Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 17 December 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (Items 2.4 – 6)
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Imran Khan	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS)
Gaynor Dalton	Privacy, Transparency and Ethics
Arjun Dhillon	Caldicott Guardian (Observer: item 2.4)
Liz Gaffney	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Dickie Langley	Privacy, Transparency and Ethics
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS) (Observer: item 2.5)
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 on COVID-19. Maria Clark noted professional links to the University of Sheffield (NIC-284866-L7K4D), 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 10th December 2020 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	**Data Applications**
2.1	<u>University of Sheffield: Safety INdEx of Prehospital On Scene Triage (SINEPOST): The derivation and validation of a risk prediction model to support ambulance clinical transport decisions on scene. (Presenter: Fran Hancox) NIC-284866-L7K4D</u> **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS) and Hospital Episodes Statistics (HES); for the purpose of research which aims to determine whether ambulance service clinical data can predict an avoidable attendance at the Emergency Department (ED) in adults using newly developed risk prediction models. These models could subsequently be used to develop a tool for paramedics on scene which can help them to determine the likelihood of treatment at an ED being of benefit to the patient. The cohort being submitted in order to create the risk decision models comprises patients aged 18 years or older who were transferred to an ED by the Yorkshire Ambulance Service (YAS) between the 1st July 2019 and the 29th February 2020, following assessment by a qualified paramedic; the paramedic must have completed an electronic patient care record (ePCR). NHS Digital advised IGARD that section 3 (Datasets Held / Requested) incorrectly stated that the common law duty of confidentiality was addressed by *"…consent…"*, and confirmed that that this would be removed. **Discussion:** IGARD noted the update from NHS Digital in respect of the error in section 3 when referring to *"consent"*, and supported the update to remove this reference. IGARD queried whether YAS, as the sponsors of the project, should also be considered joint Data Controllers, and were advised by NHS Digital that YAS were not involved with any of the analyses or processing of the data and they were content that YAS were not a joint Data Controller. IGARD noted the clarification from NHS Digital and agreed that notwithstanding YAS being the project sponsor, the facts did not support them being a joint Data Controller. IGARD noted in section 1 (Abstract), the reference to the Health Research Authority Confidentiality Advisory Committee (HRA CAG) condition of support, whereby, the applicant was asked to produce a patient notification strategy report within three months of support under s251 being confirmed. IGARD queried if this had been completed, noting that the deadline for this was October 2020. IGARD asked that confirmation from the applicant was provided confirming that the patient notification strategy report had been shared with HRA CAG; and that the written confirmation was provided that HRA CAG had confirmed that the

	condition relating to this report has been met. In addition, the relevant documentation should be uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD noted that the HRA CAG support was for a number of data fields, including *"name"*, however due to the inability to use name as a linkage tool for HES, names would not be supplied, and instead *"sex"* would be added for linkage purposes. IGARD queried the statement in section 1 that *"Given sex is not an identifier in its own right and does not require CAG approval, it will be included to increase the reliability of the linkage.";* and asked that the applicant make HRA CAG aware of the change in the data going to NHS Digital. IGARD also suggested, that given the large cohort and the usual HRA CAG conditions of support, that the YAS Caldicott Guardian, as sponsors of the project, is consulted to ensure the plans for transparency aligned with the relevant data protection laws as well as the new Caldicott Principle 8. IGARD noted the reference in section 5(c) (Specific Outputs Expected) to securing the *"intellectual property for the algorithm"*, and queried if there were any commercial benefits of the research. IGARD asked that further details were provided of any potential commercial exploitation, now or in the future; and that if it did have a commercial element, the points required by the NHS Digital DARS Commercial Standard were addressed within the application. IGARD also noted the potential wider use and impact of the algorithm in the future, and suggested that the YAS Caldicott Guardian was consulted in terms of data bias assessment and other considerations relevant to the development of an algorithm. IGARD queried the references in section 5 (Purpose / Methods / Outputs) to *"bias screening"* and *"discrimination"*, and asked that further details were provided confirming what was meant by these. IGARD also noted the statement in section 5(a) (Objective for Processing) that *"YAS data will be linked to regional hospital ED data"*, and asked that further clarification was provided how this would take place and to clarify the legal basis to undertake this linkage. IGARD noted the statements in section 5(a) in reference to historical research, for example *"In 2014 in Yorkshire, up to 16.9% of patients could have avoided being taken by ambulance to the ED",* and asked that where historical research was referred to, a further explanation was provided explaining that the new research outlined was designed to have different outputs and functionality. IGARD queried the reference in section 5(b) (Processing Activities) to *"maximum data linkage"*, and queried what was meant by this, and asked that a brief and clear explanation was provided. IGARD also noted the reference in 5(b) to *"parsimonious",* and asked that a further explanation was provided as to what was meant by the statistical term of art *"parsimonious"*. IGARD noted the statement in section 5(b) that described dementia as being a *"social factor"*, and asked that, given the sensitivity, that this was expanded to make clear it was addressing social support. IGARD queried the benefits outlined in the section 5(d) (Benefits) and noted the declarative statements used, such as *"…the information gained will inform ambulance services what the important clinical variables are…"*, and suggested the applicant revise the language in section 5(d) to ensure that the benefits were realistic and achievable, and in line with the data flowing.

