Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 23 September 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Tania Palmariellodiviney	Data Access Request Service (DARS)
Charlotte Skinner	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Maria Clark noted a previous working relationship with a member of staff involved with NIC-400790-V0Y8W (University of Leicester) application. It was agreed this did not represent a substantive conflict of interest.

	Imran Khan noted a professional link to NIC-384608-C9B4L (NHS England) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 16th September 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 Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	University of Leicester: Modelling the transition from neonatal to paediatric care: a data linkage study (Presenter: Tania Palmariellodiviney) NIC-400790-V0Y8W-v0.6 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E) and HES Admitted Patient Care (APC). The data will then be linked to the combined National Neonatal Research Database (NNRD) / Paediatric Intensive Care Audit Network (PICANet) cohort The purpose is for a research project, looking at what happens between neonatal and paediatric care, including which children are likely to experience both types of care, and how clinical services, parents and professionals manage the transition. This research will link together neonatal and paediatric care records to allow investigation of the first two years of the lives of these children. This project is part of a larger study funded by the National Institute for Health Research (NIHR) Advanced Fellowship programme, which has three workstreams; **1)** data linkage of neonatal and paediatric data to investigate outcomes in the first two years of life; **2)** exploration of neonatal discharge practices; and **3)** understanding the experiences of parents who have had a critically ill child. This data request forms the entirety of workstream 1, and the results will inform aspects of workstream 2. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that following submission of the application for review, some additional amendments had been identified within the application, these included, the Data Sharing Application (DSA) start date that would need updating, noting this had now passed; and the incorrect statement in section 3(c) (Patient Objections) *"Identifiers have been provided under section 251…"*, that would need removing. **Discussion:** IGARD noted the verbal update from NHS Digital, and supported the suggested amendments to the application, to amend the DSA start date, and to remove the incorrect information from section 3(c) in respect of the identifiers. IGARD noted and commended NHS Digital on the quality of the information provided within the application, which supported the review of the application by Members.

	IGARD also noted the excellent patient and public involvement (PPI), for example, in supporting the preparation for families being discharged from neonatal care, and advised that this was an exemplar for use both within NHS Digital (as part of any internal training) and to share with other external researchers. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted the references within the application to *"unique study ID"*, however, noted that data was flowing to NHS Digital from NNRD **and** PICANet, and queried if a child in both flows of data would have two separate identifiers (IDs). NHS Digital advised that both the NNRD **and** PICANet, would provide their own study IDs for each child. IGARD noted the verbal update from NHS Digital, and asked that for transparency, section 5(b) (Processing Activities) was amended, to clarify that there will be infants with both NNRD **and** PICANet study IDs, and that NNRD and PICANet would **not** be coordinating with each other. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course. IGARD queried the processing location noted in section 2(a) (Processing Location(s)) and the storage location in section 2(b) (Storage Location(s)), noting that both addresses stated were for the main University of Leicester campus; and asked that they were updated, to add additional level of detail, for any future NHS Digital audits. IGARD noted the last paragraph in section 5(b) that stated potentially restrictive information in respect of "R drive", and asked that this was simplified and that the restrictive information was removed, since any reference may become dated over time and if the information changed, the applicant may be in breach of their Data Sharing Agreement (DSA). IGARD noted the valuable research questions outlined within the application and protocol, and suggested that the applicant may wish to apply for additional datasets, for example, BadgerNet and the Maternity Services Data Set (MSDS). IGARD would be supportive of this flow of data should the applicant wish to apply for it with the appropriate permissions, for example, submitting an amendment form to HRA CAG. If these datasets were added to the application, IGARD would not need to re-review but would ask that an appropriate justification for this additional data should be added in section 5 (Purpose / Methods / Outputs) for transparency. IGARD noted the two-year follow up outlined within the application, and suggested that the applicant may wish to consider a longer running programme with the relevant Ethical support and appropriate permissions. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE.

	2. To update section 2(a) and section 2(b) to add additional level of detail on the storage and processing locations, for any future NHS Digital audits. 3. To amend section 5(b) to clarify that there will be infants with both NNRD and PICANet study IDs. 4. To simplify the last paragraph in section 5(b) in respect of the access to the R drive, and remove the potentially restrictive information outlined. The following advice was given: 1. IGARD noted the valuable research questions outlined within the application and protocol, and suggested that the applicant may wish to apply for additional datasets, for example, BadgerNet and MSDS. IGARD would be supportive of this flow of data should the applicant wish to apply for it. If these datasets were added to the application, IGARD would not need to re-review but would ask that an appropriate justification for this additional data should be added in section 5 for transparency. Whilst IGARD are supportive of the use of these additional datasets, we advise the applicant submit a HRA CAG amendment form to outline the new data sources. 2. IGARD noted the two-year follow up outlined within the application, and suggested that the applicant may wish to consider a longer running programme with the relevant Ethical support and appropriate permissions.
3.2	<u>University of Liverpool: ISARIC4C Coronavirus Clinical Information Network (COCIN) GPES record linkage (Presenter: Louise Dunn) NIC-402963-P0Y5D-v1.8</u> **Application:** This was a renewal application for identifiable Civil Registration (Deaths) data, pseudonymised COVID-19 Hospitalization in England Surveillance System, COVID-19 Second Generation Surveillance System, COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19), Hospital Episode Statistics Admitted Patient Care (HES APC), Improving Access to Psychological Therapies Data Set (IAPT), Mental Health Services Data Set (MHSDS), Secondary Uses Service Payment By Results Episodes (SUS PBR), SUS PBR Outpatients and SUS PBR Spells. It was also an amendment to add pseudonymised COVID-19 Vaccination Status data and COVID-19 Vaccination Adverse Reactions data. The purpose is to answer research questions directed by the Scientific Advisory Group for Emergencies (SAGE) and enable The Coronavirus Clinical Information Network (CO-CIN) to report early and accurate findings to SAGE. CO-CIN informs the Department of Health and Social Care on a weekly basis about the clinical evaluation of disease in the United Kingdom, this information is essential to help health service planning and provision and rapid evaluation of interventions. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 24th September 2020. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 22nd September 2020. IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 23rd September 2020 and that notes from this meeting had been attached to the IGARD minutes from the 24th September 2020; and the 15th September 2021 (see Appendix B). IGARD noted that PAG

