Commissioner's Office (ICO) guidance, that *"…the relevant basis in UK law is set out in section 10(3) of the DPA 2018. This means that you need to meet one of the 23 specific substantial public interest conditions set out in Schedule 1 (at paragraphs 6 to 28). You must also have an 'appropriate policy document' in place for almost all of these conditions."*. IGARD suggested, that if the processing of the COVID-19 Ethnic Category Data Set, was reliant upon the substantial public interest condition in Article 9(2)(g), then the briefing paper was updated, with further details of how this was met. Alternatively, the public interest Article 9 legal basis could be removed, since Article 9(2)(h) (Health or Social Care), already listed within the briefing, adequately covered the processing outlined.

	IGARD advised that they looked forward to receiving the finalised briefing paper, alongside a first of type application as a supporting document; and, in addition, asked that once the briefing paper had been finalised, a copy was provided to the IGARD Secretariat for information, and as per usual process. **Outcome:** IGARD welcomed the briefing paper and made the following comments. 1. If relying on the substantial public interest condition in Article 9(2)(g), then there is also a need to meet one of the 23 specific substantial public interest conditions, set out in part 2 of schedule 1 of the DPA 2018 and IGARD suggested that it was detailed how this was met. Alternatively, the public interest Article 9 legal basis could be removed, since Article 9(2)(h) adequately covers the processing outlined. 2. To provide a copy of the finalised briefing paper to the IGARD Secretariat for information. IGARD looked forward to receiving the finalised briefing paper, alongside a first of type application as a supporting document. **Addendum 13th May 2021** Following the meeting on the 6th May 2021, NHS Digital provided written confirmation via the IGARD Secretariat, that NHS Digital's Privacy, Transparency and Ethics (PTE) (formerly Information Governance) had confirmed that that the processing outlined would sit under Article 9(2)(h). NHS Digital advised that the necessary amendments would be made to the briefing paper, and references to Article 9(2)(g) would be removed from the briefing paper; and that a final copy of the briefing paper would be shared with members at the IGARD meeting on the 20th May 2021 for information.
2.2	<u>Commissioner Briefing Paper (v0.03) (Presenter: Tom Wright)</u> The briefing paper was to inform a discussion with IGARD about understanding and accepting local authorities as a health and care commissioner and agreeing a way forward to allow them a similar scope and level of access to health data held by NHS Digital. It is clear that, within NHS Digital, a precedent has been set, whereby local authorities are not regarded as commissioners, even though since 2013 local authorities have commissioning responsibilities with regard to public health. The recommendation of this paper is that local authorities are to be also regarded as commissioners along with CCGs and that the view of a commissioner is expanded to include commissioners of social care and not just traditional health services. Furthermore, local authorities, with the appropriate governance (i.e. appropriate measures including data sharing agreements), should be allowed to receive commissioning datasets that are currently available to CCGs, via the means of onward sharing (to prevent duplication of costs), or a separate Data Processing contract; both of which should be reflected within an approved NHS Digital DSA. IGARD noted that the purpose of the briefing was for commissioning, however queried references to direct care, for example, the statement to identifying dementia patients; and asked that any references to direct care, or examples of how the data could be used for direct care, were removed, since they were not relevant. IGARD noted the language used within the paper in respect of the definition of the legal entities, for example, the Local Authorities, and in light of the forthcoming system changes across healthcare, suggested that the paper was updated to future-proof it, for example, referencing the Integrated Care Systems (ICSs); which are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to