	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 that section 5(d) was updated to reflect that the potential benefits may be more effective utilisation of resources, rather than money *"saved"*. In addition, IGARD also asked that section 5 was updated throughout to ensure the potential benefits to patients were emphasised alongside the potential economic benefits. IGARD queried the statement in section 5(d) that transportation would be *"significantly reduced"* and asked if the applicant could give an indication of quantum, for example an estimated percentage. IGARD noted a number of acronyms in section 5(a) (Objective for Processing) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of HRA CAG support: a) To confirm that the patient notification strategy report that was due in October 2020 has been shared with HRA CAG. b) To provide written confirmation that HRA CAG have confirmed that the condition relating to this report has been met. c) Noting sex is not an identifier in its own right and does not require HRA CAG approval, IGARD asked that the applicant make HRA CAG aware of the change in the data going to NHS Digital (changing name for sex). 2. To provide further details of any potential commercial exploitation now or in the future, and if it does have a commercial element, to address the points required by the NHS Digital DARS Commercial Standard within the application. 3. To provide further clarification of the YAS linkage to "regional hospital data", how this will take place and the legal basis to undertake this. The following amendments were requested: 1. To amend section 3 to remove reference to *"consent"*. 2. To update section 5(a) to ensure that where historical research on ambulance episodes is referred to, to explain that the new research outlined is designed to have different outputs and functionality. 3. To update section 5 to provide further detail on the references to *"bias screening"* and *"discrimination"*. 4. To update section 5(b): a) To provide a brief and clear explanation of the reference to "maximum data linkage". b) To provide a further explanation as to what is meant by the statistical term of art *"parsimonious"*. c) Given the sensitivity of describing dementia as being a "social factor", to expand this to make clear its addressing social support. 5) To update section 5 to ensure the potential benefits to patients are emphasised alongside the potential economic benefits. 6) To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. 7) To update section 5(d): a) To revise the language to reflect that the exact benefits are not yet known; for example references to *"will"*.