	supported the application, and noted that the comments had been appropriately addressed by NHS Digital. IGARD noted the role of The Independent Data and Materials Access Committee (IDAMAC), in controlling *"all use of data and samples"*, as outlined within the protocol; and asked that confirmation was provided in section 5 (Purpose / Methods / Outputs), that NHS Digital data was **not** included in the resource overseen by IDAMAC, noting that of the requests to date, this also encompassed commercial entities and overseas entities. IGARD noted that Public Health Scotland and the University of Edinburgh were listed as Data Processors, however queried if The Health Service Control of Patient Information (COPI) Regulations 2002, could be relied on to process the data, noting that COPI only applied to England and Wales. IGARD asked that written confirmation was provided, that Data Processors **not** based in England and Wales could rely on COPI to process the data outlined in this application; and that a copy of the confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that, since COPI was being relied upon, that section 1 (Abstract) and section 5 were updated with confirmation that all Data Processors processing confidential patient information, would comply with Regulation 7(2) COPI, and must be a health professional or person who in the circumstance owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional, citing the Regulation 7(2) wording: *"No person shall process confidential patient information under these Regulations unless he is a health professional or a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional."*. IGARD noted the reference in section 5(a) (Objective for Processing) to CO-CIN working with *"external collaborators"*, and asked that confirmation was provided in section 5(a) that none of the collaborators had access to the data; and that none of the collaborators were considered joint Data Controllers and/or Data Processors, and in line with NHS Digital's DARS Standard for Data Controllers and NHS Digital's DARS Standard for Data Processors. IGARD queried the statement in section 5(a) *"The data has been used for modelling by Scientific Pandemic Influenza Group on Modelling (SPI-M)…"*, and asked that additional information was added, with the legal gateway for SPI-M to use the data, for example, was this via one of the permitted Data Controllers or Data Processors. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course. IGARD queried the information in section 3(b) that stated the Civil Registration data requested was *"identifiable"*; and were advised by NHS Digital that this was an error, and should state that the data was *"pseudonymised"*. IGARD noted the verbal update from NHS Digital, and asked that section 3(b) was amended, to correctly reflect that the Civil Registration data was pseudonymised and not identifiable. IGARD noted that in the previous version of the application, National Diabetes Audit (NDA) data had been requested, however, this was not reflected in section 3(b); and asked if this data was still required and, if so, the appropriate updates were made to section 3(b).

	IGARD noted the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), however queried if additional detail was available, for example, in relation to specific decisions that commissioners have made based on the study's findings, that have reduced mortality or better supported patients. In addition, noting that the yielded benefits formed NHS Digital's data uses register, IGARD asked that the applicant ensured that the excellent work outlined elsewhere in the application, was reflected in the yielded benefits; and that relevant updates were in line with the NHS Digital DARS Stand for Expected Measurable Benefits and in preparation for the forthcoming guidance from the National Data Guardian on evaluating public benefit. IGARD advised that upon renewal, extension or renewal, they would expect to see additional information within the application, in respect of opt outs, for example, how many people have opted out overall and by tier. IGARD also 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; given the volume of data and the scope of the work. **Outcome:** recommendation to approve subject to the following condition: 1. To provide confirmation in section 5 that NHS Digital data is not included in the resource overseen by IDAMAC. The following amendments were requested: 1. In respect of the Data Processors: a) To provide written confirmation that Data Processors not based in England and Wales can rely on COPI to process the data. b) To upload a copy of the written confirmation to NHS Digital's CRM system, for future reference. c) As COPI is being relied upon, to provide confirmation in sections 1 and 5 that all Data Processors, processing confidential patient information, comply with Regulation 7(2) COPI. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 3. To amend section 3(b) to reflect that the Civil Registration data is pseudonymised and not identifiable. 4. To update section 3(b) to include the NDA data as previously requested, if this data is still required. 5. In respect of the collaborators: a) To provide confirmation in section 5(a) that none of the collaborators have access to the data; and, b) To provide confirmation in section 5(a) that none of the collaborators are considered joint Data Controllers or Data Processors, and in line with NHS Digital's DARS Standard for Data Controllers and NHS Digital's DARS Standard for Data Processors. 6. To update section 5(a) with the legal gateway for SPI-M to use the data (for example, via one of the permitted Data Controllers or Data Processors). 7. In respect of the yielded benefits in section 5(d) (iii): a) To ensure the yielded benefits are updated in line with the NHS Digital DARS Stand for Expected Measurable Benefits.

