Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 19 August 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Deputy SIRO (Item 2.1)
Dave Cronin	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS) (Item 2.1)
Dan Goodwin	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 1- 5)
Terry Service	Data Access Request Service (DARS) (Observer: items 3.1 – 3.3)
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. Kirsty Irvine noted professional links to the Royal College of Obstetricians and Gynaecologists (NIC-461283-Q3R7K), 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 12th 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).
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2.1	Class Action Approval to Extend Data Sharing Agreements (DSAs) Prior to Expiry and to Issue DSAs in Place of Expired DSAs – **DRAFT** Briefing Paper (Presenters: Garry Coleman / Liz Gaffney / Dave Cronin) The draft briefing paper was to inform IGARD about changes to the Data Access Request Service (DARS) business process, intended to address the issue of data recipients retaining NHS Digital data beyond the expiry dates of their DSAs, which is a recognised risk area for NHS Digital. High demand related to the COVID-19 pandemic, combined with resource constraints have limited DARS' capacity to proactively manage expiring DSAs, and have had to rely on data recipients submitting requests to extend / renew their DSAs ahead of their DSA expiry dates, and to process these in time prior to the DSA expiry. Subject to approval from NHS Digital's Senior Information Risk Owner (SIRO), the briefing paper outlined a number of measures to identify, assess and progress relevant DSAs as appropriate, and dependent upon any risks identified. IGARD welcomed the draft briefing paper and provided a number of high level comments but overall noted that the approach was sensible and pragmatic. IGARD looked forward to receiving a further update at an IGARD BAU meeting before the end of September 2021. The NHS Digital Deputy SIRO thanked IGARD for their high level comments and their overall support for the project, which would be fed back to the NHS Digital SIRO.
2.2	NDA Programme Requirement Specification (no presenter) The National Diabetes Audit (NDA) Programme briefing paper had been presented to IGARD on 4th October 2018, subject to a number of minor amendments. The briefing paper had been subsequently updated and included as a supporting document to the NDA Programme Requirement Specification document v0.8 and NDA Technical Specification document v1.3. The National Diabetes Core Audit (NDA Core); National Pregnancy in Diabetes Audit (NPID); National Diabetes Footcare Audit (NDFA); National Inpatient Diabetes Audit, including National Diabetes I-Patient Audit – Harms (NaDIA-Harms); and Diabetes Prevention Programme (DPP) were all cited and outlined in the NDA Programme Requirement Specification (v0.8) issued on the 10th February 2020 which is the latest version of the specification as referred to in the Health & Social Care Information Centre (establishment of Information systems for NHS Services: National Diabetes Audit) Directions 2007.

	IGARD welcomed the NDA Programme Requirement Specification and made the following high-level comments: 1. Noting that the NDA technical Specification document references the Type 1 Objection code, but not the NDA Dissent code, IGARD asked the Deputy Caldicott Guardian to take an action to look into the application or otherwise of the NDA Dissent Code recorded on GP systems at the request of patients who have expressed their dissent from participation in the audit. 2. Updating the NHS Digital privacy notice with respect to the NDA, to include NHS England as a joint Data Controller. 3. All previous comments, not expressly addressed, remained live. 4. IGARD noted that they would wish to review any new or amendment NDA programme requirement specifications to ensure they were included in future IGARD BAU minutes and in agreement with NHS Digital. IGARD looked forward to receiving a verbal update at an IGARD BAU meeting in due course with regard to the points raised above and that any finalised document(s) should be provided back to IGARD for information so that they could be received formally and noted in published IGARD BAU minutes.
3	**Data Applications**
3.1	University of Bristol: National Child Mortality Database (NCMD) request for mortality data (COVID-19) (Presenter: Mujiba Ejaz) NIC-331142-P5K6M-v0.10 **Application:** This was a new application for identifiable Civil Registration (Deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients and Maternity Services Data Set (MSDS). The National Child Mortality Database (NCMD) Programme is an NHS England and NHS Improvement (NHSE&I) funded and Healthcare Quality Improvement Partnership (HQIP) commissioned programme that collects and analyses information on all children who die across England. The purpose of collating information nationally is to ensure that deaths are learned from, that learning is widely shared and that actions are taken, locally and nationally, to reduce the number of children who die. The aims of the NCMD are to: **1)** capture, analyse and disseminate appropriate data and learning from child death reviews; **2)** drive the quality of child death review at every stage through bench-marking and quality improvement (QI) methodology; **3)** study and analyse the patterns, causes and associated risk factors of child mortality in England, providing information to target preventative health and social care and to assist in policy decisions; and, **4)** develop a sustainable model after the lifetime of the project. The NCMD also provides a unique opportunity to accelerate understanding of how COVID-19 is impacting children and identify opportunities for intervention. The knowledge and evidence base about how COVID-19 will threaten the lives of new-born babies, infants and children is limited and more information is needed on: **1)** the impact of chronic morbidities in children on their risk of dying due to COVID-19; **2)** sudden unexpected death in infancy (SUDI); and, **3)** babies born preterm, where the mother had severe COVID-19. **Discussion:** IGARD welcomed the application and noted the importance and the sensitivity of the study. IGARD noted that aspects of this application had been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 7th July 2020 and the 24th November 2020. IGARD noted

	that the application was silent on previous IGARD reviews, and asked that section 1 (Abstract) was updated, with notes of previous IGARD reviews, for clarity and audit purposes, and as per agreed process. IGARD also asked that section 1 was updated, with a clear description of any other flows of data used for the NCMD under other Data Sharing Agreements (DSA). IGARD noted at the IGARD – NHS Digital COVID-19 Response meetings, they had previously suggested that the applicant may wish to rely on provision under The Children Act 2004 as a legal basis, rather than emergency National Health Service (Control of Patient Information Regulations) 2002 (COPI) powers, which will fall away at some point in the future, and that NHS Digital's Privacy, Transparency and Ethics (PTE) would need to be content with the proposed legal basis of Section 16M-N of the Children Act 2004, and that written confirmation be provided as a supporting document. NHS Digital advised IGARD that PTE had been consulted about the proposed legal basis, and had determined that The Children Act 2004 did **not** cover access to NHS Digital data, and that in this case, it was agreed that COPI was the most appropriate legal basis. IGARD noted the verbal update from NHS Digital, however, noting that the written analyses from PTE had not been provided as a supporting document, asked that a copy was provided that confirmed The Children Act 2004 was the legal gateway for **all** aspects of the processing, including, for example, the valuable aim of improving services to bereaved families where COVID-19 was not necessarily the cause of death; and that this was uploaded to NHS Digital's customer relationship management (CRM) system for future reference. In addition, IGARD asked that section 1 was updated with a narrative, confirming why The Children Act 2004 was no longer deemed a suitable legal basis for the flow of data, noting that this had previously been used to flow HES and MSDS from NHS Digital, and was currently referenced as the legal gateway for the flow of HES data in the supporting documents. IGARD queried the role of NHS Improvement, in light of the inconsistent information within the application which stated they were acting with NHS England as Data Controller. IGARD noted in the supporting documents provided that only NHS England and NHS Digital were cited as joint Data Controllers. NHS Digital advised IGARD that NHS Improvement had been referenced as a joint Data Controller (with NHS England and NHS Digital), due to the imminent merger between NHS England and NHS Improvement (Monitor and the NHS Trust Development Authority (TDA)). IGARD noted the verbal update from NHS Digital, however, based on the facts presented, in light of the fact that NHS Improvement remains a separate entity from NHS England, asked that the application was updated to remove any references to NHS Improvement acting with NHS England and NHS Digital as a joint Data Controller. If, however the factual situation supported NHS Improvement acting as joint Data Controller alongside NHS England and NHS Digital, IGARD asked that the application was updated to add NHS Improvement (Monitor and NHS TDA) as a joint Data Controller and that all transparency materials were updated accordingly, in line with the NHS Digital's DARS Standard for Data Controllers. IGARD also suggested that the privacy notice was reviewed and updated to ensure that it consistently reflected that NHS England and NHS Digital were **joint** Data Controllers. IGARD noted in section 7 (Ethics Approval), that the application was described as an *"audit"*, and therefore ethics approval had not been obtained; however IGARD noted that many aspects of the processing appeared to go beyond pure audit activities. In addition, HQIP did not take the opportunity to describe the activity as audit, nor did it form part of their National Audit Programme, and instead describe it as a "*Clinical Outcome Review*". IGARD suggested