	b) To reflect that the potential benefits may be more effective utilisation of resources rather than money "saved". c) To review the statement that transportation would be "significantly reduced" to give an indication of quantum (for example an estimated percentage). The following advice was given: 1. IGARD suggested, that given the large cohort and the usual HRA CAG conditions of support, that the YAS Caldicott Guardian is consulted to ensure the plans for transparency align with the relevant data protection laws as well as the new Caldicott Principle 8. 2. IGARD noted the potential wider use and impact of the algorithm in the future, and suggested that the YAS Caldicott Guardian was consulted in terms of data bias assessment and other considerations relevant to the development of an algorithm. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.2	<u>Patient Level Medicines Data Class Application (Presenter: Tom Wright) NIC-403394</u> **Application:** This was a class application for all 135 CCGs in England to receive patient-level medicines data. Data Controllership will be based on existing Data Sharing Agreements (DSAs). Patient-level medicines data is taken from electronic and paper prescriptions that are submitted to the NHS Business Services Authority (NHSBSA) for reimbursement each month. The data comprises prescriptions for medicines that are dispensed or supplied by community pharmacists, appliance contractors and dispensing doctors and prescriptions submitted by prescribing doctors in England for medicines personally administered in England. Data includes prescriptions issued by prescribers in general practice, community clinics, hospital clinics, dentists, community nursing services. NHS Digital has the legal obligation to establish and operate informatics systems for the collection or analysis of information, and to exercise systems delivery functions in respect of medicines dispensed or supplied under Direction. **Discussion:** NHS Digital noted that 135 amendment applications would need to be approved using the basis of this class action template for amendments to live CCG Data Sharing Agreements (DSAs); and IGARD commended NHS Digital for the work they had undertaken on the class action. IGARD noted that the briefing paper had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 7th July 2020 and also the business as usual (BAU) meeting on the 30th July and the 17th November 2020. IGARD noted the processing taking place for the NHS BSA data, and asked that a special condition was added to section 6 (Special conditions) of all the relevant applications, that the processing must be strictly within the scope of use set out in the NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019, relating to this data collection and dissemination. IGARD queried whether all the proposed processing could take place and the expected benefits could be achieved with the aggregated data, and suggested that applicant(s) may wish to give this further consideration. IGARD noted the point in section 5 (Purpose / Methods / Outputs) to the "Impact of admission on polypharmacy", and asked that this was reordered to ensure that it focussed the impact on admissions and re-admissions.

	IGARD advised that when these applications come up for renewal or extension, they would expect the yielded benefits to be clearly outlined in section 5(d) (Benefits), and that the applications reflected the work that has been undertaken, and the benefits accrued since the application was last seen. In addition, that the yielded benefits related to clinical safety and / or safety and effectiveness of medicines as required by the NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019 and as anticipated by the stated expected benefits. In addition, IGARD suggested that when this class of applications come up for renewal, extension or amendment in the future, a small representative sample was brought back to IGARD for review, as per usual process. IGARD asked that in addition to the updates requested in the application, that the processing instructions set out by NHS Digital were also updated to reflect that: processing was not to be used for performance management; that processing was not to not to be used for ascertaining potential cost savings; and that processing must be used for clinical safety and / or safety and effectiveness; and asked that a copy of the processing instruction was uploaded to NHS Digital's CRM system. **Outcome:** recommendation to approve the class action for 135 English CCG's. The following amendments were requested: 1. To insert a special condition in section 6 in all relevant applications, that the processing for the NHS BSA data must be strictly within the scope of use set out in the Direction relation to this data collection and dissemination. 2. To update section 5 to reorder the point on *"polypharmacy"* to ensure it focusses on the impact on admissions and re-admissions. The following advice was given: 1. IGARD suggested that the applicant(s) consider whether all the proposed processing can take place and the expected benefits be achieved with the aggregated data. 2. IGARD advised that when these application come up for renewal or extension, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application(s) was last seen, and that these yielded benefits relate to clinical safety and/or safety and effectiveness of medicines as required by the Direction and as anticipated by the stated expected benefits. 3. IGARD suggested that when this class of applications comes up for renewal, extension or amendment, a small representative sample was brought back to IGARD for review.
2.3	<u>Clinical Registry Annex x 7 (NICOR) (Presenter: Tom Wright) NIC-139035-X4B7K</u> **Application 1 National Audit of Percutaneous Coronary Interventions (NAPCI):** The National Audit of Percutaneous Coronary Interventions (NAPCI) is used to collect data for interventions when obstructions in the heart arteries occurs. Obstructions within the arteries of the heart lead to exertion-induced chest pain (angina) that cannot be controlled by medical treatment, then patients may be helped by methods to improve blood flow. One technique is to use percutaneous coronary intervention (PCI) (often referred to as 'angioplasty'). The purpose of the audit is to stimulate quality improvement through the provision of comparative information on the structure and activity of PCI services; the access to, appropriateness and quality of care against national standards; outcome for patients such as complications,