	b) To make the relevant updates to section 5(d) (iii) to reflect the excellent work, since this forms NHS Digital's Data Uses Register. The following advice was given: 1. IGARD advised that upon renewal, extension or amendment, they would expect to see additional information within the application, in respect of opt outs, for example, how many people have opted out and opted out by tier. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, given the volume of data and the scope of the work. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, given the volume of data and the scope of the work. It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair.
3.3	<u>Guy's and St Thomas' NHS Foundation Trust: Epidemiology and Prognosis in Acute Myocarditis (Presenter: Charlotte Skinner) NIC-144568-D7G6V-v3.4</u> **Application:** This was an amendment application, to **1)** request a resupply of 2017/18 pseudonymised record-level Hospital Episode Statistics Admitted Patient Care (HES APC), **2)** request additional data for Quarter (Q)1, Q2, Q3 and Q4 2021/22 to fully examine the effect of COVID-19 infection on subsequent myocarditis, and the impact of the COVID-19 vaccines, **3)** change the Data Controller to Guy's and St Thomas' NHS Foundation Trust from the Royal Brompton Hospital (previously Royal Brompton and Harefield Hospitals). The purpose is for a study that aims to describe the longitudinal epidemiological trends of acute myocarditis to provide a contemporary, population-level assessment of the burden of disease and how this may have changed over the last 23 years. Myocarditis (inflammation of the heart muscle) is known to predominantly affect young adults aged between 19 - 35 years. It is usually related to a recent viral infection, patients often present with severe, sudden-onset chest pain mimicking a heart attack, difficulty breathing due to weakened heart muscle, and/or palpitations due to electrical rhythm disturbances within the heart. However, myocarditis also affects infants and older adults where causative factors and clinical outcomes are poorly characterised. In the long-term, up to one third of patients are at risk of developing heart failure, known as dilated cardiomyopathy, or experiencing a sudden cardiac arrest. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 30th August 2018 and 15th October 2020. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 5th May 2020. IGARD noted in section 1(b) that the applicant's Data Security and Protection Toolkit (DSPT) had not fully met the Standards, however noted and supported the plans in place to demonstrate security assurance for the purpose of this Data Sharing Agreement (DSA), and that this had been reflected in a special condition in section 6 (Special Conditions). IGARD noted the stated research aims and advised that when a previous iteration of the application was reviewed at the IGARD BAU meeting on the 15th October 2020, IGARD had expressed concern that NHS Digital would be knowingly supporting research, where IGARD had already notified the applicant that they did not have the appropriate data to carry out all of the research objectives, which could lead to potentially misleading research outcomes; and

	that this was a risk to NHS Digital's reputation. IGARD advised that this concern was still ongoing, and reiterated that the research goals and outputs in section 5 (Purpose / Methods / Outputs), were adjusted to reflect the limited data requested in section 3(b) (Additional Data Access Requested); **or**, the relevant additional datasets which would reveal vaccine status, and more accurately inform infection status, were requested, and the subsequent updates were made to section 3(b). IGARD reiterated previous comments (on the 15th October 2020), that confirmation was provided, in section 1 (Abstract) and section 5 of the application, if additional data sets would be required, for example COVID-19 Hospitalisation in England Surveillance System (CHESS) or COVID-19 Second Generation Surveillance System (SGSS). IGARD also noted that a study aim was linking myocarditis to recent vaccination status; but that the COVID-19 vaccination status data had not been requested from NHS Digital, and that this information would not be fully captured in Hospital Episode Statistics (HES). IGARD suggested that the applicant may wish to request this additional data from NHS Digital via an amendment application. In addition, IGARD suggested that the applicant may wish to utilise the COVID-19 Vaccine Adverse Reactions Summary of Yellow Card Reporting; which is produced and published weekly by the Medicines and Healthcare products Regulatory Agency (MHRA). IGARD noted that section 5 did not reflect the additional COVID-19 narrative, relating to the datasets requested, and asked that section 5 was updated to reflect this information. IGARD noted that they had previously advised (on the 15th October 2020) that the applicant may wish to consider utilising the British Heart Foundation Trusted Research Environment (BHF TRE). Noting that this had not been addressed within the updated application, IGARD reiterated their comment and asked that an express statement was added to section 5(a) (Objective for Processing) clarifying why the BHF TRE was not being utilised for this research, for transparency and future reference. IGARD queried the statement in section 3(b) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course. IGARD noted the information in section 5 that referenced the proportion of patients who go on to require a heart transplant following cardiomyopathy; and asked that for transparency and to avoid any misunderstanding on reading section 5 of this application, this section was updated, to reflect that this was based on research which did not encompass cardiomyopathy following vaccination against, or infection with, COVID-19. IGARD noted the helpful glossary of terms at the end of section 5(a), and asked that to support the understanding of the information contained within this section, that the glossary was moved nearer the beginning of section 5(a). IGARD noted the inconsistent references to *"gender"* and *"sex"* in section 5(c) (Specific Outputs Expected), for example, *"Gender differences – no studies have specifically investigated age and sex differences in patients…"*; and asked that this was updated to ensure consistency, since they are not interchangeable data fields.

	IGARD queried the information within section 5(c) and section 5(d) (Benefits), noting that there were references to dates passed; and asked that these were either removed or updated as appropriate. IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and asked that further details were provided of the 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, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the information in section 1 (Abstract), in respect of the description of the history of the name change of the applicant; and asked that this was updated, to ensure this was correctly described, and to avoid the suggestion that Guy's and St Thomas' NHS Foundation Trust had changed its name. IGARD noted the information in section 1, that incorrectly made reference to the "*IGARD-COVID19 Board"* making *"recommendations";* and asked that this was amended with the correct information, for example, referring to the *"IGARD – NHS Digital COVID-19 Response meeting"* making *"observations"*. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the stated research aims: a) To adjust the research goals and outputs in section 5, to reflect the limited data requested in section 3(b); or, b) To request, the relevant additional datasets which would reveal vaccine status, and more accurately inform infection status, and include in section 3(b). The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 2. In respect of section 1: a) To ensure the description of the history of the name change of the applicant is correctly described, to avoid the suggestion that Guy's and St Thomas' NHS Foundation Trust has changed its name. b) To amend section 1 to remove the incorrect reference to the "*IGARD-COVID19 Board"* making *"recommendations"*. 3. To make an express statement in section 5(a) clarifying why the BHF TRE is not being utilised for this research. 4. To move the helpful glossary of terms nearer the beginning of section 5(a). 5. To update section 5(c) to be consistent when using the terms *"gender"* or *"sex"*, since they are not interchangeable data fields. 6. To remove or update any references to dates passed in section 5(c) and section 5(d). 7. To update section 5, to qualify that the reference to the proportion of patients who go on to require a heart transplant following cardiomyopathy is based on research which does not encompass cardiomyopathy following vaccination against, or infection with, SARS-CoV-2. 8. To update section 5, to include the additional COVID-19 narrative, in relation to the datasets requested. 9. In line with NHS Digital's DARS Standard for Expected Measurable Benefits, to provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally.