	that the applicant should speak to the Health Research Authority (HRA) to determine whether or not any further steps should be taken in respect of ethics support. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edited to provide examples that reflect the benefits to the Health and Social Care System and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the benefits outlined in section 5(d), however queried how the benefits linked to the legal basis cited (COPI), for example, how improvement of services to bereaved families could be generated under the restrictive COPI Notice gateway which covers a range of purposes related to diagnosing, managing and controlling the spread of communicable diseases (see the COPI notice frequently asked questions section on the NHSX website); and asked that section 5(d) was updated. IGARD queried the historical dates referenced in section 5(d), for example, the publication of a report in June 2021; and asked that the dates were reviewed to ensure they were still current and relevant, and the narrative was updated / removed as necessary. IGARD noted the references in section 1 to *"patients that…"*, and asked that these were updated to *"patients who…"*. IGARD noted and applauded the applicant on their excellent patient and public involvement (PPI), which was evident in the quality of their website. The Deputy Caldicott Guardian who was present at the meeting, advised NHS Digital that he would be happy to provide any additional support with this application. 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 unusual statutory arrangements and the sensitivity of the data and the processing. Noting that one specialist IGARD member dissented from the recommendation to approve (still having concerns about the legal basis and therefore recommending a deferral), a further discussion was held between the IGARD members on the process for reaching a recommendation. IGARD agreed that as per the IGARD Terms of Reference, they would recommend for approval by way of a majority vote of 4 members (approve) to 1 member (dissent). **Outcome:** recommendation to approve by a quorum of 4 members, with one member dissenting (and recommending deferral), subject to the following condition: 1. In respect of the legal basis: a) To provide a copy of the written analyses from NHS Digital's PTE supporting the use of COPI, instead of The Children's Act 2004, as the legal gateway for all aspects of the processing (including, for example, the aim of improving services to bereaved families where covid-19 is not necessarily the cause of death). b) to upload a copy of the written analysis from PTE to NHS Digital's CRM system c) To update section 1 with a narrative why The Children Act 2004 is no longer deemed a suitable legal basis for the flow of data, noting that The Children Act has previously been used to flow HES and MSDS from NHS Digital and is currently referenced as the legal gateway for the flow of HES data in the supporting documents. The following amendments were requested: 1. In respect of the data controllership:

	a) To remove any references throughout the application to NHS Improvement acting with NHS England as Data Controller, as NHS England and NHS Digital are described in the supporting documents as the only joint data controllers and NHS Improvement (comprising its component parts Monitor and TDA) remains a separate entity from NHS England. b) If, however the factual situation supports NHS Improvement acting as Data Controller, to update the application to add them as a Data Controller and update all transparency materials accordingly, in line with the NHS Digital's DARS Standard for Data Controllers. 2. In respect of section 5(d) and in line with the NHS Digital DARS Stand for Expected Measurable Benefits: a) To expand the stated benefits in section 5(d) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits, and are clear as to the benefits to the health care system, and are not simply outputs. b) To update section 5(d) to ensure that all the benefits link to the legal basis cited, for example, how improvement of services to bereaved families can be generated under the restrictive COPI gateway. c) To review the dates referenced within section 5(d) to ensure they are still current and relevant, and update the narrative / remove as necessary. 3. In respect of section 1: a) To amend the references in section 1 from *"patients that…"* to *"patients who…"*. b) To update section 1 with notes of previous IGARD reviews, for clarity and audit purposes. c) To update section 1 with a clear description of any other flows of data used for the NCMD under other NICs. The following advice was given: 1. IGARD suggested that the privacy notice was reviewed and updated to ensure that it consistently reflects that NHS England and NHS Digital are **joint** Data Controllers. 2. IGARD noted that this application was described as *"audit"*, and therefore ethics approval had not been obtained, however noted that many aspects of the processing appeared to go beyond pure audit activities. In addition, HQIP does not take the opportunity to describe the activity as audit, nor does it form part of their National Audit Programme, and instead describe it as a Clinical Outcome Review. IGARD suggested that the applicant should speak to HRA to determine whether or not any further steps should be taken in respect of ethics support. It was agreed the condition would be approved out of committee (OOC) by IGARD members who formed part of the quorum recommending approval.
3.2	Royal College of Obstetricians and Gynaecologists (RCOG): COVID Maternity Equalities Project (Presenter: Mujiba Ejaz) NIC-461283-Q3R7K-v0.6 **Application:** This was a new application for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC); for the purpose of a study to identify the impact of COVID-19 and associated modifications to maternity care; on inequalities in maternity care; and learn lessons to inform recommendations regarding ongoing modifications and changes to maternity care in the future. Prior to the COVID-19 pandemic, there were already inequalities in maternity care and outcomes in England, with black women five times more likely to die during pregnancy, birth and the postpartum period; and Asian women three times more likely, than white women. During the COVID-19 pandemic, there have been substantial shifts in the way that maternity

	care is delivered in Britain. However, the effects of these changes on maternity outcomes have not been measured, and it is also unclear whether these changes have widened or narrowed existing inequality gaps. There is an opportunity to learn lessons about how services may mitigate existing inequalities through service innovation. NHS Digital data will be restricted to a cohort for births from the 1st January 2018 to 31st March 2021 that is derived from records that contain valid information about either mode of birth or outcome of delivery, which estimated to be approximately 1.8 million women and their babies (approximately 1.8 million births). **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD queried the UK General Data Protection Regulation (UK GDPR) Article 6 legal basis for the Royal College of Obstetricians and Gynaecologists (RCOG), which was Article 6(1)(e) *"public task"*; and asked if Article 6(1)(f) "legitimate interest" would be a more suitable legal basis, noting the charitable status of the RCOG and their stated legal basis on their privacy notice IGARD asked that confirmation was provided, as to whether RCOG should note legitimate interest, rather than public task, as their legal basis. If, legitimate interest was more appropriate, IGARD asked that the application was updated as appropriate; and that reference to the specific Legitimate Interests Assessment (LIA) was referenced at the beginning of section 5(a) (Objective for Processing), as per usual process. IGARD noted the special condition in section 6 (Special Conditions), in relation to honorary contracts, and asked that in line with NHS Digital's policy on honorary contracts, the special condition was updated, to refer to counter signature by the home research institution and / or employer. IGARD queried the information in section 1 (Abstract) that the IT infrastructure would be *"…accessed remotely using 2-factor identification…"*, and noting this related to remote access, asked that section 2(a) (Processing Location(s)) was amended, to reflect the remote access arrangements as may be necessary to comply with NHS Digital's temporary remote access policy. In addition, and separate to this application, IGARD requested that NHS Digital share a copy the temporary remote access policy, to support the review of future applications. IGARD queried the statements in section 5 (Purpose / Methods / Outputs) that medical history would be *"derived"* from the HES data, and asked that for complete transparency, and noting section 5 formed NHS Digital's public data release register, and in line with NHS Digital's DARS standard for Objective for Processing, this was amended to reflect that they would only be able to derive *"significant medical history"*, directly related to hospital admissions. IGARD noted the references in section 5(a) (Objective for Processing) and section 5(c) (Specific Outputs Expected) to *"positive deviant"*, and noting that it was unclear what this meant by this term, asked that the references were removed, or that the references were updated with further explanatory information, and in line with NHS Digital's DARS standard for Objective for Processing. IGARD noted the information within section 5 to other datasets that do not flow from NHS Digital, for example, *"BadgerNet"*, and asked that for transparency, section 5 was updated with a brief explanation of the other datasets, and in line with NHS Digital's DARS standard for Objective for Processing. Noting that the benefits will require generalisation from the outcomes, IGARD suggested that the Integrated Research Application System (IRAS) Tool answer, that the outcomes would **not** be generalisable, may be misleading and may not reflect the facts. In this instance and because they were dealing with pseudonymised data, IGARD was of the view that Research

