Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 12 August 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker (Chair)	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair / Lay Representative
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS)
Tony Burton	Data Services TRE Team
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Shaista Majid	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Natalie Peachey	Data Access Request Service (DARS) (Observer: items 3.1 – 3.3)
Denise Pine	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:**

	Maurice Smith noted professional links to Liverpool CCG (NIC-14709-Z2H2R - i5 Health Limited) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. **Review of previous minutes and actions:** The minutes of the 5th August 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	Intensive Care National Audit and Research Centre (ICNARC) Case Mix Programme for Adult Critical Care data set Briefing Paper (v0.5) (Presenter: Tony Burton) The briefing paper was to inform IGARD about the ICNARC Case Mix Programme (CMP) for Adult Critical Care data set, which will be made available via NHS Digital's Trusted Research Environment (TRE) and extract. NHS Digital will make data available for COVID-19 purposes only. Requests for use of data outside of COVID-19 would need to be requested via ICNARC directly and will not be handled or supplied by NHS Digital, under current arrangements. The primary purpose of this data collection is to assess quality of care to guide local performance management and quality improvement. The data collected are also used for research purposes, ensuring maximum value from the data collection and validation processes. ICNARC collects and uses the data to enable customers to request regular comparative analyses from the CMP Database (of over 1.5 million admissions to critical care), detailing a range of quality indicators. Approved requests will help to guide national decision making and recommend potential interventions to reduce the severity of COVID-19 outcomes. In making this data available, it will substantially enhance research, for example, researchers would be able to assess the impact of a wide range of prior health conditions, risk factors and medications. IGARD provided some high-level suggestions which are included in the outcome below. **Outcome:** IGARD welcomed the briefing paper and made the following comments. 1. In respect of the legal basis: a) To confirm how the Covid-19 Public Health Directions interact with ICNARC's approval to gather information for audit. b) To clarify if PIAG 2-10(f)/2005 needs to be amended. c) To confirm if HRA CAG have been consulted as to whether PIAG 2-10(f)/2005 needs to be amended. 2. In respect of the data fields: a) Noting IVF treatment is usually excluded because of legal restrictions, to clarify if such restrictions apply here. 3. In respect of the NDO: a) To confirm if NDOs have been applied to the data flowing from Trusts to the registries; or, b) To confirm if ICNARC have their own separate opt-out policy. c) If ICNARC do not have their own opt out policy, the wording on the website to contact the ICNARC DPO, needs to be amended, in line with NHS Digital's NDO policy.

	4. To clarify if there is an equivalent audit for those under 18, since this is a large unvaccinated population, and may be a cohort impacted by COVID-19. 5. To clarify which legal entities should be considered a Data Controller, as borne out of the facts presented, and in line with the NHS Digital's DARS Standard for Data Controllers, for example, are ICNARC the sole Data Controller, or should DHSC also be considered a joint Data Controller alongside ICNARC. 6. To provide a brief narrative as to why data extractions will also be provided alongside access to the TRE. IGARD would expect a clear explanation for an extract of this data, as to why the applicant couldn't achieve their purposes in the TRE. 7. To clarify why the 1st March 2020 was picked, noting that COVID-19 was in the country prior to this date, and researchers may wish to consider data for a number of years preceding COVID-19 to look at trend analysis and the impact of COVID-19. 8. To amend the data flow diagram to reflect that the starting point of the data is from Trusts and ensure the relevant legal bases for each data flow are included. 9. IGARD noted that COPI may be extended beyond September 2021, but thought should be given to obtaining an alternative legal basis, to ensure no interruption of data flowing into the TRE. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper, either out of committee (OOC) or at a future meeting, and before any first of type applications were received by IGARD.
3	**Data Applications**
3.1	<u>Department for Health & Social Care (DHSC): IPSOS MORI/Imperial REACT I Antigen study (Presenter: Kimberley Watson) NIC-393650-B7J6F-v4</u> **Application:** This was an amendment application from DHSC and Imperial College London, to request further identifiable Demographics data for Wave 14 of the study. The purpose is to support Antigen testing study, round 2, (REACT-1-Round 2), one element of the REal-time Assessment of Community Transmission 1 (REACT 1): a study that will provide the basis for estimation of the R value in the community at regional and local authority levels. This study is one component of a larger programme and sits alongside the REal-time Assessment of Community Transmission 2 (REACT 2): Usability and feasibility study of widespread home self-testing for SARS-CoV-2 antibodies. The data requested will be used in order to select a nationally representative sample of the population aged 5+ to take part in the testing. The study needs to provide reliable estimates of infection point prevalence at the level of local authority, as this is the administrative level responsible for local government and will feed into the local public health response. It is also powered to explore differences by key sociodemographic variables. At wave 14 the national prevalence of infection will be measured at an important time, one week after schools return in September 2021, as well as the change in prevalence since late June / early July and the national average R value, with high accuracy. The Study Team, will also look at the prevalence of infection by sociodemographic characteristics including age, sex, ethnicity, area deprivation and socio-economic status, and potential changes in those patterns between the baseline and second survey. **Discussion:** IGARD noted that aspects of this application had <u>last</u> been seen at the IGARD – NHS Digital COVID-19 Response meeting on the 20th April 2021. IGARD noted that the legal basis for NHS Digital to flow the data was The Health Service Control of Patient Information (COPI) Regulations 2002, and that this was in agreement with