	plan in a way that improves population health and reduces inequalities between different groups. IGARD advised that they looked forward to receiving the finalised briefing paper, alongside a first of type application as a supporting document; and in addition, asked that once the briefing paper had been finalised, a copy was provided to the IGARD Secretariat for information, and as per usual process. **Outcome:** IGARD welcomed the briefing paper and made the following comments. 1. Noting this briefing paper concerns commissioning, to remove, as appropriate, any reference to direct care, or examples of how the data could be used for direct care, since it is not directly relevant. 2. To update the briefing paper to future-proof it in relation to the system changes across healthcare, for examples, the ICSs. 3. To provide a copy of the finalised briefing paper to the IGARD Secretariat for information. IGARD looked forward to receiving the finalised briefing paper, alongside a first of type application as a supporting document.
2.3	<u>Adult Social Care Data Briefing Paper (Presenter: Jon Coolican / Dave Roberts)</u> The briefing paper was to inform IGARD about the updated plans to extend the data collection of adult social care data from Local Authorities to cover the whole of England. Applications for the data are expected from all commissioners, including local authorities and CCGs. Data collected will also be collated at a national level and will provide an overview of activity in social care settings to NHS England /Improvement and to the Department of Health and Social Care (DHSC). NHS Digital noted that IGARD (or its predecessor DAAG) has previously approved applications for adult social care data as part of the 'North West Pilot'. The North West Pilot informed both the approach being taken and an updated data specification. DHSC Directions for the dataset are now published and, at this stage, local authorities can volunteer to submit data, though the dataflow will be mandated through the issue of a data provision notice. It is expected that as uptake increases a date will be agreed to mandate the data collection for all local authorities, but not before 2022. The Direction, known as the Collection of Client-Level Adult Social Care Data (No.2) came into force on the 7th December 2020. IGARD welcomed the briefing paper and confirmed they were supportive of the collection of data, and noted the potential value of the purpose outlined and the important work that could flow. IGARD queried the statement in section 9.3 of the briefing paper *"In line with other commissioning datasets, opt-out and patient objections will be complied with through anonymisation (pseudonymisation) of the data prior to its release from * DSCRO."* (*Data Services for Commissioners Regional Offices), and suggested that this was updated to avoid any misunderstanding, and to make it explicitly clear that opt-outs would **not** be applied to pseudonymised data. IGARD noted the language used within the paper in respect of the definition of the legal entities, for example, the Local Authorities, and in light of the forthcoming system changes across healthcare, suggested that the paper was updated to future-proof it, for example, referencing the Integrated Care Systems (ICSs); which are new partnerships between the

	organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups. IGARD noted that the work undertaken to date was a pilot, however suggested that NHS Digital gave further consideration to widening the potential access to this data since it could be valuable to a wide range of other researchers; noting that there could be a challenge to NHS Digital in respect of the data being restricted to a small number of bodies. IGARD queried if there was a Data Protection Impact Assessment (DPIA) for the collection of data, and were advised by NHS Digital that this was covered under the local flows of data. IGARD noted the update from NHS Digital, however suggested that the DPIA was updated to reflect the new collection where appropriate. IGARD noted that the Direction specified *"NHS England"* only, however the data flow diagram in section 6 of the paper, indicated data flowing to *"NHS England / Improvement"*; and suggested that amendments were made where appropriate to align the correct information. IGARD advised that they looked forward to receiving the finalised briefing paper, alongside a first of type application as a supporting document; and in addition, asked that once the briefing paper had been finalised, a copy was provided to the IGARD Secretariat for information, and as per usual process. **Outcome:** IGARD welcomed the briefing paper and made the following comments. 1. To update point 9.3 of the briefing paper in respect of the application of opt-outs. 2. To update the briefing paper to future-proof it in relation to the system changes across healthcare, for examples, the ICSs. 3. IGARD suggested that NHS Digital give further consideration to widening the potential access to this data. There could be a challenge to NHS Digital in respect of the data being restricted to a small number of bodies. 4. IGARD suggested that the DPIA is updated to reflect the new collection where appropriate. 5. IGARD noted the Direction specified NHS England only, but the data flow diagram, indicated data flowing to NHS England / Improvement. 6. To provide a copy of the finalised briefing paper to the IGARD Secretariat for information. IGARD looked forward to receiving the finalised briefing paper, alongside a first of type application as a supporting document.
2.4	<u>Un-Curated Low Latency Hospital Data Sets (Admitted Patient Care, Outpatient and Critical Care) (v1.0) Briefing Paper</u> The briefing paper presented on the 29th April 2021, was to inform IGARD about the Un-Curated Low Latency Hospital Data Sets for Admitted Patient Care, Outpatient and Critical Care. Following comments made by IGARD at this meeting, the presenter made the relevant amendments to the briefing paper, and this was circulated to members out of committee by the IGARD Secretariat. IGARD welcomed the updated briefing paper and made no further comments. IGARD looked forward to receiving the finalised briefing paper as a supporting document, alongside a first of type application.