	adverse cardiac events and death/survival. Data collected for the audit is from all centres in the UK, where PCI has been undertaken. The NAPCI assesses the process of PCI care and speed of the PCI delivery as well as the patient outcomes for example complication rates, or mortality. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership by the British Cardiovascular Intervention Society (BCIS). **Application 2 Myocardial Ischaemia National Audit Project (MINAP)**: The Myocardial Ischaemia National Audit Project (MINAP) was established in 1999 in response to the national service framework (NSF) for coronary heart disease, to examine the quality of management of heart attacks (myocardial infarction) in hospitals in England and Wales. Part of the National Cardiac Audit Programme (NCAP), the audit aims to improve the quality of care and outcomes of patients who have heart attacks. It aims to improve the whole pathway from the call to the emergency services, to the prescription of preventive medications on discharge from hospital. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership with the British Cardiovascular Society (BCS). **Application 3 National Adult Cardiac Surgery Audit (NACSA):** The National Adult Cardiac Surgery Audit (NACSA) collects data on all major heart operations carried out on NHS patients in the UK. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical direction and strategy provided by the Society for Cardiothoracic Surgeons (SCTS) and the Project Board. Data collected for NACSA is primarily for consecutive operation data from all NHS hospitals in the UK that carry out adult heart surgery. NICOR is hosted by Barts Health NHS Trust, for the operational delivery of a number of clinical databases and registries associated with specialist cardiac services commissioned by NHS England as prescribed specialised services. **Application 4 National Cardiac Heart Rhythm Management Audit (CRM):** The National Cardiac Heart Rhythm Management Audit (CRM) collects information about all implanted cardiac devices and all patients receiving interventional procedures for management of cardiac rhythm disorders in the UK. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership is provided by the British Heart Rhythm Society (BHRS). **Application 5 National Congenital Heart Disease Audit (NCHDA):** The National Congenital Heart Disease Audit (NCHDA) collects information about Congenital heart disease, which refers to any defect of the heart present from birth. It includes structural defects, congenital arrhythmias, and cardiomyopathies. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership led by the British Congenital Cardiac Association and The Society for Cardiothoracic Surgery in Great Britain and Ireland. Data collected for the audit is from all centres across the UK undertaking paediatric and congenital cardiac surgery and interventional procedures, including electrophysiology. Children with congenital heart disease are treated in a small number of specialised (tertiary) centres, all of whom send their outcome data to National Congenital Heart Disease Audit. Some adults with congenital heart disease are also treated at these specialised centres. However, many adults are also treated at other cardiac centres who do not currently send their data to National Congenital Heart Disease Audit. This means that data collected on the survival of patients over the age of 16 is not complete. NHS England continue to encourage these centres to participate in the national audit. **Application 6 National Heart Failure Audit:** The National Heart Failure Audit collects data on patients with an unscheduled admission to hospital in the UK and who are discharged with a primary diagnosis of heart failure. The audit aims to drive up the quality of the diagnosis,

	treatment and management of heart failure by collecting, analysing and disseminating data, and eventually to improve mortality and morbidity outcomes for heart failure patients. The audit is managed by NICOR, with clinical direction and strategy provided by the British Society of Heart Failure (BSH). **Application 7 Transcatheter Aortic Valve Implantation (TAVI) Audit:** The main purpose of the TAVI data collection is to provide a detailed and accurate description of this non-surgical alternative to open heart surgery to replace the aortic valve. It is mainly for patients where their condition (severe aortic stenosis and significant comorbidity) raises them to high operative risk status. The registry is managed by National Institute for Cardiovascular Outcomes Research (NICOR) with clinical direction and strategy provided by the British Cardiovascular Interventional Society (BCIS), the Society for Cardiothoracic Surgeons (SCTS). Data collected for the audit is from all units in the UK, implanting transcatheter aortic valves will complete this dataset for each procedure. A web-based user interface allows the data to be directly entered into TAVI dataset held by NICOR. **Discussion:** IGARD noted that the seven NICOR annexes had previously been discussed at the IGARD business as usual meeting on the 17th November, when NHS Digital had brought them for advice. IGARD discussed and agreed that no further comments or amendments were required and confirmed they were content for the seven NICOR annexes to be added the Clinical Registries Database. IGARD discussed National Data Opt-outs (NDOs), and whether NHS Trusts were currently able to apply, as specified by NICOR; and if not, queried how this was being addressed. IGARD suggested that NHS Digital confirmed that the NDO was currently being applied prior to records being delivered to NICOR, and if not, that NHS Digital applied its current process for applying the NDO prior to dissemination pending the full roll out of the NDO. **Outcome:** recommendation to approve for the seven NICOR annexes.
2.4	Office for National Statistics (ONS): ONS / NHS Digital TRE Public Health Asset (Presenter: Garry Coleman / Gaynor Dalton) **(**NIC-420710-X0H1P) **Application:** This was a new application to seek permission for ONS to make an anonymised 'Public health data asset' available for use by accredited external researchers in its Trusted Research Environment (TRE). This research dataset includes a number of underlying data sources that have been linked at a record level for statistical purposes. There will be no new data disseminated under this DSA, and this application will use data already disseminated under NIC-400304-S1P1B and NIC-175120-W5G2. ONS currently has approved access to the following NHS Digital controlled identifiable data: a) Hospital Episode Statistics (HES) Inpatient, Outpatient and Accident and Emergency datasets b) Emergency Care Data Set (ECDS). In addition, ONS expect to shortly acquire HES Critical Care data. **Discussion:** IGARD noted that the briefing paper / presentation for the ONS and NHS Digital Public Health Trusted Research Environment (TRE) had been presented at the IGARD meeting on the 10th December 2020. IGARD queried the status of the Data Protection Impact Assessment (DPIA), and were advised by NHS Digital that this was still in draft and not available to share with IGARD. Noting Article 35(3)(b) a DPIA is required for processing special category data of this scale, IGARD