	NHS Digital's Privacy, Transparency and Ethics (PTE). IGARD noted that COPI allowed the sharing of confidential patient information, however queried the statement in supporting document 7.1, the amended privacy notice, that stated *"This personal data is not classified as confidential patient information as no clinical information is used or accessed"*, and the information provided in supporting document 8.0, e-mail correspondence from NHS Digital, that stated *"The data being shared is demographic data only therefore not confidential patient information"*. NHS Digital advised that under this Data Sharing Agreement (DSA), COPI would be used as the legal basis to support the release of the demographic data; and that that there were ongoing discussions in respect of the patient demographic data and whether this was confidential patient information or not, and that until advised otherwise, NHS Digital would continue to treat it as confidential data and as such it was owed a duty of confidence. IGARD noted the verbal update from NHS Digital and asked that, since COPI was being relied upon, that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) 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 decision not to apply the National Data Opt-out (NDO), due to the data being confidential patient information supplied under the COPI notice as the legal basis, and suggested that NHS Digital made Ipsos MORI aware of this fact. In addition, IGARD asked that section 1 was updated to provide a reason for not applying the NDO in line with NHS Digital's NDO policy. IGARD noted that they had previously suggested taking a similar approach to other applications where COPI was also relied on, in electing to uphold the NDO; in that, people who had opted out of having their identifiable information used for research may also object to having their identifiable information used to invite them to take part in research. IGARD asked that Ipsos MORI review the complaints received with regard to be being contacted about the study and provide an update to NHS Digital on renewal, extension or amendment. In addition, IGARD advised that on renewal, IGARD would expect to see an analysis on the number of opt outs from further contact that Ipsos MORI had received. IGARD noted the high number of people asking not to be contacted by Ipsos MORI, and asked that section 1 was updated with confirmation as to whether the applicant had reconsidered their decision in respect of the NDOs and if not, to provide relevant narrative on this point. IGARD also queried the difference between those people that were opting out of being contacted again by Ipsos MORI, those people who made a formal complaint, and those withdrawing from the study once signed up; and asked that section 1 and section 5 were updated with clarification. IGARD queried if Ipsos MORI would retain data for those who had opted out of communications in order to ensure they are not contacted again, noting that it seemed that Ipsos MORI were deleting the identifiable data after each wave and asked that section 5 was updated to clarify this point. IGARD also queried, in respect of data minimisation, how NHS Digital would avoid repeated use of the same individuals, and asked that an explanation was provided in section 3(a) and section 3(b). IGARD queried why mobile telephone numbers had been requested since it was not explicitly stated in section 5 of the application and were advised by NHS Digital that that the mobile numbers were required to send up to two text messages reminding those invited to take part in