3	Data Applications
3.1	University Of Manchester**:** MR1210 - The Long-term Safety and Efficacy of Biologic Therapies in Children with Rheumatic Diseases (Presenter: Denise Pine) NIC-147774-MZT95-v1.1 **Application:** This was a new application for identifiable Demographics data, Medical Research Information Service (MRIS), Cancer Registration Data and Civil Registration (Deaths) data. The University of Manchester requires data in order to enhance the safety data already captured in the Biologics for Children with Rheumatic Diseases Study (BCRD). The purpose is for a long-term observational study to monitor the safety of new biologic and targeted therapies prescribed for juvenile idiopathic arthritis (JIA) in routine healthcare, specifically to understand if these new drugs increase the risks of developing cancer or premature death above the expected risks in a population with similar disease characteristics not receiving these therapies. The first patient was enrolled in to BCRD in 2010, and the study team have been observing who has been receiving biologic therapies for over 10 years. This is an unexplored area and the BCRD study will give unique insight into the very long-term use of biologic therapy, including treatment persistence and long-term safety, such as late occurrence of malignancies. The presence of equally long follow-up in an untreated comparison cohort will add to these analyses. The study is a prospective cohort study comparing the risk of development of the endpoints between, 1) an exposed group of children with JIA with their first exposure to a biologic drug (other than etanercept); and 2) a comparison cohort of children with JIA with similar disease characteristics receiving methotrexate therapy. **Discussion:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. 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 queried when the study would end, or if it would end, noting that this was not clearly defined in the materials provided as part of the review and the study website referred to *"60 years"*; and asked that for transparency, the application, consent materials and website were updated to specify that the study did **not** currently have a prescribed end date and may continue on for a considerable number of years, dependent on funding, or otherwise to reflect whatever the factual scenario may be. IGARD suggested the applicant prepared updated transparency materials and a communication to cohort members, to update families on what has been happening with the study, to note that the follow up was continuing and details about the proposed life span of the study. In addition, the study team should ensure that any communication to the cohort and their families should make clear how to withdraw from the study if they no longer wanted to take part in it. IGARD noted that supporting document 5.8, the reconsent template, had been provided, however queried what would happen if an individual did not provide such consent and what would happen to the data for those who had not consented in their own right, once they reached adulthood. NHS Digital advised that they had communicated with the applicant prior to the meeting, who had advised that the participant's clinical team would request consent

	when the participant reached the age of 16, or if they moved clinic; and that if consent was not provided, the clinic would therefore not be permitted to flow the data to the study team. In addition, NHS Digital would be advised by the study team of the participants who had not consented in their own right, and the follow-up data would therefore not flow to the applicant. Noting that there may still be children under the age of 16 in the study, NHS Digital advised that the applicant had confirmed that there were 294 participants, out of 870 that had been recruited, that were still under the age of 16. IGARD suggested that when taking consent from cohort members at age 16 onwards, the consent materials should expressly state that this was potentially a very long-term study, dependent on continuation of funding, and could potentially follow the cohort member's entire life span, or otherwise to reflect whatever the factual scenario may be. NHS Digital advised IGARD that the applicant may submit an amendment to the Data Sharing Agreement in the future, for example, to request additional data sets for linkage, to support the study purpose. IGARD noted the verbal update from NHS Digital and suggested that if there was an intention to apply to NHS Digital for additional data for linkage in the future, that the applicant may wish to address that potential linkage in the updated transparency materials, communication to cohort members / families and the consent materials, both initially and at 16 onwards. IGARD noted and commended the applicant on the efforts made to date to communicate with the public about the study, for example, via the study website, twitter, etc. **Outcome:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. To update the application, consent materials and website to specify that the study did not currently have a prescribed end date and may continue on for a considerable number of years, dependent on funding (or otherwise to reflect whatever the factual scenario may be). 2. IGARD suggested the applicant prepare updated transparency materials and a communication to cohort members to update families on what has been happening with the study, to note that the follow up is continuing and details about the proposed life span of the study (as per point 1). Any such communication to the cohort and their families should make clear how to withdraw from the study if they no longer wanted to take part. 3. When taking consent from cohort members at age 16 onwards, to expressly state in the materials that this is potentially a very long-term study, dependant on continuation of funding, and could potentially follow the cohort member's entire life span (or otherwise to reflect whatever the factual scenario may be). 4. If there is an intention to apply to NHS Digital for additional data for linkage in the future, to address that potential linkage in the updated transparency materials, communication to cohort members/families and the consent materials (both initially and at 16 onwards).
3.2	<u>Barts & the London School of Medicine & Dentistry: Genes and Health (Presenter: Vicky Byrne-Watts) NIC-338864-B3Z3J-v0.12</u> **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health