	Ethics Committee (REC) support was probably not required, however suggested that this was kept under review as the study progressed, and that ethical review may be required at some point in the future. IGARD noted and applauded the excellent patient and public involvement (PPI), for example, the role of the Women's Reference Group, and advised that this was an exemplar both within NHS Digital (as part of any training) and to other researchers. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the legal basis: a) To confirm if RCOG should cite legitimate interest (rather than public task) as their legal basis, noting the charitable status of the RCOG and their stated legal basis on their privacy notice. b) If legitimate interest is appropriate in this instance, to update the application as necessary. c) If legitimate interest is appropriate, to ensure reference to the specific Legitimate Interests Assessment is referenced at the beginning of section 5(a). 2. In line with NHS Digital's policy on honorary contracts, to update the special condition in this application to refer to counter signature by the home research institution and / or employer. 3. To amend section 2(a) to reflect the remote access arrangements as may be necessary to comply with NHS Digital's temporary remote access policy. 4. As section 5 forms NHS Digital's public data release register in line with NHS Digital's DARS standard for Objective for Processing: a) To amend the statements in section 5 that medical history will be *"derived"* from the HES data, to reflect that they will only be able to derive significant medical history", directly related to hospital admissions. b) To explain or amend the references in section 5(a) and section 5(c) to *"positive deviant"*. c) To update section 5 to provide a brief explanation of the other datasets referred to that do not flow from NHS Digital, for example, *"BadgerNet"*. The following advice was given: 1. Noting that the benefits will require generalisable outcomes, IGARD suggested that the IRAS Tool answer (that the outcomes would **not** be generalisable), may be misleading and may not reflect the facts. In this instance and because they are dealing with pseudonymised data, IGARD was of the view that REC support was probably not required, however suggested that this was kept under review as the study progressed, and that ethical review may be required at some point in the future. Separate to this application, IGARD requested that NHS Digital share a copy the temporary remote access policy, to support the review of future applications.
3.3	NHS East Leicestershire and Rutland CCG: GDPPR COVID-19 – CCG & LA - Pseudo (Presenter: Dan Goodwin) NIC-407274-Q4N0X-v2.4 **Application:** This was an amendment application to add Leicestershire County Council, Rutland County Council and Leicester City Council as Data Controllers to the existing Data Sharing Agreement (DSA), for the purpose of processing pseudonymised GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR) and Commissioning datasets.

	Each of the Local Authorities currently have access to datasets for commissioning purposes under DSA NIC-398666-H2S4K-v1.2. The purpose of requesting the GDPPR data, is to provide intelligence to support the local response to the COVID-19 emergency. The data is analysed so that health care provision can be planned to support the needs of the population within the Data Controller's geographical area for the COVID-19 purposes. NHS Digital advised IGARD that as per process with applications requesting GDPPR data, this application was due to be discussed at the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG), on the 18th August 2021; however due to a change in the frequency of the PAG meetings, changing from weekly to fortnightly, this would now be discussed at the PAG meeting scheduled on the 25th August 2021. **Discussion:** IGARD noted that the application had **not** been reviewed by PAG and as per the agreed process, and noted the verbal update from NHS Digital, in respect of the change of meeting frequency for PAG meeting. IGARD asked that following the PAG review on the 25th August 2021, written evidence was provided of PAG support of the flow of the GDPPR data; and that this was uploaded to NHS Digital's CRM system for future reference and a copy attached to these minutes as Appendix B and before ratification. (**Subsequent to the meeting and at ratification of the IGARD BAU minutes on the 26/08/21:** Separate to this application, IGARD reminded NHS Digital of the process that had been agreed last year, that applications should go to PAG and the PAG minutes should be made available to IGARD, prior to the application being included on the IGARD BAU agenda) IGARD noted that *"compliance with a legal obligation"* was cited as the Article 6 legal basis and reiterated their queries previously raised about whether Article 6(1)(c) was the most appropriate limb. IGARD noted that this was still an open issue and was subject to ongoing discussions with NHS Digital. IGARD noted that pseudonymised data was being disseminated under COPI, and in line with discussions on other applications, advised that this was still an open issue, and was subject to ongoing discussions with NHS Digital. IGARD queried the incorrect references within section 3 (Datasets Held / Requested), to the data being *"confidential"*, and asked that this was updated to correctly reflect that the data requested was *"pseudonymised"*. IGARD noted the large number of storage and processing locations in section 2 (Location(s)), and noted that this may cause difficulty for NHS Digital, in respect of auditing; and suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated and that the application be updated accordingly. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the PAG review: a) To prove written evidence of PAG support from the meeting on the 25th August 2021 (as per the verbal update from NHS Digital). b) To upload the written PAG support to NHS Digital's CRM system for future reference. The following amendments were requested: 1. To update the relevant limbs of section 3 to correctly reflect that the data requested is *"pseudonymised"* and not confidential. The following advice was given:

	1. IGARD noted the large number of storage and processing locations, and noting this may cause difficulty for NHS Digital issue in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. 2. IGARD noted that *"compliance with a legal obligation"* was cited as the Article 6 legal basis and reiterated their queries previously raised about whether this was the most appropriate limb. IGARD noted that this was still an open issue and was subject to ongoing discussions with NHS Digital. 3. IGARD noted that of pseudonymised data was being disseminated under COPI, and in line with discussions on other applications, advised that this was still an open issue, and was subject to ongoing discussions with NHS Digital. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.4	University of Warwick: Digital triage: investigating patient service use and health outcomes following triage in Urgent Care settings (Presenter: Charlotte Skinner) NIC-353882-J5X9Q-v0.12 **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS) and Hospital Episode Statistics Admitted Patient Care (HES APC); for the purpose of research on the digital triage tool (telephone triage), used for out of hours care, to help signpost patients to the most appropriate service to receive health care. The research will investigate, how patients use these types of services; and how telephone triage affects patients' use of other health care services, such as A&E, and what happens to patients following telephone triage, in terms of their health. The aims is to understand how clinician led digital triage is used in different settings, and how this may be influenced by previous care advice through NHS 111 and the associated patient outcomes following triage. The two research aims that will be addressed before and after the start of the COVID-19 Pandemic: 1) how do patients use urgent care services that are delivered though telephone based digital triage; and 2) how do patients use health care services following telephone based digital triage. The research consists of patients who attended A&E following telephone triage between the 1st April 2019 and 30th September 2020; and is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD noted that the application stated the cohort size was 231,419, however queried if this figure was correct in light of the information within the Health Research Authority Confidentiality Advisory Group (HRA CAG) application, and the HRA CAG Register, that stated the cohort size was circa 100,000. Noting the significant difference in the two cohort figures cited, IGARD asked that in line with NHS Digital DARS Standard for Data Minimisation, the proposed cohort size of 231,419 was minimised to be closer to the 100,000 figure notified to HRA CAG, and that the application was updated accordingly. If the cohort size could not be minimised within the application to 100,000, IGARD asked that written justification was provided in section 5 (Datasets Held / Requested), as to why the significantly larger cohort size of 231,419 was required. In addition, if the cohort size could not be minimised within the application to 100,000, IGARD asked that the applicant update HRA CAG with further details of the significantly increased cohort number, and in addition that the HRA CAG Resister was updated accordingly; and that any appropriate action as requested by HRA CAG was actioned, for example, submitting an amendment application.