	the study to register. IGARD noted the verbal update from NHS Digital, and asked that section 5(b) (Processing Activities) was updated, with confirmation of what text reminders were being sent, how many text reminders were being sent, and when they would be sent, prior to patients enrolling in the study. IGARD noted that the cohort starting age was 5-years old and queried why this was the case. NHS Digital noted that this was because of the invasive nature of the test. IGARD noted the verbal update from NHS Digital but noted that since it was not clear in the application, asked that a brief narrative was added to section 5 clarifying the rationale. IGARD noted that the application was silent on the cohort numbers, and asked that in line with NHS Digital's DARS Standard for Data minimisation, section 3(a) (Data Access Already Given), 3(b) (Additional Data Access Requested) and section 5(b) were updated with indicative cohort sizes. IGARD noted the references within section 5(b) to "*any records marked as invalid or sensitive are excluded from the data extract*" and "r*ecord not marked as sensitive or invalid*" , and asked that clarification was provided as to whether s-flags were being applied, and to update the application as appropriate. IGARD noted the incorrect references in section 5(a) (Objective for Processing) and section 5(b) to *"Demographics GPES data"*, and asked that they were removed, and correctly replaced with *"PDS"* data. IGARD noted that section 5(a) contained a lot of historical information, and asked in line with NHS Digital's DARS standard for Objective for Processing, section 5(a) was updated to include an initial paragraph outlining the history of this application; and that all references to dates and times were removed, to make it more agnostic, noting that the application was being continuously updated and amended. IGARD noted the inclusion of a number of technical phrases and words within section 5(a) such as *"infection point prevalence"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms were either removed, or used only where necessary, and further explained upon first use. IGARD noted the benefits in section 5(d) (Benefits) and, noting these were not very clear, asked that further details were provided of the specific 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 for example how this study has impacted on mortality and morbidity, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the first paragraph in section 5(d) that referred to *"a direct public health benefit…"*; and asked that this was reviewed and updated, to provide further clarity as to the actual benefit, for example, public health control measures, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the yielded benefits outlined in section 5(d) (iii) (Yielded Benefits), and asked that they were updated, to reflect that public access to the data will support those in a position to make choices. IGARD queried the statement in section 1 that Imperial College London was a *"health body"*, and asked that this was updated to correctly reflect that ICL were not a health body. 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, 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. **Outcome:** recommendation to approve subject to the following condition: 1. 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. The following amendments were requested: 1. In respect of the NDO: a) To update section 1 and section 5, to clarify the difference between people opting out of being contacted again by Ipsos MORI, people who make a formal complaint, and those withdrawing from the study once signed up. b) Noting the high number of people asking not to be contacted by Ipsos MORI, to update section 1, to confirm whether the applicant has reconsidered their decision in respect of the NDOs. c) To update section 1 to provide a reason for not applying the NDO in line with NHS Digital's NDO policy. 2. To clarify in section 5, if Ipsos MORI will retain data for those who have opted out of communications, in order to ensure they are not contacted again. 3. To update section 1 to reflect that ICL are not a health body. 4. To update section 5(b) to confirm what text reminders are being sent, and when, prior to patients enrolling in the study. 5. In respect of data minimisation and in line with NHS Digital's DARS Standard for Data minimisation: a) To update section 3(a), section 3(b) and section 5(b) with indicative cohort sizes. b) To provide an explanation in section 3(a) and section 3(b) as to how NHS Digital will avoid repeated use of the same individuals. 6. To include a brief narrative in section 5, as to why the cohort starting age is 5. 7. In respect of section 5(a) in line with NHS Digital's DARS standard for Objective for Processing: a) To include an initial paragraph outlining the history of this application. b) To remove all references to dates and times, to make it more agnostic (due to the fact this application is continuously updated and amended). c) To amend section 5(a) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, *"infection point prevalence"*. 8. To clarify if the s-flag is being applied and to update the application as appropriate. 9. To remove the incorrect references to *"Demographics GPES data"* in section 5(a) and section 5(b), and correctly replace with *"PDS"* data. 10. In respect of section 5(d) and in line with the NHS Digital DARS Stand for Expected Measurable Benefits: a) To provide further details in section 5(d) of the benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally, for example, how this study has impacted on mortality and morbidity. b) To review the first paragraph in section 5(d) that refers to *"a direct public health benefit…"*, and provide further clarity as to the actual benefit, for example, public health control measures. c) To update the yielded benefits in section 5(d) (iii) to reflect that public access to the data will support those in a position to make choices. 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. It was agreed the condition would be approved out of committee (OOC) by the IGARD Deputy Chair.
3.2	<u>Cambridgeshire & Peterborough NHS Foundation Trust (FT): Improving diagnosis and management in dementia with Lewy bodies using the CPFT Research Database (CRATE). (Presenter: Denise Pine) NIC-170100-T1Q8C-v1.4</u> **Application:** This application, was a request to extend the current Data Sharing Agreement (DSA), which expired on the 31st March 2021. The data requested is identifiable Civil Registration (Deaths) data, Hospital Episode Statistics (HES): Civil Registration (Deaths) bridge, HES Accident and Emergency (A&E), HES Admitted Patient Care (APC) and HES Outpatients. The purpose is for a project that will identify a cohort with Lewy bodies (DLB) cases and non-DLB disease dementia controls, to allow a detailed examination of their characteristics and outcomes. The Research Team will examine the patterns of early predictors, presentations and symptoms associated with DLB to facilitate early diagnosis. This will inform the development and testing of a natural language processing (NLP) app to aid diagnostic decision making for clinicians in real time. The data subjects for the project contain two cohorts: one DLB cohort consisting of 1,000 participants, and one non-DLB disease dementia control cohort consisting of 21,000 participants. The cohort consists of 1,000 DLB patients; and 21,000 non-DLB patients, and the study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD noted and commended NHS Digital on quality of the information provided within the application, which supported the review of the application by Members. IGARD noted that recent Research Ethics Committee (REC) support, and continuous s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG), had been provided and reviewed. 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 Health Research Authority Confidentiality Advisory Group (HRA CAG) condition of support, that stated the applicant should *"Provide an overview of the engagement*

	activity undertaken with the patient and public representatives appointed to the study"; and asked that section 5 (Purpose / Methods / Outputs) was updated to include a brief summary of the PPI undertaken to date, and in line with the HRA guidance on Public Involvement. 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 will be revealed, asked that this was updated to also include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted the reference in section 5(a) (Objective for Processing) to there being *"210,000"* cohort members, and asked that this was reviewed and amended to *"21,000"*, and in line with the cohort numbers specified elsewhere in the application. IGARD noted that there was one processing location and one storage location within section 2 (Locations), and queried if this was correct, for example, was there a back-up or disaster recovery site; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) (Storage Location(s)) if appropriate. IGARD noted the volume of information within section 5, and asked that this was edited, to remove excessive detail to reduce the description, which was potentially too lengthy for NHS Digital's data release register, whilst ensuring the information still provided reassurance to the public. IGARD noted that some of the information in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, for example, replacing the term *"cases"* with *"people with DLB / non-DLB"*; and that further sensitive consideration was given to the patient audience and how this type of language could be perceived. IGARD noted the volume of information within section 5(d) (Benefits), and asked that this was edited, to remove excessive detail to reduce the description, which was potentially too lengthy for NHS Digital's data release register, for example, by providing three or four key benefits. IGARD suggested that section 5(c) (Specific Outputs Expected)be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* **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. 2. To amend section 2(b) to add any additional storage locations, for example back-up or disaster recovery. 3. To edit section 5 to remove excessive detail to reduce the description, which is potentially too lengthy for NHS Digital's data release register. 4. To review the cohort numbers cited in section 5(a) and amend as appropriate. 5. To update section 5 throughout to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example replacing the term *"cases"* with *"people with DLB / non-DLB"*. 6. To update section 5(c) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 7. To update section 5 to include a brief summary of the PPI undertaken to date, as per the HRA CAG condition of support, and in line with the HRA guidance on Public Involvement.