	suggested that the DPIA, should expressly consider the nature of the data, and analyse why the data can be treated as *"anonymous"* under the GDPR. IGARD noted the reference in section 5(a) (Objective for Processing) to the data being *"anonymous"*, and queried what was gained by asserting that the data was anonymous in the hands of the researcher. IGARD asked that a narrative exposition was provided of why the combination of data in the TRE would be anonymous to the researchers in terms of specific General Data Protection Regulation (GDPR) considerations; and advised that this may be, by way of providing a copy of the DPIA with this point addressed. IGARD noted the information in section 7 (Ethics Approval) that ethics approval was not required as it was already provided under the other DSAs, however in light of the new purpose outlined in this application for the data disseminated under NIC-400304-S1P1B and NIC-175120-W5G2, asked that written evidence was provided confirming that support had been sought and given by the National Statistician's Data Ethics Advisory Committee (NSDEC). Or, that a written justification was provided as to why NSDEC support had **not** been sought, noting the significant scale of processing of personal data. In either case, all relevant supporting documentation should be uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. In addition, IGARD also asked that section 7, was amended to remove the reference to ethics approval not being required; and updated to provide confirmation as to whether NSDEC had considered this significant project. IGARD discussed National Data Opt-outs (NDOs), and whether they should be applied. IGARD suggested that if ONS was relying on Section 45a of the Statistics and Registration Services Act the NDO was applied but if ONS was relying on its mandatory powers (Section 45c), then the NDO would not be upheld. However, it was not clear to IGARD that the proposed activities would be covered by Section 45c. In either event, IGARD emphasised the importance of ensuring transparency in relation to the NDO. In addition, IGARD queried the conflicting information on the NHS Digital website with regard to flows of data to ONS for research which stated *"The application of the national data opt-out to any disclosures of confidential patient information to the ONS for any other purposes (for example, research) and which are not for the production of official statistics will be considered in line with this policy…"*. IGARD therefore asked that the legal basis was finalised, and the adoption of the NDO and that the necessary consequential amendments to the application and transparency materials were made to reflect this. IGARD noted that the NDO web link that had been added to section 3(c) (Patient Objections) was not working, and asked that this updated with the correct working link. NHS Digital advised IGARD that the joint data controllership agreement between ONS and NHS Digital was in the process of being drafted; IGARD noted the update and asked that the essence contained within this document should also be included in the relevant transparency materials. IGARD noted that the application and transparency materials did not clearly reflect the joint data controllership arrangements, and asked that the application and the transparency materials (as already requested), were updated throughout, to reflect that ONS was a joint Data Controller with NHS Digital. In addition, IGARD noted that section 1(b) (Data Controller(s)) referred to ONS as being the "*sole"* Data Controller, and asked that this was removed.