	IGARD confirmed that, with the exception of the query raised about the cohort figures, 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. Prior to the meeting, NHS Digital shared with IGARD links to the privacy notices of the four suppliers of the underlying data, that is, the patient data which was gathered using the digital triage tool: Mastercall, Bardoc, GTD Health Care and Practice Plus Group. IGARD noted and thanked NHS Digital for sharing the privacy notices, and suggested that NHS Digital should satisfy itself that the correct parties had been identified, and the rights of the individuals had been observed, in particular have data subjects been advised with appropriate transparency as to who is handling their data and for what purposes? IGARD queried the relationship of the University of Warwick and Advanced Health and Care Ltd, for example, who approached whom with regard to funding; and noting that this may impact on the legal basis cited, asked that a further explanation was provided in section 5(a) (Objective for Processing) of the genesis of the parties working together. IGARD queried the UK General Data Protection Regulation (UK GDPR) Article 6 legal basis for the University of Warwick, which was Article 6(1)(e) *"public task"*; and asked if Article 6(1)(f) "legitimate interest" would be a more suitable legal basis, noting the commercial connection of the study. IGARD asked that confirmation was provided, as to whether the University of Warwick should note Article 6(1)(f) (legitimate interest), rather than Article 6(1)(f) (public task), as their legal basis. If, legitimate interest was more appropriate, IGARD asked that the application was updated as appropriate; and that reference to the specific Legitimate Interests Assessment (LIA) was referenced at the beginning of section 5(a), as per usual process. IGARD queried the statement in section 3(c) (Patient Objections) that *"Patient exemptions need to be applied (s251)"*, and asked that this was amended to refer to *"patient objections"*. IGARD noted the benefit in section 5(d) (Benefits) that stated *"…this work is important to* ***demonstrate*** *the safety of digital triage…"*, and asked that in line with NHS Digital's DARS Standard for Expected Measurable Benefits, this was amended to *"…evaluate the safety of digital triage".* In respect of the digital triage tool, IGARD queried the information within section 5(d) that stated *"…there is very little evidence of its safety…"*, and asked that this was updated to more accurately state that there was *"little real-world evaluation"*. IGARD queried benefit points 3 and 5 in section 5(d) that referred to *"potential triage errors"*, and asked that for transparency, further information was provided, for example, what, if anything, would happen with this error information. **Outcome:** recommendation to approve subject to the following condition: 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. The following amendments were requested: 2. In respect of legitimate interest:

	a) To consider if, in light of the commercial connection, the University of Warwick should cite legitimate interest (rather than public task) as their legal basis. b) If legitimate interest is appropriate, to update the application as appropriate. d) If legitimate interest is appropriate, to ensure reference to the specific Legitimate Interests Assessment is referenced at the beginning of section 5(a). 3. To provide a further explanation in section 5(a) of the genesis of the parties working together, for example, who approached whom with regard to funding (noting this may impact on the legal basis cited). 4. To amend the reference in section 3(c) from *"patient exemptions"* to *"patient objections"*. 5. In respect of the benefits in section 5(d) and in line with NHS Digital's DARS Standard for Expected Measurable Benefits: a) To amend the reference in section 5(d) from *"demonstrating"* the safety, to *"evaluate"*. b) To amend the reference in section 5(d) from *"little evidence"* of its safety, to *"little real-world evaluation"*. c) To provide further information on the references in section 5(d) to *"potential triage errors"*, for example, what, if anything, will happen with this error information. The following advice was given: 1. IGARD noted the privacy notices provided prior to the meeting for the four suppliers of the underlying data, and suggest that NHS Digital should satisfy itself that the correct parties have been identified and the rights of the individuals have been observed, in particular have data subjects been advised with appropriate transparency as to who is handling their data and for what purposes. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.5	The Nuffield Trust For Research And Policy Studies In Health Services: Nuffield RSET DSA - April 2021 Amendment - Upgrade Dissemination frequency from quarterly to monthly between 1/7/21 30/6/22. (Presenter: Catherine Day) NIC-194629-S4F9X-v3.6 **Application:** This was an amendment application to update the frequency of data distribution from quarterly to monthly drops of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients, and Emergency Care Data Set (ECDS) from the 1st July 2021 to 30th June 2022; for the purpose of accessing more timely data, for example, in relation to COVID-19 research. The purpose is for a number of projects (outlined in now NIC-226261-M2T0Q – formally NIC-384572-J7P6Y), to investigate the impact of COVID-19 on the use of health services which are dependent on or would benefit from access to more timely data. These include, for example, an analysis of outpatient attendances with a view to identify variations in activity by trust and specialty over the early pandemic period as part of evaluation work. The Trust are starting a project to understand the profile of patients discharged before and during the pandemic, and their subsequent use of services in the community. As part of the Trusts Quality Watch programme the Trust are also planning more wide-ranging analysis of hospital activity and performance over the pandemic period and especially in the run up to, and over, the winter period for which again, more timely data would be of benefit. **Discussion:** IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 18th February 2021.

	IGARD noted the request to amend the frequency of the data disseminated, from quarterly to monthly, and queried what the purpose of this was, noting it was not clear within the application. IGARD asked that section 5(a) (Objective for Processing) was updated with a justification as to how the monthly data request would benefit the research study, for example, would it enable The Nuffield Trust to act and realise public benefits in a more timely manner. In relation to any remote working, as referred to in the application, IGARD suggested that the Data Access Request Service (DARS) should clarify with the NHS Digital Security Advisor, what (if any) special conditions should be included within Data Sharing Agreements (DSA) as standard to address any remote working arrangements and particularly during the COVID-19 pandemic and consequent changes in working practices. IGARD queried the statement in section 5(b) (Processing Activities) that *"…the Nuffield Trust is also scoping out analyses to monitor the impact of remote monitoring services for Covid-19 patients (supported by *PHE)…"* (*Public Health England), and asked that for transparency, this was updated with further information as to the nature of the support from PHE. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that in line NHS Digital's DARS Standard for Expected Measurable Benefits, section 5(d) was updated to remove any outputs and edit to only leave examples of benefits to health and social care. 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, for example, in respect of the analysis of quality of ethnicity coding, the changes that have been made that impact patient care as a result of that valuable analysis, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. **Outcome:** recommendation to approve The following amendments were requested: 1. To provide justification in section 5(a), as to how the monthly data request will benefit the research study, for example, will it enable The Nuffield Trust to act and realise public benefits in a more timely manner. 2. To note in section 5(a) the nature of the *"support" from PHE "…(supported by PHE)…"*. 3. In respect of the benefits and in line NHS Digital's DARS Standard for Expected Measurable Benefits: a) To remove any specific outputs from section 5(d) and move to section 5(c). b) 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, for example, in respect of the analysis of quality of ethnicity coding, the changes that have been made that impact patient care as a result of that valuable analysis. The following amendments were requested: 1. IGARD suggested that DARS clarify with the NHS Digital Security Advisor, what (if any) special conditions should be included within DSA's as standard to address any remote working arrangements and particularly during the COVID-19 pandemic.
3.6	Imperial College London: An evaluation of the relationship between simulation-based training assessment tools and performance in real world settings (Presenter: Dave Cronin) NIC-80304-H6P6R-v5.3