	Minimum Data Set (MHMDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), National Diabetes Audit (NDA), HES to MHMDS Bridge File, and Emergency Care Data Set (ECDS). The purpose is for a study run by the Queen Mary University of London, aiming to develop and maintain a bioresource of genetic and health record data available to the research community to improve the health of British people with Pakistani and Bangladeshi heritage through high quality research. Health record data is a key requisite of this objective, as it is used to characterise in detail health and disease in study volunteers across their life course. The applicant wishes to combine data from NHS Digital with data from the Genes and Health BioResource, which will be made available to researchers via sub-licensing arrangements. The study recruitment started in 2015 in east London, where limited health data has been obtainable through linkage to local health systems. Over 47,000 volunteers have been recruited, and this is now expanding nationally with recruitment taking place across multiple geographical regions in the UK. Linkage to national datasets is required to a) expand the geographical coverage of data linkage where local datasets are not available or where healthcare is accessed beyond its limits, and b) to enrich the datasets available using high quality multisource national data that are not available through local health systems. This application is limited to patients who have consented, and the estimated size of the cohort is approximately 50,000 patients, with the aim of recruiting 100,000 patients overall by 2023. **Discussion:** IGARD noted this application and supporting documents had previously been presented at the IGARD business as usual meeting on the 29th October 2020, where IGARD had provided advice on the consent materials and patient information leaflets only. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was *"worldwide"*, and queried how this would work, noting that as per NHS Digital's public-facing UK General Data Protection Regulation (GDPR) information on its website, some of NHS Digital's datasets had geographical restrictions, such as England and Wales, UK or EEA. IGARD asked that NHS Digital provided written confirmation that the use of the NHS Digital datasets requested that had geographical restrictions, were compatible with the worldwide use as described by the application. IGARD noted that when they had provided advice on the 29th October 2020, they had suggested that a future newsletter dissemination may be supported by a list clean, and that a future iteration should include, amongst other things, detailed information about the proposed sub-licencing. Noting that this information had been shared with the applicant, and that no update had been provided, IGARD reiterated the previous advice, noting that this was still relevant. IGARD noted that section 1(c) (Data Processor(s)) stated that UK Secure eResearch Platform (UK SeRP) was the Data Processor, however, noting that UK SeRP was not a legal entity and was part of the University of Swansea, asked that this was updated to accurately reflect that the University of Swansea was the Data Processor and not UK SeRP. In addition, IGARD noted reference within section 5(b) (Processing Activities) to UK SeRP being the Data Processor, and asked that, to align with section 1(c), this was also updated to reflect that the University of Swansea was the Data Processor.

	IGARD also noted the references within section 5(b) to *"employees"*, and asked that this was updated to accurately reflect that they were employees of the University of Swansea and not UK SeRP and therefore the processing would only be undertaken by University of Swansea employees. IGARD noted the special condition in section 6 (Special Conditions), in respect of the Queen Mary University of London Data Security and Protection Toolkit (DSPT), and noting the role of UK SeRP, asked that an addition special condition was inserted, that provided appropriate assurances about the UK SeRP's DSPT. IGARD noted the inconsistency in respect of the permitted sub-licensees description the types of entities that can be sub-licensees, and asked that the application, sub-licensing agreement and supporting documents were updated to ensure there was a consistent description across all documentation. IGARD also asked that the existing special condition (point a) in section 6 that stated: *"NHS Digital must approve QMUL's sub-licencing agreement, which must be maintained under change control and used wherever any record level data covered by this Data Sharing Agreement (DSA) is provided by QMUL* ***to any 3rd party****."* was updated, to set out the parameters of **who** may be granted a sub-licence. IGARD noted the special condition (point f) in section 6 that stated *"QMUL must provide, on request, details of all sub-licenses live in that period."*, and asked that this was updated, to state that the applicant will provide to NHS Digital a list of sub-licensees **on an annual basis**, rather than on request. In addition, IGARD also noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) contained a comprehensive summary of the commercial use, and asked that the description of the sub-licensees aligned with the commercial use description. IGARD advised NHS Digital that the permitted sub-licensees should be compatible with the consent taken from the cohort, for example, if the consent materials state that there would be no commercial use, then they would not be compatible. IGARD asked that the applicant ensured that the permitted sub-licensees were compatible with the consent taken from the cohort. IGARD noted the importance of the transparency and communication with the cohort, in respect of the permitted sub-licensees and processing activities, and asked that the applicant ensured that the suggested transparency and communication with the cohort expressly described the permitted sub-licensees and processing activities. IGARD queried if the data was still pseudonymised noting that Queen Mary University of London would be able to link pseudonyms to individuals, and were advised by NHS Digital, that this could only be done via a study ID, which was pseudonymised, and therefore the data was potentially identifiable in the hands of the Data Controller, but that the data was always pseudonymised in the hands of the sub-licensees. IGARD noted the verbal update from NHS Digital, and asked that section 5(a) (Objective for Processing) was updated, to make it clear that the data was not always pseudonymous and was potentially identifiable in the hands of the Data Controller; and to clearly state that the data would, however, always be pseudonymised in the hands of the sub-licensees. IGARD noted the reference in section 3(b) (Additional Data Access Requested) to the ECDS data being identifiable, and were advised by NHS Digital that this was an error, and the data was in fact *"pseudonymised".* IGARD noted the verbal update from NHS Digital, and asked that section 3(b) was amended, to correctly state that the ECDS data was *"pseudonymised"* and not identifiable.