	8. To edit section 5(d) to remove excessive detail to reduce the description, which is potentially too lengthy for NHS Digital's data release register, and provide 3 or 4 key benefits.
3.3	<u>i5 Health Limited: NHS Commissioning Support (Presenter: Frances Hancox) NIC-14709-Z2H2R-v6.9</u> **Application:** This was an extension and renewal application, for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients, Secondary Uses Service (SUS) Payment By Results (PBR) A&E, SUS PBR Episodes, SUS PBR Outpatients and SUS PBR Spells data. The purpose of this application is to: **1)** to analyse the economic impact of NonMedical Prescribing (NMP); **2)** to provides consultancy services to support to Clinical Commissioning Groups (CCGs), Commissioning Support Units (CSUs), Sustainability and Transformation Plans (STPs), Acute services, NHS England and Local Authorities (LAs) in their decision-making for commissioning purposes; **3)** To identify realistic NHS Quality, Innovation, Productivity and Prevention (QIPP) initiatives for specific CCGs, CSUs and Providers in order to spot trends and to perform benchmarking that support commissioners in particular with their operational, strategic planning and co-commissioning; **4)** to advise Voluntary Sector Organisations (VSOs) that have charitable status and exist to complement the work of the NHS in improving patient care; **5) t**o measure standards of care and identify gaps in provision to inform commissioning strategy; and, **6)** to provide Case Finding and Risk Stratification services. **Discussion:** IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 6th October 2020. IGARD queried the special condition in section 6 (Special Conditions), that stated *"i5 Health will hold a maximum of 7 years of data…"*, noting that some of the data that the applicant would need to destroy was outside the 7-year period. NHS Digital advised IGARD that the applicant did currently hold data from 2013, which would be outside the 7-year period, however this would need to be destroyed on an annual basis, and before the latest data was disseminated. IGARD noted the verbal update from NHS Digital and advised that the special condition would need amending to reflect this, and to ensure that the applicant was not in breach of the Data Sharing Agreement (DSA) and amended as appropriate to reflect the factual scenario. IGARD noted the statement in purpose 2.4 in section 5(c) that stated *"NHS England requires i5 Health to carry out a study…"*, and asked that this was reviewed, and consideration was given, as to whether it would be more appropriate to replace with *"NHS England commission"*; and to update accordingly, as if NHS England do require this it could have an impact on the facts relating to data controllership. In addition, IGARD noted that if NHS England do *"require"* i5 to undertake the work then a further review should be undertaken, as to whether this impacted on the facts as related to data controllership, and that any necessary updates should be made to the application to reflect the factual scenario. IGARD queried purpose 2.1 in section 5(c) (Specific Outputs Expected), that stated *"The key outcomes provided by i5 Health are the creation of cohorts of patients…"*, and asked that this was updated, to clarify the nature of the cohort identification and how this is not reidentifying individuals, since this was not clear. IGARD noted that some of the information in section 5(c) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, for example,

	replacing the term *"Q1"*; and that further sensitive consideration was given to the patient audience and in line with NHS Digital's DARS standard for Expected Outputs. An IGARD specialist member queried the information in section 5(a) (Objective for Processing) that specifically referred to the involvement of GP Practices in Merseyside, and asked that section 5(a) was updated with clarity of the extent of the involvement of the GP Practices in Merseyside, for example, specifying a more precise geographical area or within a particular CCG(s). IGARD noted the historical dates within section 5(a), for example *"September 2020"*, and asked that they were reviewed, to ensure they were still current and relevant, and updated / removed as necessary, in line with NHS Digital's DARS standard for Objective for Processing. IGARD noted the last paragraph in section 5(a) that stated *"i5 Health provides the services solely for the benefit of the NHS and its patients"*, and asked that this was reviewed and amended as appropriate to reflect the commercial element. In addition, IGARD queried if i5 Health Limited provided or would provide services to commercial sector health bodies, and asked that confirmation was provided in section 5(a). IGARD noted the information provided in section 5(e) (Is the Purpose of this Application in any way commercial) that outlined the commercial element of the application, and asked that this was reviewed and updated in line with NHS Digital DARS Standard for Commercial Purpose; and that for transparency, the public facing section 5(a) was updated with the relevant wording from section 5(e) to reflect any commercial purpose. IGARD noted the verbal update from NHS Digital that this was not academic research and therefore no Research Ethics Committee approvals had been sought by the application, however IGARD noted that there were ethical issues relating to research and development of algorithms, and suggested that the applicant may wish to seek independent ethical review in respect of their processes. IGARD noted the benefits outlined in section 5(d) (Benefits), however asked that in line with NHS Digital's DARS Standard for Expected Measurable Benefits, this was updated with clarity that the algorithm that was an output from this study, was then being applied by other agencies to deliver benefits to individual patients; and that i5 Health Limited would not identify individual patients as part of this process. IGARD noted the references to the *"interventions"* within section 5(d), however asked that this was updated further with specific examples of the benefits of the interventions, noting that this was not currently clear. IGARD queried the references within section 5(d) to the development of National Institute for Health and Care Excellence (NICE) guidelines, being a specific benefit; and asked that for transparency, further examples were provided of where the input had been used by NICE, in line with NHS Digital's DARS Standard for Expected Measurable Benefits IGARD noted the benefits outlined in section 5(d) of the COVID-19 Tool, however, asked that further evidence was provide of where the Tool had been applied and the benefits derived from this, in line with NHS Digital's DARS Standard for Expected Measurable Benefits IGARD also noted in section 5(d) the potentially hyperbolic statements made in terms of the money that will be saved from the research, and asked this was reviewed and updated where necessary, to reflect that the potential benefits may be more effective utilisation of resources, rather than money *"saved"*.