	Application: This was a request to extend the current Data Sharing Agreement (DSA) that expired on the 6th March 2021; the application is for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC). The data will be linked to consented surgeon simulation-based skill assessment data, for the purpose of a research study: '*An evaluation of the relationship between simulation based training assessment tools and performance in real world settings*' which aims to establish what, if any, association there is between simulation-based skills assessment and clinical and patient outcomes. This study will be the first to link data from 20 consenting participants of surgical skills assessment to HES data to investigate performance, to allow measures, such as readmission, mortality and re-operation rates to be investigated. The benefit of validating these tools, is to accurately reflect real world practice, is that they can then be used to assess surgeons who are still trainees and would not have sufficient evidence for performance review. In this context, they can also increase engagement of trainees and trainers in simulation training. This study may also find that the tools have no link with actual performance, in that they can then be used to encourage redesign of training. NHS Digital advised IGARD that following submission of the application for review, additional information had been received from the applicant in relation to the benefits, and that the application would need updating to reflect this additional / new information. NHS Digital noted that section 5(a) (Objective for Processing) referred to *"section 3(a)"* (Data Access Already Given) of the application, and that this would need removing, noting that section 3(a) did not form part of NHS Digital's public data release register. NHS Digital also noted that section 3(a) referred to data being *"binned"*, and that noting this was not a definition used by NHS Digital, would be reviewed and amended as appropriate. **Discussion**: IGARD noted and supported the verbal updates from NHS Digital in relation to the removal of the reference to *"section 3(a)"* in section 5(a), and the update to the reference *"binned"* in section 3(a). In addition, IGARD noted the verbal update from NHS Digital, in respect of the updated benefits received following submission of the application for IGARD to review; and asked that in line NHS Digital's DARS Standard for Expected Measurable Benefits, section 5(d) (Benefits) was updated with the additional / new benefits. IGARD noted that 'Virtus SDC Limited' were listed as a processing and storage location in section 2 (Location(s)), and asked that the application was reviewed throughout, to ensure that the information provided about this company was consistent and in line with other applications, for example, aligning the processing locations. IGARD queried the information in section 5(b) (Processing Activities) that stated there was a Memorandum of Understanding (MoU) between Imperial College London's (ICL) Big Data and Analytical Unit (BDAU) and ICL's Information and Communication Technologies (ICT); and asked that for transparency, section 5(b) was updated to provide further information on the MoU and why this was necessary. IGARD suggested that section 5(d) (ii) (Expected Measurable Benefits) 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 queried the funding source of the study, noting that section 8(b) (Funding Sources) was silent on this point, and asked that this was updated to include (but not limited to) the

	funding source, and the apparent inconsistency with the named researchers as outlined in the protocol and ethics approval. **Outcome:** recommendation to approve The following amendments were requested: 1. In line NHS Digital's DARS Standard for Expected Measurable Benefits, to update section 5(d) with the updated benefits (as per the verbal update from NHS Digital). 2. To review the application throughout, to ensure the references to Virtus SDC Limited are in line with other applications, for example, aligning the processing locations, and update as appropriate. 3. To update section 5(b) to provide further information of the MoU between the ICL BDAU and ICL ICT, and why this is necessary. 4. To update section 5(d) (ii) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 5. To update section 8(b) to include (but not limited to) the funding source, and the apparent inconsistency with the named researchers as outlined in the protocol and ethics approval.
3.7	NHS England: DSfC NCDR amendment (Presenter: none) NIC-139035-X4B7K-v8.1 **Background:** This was an amendment application to clarify that the National Diabetes Audit (NDA) data by default includes the modules that sit under the current NDA programme which are: National Diabetes Core Audit (NDA Core); National Pregnancy in Diabetes Audit (NPID); National Diabetes Footcare Audit (NDFA); National Inpatient Diabetes Audit, including National Diabetes I-Patient Audit – Harms (NaDIA-Harms); and Diabetes Prevention Programme (DPP). All the models cited are outlined in the NDA Programme Requirement Specification (v0.8) issued on the 10th February 2020 which is the latest version of the specification as referred to in the Health & Social Care Information Centre (establishment of Information systems for NHS Services: National Diabetes Audit) Directions 2007. **Discussion:** IGARD noted that it was proposed by NHS Digital that IGARD would be informed of any changes or additions to the specification and that the application would be submitted without a presenter with the proposed change to the application wording and relevant specification documentation. IGARD noted that all previous comments made on this application at either an IGARD business as usual (BAU) or NHS Digital-IGARD COVID-19 response meeting remained live and that they were only focusing on the very narrow amendment of the addition of the NDA and specific highlighted text. **Outcome:** recommendation to approve for the addition of the NDA and the specific highlighted new text only. The following advice was given: 1. IGARD reiterated their previous advice, that this overarching application, should be broken up into relevant bespoke project applications. IGARD noted that they would want to be involved in early stage work on the rationalisation of the applications, as appropriate, in order to support both NHS Digital and the applicant. 2. IGARD reiterated their previous action point that NHS Digital convene a working group, to review the process of assuring and onboarding of the additional datasets. 3. IGARD advised that they would wish to review this overarching application and any spin-off applications when it comes up for renewal, extension or amendment.

	4. IGARD suggested that this overarching application and any spin-off applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
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	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 17th August 2021** can be found attached to these minutes as Appendix C.
6	AOB: There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 13/08/21

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-448129-H1V1G -	COVID-19 Vaccine Data for CCGs and Local Authorities	25/03/2021	In respect of the legal basis: a. To provide written **justification** from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI. b. To ensure a consistent narrative throughout the application to support the identifiability status of the data. c. To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference. d. to make requisite changes to the special condition wording in section 6, to reflect any changes to the legal basis 2. To remove from the **LA templated wording*** "*ensuring vulnerable individuals and groups are identified and supported through the vaccination process to ensure the maximum possible vaccination uptake*" since this identification is usually a role undertaken by the CCG in providing direct care	IGARD Chair	OOC by IGARD Chair	IGARD Chair comments: **Significant risk (new) raised:** *I am writing to confirm that condition 2 has been satisfied and condition 1 has been put in abeyance until formal advice on point has been provided by PTE. Accordingly, these templates are ready for use, however, I must stress that the* ***risk to NHS Digital remains and the PTE advice is still urgently needed****. Depending on the content of the PTE advice, when received, the template may still need to be changed in accordance with the original condition, or in a different form altogether (again depending on the nature of*

						the advice). We will need to keep this under review.
NIC-294590-B6V3F-v0.11	The University of Manchester	22/07/2021	In respect of the HRA CAG annual review: a) The applicant to provide written confirmation that they submitted their annual review by December 2020, OR b) To otherwise provide express confirmation that the amendment submitted to HRA CAG in October 2020 replaced the annual review in December 2020.	IGARD Chair	OOC by IGARD Chair	IGARD Chair comments: In respect of the written confirmation *"for audit purposes and future reference, could the email with this confirmation be uploaded to CRM".*

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-362208-G8K6D-v2 DSfC – NHS Norfolk and Waveney CCG - Comm, IV, RS

Graphnet Class Actions:

- None

Appendix B

Professional Advisory Group Outcomes
Record of feedback Wednesday, 25 August 2021

Application & version	DARS-NIC-407274-Q4N0X-v2.4
Applicant Organisation	NHS EAST LEICESTERSHIRE AND RUTLAND CCG
Data Controller Organisation	LEICESTER CITY COUNCIL RUTLAND COUNTY COUNCIL LEICESTERSHIRE COUNTY COUNCIL NHS WEST LEICESTERSHIRE CCG NHS EAST LEICESTERSHIRE AND RUTLAND CCG NHS LEICESTER CITY CCG
Professional Advisory Group Agenda Item	4

The profession welcomed this application and noted this was an amendment request for the addition of Data Controllers and the processing of GDPPR data.