	IGARD noted that given the breadth of the dataset requested and the extent of the processing, suggested that transparency from both NHS Digital and ONS was critical, in addition to the GDPR principles, and in alignment with the new Caldicott Principle of informing individuals about how their confidential information is used. There was a lengthy discussion with regard to the approval process for researchers to access data in the TRE, and noting the update provided by NHS Digital, IGARD put in place an action for NHS Digital, separate to this application: **ACTION:** IGARD would wish to be reassured that the joint approval process for access to the TRE is appropriate for access to such data, and NHS Digital / ONS ensure that opportunities to simplify the process are taken. With that in mind, IGARD has requested the following actions: a) IGARD to review both controllers' DPIAs. b) IGARD to review ONS' existing approvals process. c) ONS to provide further information as to what point NSDEC would be involved in the approvals process. d) IGARD to provide suggestions on any proposed NHS Digital involvement in the said approval process. IGARD noted the references in section 5 (Purpose / Methods / Outputs) to information within NIC-400304-S1P1B and NIC-175120-W5G2, and asked that section 5 was updated, to ensure that where the underlying DSAs containing the data being used in this agreement were referred to, that a brief summary of the salient points of the DSAs, including the NIC numbers and the hyperlink to the NHS Digital Data Release Register, was also included. IGARD queried the reference in section 5(b) (Processing Activities) to researchers being able to "ingest" their own data into the TRE, and asked that this was removed as it was misleading. IGARD queried the references in section 5(a) to *"binary variables"*, and asked that these were updated and rephrased in terms of being accessible to the general public, and to make it clear that that the data visible to researchers would be heavily derived. IGARD noted references throughout the application to GPES Data for Pandemic Planning and Research (GDPPR) data, and were advised by NHS Digital that this data would not be flowing under this agreement, and that this was an aspiration for the future; IGARD noted and asked that the application was updated to make this clear. IGARD also noted the references throughout the application to the *"Census data"*, and queried which Census data this was referring to, and were advised by NHS Digital that this was the 2011 Census data, with the prospect of adding the 2021 Census data; IGARD noted and asked that the application was updated throughout to confirm this. Given the significant amount of work that has gone into this project, and that the general approach may be rolled out more widely to other significant national projects, IGARD suggested NHS Digital may wish to consider wider stakeholder engagement endorsing the approach taken. In addition, IGARD suggested that notwithstanding the pseudonymised data requested, the applicant may wish to consult with the Health Research Authority (HRA) to see if they are minded to review the data processing. IGARD noted that on return they would expect to be provided with a detailed analysis of the outputs and yielded benefits achieved with the data received under 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. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide a narrative exposition of why the combination of data in the TRE will be anonymous to the researchers in terms of specific GDPR considerations (which may be by way of providing a copy of the DPIA with this point addressed). 2. In respect of ethical approval, to either: a) Provide written evidence that support has been sought and given by NSDEC; **or** b) Provide a written justification as to why NSDEC support has not been sought (noting the significant scale of processing of personal data); c) To upload a copy of any relevant documentation to NHS Digital's CRM system. 3. To finalise the legal basis and the adoption of the NDO and make the necessary consequential amendments to the application and transparency materials. The following amendments were requested: 1. To remove reference in section 5(b) to researchers being able to ingest their own data into the TRE. 2. To update the reference in section 5(a) to *"binary variables"*, to rephrase in terms accessible to the general public, and to make clear that that the data visible to researchers will be heavily derived. 3. To update the application throughout to be clear that GDPPR data is **not** flowing under this agreement, and that this is an aspiration for the future. 4. In respect of the data controllership: a) To update the application throughout to reflect the joint data controllership arrangements, and that ONS is a joint Data Controller with NHS Digital. b) To ensure the transparency materials reflect the joint data controllership arrangements. c) To remove the reference to *"sole"* Data Controller in section 1. 5. To update the application throughout to confirm that the Census data only comprises of the 2011 Census data (with the prospect of adding 2021 data). 6. In respect of the NDO: a) If ONS is relying on its permissive powers, to apply the NDO. b) If, notwithstanding IGARD's observations in the minutes above, ONS is relying on its mandatory powers, the NDO would not be upheld. c) In either event, to ensure the transparency in relation to the NDO is clear. d) To ensure the NDO web link in section 3(c) is working correctly. 7. To update section 5 to ensure that where the underlying DSAs containing the data being used in this agreement are referred to, that a brief summary of the salient points of the DSAs, including the NIC numbers and the hyperlink to the NHS Digital Data Release Register, is included. 8. In respect of the ethics approval: a) To amend section 7 to remove the reference to ethics approval not being required. b) To provide confirmation in section 7 whether NSDEC have considered this significant project (Condition 2 above refers). The following advice was given:

	1. IGARD noted that given the breadth of the dataset requested and the extent of the processing, suggested that transparency from NHS Digital and ONS is critical, in addition to the GDPR principles, an in alignment with the new Caldicott Principle 8. 2. IGARD noted the joint data controllership agreement being drafted, and that the essence contained should be included in relevant transparency materials. 3. Given the significant amount of work that has gone into this project, and that the general approach may be rolled out more widely to other significant national projects, IGARD suggested NHS Digital may wish to consider wider stakeholder engagement endorsing the approach taken. 4. IGARD suggested that notwithstanding the pseudonymised data requested, the applicant may wish to consult with the HRA to see if they are minded to review the data processing. 5. IGARD noted that on return that a detailed analysis of the outputs and yielded benefits achieved should be provided. 6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 7. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.5	<u>Office for National Statistics (ONS): Request for remote access to data in NHS Digital's environment for COVID-19 purposes (Presenter: Dave Cronin) NIC-388794-Z9P3J</u> **Application:** This was an amendment application to permit access to the following additional datasets, 1) COVID-19 Second Generation Surveillance System (Beta version), and 2) COVID-19 UK Non-hospital Antigen Testing Results (pillar 2) Service Types. The purpose is for research into the production of official statistics in respect of COVID-19. The results of the analysis will be used to inform members of the Scientific Emergency Group for emergencies (SAGE), Members of Parliament (MPs) and other government officials of the differing COVID-19 risk profiles experienced by UK citizens. This will enable the government to refine its policy response to the pandemic using the best evidence available. The analysis may also improve the public's understanding of the risk faced by individuals, leading to more informed personal decision making, and add to the growing body of literature being produced and evaluated by the global academic community. NHS Digital advised IGARD, that following the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) meeting on the 9th December, amendments had been made to the application to address the points raised. **Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 14th July, 28th July, 8th September, 15th September and 8th December 2020. IGARD noted that this application had been reviewed at PAG on the 8th July 2020, and that notes from this meeting had been attached to the IGARD minutes from the 9th July 2020; and on the 9th December (see Appendix B). IGARD noted and endorsed the specific points raised by PAG on the 9th December, and the subsequent amendments to the application by NHS Digital to address the points. As also recorded by PAG, IGARD noted that there were no yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) as yet, and asked that further details were provided of the specific yielded benefits accrued to date, for example the briefing paper provided to Ministers,

	and what benefit this provided; and in addition, if this was made publicly available, to make this clear. IGARD noted that the Data Protection Impact Assessment (DPIA) did **not** address the proposed processing outlined in the application, and strongly suggested that ONS address this. IGARD noted that the purpose of the DPIA is to assess the risk to the rights and freedoms of natural persons, not the risk of access to data as noted within the application by the applicant. In addition, IGARD also noted the importance of transparency, and suggested that the proposed processing was reflected in the relevant privacy notices. IGARD also suggested that NHS Digital made the applicant aware of the new Caldicott Principle 8, which sits alongside the Data Protection Legislation. IGARD observed that National Statistician's Data Ethics Advisory Committee (NSDEC) would be consulted as specific urgent points arise, however advised that it may be more expedient to discuss this project and proposed access in general terms, in advance of any urgent application. **Outcome:** recommendation to approve The following amendment was requested: 1. To provide further details in section 5(d) of the yielded benefits accrued to date, for example the briefing paper provided to Ministers. The following advice was given: 1. IGARD strongly suggested that ONS consider expressly addressing the proposed processing within its DPIA (which is designed to assess the risk to the rights and freedoms of natural persons). 2. IGARD noted the importance of transparency, and suggested that the proposed processing was reflected in the relevant privacy notices.
3	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-137864-T1P9B University College London • NIC-237669-T9W5N University of Nottingham IGARD welcomed the two applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	<u>Information Governance (IG) Oversight and Assurance</u> IGARD noted that in agreement with NHS Digital, that they would provide support by reviewing and providing feedback on two Information Governance (IG) COVID-19 and the Health Service