	IGARD noted that section 5(d) was silent on direct benefit to patients, for example, stroke prevention; and asked that section 5(d) was updated to reflect this important benefit, in line with NHS Digital's DARS Standard for Expected Measurable Benefits. **Outcome:** recommendation to approve The following amendments were requested: 1. To review the special condition in section 6, that *"i5 Health will hold a maximum of 7 years of data…"*, and amend as appropriate to reflect the factual scenario as per the verbal update from NHS Digital. 2. In respect of data controllership: a) To review section 5(c) in respect of purpose 2.4 and consider whether NHS England *"require"* i5 to undertake the work mentioned or whether it would be more appropriate to replace with *"NHS England commission"*. b) If NHS England do *"require"* i5 to undertake the work then to review whether this impacts on the facts as they relate to data controllership and to make any necessary updates to the application to reflect the factual scenario. 3. In respect of section 5(a) in line with NHS Digital's DARS standard for Objective for Processing: a) To update section 5(a) to clarify the extent of the involvement of the GP Practices in Merseyside, for example, specifying the area. b) To review the dates referenced within section 5(a) to ensure they are still current and relevant, and update / remove as necessary. c) To provide confirmation in section 5(a) if i5 Health Limited provide or would provide services to commercial sector health bodies. 4. In respect of section 5(c) in line with NHS Digital's DARS standard for Expected Outputs: a) To update section 5(c) to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example when referring to *"Q1"*. b) To update point 2.1 to clarify the nature of the cohort identification and how this is not reidentifying individuals. 5. In respect of section 5(d) and in line with NHS Digital's DARS Standard for Expected Measurable Benefits.: a) To clarify in section 5(d) that the algorithm that is an output from this study, is then being applied by other agencies to deliver benefits to individual patients; and that i5 Health Limited will not identify individual patients as part of this process. b) To update section 5(d) to provide specific examples of the benefits in relation to the interventions. c) To provide examples in section 5(d) of where the input has been used by NICE. d) To provide further evidence in section 5(d) of where the COVID-19 Tool has been applied and the benefits derived from this. e) To review any hyperbolic statements made in section 5(d), for example, in relation to projected savings. f) To update section 5(d) to provide a list of the benefits in respect of patient information, for example stroke prevention. 6. In respect of the commercial element: a) To review section 5(e) in line with NHS Digital DARS Standard for Commercial Purpose. b) To update section 5(a) with the relevant wording from section 5(e) to reflect any commercial purpose.

	c) To review the language in the last paragraph of section 5(a) relating to the commercial element, and amend as appropriate. The following advice was given: 1. IGARD noted the ethical issues relating to research and developing algorithms and suggested that the applicant may wish to seek independent ethical review in respect of their processes.
3.5	<u>Imperial College London (ICL): Identification of Low-Uptake Population Segments in Cancer Screening (Presenter: Louise Dunn) NIC-372498-R9Z9J-v0.9</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients; for the purpose of a study, aiming to establish the extent to which socio-demographic and co-morbidity factors predict breast screening adherence. Breast cancer screening invites women between 50 and 70 years old every three years for a mammogram, in order to detect cancers at a stage in which treatment is less invasive and survival higher. Despite this, the number of eligible patients who take up the invitation to screen is falling, with coverage rates falling nationally by 1.3% over the past five years. There also exists demonstrable geographical variability in uptake rates. The study will inform targeted measures to increase breast cancer screening attendance. This will be measured by the strength of association between investigated socio-demographic factors and attendance at Breast Cancer Screening by means of multivariate analysis. The Secondary aims will involve examining regional data, to assess if the population-level findings of the primary outcome are seen in areas with historically poor uptake, to better define the low-uptake subgroups. This will also act as a means of validation of the primary results. The secondary outcomes will entail the difference in the socio-demographic factors and nature of association with attendance at breast screening across regions in England, as determined by separate multivariate analysis models using regional data. The study is relying on s251 of the NHS Act 2006, for the flow of data from Public Health England (PHE) to NHS Digital. NHS Digital advised IGARD that section 3(c) (Patient Objections) in the application incorrectly stated that National Data Opt-outs (NDO) would **not** be applied, and confirmed that following submission of the application to IGARD for review, this had been updated to correctly state that NDOs would be applied. NHS Digital advised IGARD that section 2(c) (Territory of Use) currently stated that the territory of use was the *"UK"* but noted this may be incorrect and would need to be checked to confirm if it was "*England and Wales*". **Discussion:** IGARD noted and supported the amendment to the application, as per the verbal update from NHS Digital in respect of the update to section 3(c) to reflect that NDOs would be applied, in line with NHS Digital's NDO policy. IGARD also noted the verbal update from NHS Digital in respect of the territory of use, and asked that once NHS Digital had reviewed, section 2(c) amended as appropriate. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was compatible with the processing outlined in the application. IGARD queried the conflicting information in the application, in respect of the number of years of data requested, for example, section 3(b) (Additional Data Access Requested) referred to 7-years, and section 5(a) (Objective for Processing) referred to 9-years. IGARD asked that this