	IGARD queried the reference in section 5(b) to *"small number being disseminated"*, and asked that section 5 (Purpose / Methods / Outputs) was updated to reflect that this was *"small number suppression"* in line of the *HES analysis guide*; or if it was for the rare variant scenario with small numbers, in which case it would be necessary to share the data, which may then become identifiable; to provide clarity in section 5 and confirmation of the appropriate legal gateway for sharing the data. IGARD noted that section 5(a) was particularly lengthy, and asked that this was reviewed to remove or edit any duplicate text, for example, the repeated reference to *"The strategic objective of Genes & Health is to…"*. IGARD also noted that section 5(a) contained a number of outputs, and asked that there were removed and correctly added to section 5(c) (Specific Outputs Expected). IGARD noted a number of acronyms in section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. IGARD suggested that section 5(c) and section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is anticipated*…" IGARD advised that they supportive of the Community Advisory Group, its structure and its remit. However, suggested that the Community Advisory Group was kept appraised with a brief overview on **all** matters, so it was not left to the scientific researchers' discretion what projects the Advisory Group are consulted about. **Outcome:** recommendation to approve subject to the following condition: 1. NHS Digital to provide written confirmation that the use of the NHS Digital datasets that have geographical restrictions (as per the NHS Digital public-facing UK GDPR information on its website) are compatible with worldwide use as permitted by the application. The following amendments were requested: 1. In respect of the sub-licensees: a) In respect of the permitted sub-licensees, to ensure that there is a consistent description between the application, sub-licensing agreement and supporting documents in respect of the types of entities that can be sub-licensees. b) To ensure the description of the sub-licensees aligns with the commercial use in section 5(e). c) To ensure that these permitted sub-licensees are compatible with the consent taken from the cohort. d) To ensure that the suggested transparency and communication with the cohort expressly describes the permitted sub-licensees and processing activities. 2. In respect of the Data Processor: a) To update section 1(c) to reflect that the University of Swansea is the Data Processor and not UK SeRP. b) To update section 5(b) to reflect that the University of Swansea is the Data Processor and not UK SeRP. 3. In respect of section 5(a): a) To remove or edit any duplicate text, for example, the repeated reference to *"The strategic objective of Genes & Health is to…"*. b) To remove the outputs outlined in section 5(a) and add to section 5(c).