	10. IGARD reiterated previous comments from October 2020: To provide confirmation in section 1 and section 5 if additional data sets would be required, for example CHESS or SGSS. The following advice was given: 1. In respect of the stated aims and benefits: a) IGARD noted that a study aim is linking myocarditis to recent vaccination status; IGARD noted that the COVID-19 vaccination status data had not been requested, and would not be fully captured in HES, and suggested that the applicant may wish to request this data from NHS Digital via an amendment application. b) IGARD suggested that the applicant may wish to utilise the COVID-19 Vaccine Adverse Reactions Summary of Yellow Card Reporting; which is produced and published weekly. **Significant risk area:** NHS Digital would be knowingly supporting research where IGARD have already notified the applicant (15th October 2020) that they do not have the appropriate data to carry out all of the research objectives, which could lead to potentially misleading research outcomes. This is a risk to NHS Digital's reputation. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.4	University of Oxford: Real-world drug data from electronic health records in the NHS: exploring the Medicines Dispensed in the Community dataset (Presenter: Charlotte Skinner) NIC-364245-C8C6X-v0.10 **Application:** This was a new application for pseudonymised Medicines dispensed in Primary Care (NHSBSA data); for the purpose of clinical trials methodology research. As a result of the research, a report will be produced and fed back to NHS Digital detailing the research findings. The report will focus on the advantages and limitations faced by the research team when analysing it, for example, **1)** coverage of different groups of drugs, geographic locations, and age groups, **2)** ease of interpretation of the data fields, **3)** any discrepancies (per example between prescribed versus dispensed drug codes at a higher-level) or missing data found in the dataset, and **4)** suggestions for data recoding or release of additional data fields if appropriate. The research, will be developed with support from Health Data Research UK (HDR UK), and its findings will be communicated to the NHS Digi-Trials Hub at the University of Oxford (known as "The Hub"). The Hub aims to reduce the cost and complexity of running clinical trials in order to develop new treatments for patients and improving the quality of the evidence available on the effectiveness and safety of new treatments. Technical development surrounding use of routinely collected data held by the NHS is a major part of The Hub's mission. The insights and outputs derived from this research project (namely data pipelines) will be directly informative to future use of medicines data in clinical trials and may be incorporated in NHS DigiTrials services offered to researchers in the future. Although the focus will be the potential use of these data in clinical trials, and particularly in cardiovascular disease (as this is the main body of research undertaken at the Clinical Trial Service Unit within the University of Oxford), the insights should be translatable to other types of research, such as epidemiological, health-economics, and pharmacovigilance studies. **Discussion:** IGARD noted the constraints placed in the Direction for the collection of NHSBSA Medicines dispensed in Primary Care data, by NHS Digital, specifically *"Providing intelligence about the safety and effectiveness of medicines…"*; and asked that the application was

	updated throughout, to align with the scope of the Direction to ensure that the objectives, processing and outputs are permitted uses of the data. IGARD queried how, in respect of the Medicines dispensed in Primary Care NHSBSA dataset, the full extent of the processing of the data outlined in the application was within the scope of the Direction, namely, *"to deliver comprehensive data about the medicines dispensed, and drive the linkage of data* ***to provide intelligence about the safety and effectiveness of medicines***"; and asked that NHS Digital provided written confirmation from the NHS Digital Information Asset Owner. In addition, IGARD asked that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD also asked, that a special condition was inserted in section 6 (Special Conditions), that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection. IGARD noted in section 3(b) (Additional Data Access Requested) the volume of data fields requested, and asked that for transparency, section 3(b) and section 5(a) (Objective for Processing) were updated, to provide clarity as to why data minimisation was not possible, and in line with NHS Digital's DARS standard for Data Minimisation. IGARD queried the conflicting information in the application, *that "All outputs will contain only data that is aggregated with small numbers suppressed…"*; and the information in supporting document 3, the study plan, that stated *"…small-number fields will be suppressed by NHS Digital before dissemination to the University of Oxford."*. IGARD asked that the conflicting information was addressed, in respect of NHS Digital supressing the small number fields versus the applicant supressing the small number fields, since it was not clear. IGARD noted in section 1(b) (Data Controller(s)), that the University of Oxford's Data Protection Act (DPA) Registration had expired, and asked that this was updated to reflect the correct DPA Registration expiry date. IGARD queried the statement in section 5(b) (Processing Activities) *"Data analysis will include basic sanity checks…"*, and asked that the reference to *"sanity checks"* was updated to more appropriately refer to *"sense check".* IGARD noted that the outputs were potentially a very useful resource for NHS Digital and would welcome further detail of how the outputs would be fed into NHS Digital and utilised for other applicants. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the Medicines dispensed in Primary Care NHS BSA dataset: a) To update the application throughout to align with the scope of the Direction to ensure that the objectives, processing and outputs are permitted use of the data. b) To insert a special condition in section 6, that any use of the Medicines dispensed in Primary Care NHSBSA data must be within the parameters of the relevant Direction authorising that collection. c) NHS Digital to provide written confirmation from the NHS Digital Information Asset Owner for the Medicines dispensed in Primary Care NHSBSA dataset as to how the full extent of the processing of the data outlined in the application is within the scope of the Direction, namely *"to deliver comprehensive data about the medicines dispensed, and drive the linkage of data* ***to provide intelligence about the safety and effectiveness of medicines****"*. d) To upload the written confirmation from the IAO to NHS Digital's CRM system for future reference.