	information was reviewed, and section 3 (Datasets Held / Requested) and section 5 (Purpose / Methods / Outputs) were updated where necessary, to reflect the correct information. IGARD noted the information within supporting document 2.0, the protocol, that referred to educational data and asked that section 5 was updated with confirmation as to whether the NHS Digital data would be linked to any educational data, as this was not clear within the application. IGARD queried the statement in section 1 (Abstract) that Imperial College Healthcare NHS Trust were *"joint sponsors"*, and noted that this did align with the information provided within the supporting documents; and asked that the statement was reviewed and amended as appropriate to reflect the factual scenario. IGARD queried the statement in section 5 that the data requested, and its analysis will inform a programme of work funded by *"Public Health England"* (PHE); and noting that this did not align with the funder stated in section 8(b) (Funding Sources), asked that section 5 and section 8(b) were amended as appropriate, to ensure the correct funding bodies were stated. IGARD noted the inclusion of a number of technical phrases and words within section 5(a) such as *Descriptive statistics, associative univariate and multivariate analyses"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms were either removed, or used only where necessary, and further explained upon first use, and in line with NHS Digital's DARS Standard for Objective for Processing In addition, IGARD noted that some of the information in section 5(a) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, for example, the reference to *"non-compliant populations"*. and that further sensitive consideration was given to the patient audience and how this type of language could be perceived, and in line with NHS Digital's DARS Standard for Objective for Processing IGARD queried the statement in section 5(a) that dissemination of the data was *"unlikely to lead to ethical issues"*, and asked that this was reviewed and updated, for example, to address any ethical issues of singling out specific subgroups for perceived criticism in not taking up the offer of breast screening. IGARD noted the limited public and patient (PPI) involvement, and suggested PPI involvement throughout the study, in particular, noting that it may be helpful to have relevant patient groups reviewing the language used in this public facing application, and to have input into all outputs to mitigate the risk of harm to potentially stigmatised groups, and in line with the HRA guidance on Public Involvement, for example using language such as "non-compliant" and "screening adherence". IGARD noted the reference in section 5(b) (Processing Activities) that the data flowing from PHE to NHS Digital was *"pseudo-anonymised"*, and asked that this was updated to correctly state that the data was *"identifiable"*, and in line with the NHS Digital DARS Standard for Processing Activities. In addition, IGARD also noted the reference in section 5(b) to the HES ID data being *"anonymous"*, and asked that this was updated to correctly state that the data was *"pseudonymised"*, and in line with the NHS Digital DARS Standard for Processing Activities. IGARD suggested that section 5(c) (Specific Outputs Expected)be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".*

	IGARD noted the reference in section 5(d) (Benefits) to the *"Richard's review"*, and noting that this could refer to a number of reviews, asked that this was updated with confirmation of the specific review, and to provide a relevant web link. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3(c) with confirmation that NHS Digital will apply NDOs in line with NHS Digital's NDO policy. 2. To review the number of years of data and ensure this is correctly stated in section 3 and section 5. 3. To confirm in section 5 if the NHS Digital data will be linked to any educational datasets, as referenced in the protocol. 4. To review the territory of use stated in section 2(c) and amend as appropriate, for example, *"UK" or "England and Wales"*. 5. To review the statement in section 1 that Imperial College Healthcare NHS Trust are *"joint sponsors"*, and amend as appropriate to reflect the factual scenario. 6. To amend section 5 and section 8(b) as appropriate, to ensure the correct funding bodies are stated. 7. In respect of the language in section 5(a) and in line with NHS Digital's DARS Standard for Objective for Processing: a) To amend section 5(a) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, *"Descriptive statistics, associative univariate and multivariate analyses"*. b) To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example when referring to *"non-compliant populations"*. c) To review the statement in section 5(a) that dissemination of the data is *"unlikely to lead to ethical issues"*, and update, for example, to address any ethical issues of singling out specific subgroups for perceived criticism in not taking up the offer of breast screening. 8. In respect of section 5(b) and in line with the NHS Digital DARS Standard for Processing Activities: a) To clarify in section 5(b) that the data from PHE to NHS Digital is identifiable and not *"pseudo-anonymised"*. b) To update section 5(b) to clarify that the HES ID data is pseudonymised and not *"anonymous"*. 9. To update section 5(c) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 10. To update the reference in section 5(d) to the *"Richard's review"*, to confirm which review this refers to and to provide a relevant web link. The following advice was given: 1. IGARD noted the PPI involvement, and suggested that this should continue throughout the study, in particular, noting that it may be helpful to have relevant patient groups reviewing the language used in this public facing application, and to have input into all outputs to mitigate the risk of harm to potential stigmatised groups , and in line with the HRA guidance on Public Involvement.
3.6	NHS Bath & North East Somerset, Swindon & Wiltshire CCG: DSfC - NHS Bath and North East Somerset, Swindon and Wiltshire CCG - Comm/RS/IV (Presenters: Michael Ball / Shaista Majid) NIC 362237-Y5K7L-v3.2