	c) To update section 5(a) to make it clear that the data is not always pseudonymous and is potentially identifiable in the hands of the Data Controller. d) To update section 5(a) to clearly state that the data will, however, always be pseudonymised in the hands of the sub-licensees. 4. To update section 5(b) to reflect that the *"employees"* are employees of the University of Swansea and not UK SeRP. 5. In respect of the references to *"small number being disseminated"*: a) To update section 5 to reflect that this is *"small number suppression"* in line of the *HES analysis guide*; or b) If it is for the rare variant scenario with small numbers, in which case it would be necessary to share the data, which may then become identifiable; to provide clarity in section 5 and confirmation of the appropriate legal gateway for sharing the data. 6. In respect of the special conditions in section 6: a) To update the existing special condition to state that the applicant will provide to NHS Digital a list of sub-licensees on an annual basis (rather than on request). b) To update the existing special condition to set out the parameters of who may be granted a sub-licence (as per 1(a) above). c) To insert a special condition that provides appropriate assurances about the UK SeRP DSPT. 7. To amend section 3(b) to reflect that the ECDS data is *"pseudonymised"* and not identifiable. 8. To update section 5(c) and section 5(d) to use a form of wording such as "*it is anticipated*…", rather than "*it will…*". 9. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. The following advice was given: 1. IGARD noted that a future newsletter dissemination may be supported by a list clean and suggested a future iteration should include, amongst other things, detailed information about the proposed sub-licencing. 2. IGARD was supportive of the Community Advisory Group and its structure and remit. However, IGARD suggested that the Community Advisory Group was kept appraised with a brief overview on **all** matters, so it was not left to the scientific researchers' discretion what projects the Advisory Group are consulted about. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	<u>University of Oxford: Revision Hip and Knee Replacements: Evaluation of Clinical, Psychological and Surgical Outcomes (Presenter: Vicky Byrne-Watts) NIC-380650-K4F6X-v0.14</u> **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Patient Reported Outcome Measures (PROMs) data. The purpose is for a study to determine the outcomes from revision hip and knee joint replacement, and will investigate temporal and geographic variation in these outcomes, and will analyse both national practices and geographic variations in practice across England. A revision joint replacement is a procedure to replace an implant that is no longer functioning correctly. These procedures are major surgery because performing a joint replacement can be much more complicated the second (or third) time, this may be due to the presence of

	infection or formation of scar tissue and loss of bone over time. Around 13,000 revision operations are performed each year in the United Kingdom at a cost of up to £200 million. Whilst many procedures are successful, previous studies have estimated that up to one in three patients do not report any benefit from surgery, the reasons for this are not well understood. It is hoped that the information from this study can be used to support shared decision making, to allow patients to make a better-informed decision of whether to undergo revision surgery. The cohort of patients for the study is approximately 150,000; and is relying on s251 of the NHS Act 2006 for the flow of data to NHS Digital. NHS Digital advised IGARD that the applicant also wants pseudonymised data for all patients who have had such surgery. **Discussion:** IGARD noted the verbal update from NHS Digital. IGARD confirmed that they were of the view that the s251 support provided an appropriate legal gateway to support the processing outlined in the application. IGARD noted that supporting document 2.3, the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval letter dated the 5th March 2021, stated *"The Group agreed that the NJR will be enhanced by data from HES that is missing from the *NJR at resent because patient data from Trusts has not submitted to the NJR through error"*, (*National Joint Registry (NJR)) and queried if the data missing from the NJR purely related to Trust error or included those who have refused NJR participation. NHS Digital advised that the data that the applicant would supply to NHS Digital was regarding people who have consented to be in the NJR. IGARD noted the verbal update from NHS Digital, however advised that there was a reputational risk to NHS Digital since data would seemingly also flow based on codes in HES, not just for the participants in the NJR. This could be perceived as the applicant circumventing a patient's wish **not** to provide their data for research. IGARD noted the reference in section 5(b) (Processing Activities) to filtering *"children"*, and asked that this was updated and replaced with *"under 18s"*,. IGARD noted the reference in section 1 (Abstract) to *"Master Patient Service (MPS)"*, and asked that this was amended to refer to the correct acronym which was *"Master Person Service"*. IGARD queried the statement in section 5(c) (Specific Outputs Expected) to *"This has been tested in 4 patients."*, and asked that further clarity was provided of how the patients were chosen, as this was not clear. IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…" IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as *"PROMs underscoring number"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use. IGARD noted the reference in section 5(c) to *"PPI group of 8-12 patients"*, and suggested that the applicant may wish to give further consideration to engaging with the NJR patient network, who may be able to provide support with the recruitment and / or expansion of the PPI group. 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 processing of pseudonymised data of patients who had not consented to their inclusion on the NJR which may be seen as circumventing a patient's wish not to provide their data for research. IGARD advised that they would expect that when this application returns, that both the Research Ethics Committee (REC) and Health Research Authority Confidentiality Advisory Group (HRA CAG) have been expressly informed that the HES data would not only cover data that Trusts should have submitted to the National Joint Registry (NJR); but also data regarding those patients that had expressly declined to consent to be part of the NJR. Furthermore, IGARD advised that the applicant formally seek REC's advice on this specific point. IGARD asked that the advice was furnished as a supporting document. **Outcome:** recommendation to approve The following amendments were requested 1. To update the reference in section 5(b) to filtering *"children"* and replace with *"under 18s"*. 2. To amend the 'MPS' acronym to correctly refer to *"Master Person Service"*. 3. In respect of the *"4 patients"* referred to in section 5(c), to provide further clarity of how the patients were chosen. 4. To update section 5 to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 5. To amend section 5 to ensure the use of technical jargon is used only where necessary such as *"PROMs underscoring number"*. The following advice was given: 1. IGARD suggested that in respect of the *"PPI group of 8-12 patients"* referenced in section 5(c), the applicant may wish to give further consideration to engaging with the NJR patient network, who may be able to provide support with the recruitment and / or expansion of the PPI group. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the processing of pseudonymised data of patients who had not consented to their inclusion on the NJR which may be seen as circumventing a patient's wish not to provide their data for research. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the processing of pseudonymised data of patients who had not consented to their inclusion on the NJR which may be seen as circumventing a patient's wish not to provide their data for research. 4. IGARD would expect that when this application returns, that both REC and HRA CAG have been expressly informed that the HES data will not only cover data that Trusts should have submitted to the NJR, but also data regarding those patients that had expressly declined to consent to be part of the NJR. Furthermore, IGARD advised that the applicant formally seek the REC's advice on this specific point. IGARD would ask that the advice be furnished as a supporting document. **Significant Risk Area:** 1. Reputational risk to NHS Digital of being associated with a flow of data where the perception may be that the applicant is effectively circumventing a patient's wish not to provide their data for research (in the case where that patient has already expressly declined to be part of the NJR).