	The following amendments were requested: 1) To update section 1(b) to reflect the University of Oxford's updated DPA Registration expiry date. 2) To update section 3(b) and section 5(a), to provide clarity as to why data minimisation is not possible, and in line with NHS Digital's DARS standard for Data Minimisation. 3) To address the conflicting information between the application and the study plan in respect of NHS Digital supressing the small number fields versus the applicant supressing the small number fields. 4) To update the reference in section 5(b) from *"sanity checks"* to *"sense check"*. The following advice was given: 1) IGARD noted that the outputs were potentially a very useful resource for NHS Digital and would welcome further detail of how the outputs will be fed into NHS Digital and utilised for other applicants. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.5	NHS Blood and Transplant (NHSBT): Convalescent Plasma (Vaccination Linkage) (Presenter: James Gray) NIC-476579-S9J4D-v0.2 **Application:** This was a new application for identifiable COVID-19 Vaccination Status; for the purpose of research, to identify which blood donors registered with NHS Blood and Transplant (NHSBT), who have previously donated convalescent plasma, have been vaccinated, and when they were vaccinated. NHSBT also require information on the type of vaccine given to each donor and the date of each dose, as well as indicators as to if donors have not been vaccinated. NHSBT research, in association with the SUPPORT-E consortium (The Pan-European project SUPPORT-E (SUPPORTing high quality evaluation of COVID-19 convalescent plasma throughout Europe)), has shown that the anti-SARS-CoV-2 antibody levels in plasma collected from donors who have a natural infection and then are vaccinated, are up to ten times higher than those who have not been vaccinated. It is also known that plasma from donors who have been vaccinated demonstrates effective neutralisation of the delta and beta variants of the virus in laboratory assays, whereas stored convalescent plasma from unvaccinated donors is not effective against current variants. NHSBT will send a donor cohort of approximately 50,000 individuals who have consented, to NHS Digital from their donor database to identify the vaccination status of blood donors. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 17th August 2020. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD however, suggested that when the applicant next reviewed the consent materials, they consider if it could be made clearer that the information gathered would also be used to improve the service to blood recipients (so not just improving knowledge about the donor population and the possible health effects of blood donation). In addition, IGARD suggested that it may be helpful for the consent materials and welcome pack to cross reference with relevant version numbers, particularly if the consent materials referred to a version number of the welcome pack. **Outcome:** recommendation to approve

	The following amendments were requested: 1. IGARD suggested that, when the applicant next reviews the consent materials, it is considered if it could be made clearer that the information gathered would also be used to improve the service to blood recipients (so not just improving knowledge about the donor population and the possible health effects of blood donation). 2. IGARD suggested it may be helpful for the consent materials and welcome pack to cross reference with relevant version numbers, particularly if the consent materials refer to a version number of the welcome pack.
3.6	<u>NHS England (Quarry House): COVID-19 – NHS England Application (Presenter: Duncan Easton) NIC-384608-C9B4L-v3.2</u> **Application:** This was a renewal application for pseudonymised GPES Data for Pandemic Planning and Research (COVID-19), COVID-19 Second Generation Surveillance System, Medicines dispensed in Primary Care (NHSBSA data), NHS Pathways Data Set, Shielded Patient List and Secondary Uses Service for Commissioners. It was also an amendment to **1)** update the processing and storage locations, **2)** add the Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19, COVID-19 Ethnic Category Data Set, and COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), to the agreement. COVID-19 has led to a change in demand on general practices (GPs), including an increasing number of requests to provide patient data to inform planning and support vital insights on the cause, effects, treatments and outcomes for patients of the virus. To support the response to the COVID-19 outbreak, NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). All GP practices in England are legally required to share data with NHS Digital for this purpose under the Health and Social Care Act 2012. This collection will reduce burden on general practices, allowing them to focus on patient care and support the COVID-19 response. NHS Digital advised IGARD that following submission of the application for review, NHS England had provided some additional yielded benefits to include within section 5(d) (Benefits) (iii) (Yielded Benefits) of the application. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 23rd July 2020, 6th August 2020 and the 27th May 2021. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st July 2020, 4th August 2020 and 23rd March 2021. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 22nd July 2020, (notes from that meeting had been attached to the IGARD minutes from the 23rd July 2020); the 5th August 2020 (notes from that meeting had been attached to the IGARD minutes from the 6th August 2020); the 31st March, 5th May, and 26th May 2021 (notes from that meeting had been attached to the IGARD minutes from the 27th May 2021). IGARD suggested, that due to the inclusion of GDPPR data, that the application be presented at the next meeting of PAG for information under *"any other business"* (AOB).

	IGARD noted the verbal update from NHS Digital in respect of the additional yielded benefits received following submission of the application. IGARD asked that in relation to both the benefits and yielded benefits, and given the national and international impact of the data store, and the recent annual report from the National Data Guardian citing the need for transparency about the data store; asked that the benefits and yielded benefits were updated, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, noting that section 5 (Purpose / Methods / Outputs) formed NHS Digital's data uses register. IGARD had a lengthy discussion on a number of aspects in relation to the applicants transparency materials. IGARD noted that the publicly accessible Data Protection Impact Assessment (DPIA), stated that there would be no processing involving data relating to racial or ethnic origin, however, in light of the additional data requested, for example, the COVID-19 Ethnic Category Data Set, IGARD asked that the public facing DPIA was updated, to address the ethnicity data requested under this DSA. IGARD queried the UK General Data Protection Regulation (UK GDPR) Article 6 legal basis cited within the DPIA, privacy notice and the application, noting that different Article 6 legal bases had been cited across the documentation; and asked that all three documents were aligned and updated where appropriate, to ensure the correct Article 6 legal basis was cited. In addition, IGARD noted that more than one UK General Data Protection Regulation (UK GDPR) Article 9 legal basis had been cited within the application and the privacy notice; and asked that the documents were aligned, and it was clearly outlined, what processing was being undertaken under which Article 9 legal basis, and as outlined in the Information Commissioner's Office (ICO) guidance. IGARD queried the statement in the privacy notice *"The NHS COVID-19 Data Store brings data sources from across the health and care system in England together into a single, secure location."* noting that the application listed over twenty storage locations including two Cloud based storage providers. IGARD asked that the statements within the application and those in the public domain were aligned, as borne out of the facts. IGARD also noted that the privacy notice stated that the Store *"sits on a Microsoft Azure platform"*, however the application stated that the data was being held on Amazon Web Services (AWS); and asked that clarity was provided, as to why both Microsoft Azure **and** AWS, were listed as Cloud providers in the application, noting that this did not align with the public facing materials, and asked for section 5 to be updated as may be necessary. IGARD noted that section 5 of the application stated that Faculty AI, McKinsey and Deloittes **do not** have access to pseudonymised data, however noted that this was not reflected in the privacy notice provided as a supporting document, which stated that they **do** have access to the data. IGARD asked that the statement in section 5 was aligned with the privacy notice, and in line with the contracts between the organisations (Faculty AI, McKinsey and Deloittes) and the Department of Health and Social Care (DHSC). IGARD also noted that this may be a breach of the applicant's DSA. In addition, IGARD queried if the contractual arrangements between the organisations, gave rise to Faculty AI, McKinsey and Deloittes, being listed as Data Processors; and asked that further clarity was provided, as borne by the facts and in line with NHS Digital's DARS Standard for Data Processors. IGARD noted that they did not have sight of the contractual analysis or any supporting contractual information. IGARD noted the inconsistent use of the words *"effect"* and *"affect"* within section 5, and asked that this was reviewed and amended where necessary, to ensure the correct term was used.