As this application received previous support from the profession the profession noted the previous special conditions were included within the application and requested that the application be updated with an additional special conditions as recently identified by the profession below;

All efforts **MUST** be made to ensure **no** individual (including an individual healthcare professional) can be identified (i.e. any published/shared results are statistically non-disclosive).

The profession also request email evidence that the CCG has sought clinical director or clinical lead for the commissioner/ICS endorses the application, that they confirm GP practices and relevant LMCs have been informed, as per draft PAG requirement 4.

Should the above conditions be met the profession is happy for this to proceed.

Attendees	Role	Organisation
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Peter Short	NHS Digital Clinical Lead	NHS Digital
Mark Coley	Profession Representative	BMA
Marcus Baw	Profession Representative	RCGP
Liz Gaffney	Head of Data Access	NHS Digital
Dan Goodwin	SCO Presenting	NHS Digital

Appendix C

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

held via videoconference, Tuesday, 17th August 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):	James Gray (Digi-Trials)
	Karen Myers (IGARD Secretariat)
	Ngozi Okwudili-Ince (Digi-trials)
	Any Rees (Digi-Trials)
	Vicki Williams (IGARD Secretariat)

1	**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.
2.1	<u>Development of research guidance (informal discussion – business as usual item)</u> **Background:** NHS Digital provided a brief overview of work being undertaken by the Digi-trials team with regard to the production of templated / standard wording for use in consent and patient information sheets to support clinical research. NHS Digital noted the work they were undertaking with the Medicines and Healthcare products Regulatory Agency (MHRA), Health Research Authority (HRA) and researchers and noted the requirements set out by IGARD. **IGARD Observations:** In principal, and without sight of the Digi-trials proposal, IGARD members were supportive of the idea, however IGARD members were clear that the requirements were not theirs and IGARD were not placing barriers to any research. IGARD members noted the NHS Digital legal requirements under the Health & Social Care Act, relevant ICO guidance and UK General Data Protection Regulation (UK GDPR) which applied to all organisations, alongside

	the published NHS Digital DARS standards which aligned with specific statutory frameworks, legalisation and guidelines already in place. IGARD noted the use of the HRA decision tool and concerns from researchers of the additional requirements needed to access data from NHS Digital, and suggested that NHS Digital speak to HRA with regard to adding a link to the NHS Digital DARS standards on the HRA decision tool. IGARD also noted the updated HRA pro forma consent materials published on the HRA website which had been published last year and addressed a great many of the issues with consent. IGARD members also suggested that NHS Digital speak with the Executive Director Privacy, Transparency & Ethics (PTE), noting that PTE may be undertaking work with various stakeholders with regard to consent. IGARD members noted that they would like to be involved in the drafting of any guidance or pro forma wording for consent and patient information sheet (PIS), but suggested that NHS Digital ensure that they are not repeating work already undertaken or in-train by others, both internal and external and all relevant discussions had taken place. IGARD members noted that they would welcome NHS Digital returning to an IGARD business as usual (BAU) meeting in due course with a fully worked up proposal for consideration by IGARD and the SRO for IGARD to support the ongoing work.

2.2	Proposed Precedent for Approving Permission to Contact Applications
	
	Background: this was a business as usual (BAU) item. NHS Digital presented a draft precedent for standard applications utilising the Permission to Contact (PtC) service for access to the NHS Digital COVID-19 vaccine research registry (via the Digi-trials permission to contact service).
	
	IGARD Observations:
	
	IGARD members noted that this was not a full review of the precedent and that due process should be followed.
	
	IGARD members made the following high level initial comments:
	
	• The qualifying criteria should include a requirement that that the purpose of an application and the purpose of the research to be carried out with the cohort gathered via the PtC registry, must be clearly within the scope of the consent given by those on the PtC registry.
	• That a copy of the relevant sections of the PtC consent materials should be appended to the precedent for information and easy reference in order to check the above point.
	• The exclusion criteria should include:
	  o any application that is not within the scope of the consent given by those on the PtC registry;
	  o any applicant that has failed a previous audit;
	  o plus any other relevant exclusion criteria carried over from the already approved DARS specific risk criteria document.
	• The precedent and templated wording should be carefully reviewed with regard to language to ensure that terms such as "*site*", "*data controller*", "*data processor*" are not used interchangeably and that it should be clear throughout the precedent who and what is being referred to.

	• The precedent and templated wording should use the standard wording in other precedents "*Data Controller*" and "*Data Processor*" and not use shorthand such as "*controller*" or "*processor*". • The precedent should use generalised wording for writing to participants, since using the term "*email*" may preclude any other type of written communications, such as letter. • Noting use of the word "*treatments*", IGARD noted that a vaccine was not a treatment and the wording be updated accordingly, and that the precedent wording should appropriately encompass the vaccine research. • The bulleted points should be formatted appropriately. **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.
2.3	<u>NIC-420105-M8Y5X-v2.2 Novavax Inc</u> **Background:** This was a verbal update having been previously discussed at the 9th March 2021, 2nd March 2021 and 8th December 2020 COVID-19 response meetings. Novavax are conducting a Phase 3 clinical trial of SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1Tm Adjuvant with the primary objective to demonstrate the efficacy of SARS-CoV-2 rS with Matrix-M1 adjuvant in the prevention of virologically confirmed (by PCR*) symptomatic COVID-19, when given as a 2-dose vaccination regimen as compared to a placebo, in serological negative (to SARS-CoV-2) adult participants. The trial originally recruited its cohort of 15,000 members through NHS Digital's Permission to Contact (PtC) service * Polymerase chain reaction (PCR) NHS Digital noted that the applicant had taken on board some of the comments previously made by IGARD on the consent materials and that these had been updated with v5 provided for comment. NHS Digital noted that the amendment to the application was to link to the PCR testing data only. The following observations were made on the basis of the verbal update from NHS Digital and a copy of the "*informed consent form – information for participants 2019nCoV-302, v5.0 clean 15 March 2021*". IGARD did not receive a copy of the application or any other relevant supporting documentation. **IGARD Observations:**