	Application: This was an amendment application to add linkage to the COVID-19 testing data the CCG receives from Public Health England (PHE). The overall purpose for this application is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care, and to provide intelligence to support the commissioning of health services. The pseudonymised data is required to ensure that analysis of health care provision can be completed to support the needs of the health profile of the population within the CCG area based on the full analysis of multiple pseudonymised datasets. **Discussion:** IGARD noted that to further support NHS Digital and the applicant, an IGARD specialist member had provided an annotated copy of the application, with suggested amendments, to help strengthen the information already noted within the application. IGARD asked that the application, was updated where appropriate to reflect the annotated application. IGARD advised IGARD, that there was a high risk to NHS Digital, in respect of Risk Stratification, that the current flows of data mean that the National Data Opt-out (NDO) and Type 1 objections will prevent individuals receiving direct care, despite those individuals being informed that the NDO and type 1 objections do not prevent data sharing for direct care. IGARD queried why *"NHS Bath & North East Somerset, Swindon & Wiltshire CCG"* did not appear on the NHS risk stratification approved organisations list; and were advised by NHS Digital, that this was due to the recent merger of the CCGs, and that the applicant had been made aware, and was in the process of resolving this. IGARD noted the verbal update from NHS Digital, and asked that the applicant ensured that this was investigated and resolved as appropriate. IGARD queried the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), and asked that a satisfactory update was provided of the yielded benefits to date, and were clear as to the benefits to the local population and the health care system and to ensure they complied with the NHS Digital's DARS Standard for Expected Measurable Benefits. In addition, IGARD noted that the yielded benefits did not reflect the purpose(s) for processing, and asked that for transparency, section 5(d) (iii) was updated accordingly to reflect this information, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD also noted that the yielded benefits in section 5(d) (iii) did not clearly distinguish between 'initiatives' and 'strategic objectives', and asked that the appropriate updates were made to clearly outline this, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted that some of the information in section 5(b) (Processing Activities) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, for example, to clarify what is meant by the term *"similar primary use tools"*, and in line with NHS Digital DARS Standard for Processing Activities. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the yielded benefits: a) To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits, and are clear as to the benefits to the local population and the health care system. b) To update the yielded benefits in section 5(d) (iii), to reflect the purpose(s) for processing.

	c) To update the yielded benefits in section 5(d) (iii) to clearly distinguish between 'initiatives' and 'strategic objectives'. The following amendments were requested: 1. As section 5 forms NHS Digital's public data release register, to amend section 5(b) in line with NHS Digital DARS Standard for Processing Activities in a language suitable for a lay reader for example, to clarify what is meant by the term *"similar primary use tools"*. 2. To update the application where appropriate, in line with the annotated application shared with NHS Digital by an IGARD specialist member. The following advice was given: 1. IGARD noted the verbal update from NHS Digital that *"NHS Bath & North East Somerset, Swindon & Wiltshire CCG"* does not currently appear on the NHS risk stratification approved organisations list due to the recent merge of the CCGs. IGARD asked that the applicant ensured that this was investigated and resolved as appropriate. **Significant Risk area:** 1. There is a high risk to NHS Digital in respect of Risk Stratification, that the current flows of data, mean that the NDO or Type 1 Opt-out, may affect direct care for individuals who have these opt-outs in place, despite their being told that their direct care would not be affected. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
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 June and July 2021 IGARD noted that the IG COVID-19 Release Register June and July 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. IGARD agreed that, from the 12th August 2021, where a major issue is raised in respect of the IG COVID-19 Release Register, that a high-level summary of these points would be included within the published minutes for transparency and audit purposes. • Should PAG have been advised re any use of GDPPR data / was data handled in accordance with the PAG ToR and as advised to the public (GPES data for pandemic planning & research (COVID-19) – NHS Digital?) (IG-02683_2 and IG-02683_3)

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. The ratified action notes from **Tuesday 10th August 2021** can be found attached to these minutes as Appendix B.
7 **7.1**	AOB: NIC-454217-D9J5X NHS Lincolnshire CCG & LA (Presenters: Michael Ball / Shaista Majid) IGARD noted that this application was recommended for approval on the 24th June 2021, with amendments; and that two of the outstanding amendments were subsequently discussed under 'AOB' at the IGARD business as usual meeting, on the 15th July 2021, where IGARD had requested that further written information was provided to support the discussion, and why the amendments could not be met. The two outstanding amendments, which NHS Digital advised, could not be met by the applicant, are as follows: 1. To amend the application throughout to ensure that the date range for the datasets requested is **only** from 2016 onwards at the earliest. 2. To update section 5(c) to remove references to the application permitting *"reidentification for direct care"*. IGARD noted the written information provided to NHS Digital (via the IGARD Secretariat), confirming why the amendments could not be met. IGARD amended their original outcome further and included the following advice which would need to be updated to section 1 (abstract) of the application summary: • 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 volume of data requested and the yielded benefits that have accrued. There was no further business raised, the IGARD Deputy 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 06/08/21

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-431355-B1L8W-v0.9	University of Oxford	22/07/2021	1. In respect of the proposed processing: a) To provide written confirmation that the processing under this DSA, is not excessive processing when aligned with other uses of data by the applicant, or b) To amend this DSA and / or the main route agreement (NIC-381683-R6R6) as required.	IGARD Members	Quorum of IGARD Members	N/A