	IGARD suggested that NHS Digital may wish to audit this Data Sharing Agreement (DSA) / organisation, in light of the information within the application conflicting with the public transparency materials and the potential breach of the 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 of data flowing. IGARD noted that the application was due to expire on the 30th September 2021, and suggested that NHS Digital put in place a short-term extension until the conditions and amendments above had been addressed. **Outcome**: recommendation to approve by a quorum of 4 members, with one member dissenting (and recommending deferral), subject to the following conditions: 1. In respect of the transparency materials: a) To update the public facing DPIA to address the ethnicity data requested under this DSA. b) To align the DPIA, privacy notice and application with regard to the Article 6 legal bases cited. c) To align the application with the privacy notice with regard to the Article 9 legal basis and outline clearly what processing is being undertaken under which Article 9 legal basis. 2. In respect of the storage and cloud-based providers: a) To align the statements in the application and public domain with regard to the 20+ storage locations and 2 cloud based providers, as borne out of the facts. b) To clarify why both MS Azure and AWS are listed as cloud providers in the application, which does not align with the public facing materials, and update section 5 as may be necessary. 3. With reference to the overarching contracts between organisations and the honorary contracts: a) Noting that section 5 of the application states that Faculty AI, McKinsey and Deloittes, **do not** have access to the data, to align the statement in section 5 with the public facing transparency materials which state that Faculty AI, McKinsey and Deloittes, **do** have access to the data in line with their organisation contracts between the organisations and DHSC. b) To clarify if the contractual arrangements between organisations give rise to those organisations (Faculty AI, McKinsey and Deloittes) being listed as Data Processors, as borne by the facts and in line with NHS Digital's DARS Standard for Data Processors (IGARD did not have sight of the contractual analysis or any supporting contractual information). 4. With reference to the benefits and yielded benefits and given the national and international impact of the data store and the recent annual report from the NDG citing the need for transparency about the data store, to update the benefits and yielded benefits in line with NHS Digital's DARS Standard for Expected Measurable Benefits, noting that section 5 forms NHS Digital's data uses register. The following amendments were requested: 1. To amend section 5 to ensure that the words *"effect"* and *"affect"* are used correctly. The following advice was given:

	1. IGARD suggested, due to the inclusion of GDPPR data, that the application be presented at the next meeting of PAG for information under AOB. 2. IGARD suggested that NHS Digital may wish to audit this DSA / organisation. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the quantum of data flowing. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, due to the quantum of data flowing. 5. Noting that the application was due to expire on the 30th September 2021, IGARD suggested that NHS Digital put in place a short-term extension until the conditions and amendments above had been addressed. **Significant risk area:** IGARD noted the potential breaching of the DSA, by the Data Processor, noting that the application stated in section 5 Faculty AI, McKinsey and Deloittes, were not accessing the data, but the privacy notice and presenter confirms that they were accessing the data. It was agreed the condition would be approved out of committee (OOC) by those IGARD members recommending approval.
3.7	Renal Registry: Commissioning through Evaluation (CtE) Rituximab for Idiopathic Membranous Nephropathy (IMN) (Presenter: None) NIC-386376-Z1H5J V0.9 **Application:** This was a new application presented at the IGARD business as usual (BAU) meeting on the 3rd June 2021, for pseudonymised Civil Registration (Deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU) meeting on the 3rd June 2021; where the application had been recommended for approval with conditions, amendments and advice. IGARD noted that as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken. The conditions from the 3rd June 2021 BAU meeting were as follows: 1. In respect of data controllership, and in line with NHS Digital's DARS Standard for Data Controllers: a) To provide written confirmation that King's College London as the legal entity for KiTEC is **not** a joint Data Controller, given KiTEC's activities outlined in the application. b) To provide written confirmation that NHS England is **not** a joint Data Controller, given NHS England's activities outlined in the application. 2. To provide written confirmation that NICE is **not** a joint Data Controller, given NICE's activities outlined in the application. To update the application throughout, as may be required, to reflect the factual scenario.

	3. To provide evidence that the OMB and Lead Clinician, have approved the sharing of data with KiTEC in accordance with the information provided to patients in the PIS as stated in Section 5. A quorum of IGARD members were content that the conditions had been met subject to the following amendments: 1. In respect of condition 1(a): to remove KiTEC as a Data Processor and add King's College London as the legal entity. 2. In respect of condition 1(c): to remove reference in section 5(a) to NICE *"commissioning"*.
4	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). *No items discussed.*
5	<u>Returning Applications</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. 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.
6	<u>COVID-19 update</u> 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. The ratified action notes from **Tuesday 22nd September 2021** can be found attached to these minutes as Appendix C.
7	<u>AOB:</u> 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 17/09/21