	IGARD members noted that although version 2.2 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had not been provided for review at this meeting and their observations were based on the verbal update from NHS Digital only plus a copy of v5 of the informed consent. 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 despite the Health Service (Control of Patient Information) Regulations 2002 (COPI) Notice being in place until the 30th September 2021 and that this may be extended by the UK Government to the 31st March 2022, and that the trial would end on the 31st January 2022, the applicant had reconsented the cohort. IGARD members noted that the consent wording in v5 clearly allowed for the information to flow with regard to the PCR test results. For those that had not reconsented on v5 of the informed consent materials provided, COPI could still be relied upon. IGARD members reiterated their point previously made that an assessment of whether PPD Global Ltd should be noted as a Data Controller or Data Processor in the DARS application should be undertaken, or was their handling of data separate from the handling of NHS Digital data and in line with NHS Digital's DARS Standard for Data Controllers / Data Processors, and IGARD members were clear that in line with UK General Data Protection Regulation (UK GDPR), Novavax could not delegate its Data Controllership responsibilities to PPD Global Ltd, and the Data Controller arrangements should be borne of the facts presented. IGARD members reiterated their comments with regard to "*the Public Health of England (PHE)*" and queried if this was the health body Public Health England (PHE) or just the public health of England in general. IGARD members reiterated their comments that additional reviews should take place to ensure compliance with UK GDPR / Data Protection Act 2018 – in particular, appropriate transparency about the handling and use of data – and any additional relevant UK legislation relating to clinical trials. Noting that not all data subjects are available to clinical trial participants, basics such as how to contact the Data Protection Officer should be included and in line with the NHS Digital DARS Standard for Transparency (fair processing). IGARD members reiterated their previous comments that the applicant take the opportunity to inform the cohort of any possible long term follow up and any possible linkage to health data held by NHS Digital (since there appeared to be none outlined). As no consent had been taken for any such long term follow up this consent material appeared to be markedly out of step with other similar vaccine trials. IGARD members were concerned that this shortcoming in the consent materials may hamper future research efforts. Finally, IGARD members noted that a number of points had been previously raised, and that they had not been provided with a copy of the updated application summary, and that all previous points raised remained outstanding until fully addressed (see appendix A). IGARD members noted that **if** the only change on the DARS application was to update the tables in section 3 in relation to the legal basis moving from COPI to consent and for the PCR data **only**, they were content for this application to proceed under the NHS Digital SIRO precedent. However, for **any** other changes to the application, including requests for additional

	datasets or any linked applications, IGARD would wish to review this application or any other linked application when it comes up for renewal, extension and amendment and that this application would not be suitable for the precedent route, including SIRO. **Significant risk area:** that despite IGARD's repeated advice, the redrafted consent material still did not allow for any future follow up on the cohort members via data linkage with health data held by NHS Digital or other health bodies. IGARD remains concerned that this potentially significant shortcoming may affect the research efforts of the applicant. IGARD queried whether the applicant appreciates that their consent materials are out of step with other vaccine trials.
2.4	<u>NIC-476579-S9J4D-v0.1 NHS Blood and Transplant (NHSBT)</u> **Background:** This was a new application that seeks to follow on from an earlier application NIC-372791-X0H3Q NHSBT, whereby NHS digital provided details to NHSBT of potential plasma donors to recruit for a trial in order to help treat COVID-19. The trial has now completed and NHSBT are now in apposition where they have accumulated plasma donations to re-purpose either for future clinical trials or for medicinal use. NHSBT are seeking to link their cohort to the COVID-19 vaccination status dataset held by NHS Digital to determine which members were vaccinated prior to donating plasma. NIC-372791-X0H3Q NHSBT had been previously discussed at the 28th July 2020, 18th August 2020, 10th November 2020 and 8th December 2020 COVID-19 response meetings, and at the business as usual (BAU) meeting on the 27th August 2020. The following observations were made on the basis of the verbal update from NHS Digital and a copy of the following documents: "*FRM420/8 – consent for regular donors*", "*FRM421/8 – consent for new or returning donors*", "*INF234 – welcome booklet provided with consent form*" and "*INF1528v2 – additional leaflet provided with consent form*". **IGARD Observations:** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. Should a full review of the application and documentation be required including the consent materials and patient information leaflets, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted the update from NHS Digital and that the application was to be presented at an IGARD BAU yet to be determined. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting and thanked NHS Digital for the update and looked forward to receiving the full suite of documentation at the BAU meeting in due course.
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, 8th December 2020

2.1	Novavax Vaccine study (NIC number unknown) **Background:** This was a verbal briefing for a new application for the Novavax vaccine study cohort of approximately 50,000 consented participants across the UK who, as part of the study, had been given three bar coded self-test kits and instructed that should they show any symptoms, that they complete the test kit and return as per usual process for a positive or negative test to be ascertained. NHS Digital were being asked to be a trusted 3rd party to link the cohort details to the study ID and provide a pseudonymised dataset back to Novavax. NHS Digital noted that work was ongoing across all four devolved nations. The following observations were made on the verbal briefing only. **IGARD Observations:** IGARD members noted the importance of the study and vaccine trial being undertaken, and that it was vitally important that Novavax could receive pseudonymised data to match the self-reported information from cohort members with NHS Digital pillar 2 test data. IGARD members noted that although this was a consented cohort, the applicant was relying on the National Health Service Control of Patient Information Regulations 2002 (COPI), which IGARD accepted was appropriate given the wording of the consent materials (that did not explicitly address potential flow of data to and from NHS Digital). IGARD noted that COPI only applies to England and Wales and also suggested that a sunset clause should be inserted in section 6 of the application due to the time-limited nature of the relevant notice issued under COPI. IGARD members therefore suggested that whilst using COPI, the applicant should take the opportunity to inform the cohort of any possible long-term follow up (since there appeared to be none outlined); listing NHS Digital and other potential data sources or processors; and including reference to possible data linkage that may be part of any future processing. Noting that the parent company of both the Data Controller and Data Processor were based in the USA, that appropriate security assurance was in place and aligned to COPI for the involvement of an additional processor, and that an assessment had been undertaken with regard to Article 46 of GDPR. IGARD members noted the update from NHS Digital on this particularly urgent application of vital importance and supported NHS Digital's assessment that the application would be approved under the DARS SIRO precedent.

COVID-19 Action Notes extract: Tuesday, 2nd March 2021

2.1	NIC-420105-M8Y5X-v1.1 Novavax Inc

	Background: This was v1.1 application and v 4.1.0 Main Participant Information Sheet (PIS) and Consent Form UK following a verbal briefing at the COVID-19 response meeting on the 8th December 2020. Since the verbal update to IGARD on the 8th December 2020, the application had been updated to include changes to the proposed processing activities and inclusion of a special condition that a Legitimate Interest Assessment (LIA) would be completed within two weeks of the data sharing agreement (DSA) being signed – this special condition had been completed and the special condition removed. IGARD members noted the update. The amendment to the current application v1.1 was to include a regular flow of one extra item 'Specimen Processed Data' into NHS Digital from PPD Global Ltd (Data Processor), with matching undertaken by NHS Digital; and, to regularly flow one extra data item 'Specimen Processed Date' in addition to those already being provided, with additional detail added in sections 3(b) and 5(b). Novavax are conducting a Phase 3 clinical trial of SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1Tm Adjuvant with the primary objective to demonstrate the efficacy of SARS-CoV-2 rS with Matrix-M1 adjuvant in the prevention of virologically confirmed (by PCR) symptomatic COVID-19, when given as a 2-dose vaccination regimen as compared to a placebo, in serological negative (to SARS-CoV-2) adult participants. The trial originally recruited its cohort of 15,000 members through NHS Digital's Permission to Contact service The following observations were made on v1.1 of application and v4.1.0 of the PIS and consent form UK **IGARD Observations:** IGARD members noted that section 1 of the application should be updated to be clear that on the 8th December 2020, IGARD did **not** review this or any previous iteration of the application and that the briefing had been verbal. IGARD noted that this was the first time they had seen the application and consent materials and that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the two documents provided. 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 meeting for a recommendation. IGARD members noted reference to "*NIC-411171*" within section 5 of the application and suggested that this was checked to reference the full NIC reference, for transparency since this section formed part of NHS Digital's data release register. NHS Digital noted that the applicant wished to reconsent the 15,000 participants on the trial, noting that they were presently relying on the Health Services Control of Patient Information (COPI) Regulation 2002 and that the COPI Notice was in place until the 30th September 2021. IGARD were unclear why the applicant would wish to move to the reconsent model whilst COPI was still in place and since it was still unclear at this early stage whether COPI would be extended further, noting that the trial would end on the 31st January 2022. IGARD suggested that further discussions be undertaken with the applicant with regard to Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support, since them being a US based organisation did not necessarily preclude them from applying for s251 in respect of confidential information pertaining to English patients. In addition, and noting that the future of