3.4	Clinical Registries Class Action Application (Presenter: Tom Wright) NIC-454213-T5X5R **Application:** This was a new application for all Clinical Commissioning Groups (CCGs) in England to receive pseudonymised Clinical Registry data; for the purpose of commissioning. CCG's require access to the Clinical Registry data collected within Clinical Registries, Databases and Audits in order to fulfil their function to manage their budget, plan care and service delivery accordingly including day-to-day operation of their commissioning role as set out in the Health and Social Care Act 2012. CCG's continually commission, recommission and procures health services from health service providers. It is a complex process, involving the assessment and understanding of a local population's health needs, the planning of services to meet those needs and securing services on a limited budget, then monitoring the services procured. **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 queried the data minimisation efforts that had been undertaken by the CCGs, and asked that in line with NHS Digital DARS Standard for Data Minimisation, the clinical registry dataset was minimised to **only** those individual clinical registries directly relevant and necessary to the CCG's processing; or, if there was no minimisation that could be undertaken, that a justification was provided for the data requested for each individual clinical registry and how it was directly relevant to each CCG. IGARD noted that for clinical registries where the initial legal gateway for onboarding the data was consent, consideration needed to be given to whether that consent was compatible with the proposed commissioning use by CCGs. In addition, the transparency materials for the respective registries would also need to be clear about such use (separate from the transparency obligations of the relevant CCGs). IGARD asked for clarification that the processing for each registry by CCGs was compatible with the specific features of the registry collection. IGARD noted the language used in the application and suggested it was future-proofed, for example, referencing the Integrated Care Systems (ICSs); which are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups. **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. In respect of the NHS Digital DARS Standard for Data Minimisation: a) To minimise the clinical registry dataset to only those individual clinical registries directly relevant and necessary to the CCG's processing; or b) If no minimisation can be undertaken, to provide a justification for the data requested for each individual clinical registry and how it is directly relevant to each CCG. 2. With regard to the legal basis for each of the clinical registries, and the conditions of support for each of those registries, to clarify that the processing for each registry is compatible with the specific features of the dataset. 3. To update the clinical registries privacy notices and / or relevant legal bases' to future-proof in relation to the system changes across healthcare, for examples, the ICSs.

4	Returning Applications 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 applications as part of their oversight and assurance role.
5	IG Covid-19 Release Register February 2021 IGARD noted that the IG Covid-19 Release Register February 2021 had been circulated and reviewed out of committee by members, and discussed and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate.
6	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that due to the Bank Holiday, and as agreed between IGARD and NHS Digital, the COVID-19 response meeting on Tuesday 4th May 2021 was cancelled.
7 **7.1**	AOB: CRM System Change to mark applications for returning to IGARD (Presenters: Liz Gaffney / Vicki Hartley) Colleagues from Data Access Request Service (DARS) attended, to update IGARD on the ongoing work to NHS Digital's customer relationships management (CRM) system, to ensure that for audit purposes, this can accurately reflect where IGARD have requested that an application returns for an IGARD review, for example, when it comes up for renewal, extension or amendment; and / or where IGARD have suggested that an application would not be suitable for NHS Digital's Precedent route, including the Senior Information Risk Owner (SIRO) Precedent. IGARD members welcomed the brief update and thanked NHS Digital on the work undertaken to date, and looked forward to a further update on changes undertaken to CRM.
7.2	Tracked change document update (Presenters: Liz Gaffney / Vicki Hartley) Colleagues from Data Access Request Service (DARS) attended, to update IGARD on the work being undertaken by NHS Digital to provide IGARD members with tracked change versions of the application summaries; and as originally outlined at the IGARD – NHS Digital COVID-19 Response meeting on the 26th January 2021. IGARD members welcomed the brief update and thanked NHS Digital on the work undertaken to date, and looked forward to a further update before the system went "live".