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-353882-J5X9Q-v0.12	University of Warwick	19/08/2021	1. In respect of the proposed cohort size (noting this is twice the size recorded on the HRA CAG register) and in line with NHS Digital DARS Standard for Data Minimisation: a) To minimise the proposed cohort size of 231,419 closer to the 100,000 figure advised to HRA CAG and update the application accordingly; or b) If the cohort cannot be minimised, to provide written justification in section 5 as to why the significantly larger cohort size is required; and, c) To update HRA CAG with the significantly increased cohort number and request that the HRA CAG Resister is updated accordingly, and take any appropriate action as requested by HRA CAG, for example, submitting an amendment.	IGARD members	OOC by quorum of IGARD members	*Comments from IGARD:* *The applicant has agreed to notify CAG of the change in cohort size, it would be good to have this notification logged on CRM when available*

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

Appendix B

Professional Advisory Group Outcomes
Record of feedback Wednesday, 15 September 2021

Application & version	DARS-NIC-402963-P0Y5D
Applicant Organisation	University of Oxford
Data Controller Organisation	University of Oxford
Professional Advisory Group Agenda Item	2

The profession welcomed this application and supported the application with the addition of the special condition to meet the new PAG standard requirement including;

To encourage best practices around open science, all applicants **should** agree to work towards making public their finalised protocols, analysis code, and code lists, both for review but also re-use under an Open Source Initiative approved licence; copyright must be equivalent to CC-BY or CC0 GitHub is a commonly used tool to share such content, but organisational websites are also acceptable; https://www.opencodelists.org/ can be used to create and host code lists. Links to such content **MUST** be referenced in published works.

Attendees	Role	Organisation
Peter Short	NHS Digital Clinical Lead	NHS Digital
Mark Coley	Profession Representative	BMA
Amir Mehrkar	Profession Representative	RCGP
Liz Gaffney	Head of Data Access	NHS Digital
Catherine Day	SCO NHS Digital	NHS Digital

Appendix C

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 21st September 2021

In attendance (IGARD Members):	Prof. Nicola Fear (IGARD Specialist Academic Member)
	Kirsty Irvine (IGARD Chair / Lay representative)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Kimberley Watson (DARS)
	Vicki Williams (IGARD Secretariat)

3	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.
2.3	NIC-393650-B7J6F-V4.2 Department for Health & Social Care (DHSC) **Background:** This was an urgent COVID-19 application from the DHSC and Imperial College London for record level identifiable demographic data to flow to Ipsos MORI to support the REACT1 study (Real-time Assessment of Community Transmission 1). V4.2 of the application had been previously discussed at the IGARD business as usual (BAU) meeting on the 12th August 2021. A previous version of this application and relevant supporting document had been discussed at the COVID-19 response meetings on the 4th August 2020, 8th December 2020, 20th April 2021 and 24th August 2021. The update was in relation to: • The DHSC have required NHS Digital to move to a postal return system as used for Pillar 2 testing • The DHSC are currently tendering for laboratory for rounds 15 to 20 and Ipsos MORI do not know the outcome as yet and DHSC have committed to update Ipsos MORI as soon as the outcome of the tendering process is known • The participant information will be updated to reflect the postal system.

	NHS Digital noted that v5.2 of the application had been approved under SIRO with regard to a further amendment for identifiable demographic data for wave 14 for a randomised cohort of 45,000 individuals under an additional incentive scheme for the study. The following observations were made on the basis of the verbal update from NHS Digital, alongside v6.2 of the application and SD13.4 "*DHSC statement of intent for rounds 15 to 20*" **IGARD Observations:** IGARD members noted that due to the nature of the meeting should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD welcomed the update from NHS Digital and noted that they had been asked to review version 6.2 of the application summary and noted that although not previously mentioned when discussed at the business as usual or COVID-19 response meetings, the applicant should ensure that terminology is consistent and in particular noted the use of the word "incentive". IGARD suggested that noting that section 5 of the application formed part of NHS Digital's data uses register suggested that use of the word "incentive" may have inappropriate ethical connotations and that it should be replaced with the wording that had been ethically approved such as "Thank You" scheme. IGARD members present were content that all major ethical considerations had been considered and addressed and as outlined when discussed at the 24th August 2021 COVID-19 response meeting. In particularly, IGARD noted the applicant's decision not to offer the "thank you" (incentive) to those in the study aged 5 to 12 years (noting those under 5 years were not part of the study) since it may inadvertently incentivise parents to include their children in the study. IGARD reiterated their comments from the 24th August 2021 COVID-19 response meeting that noting the potential reputational risk of NHS Digital supplying data to the applicant if the vouchers were not deemed appropriate (recent media coverage of NHS voucher incentives refers), IGARD members suggested that a wide range of vouchers be offered to those that are part of wave 15, as noted on Ipsos MORI's Iris Reward webpage, which included the opportunity to donate rewards back to charity. IGARD members reiterated their comments from the 24th August 2021 COVID-19 response meeting that they would expect the application to be updated with the analysis undertaken of how successful or unsuccessful the "thank you" (incentive) trial had been for wave 15 and how, if at all, future waves would be affected as a result of this research (for example, were "thank you" (incentives) effective and did they increase participation rates such that the quantum of data from NHS Digital could be minimised further?). IGARD members suggested that the patient information sheet was updated, since they formed the public facing transparency materials, and that they were made available at the next review by IGARD, to include but not limited to the updated processing arrangements, in order to maintain public trust and confidence. IGARD members also noted that Data Protection Impact Assessment's (DPIA) were living and active documents and that the applicant should ensure that the DPIA was regularly reviewed and updated, for example to reflect the cumulative waves of data.