	COPI had not been outlined by the UK Government, IGARD suggested that the applicant may wish to wait to reconsent, alongside other applicants who were also relying on COPI as their legal basis, as to the decision that may come as to whether COPI would be extended beyond the end of September 2021. In addition IGARD members suggested that NHS Digital discuss this application with the Caldicott Guardian, as there may be other avenues to explore, other than consent and s251 support. IGARD members noted that should the applicant now wish to store blood samples, for example, that reconsenting would certainly be required. However, without knowing the other changes to the study protocol, it was difficult to opine on whether consenting was necessary in this instance. If the reconsenting was *only* to facilitate NHS Digital handling confidential patient information, then IGARD would urge an alternative approach to minimise loss of cohort members. Notwithstanding these queries, IGARD members noted the update from NHS Digital that the applicant thought that reconsenting was the best option. Consent material review comments including, but not limited to: • IGARD members were unclear what changes had been made to this version, since it was standard practice for any amendments to be noted at the start of a reconsenting document for example the inclusion of reference to NHS Digital, how the consent document had changed since the signing of the previous iteration etc. • IGARD members noted that the first paragraph of v4.1.0 stated "*you are being asked to consider whether you would like to participate in a clinical trial study*…" and suggested the language be updated appropriately to reflect a reconsent process. • IGARD members noted reference to the participant being able to withdraw from the study, however there were no explicit details in v4.1.0 of ***how*** the participant could withdraw such as a telephone number, email address or postal address. • IGARD members noted that NHS Digital had been referred to in v4.1.0 as a "*vendor*", noting that the Oxford English Dictionary definition of "*vendor*" was "*a person or company offering something for sale…*" suggested this was a Americanism, but should be updated to accurately reflect NHS Digital did not sell data and clearly detail the role they were undertaking in this important clinical trial including, but not limited to, their role, the data flowing to and from NHS Digital and any data linkages being undertaken by NHS Digital etc. • IGARD members queried reference within v4.1.0 to "*the Public Health of England (PHE)*" and if this was the health body Public Health England (PHE) or just the public health of England in general. • IGARD reiterated their previous comment that the applicant take the opportunity to inform the cohort of any possible long term follow up and any possible linkage to health data held by NHS Digital (since there appeared to be none outlined) • While amendments were required throughout the document, the key pages were the "consent form" at the back of v4.1.0 which contained tick boxes for the participant to acknowledge. NHS Digital's involvement – both current and potential in the future – should be clearly articulated here. IGARD members noted that on balance anyone consented on v4.1.0 was not incompatible with the flow of confidential data as there is no express bar with sharing the data, and NHS

	Digital are mentioned in the document, however further transparency materials should be provided to all those consented on this v4.1.0 to update on points outlined above. In addition to the above comments relating to the compatibility of the materials with the common law duty of confidentiality (the legal gateway for NHS Digital to handle the data), there were additional reviews that should take place to ensure compliance with UK General Data Protection Regulations (UK GDPR) /Data Protection Act 2018 – in particular, appropriate transparency about the handling and use of data – and any additional relevant UK legislation relating to clinical trials. IGARD members suggested that a verbal update be given at next week's COVID-19 response meeting with progress to date in order for IGARD to give support to both NHS Digital and the applicant. **Significant area(s) of risk:** loss of a statistically significant proportion of the cohort due to reconsenting; particularly if reconsenting is not necessary due to other available avenues. **Subsequent to the meeting:** The IGARD Chair raised the query if PPD Global Ltd should be noted as a Data Processor in the DARS application or was their handling of data separate from the handling of NHS Digital data? Notwithstanding this, "PPD" should be referred to by its full legal name on first use in the public facing section of the application and its involvement in the processing should be clearly articulated in the DARS application.

COVID-19 Action Notes extract: Tuesday, 9th March 2021

2.4	<u>NIC-420105-M8Y5X-v1.1 Novavax Inc</u> **Background:** This was a verbal update having been previously discussed at the 2nd March 2021 and 8th December 2020 COVID-19 response meetings. Novavax are conducting a Phase 3 clinical trial of SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1Tm Adjuvant with the primary objective to demonstrate the efficacy of SARS-CoV-2 rS with Matrix-M1 adjuvant in the prevention of virologically confirmed (by PCR) symptomatic COVID-19, when given as a 2-dose vaccination regimen as compared to a placebo, in serological negative (to SARS-CoV-2) adult participants. The trial originally recruited its cohort of 15,000 members through NHS Digital's Permission to Contact service NHS Digital noted that reconsenting had commenced on the 5th February 2021 and was due to be completed by the 5th April 2021 and that it was the applicant updating their protocol regarding unblinding, rather than any advice received from NHS Digital, that had prompted them to reconsent their cohort. NHS Digital noted that 7,500 members of the cohort had been unblinded and that no further data would flow from NHS Digital to the applicant for those cohort members who had been withdrawn from the study. In addition, NHS Digital noted that the applicant had taken on board comments previously made by IGARD on the consent materials. The following observations were made on v3.0 (dated 20 December 2020) of the *Clinical Study Protocol* and verbal update only. IGARD did not receive a copy of the application or any other relevant supporting documentation.

	IGARD Observations: IGARD members noted the update from NHS Digital with regard to the updated consent materials, and reiterated their previous comments that due to the nature of the meeting and when papers were disseminated, they had not conducted a full consent review. 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 the substantial numbers of unblinded trial participants and hoped that this would not unduly affect the validity of the ongoing trial, noting this was a multinational trial across a number of countries and required 15,000 participants. NHS Digital noted that there were a number of orphaned bar codes which were positive tests taken by the trial member but had no identifiers and the applicant had requested this data. IGARD members were supportive of the applicant receiving this data but to clarify the nature of the bar code as an identifier, who could re-identify, the legal basis to flow this from NHS Digital to the applicant and the legal basis for the applicant to receive this data from NHS Digital. IGARD reiterated their point previously made that an assessment of whether PPD Global Ltd should be noted as a Data Processor in the DARS application should be undertaken, or was their handling of data separate from the handling of NHS Digital data and in line with NHS Digital's DARS Standard for Data Controllers / Data Processors. In addition, "PPD" should be referred to by its full legal name on first use in the public facing section of the application and its involvement in the processing should be clearly articulated in the DARS application. Finally, IGARD noted that a number of points had been previously raised, and that they had not been provided with a copy of the updated application summary, and that all previous points raised remained outstanding until fully addressed. IGARD members 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. Notwithstanding the above points, IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital SIRO precedent for a 6 month extension and in line with the Health Service (Control of Patient Information) 2002 (COPI) Notice end date.