	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 30/04/21

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-381634-X8H0H-v2.2	Public Health England (PHE)	18/03/21	1. To provide written clarification and justification as to why S flags are being upheld. 2. In respect of the legal basis for dissemination: a) To update the legal basis for dissemination to reflect that the data flowing is pseudonymised. b) To clarify in the abstract and section 5 if at any point confidential data is flowing. c) In either case, to provide a consistent narrative as to what level of data is being disseminated and processed, and under what legal basis. d) To clarify in section 5(b) if the vaccination data / person ID is identifying data in the hands of the recipient.	Quorum of IGARD members	Quorum of IGARD members	*In line with NHS Digital's PTE directorate advice: please could the application be recast as a pseudonymised flow of data, being disseminated under NHS D's usual HSCA legal basis for disseminating pseudo data to applicants*
NIC-381634-X8H0H-v2.2	Public Health England (PHE)	18/03/21	1. To provide written clarification and justification as to why S flags are being upheld. 2. In respect of the legal basis for dissemination: e) To update the legal basis for dissemination to reflect that the data flowing is pseudonymised.	Quorum of IGARD members	Quorum of IGARD members	*In line with NHS Digital's PTE directorate advice: please could the application be recast as a pseudonymised flow of data, being disseminated under NHS D's usual HSCA legal*

			f) To clarify in the abstract and section 5 if at any point confidential data is flowing. g) In either case, to provide a consistent narrative as to what level of data is being disseminated and processed, and under what legal basis. h) To clarify in section 5(b) if the vaccination data / person ID is identifying data in the hands of the recipient.			*basis for disseminating pseudo data to applicants*
NIC-353126-Y1S5F	University of Surrey	18/02/21	1. With reference to the data request for those in the cohort aged 50 to 64: a. To provide a clarification in section 5 as to how the eFI tool will be utilised to stratify a cohort aged 50 to 64, since they would not have the 36 variables necessary for the tool. b. Since the eFI tool is a population risk stratification tool, to clarify in section 5 how clinical diagnosis will be undertaken. c. To clarify in section 5 how the eFI tool will be used to identify individuals, since the eFI tool cannot identify varying degrees of frailty in individuals.	Quorum of IGARD members	Quorum of IGARD members	*N/A*
NIC-411785-Z6X7M	NHS England (Quarry House)	21/01/21	1. In respect of the data controllership: a) To clarify which legal entities should be considered a Data Controller, as borne out of the facts presented with particular reference to Monitor and NHS TDA, and also to the sub-contracting arrangements,	Quorum of IGARD members	Quorum of IGARD members	*IGARD made the following comment:* *The approach to data controllership may well have implications for other applications from NHS E/I. It is*

			in line with the NHS Digital's DARS Standard for Data Controllers. b) To update the application and any relevant supporting documents with a clear justification, and in line with the NHS Digital's DARS Standard for Data Controllers. 2. In respect of the ToR: a) To provide a copy of the Oversight Committee's ToR. b) To ensure the ToR aligns with the processing undertaken within this application. c) To upload a copy of the ToR to the NHS Digital CRM system. 3. To update section 5 to clearly articulate and explain the involvement of the commercial organisations outlined in the application and supporting documents.			*confirmed that the Midlands and Lancashire Commissioning Support Unit (CSU) is part of NHS England. This means NHS England and NHS Improvement are commissioning Ipsos MORI who in turn is subcontracting work back to NHS England (in the form of the CSU). From an external perspective this is a strange arrangement.*

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:

- NIC-348357-W0P1W-v2.3 NHS Devon CCG, NHS Kernow CCG & Cornwall Council - Commissioning

Graphnet Class Actions:

- None