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

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

held via videoconference, Tuesday, 10th August 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Prof Nicola Fear (IGARD Specialist Academic Member)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	James Gray (Digi-Trials)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Deputy 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.
2.1	NIC-526384-M3T5R St George's University Hospitals NHS Foundation Trust (PTC) **Background:** this was a new application for a phase II randomised, single-blind, platform trial to assess the safety, reactogenicity and immunogenicity of the COVID-19 vaccines in pregnant women in the UK (Preg-CoV). The study is looking to recruit up to 900 cohort participants aged 18 to 47 years and between 13 and 34 weeks gestation on the day of the planned vaccination. St George's will be the sole Data Controller, with NHS Digital as the sole Data Processor. NHS Digital will contact the potential participants directly as per the previous permission to contact applications and St George's will have no access to any data provided by NHS Digital. The following observations were made on the basis of the verbal update from NHS Digital plus a copy of the signed Data Sharing Agreement (DSA) which had previously progressed via the NHS Digital SIRO precedent. **IGARD Observations:** IGARD members noted that due to the nature of the meeting and the fact that they had received no further documentation, that 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 v0.2 of the application had been provided for review at this meeting and their observations were based on the verbal update by NHS Digital only, alongside a copy of the signed DSA . IGARD members noted this was incredibly important research into vaccination and pregnancy. IGARD members welcomed the verbal update and copy of the signed DSA and noted that NHS Digital had indicated that due to the urgency of the application, the application had already progressed under NHS Digital's SIRO Precedent and had been signed by the applicant. IGARD queried the statement in section 5(b) (Processing Activities) which referenced "males", noting this was a clinical trial into vaccination and pregnancy, namely: "*It is not known in advance how many individuals meeting the above criteria will have records in the PtC dataset. The number may be amended and the process may be repeated depending on the level of response. In the event of the trial not achieving a suitable balance in recruited participants, such as an uneven ratio of* ***males*** *to females, subsequent mail outs may restrict the required criteria to a greater degree than previously, for example, only requesting details for* ***male*** *participants as opposed to both* ***males*** *and females. This could encompass any part of the criteria, such as age, gender, ethnicity or location and various others, depending on how the recruitment progresses*". NHS Digital noted this was templated wording. IGARD noted the verbal update from NHS Digital but stressed the importance of ensuring that templated wording in section 5 of an application which formed NHS Digital's DSA and published data release register, be carefully read to ensure that the templated wording applied to the applicant, and it was what the applicant was actually doing as part of the trial or study. IGARD noted this reference to "*males*" in a study about vaccination and pregnancy may undermine public trust in NHS Digital. A fundamental risk of not checking template wording is that the applicant may unknowingly breach their contract with NHS Digital due to text being included which is not relevant to their study or clinical trial. IGARD commended the applicant for consulting with the Miscarriage Association and SANDS with regard to their communications, but queried if the NHS Digital communications team had removed wording with regard to "*recent loss*" after the patient groups had seen the communications. IGARD suggested that the applicant may wish to forward a finalised copy of the communication to the Miscarriage Association and SANDS for their information. IGARD members noted this was an important potentially long-term study, and noting they had not been provided with a copy of the supporting documentation, including the consent forms or patient information leaflets, queried why the applicant's website only noted that the "*Participants will be followed up until one year after delivery*". NHS Digital noted that a copy of the draft consent materials were uploaded to NHS Digital's customer relationship management (CRM) system and provided a verbal update of their content. NHS Digital confirmed that they had reviewed the consent and PIS materials in line with the processing outlined in the application, however IGARD noted that the draft informed consent materials appeared to be relying solely on the GP record and did not reference NHS Digital nor any linkage to other data that NHS Digital held that may be useful to the applicant in any long-term follow-up of mothers and their children. For example, mortality data or hospital episode statistics (HES). IGARD members also noted reference to "*regulatory authorities*" in the draft informed consent materials, but that this overarching phrase would not encompass requesting data held by NHS Digital, such as HES. IGARD members noted the importance of

	this clinical trial and that a careful review of the consent and PIS materials should have been undertaken, so that the materials did not preclude the applicant, for example, receiving further datasets, linkage to other datasets, and long terms follow up due to the nature of the clinical trial, the nature of the disease and the scientific interest in long term follow-up. IGARD suggested that NHS Digital urgently discuss this aspect with the applicant. **Risk area:** reputational risk to NHS Digital by referring to "*males*" in an application and clinical trial about vaccination and pregnancy; separate to the application that an applicant may have entered into a DSA with text in section 5 that is not relevant to their clinical trial which may inadvertently cause them to "breach" their DSA. **Subsequent to the meeting:** IGARD reiterated comments made previously: Noting the language used in this and other applications using the NHS Digital COVID-19 permission to contact register (CV19 PtC) (internal process name), consideration should be given to the external name of the registry: "NHS Digital COVID-19 vaccine research registry". Since the vaccine registry was a standalone registry that cannot be linked to any other registry, consideration should be given to its external name, since it could imply that the registry contained all those that had had a vaccine, rather than what the database is; a database of those who have consented to be part of a registry of people who are happy to be contacted about vaccine research. IGARD suggested that in due course the language within this and other permission to contact applications should be updated to ensure that section 5, which forms part of NHS Digital's data release register, contained an accurate description of the registry.
3	<u>AOB</u> There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the meeting.