	IGARD members were **not** supportive of the application progressing down the SIRO precedent for waves 16 to 20 and asked that the application was updated throughout to remove reference to these waves, and that the application and relevant supporting documentation relating to waves 16 to 20 should be presented to a future BAU IGARD meeting due to the quantum of data requested and the current state of the uncertainty around the processing arrangements (which DHSC had openly confirmed were still at the tendering stage). IGARD members noted that NHS Digital had indicated that due to the urgency of the application, the application would proceed under NHS Digital's SIRO Precedent and were supportive of this approach, for wave 15 only, and given that a timely response to this research question could improve future response rates and/or reduce the amount of NHS Digital data required to reach the appropriate cohort numbers. IGARD noted that the advice points noted in the IGARD BAU minutes from the 12th August 2021 remained live, namely: The following advice was given: 1. IGARD noted the decision not to apply the NDO, due to this being confidential patient information supplied under COPI notice as the legal basis, and suggested that NHS Digital made Ipsos MORI aware of this fact. 2. Ipsos MORI to review the complaints received with regard to NDOs with the Data Controller, and provide an update to NHS Digital, on renewal, extension or amendment. 3. On renewal, IGARD would expect to see an analysis on the number of opt outs from further contact that Ipsos MORI have received. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, given the volume of data, further analysis on the number of opt-outs, and the outputs from the discussion with the Data Controller regarding complaints. **5.** IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, given the volume of data, further analysis on the number of opt-outs, and the outputs from the discussion with the Data Controller regarding complaints. *(IGARD noted that today's support for this urgent review into incentives was an exception to this point of advice which still stood in respect of future amendments).*
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

COVID-19 Action Notes extract: Tuesday, 24th August 2021

NIC-393650-B7J6F-V4.2 Department for Health & Social Care (DHSC)

Background: This was an urgent COVID-19 application from the DHSC and Imperial College London for record level identifiable demographic data to flow to Ipsos MORI to support the REACT1 study (Real-time Assessment of Community Transmission 1).

V4.2 of the application had been previously discussed at the IGARD business as usual (BAU) meeting on the 12th August 2021. A previous version of this application and relevant supporting document had been discussed at the COVID-19 response meetings on the 4th August 2020, 8th December 2020, and 20th April 2021.

The update was in relation to the proposal to add a monetary incentive to participate in the trial known as the "*incentive trial*". When the application had been reviewed at the IGARD BAU Meeting on the 12th August 2021, there was reference in the application to a "*proposed drop 2*" of data for wave 14 which would be subject to an amendment of the data sharing agreement (DSA). NHS Digital confirmed that ethical approval had been confirmed for the second drop of data. The applicant had also confirmed that they were not intending to update their Privacy Notice because Ipsos Market and Opinion Research International (MORI) would administer the voucher (purchase and administer their emailing) and there would be no data transfer to the supplier for the incentive process. DHSC wish to be able to include the incentive trial in the next round (wave 14), due to it being an important pre-Autumn juncture.

The following observations were made on the basis of the verbal update from NHS Digital, alongside v4.2 of the application and relevant supporting documents.

IGARD Observations:

IGARD members noted that due to the nature of the meeting should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation.

IGARD members noted that v4.2 of the application and relevant supporting document had been presented to the 12th August 2021 BAU meeting of IGARD and NHS Digital confirmed that the condition and amendments had been satisfactorily updated to the application and prior to its presentation at today's COVID-19 response meeting.

IGARD members expressly noted that there were two distinct areas that required ethical support: one being the new offer of an incentive for wave 14; the other being the study to look at the quantum of the incentive and which elicits the better response and in which age group. It was important (noting that neither IGARD nor NHS Digital have had sight of the Research Ethics Committee (REC) application) that ethics were supportive of both limbs. Although IGARD members can take inference from the documentation provided, it should be explicitly clear in section 5 (purpose / methods / outputs) of the application summary which forms NHS Digital data release register that there are two aspects to the incentive trial.

IGARD members applauded the applicant's detailed consideration of the wide-ranging ethical issues that are raised when introducing incentives for participation in research. On the basis of the detailed analysis provided, IGARD members present were content that all major ethical considerations had been considered and addressed. In particularly, IGARD noted the applicant's decision not to offer the incentive to those in the study aged 5 to 12 years (noting those under 5 years were not part of the study) since it may inadvertently incentivise parents to include their children in the study.

IGARD members discussed the Data Controllership element, since Ipsos MORI would be the organisation, as Data Processor, offering the incentive, and were advised by NHS Digital that Ipsos MORI were offering the incentive under direction from DHSC and Imperial College London (the joint Data Controllers).

Noting the potential reputational risk of NHS Digital supplying data to the applicant if the vouchers were not deemed appropriate (recent media coverage of NHS voucher incentives refers), IGARD members suggested that a wide range of vouchers be offered to those that are part of wave 14, as noted on Ipsos MORI's Iris Reward webpage, which included the opportunity to donate rewards back to charity.

IGARD members also noted that prior to wave 15 and beyond, IGARD would expect the application to be updated with the analysis undertaken of how successful or unsuccessful the incentive trial had been for wave 14 and how, if at all, future waves would be affected as a result of this research (for example, were incentives effective and did they increase participation rates such that the quantum of data from NHS Digital could be minimised further?).

IGARD members noted that NHS Digital had indicated that due to the urgency of the application, the application would proceed under NHS Digital's SIRO Precedent and were supportive of this approach, on this occasion, given that a timely response to this research question could improve future response rates and/or reduce the amount of NHS Digital data required to reach the appropriate cohort numbers. IGARD noted that the advice points noted in the IGARD BAU minutes from the 12th August 2021 remained live, namely:

The following advice was given:

1. IGARD noted the decision not to apply the NDO, due to this being confidential patient information supplied under COPI notice as the legal basis, and suggested that NHS Digital made Ipsos MORI aware of this fact.
2. Ipsos MORI to review the complaints received with regard to NDOs with the Data Controller, and provide an update to NHS Digital, on renewal, extension or amendment.
3. On renewal, IGARD would expect to see an analysis on the number of opt outs from further contact that Ipsos MORI have received.
4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, given the volume of data, further analysis on the number of opt-outs, and the outputs from the discussion with the Data Controller regarding complaints.
5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, given the volume of data, further analysis on the number of opt-outs, and the outputs from the discussion with the Data Controller regarding complaints. *(IGARD noted that today's support for this*

urgent review into incentives was an exception to this point of advice which still stood in respect of future amendments).