	Control of Patient Information (COPI) Regulations 2002 applications, as part of their oversight and assurance role. The requests reviewed were: • IG-0294 NHS England • IG-00492 NHS England IGARD welcomed the two applications for the two data disseminations as part of their oversight and assurance role and noted a number of comments that would be shared in writing to NHS Digital.
5	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 15th December 2020 can be found attached to these minutes as Appendix C.
6 **6.1** **6.2**	<u>AOB:</u> <u>GDPR Legal Basis Register</u> NHS Digital shared a copy of the internal GDPR Legal Basis Register with IGARD, and advised that this was a live document and is updated regularly. IGARD thanked NHS Digital for sharing the document and verbally provided initial thoughts and feedback, and advised they would discuss further at a future IGARD meeting. CCGs, Risk Stratification and the National Data Opt-out (NDO) Due to time constraints this AOB item was not discussed and it was agreed that this would be included on the 14th January 2021 business as usual (BAU) agenda. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 11/12/20

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-365602-V5H3Z	King's College London	19/11/2020	1. In respect of the date of death (noting NHS Digital policy): a) To provide a rationale as to why the date of death is considered not to be owed a duty of confidence given the other data sets involved and the context within which this data sits. b) To provide a statement in section 1 asserting that, in light of an assessment of the fact, the data is not owed a duty of confidence.	IGARD members	Quorum of IGARD members	None
NIC-327960-M2P9M	Swansea University	26/11/2020	2. In respect of the references to "presumed consent", to update section 5 throughout: a) To remove all references to *"presumed consent"*. b) To replace with a clear explanation of how the cohort members are selected and identified. c) To also include the legal basis for following and processing the cohort's health information (for example by reference to the s251 support).	IGARD members	Quorum of IGARD members	In respect of amendment 5, IGARD noted: There is one more reference to aggregate data in Section 5: *"Study outputs will present aggregate data only; small groups will be merged where possible and meaningful."* IGARD suggested adding a further query about the study output small numbers being supressed *"where possible"*

						and would check this aligns with permissions and policy.

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

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 9th December 2020

Application & application version: DARS-NIC-388794-Z9P3J-v2.2 **Organisation name: Office for National Statistics (ONS)** **Profession Advisory Group Agenda item: 2**
PAG noted that the application sought to permit ONS to access the data for a longer period, and access two additional datasets. It was noted that these datasets were not GP datasets. PAG were assured that no data linkages beyond those listed within the agreement were permitted. It was noted that a typo existed in relation to SAGE, and NHSD agreed to update. PAG noted the current wording around sharing of outputs in relation to official statistics, and that the data may be shared with the profession upon request. PAG stated that the RCGP and BMA must be added to the list of organisations/groups to receive the official statistics at the same time as those groups. PAG must receive briefings directly and with no requirement for BMA/RCGP to request such briefings. PAG noted the wide scope of the request, and the wish to access data for Long COVID and other work. It wanted clinical issues to drive the research requests, and requires the requests for analysis to come from SAGE or the CMO. PAG requires it be made aware of the research questions being asked in relation to those requests. Finally, PAG noted that access had been provided for some time to the data, but no yielded benefits were listed. It asked that ONS provide details on the benefits achieved to date.

Attendees	Role	Organisation
Peter Short	Deputy Chair	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Julian Costello	GP	RCGP
Pam Soorma	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 15th December 2020

In attendance (IGARD Members): Kirsty Irvine (IGARD Lay Chair)
Dr. Imran Khan (IGARD Specialist GP Member)
Dr Geoff Schrecker (IGARD Specialist GP Member)

In attendance (NHS Digital): Vicky Byrne-Watts (DARS)
Dave Cronin (DARS)
Louise Dunn (DARS)
Mujiba Ejaz (DARS - observer)
Karen Myers (IGARD Secretariat)
Vicki Williams (IGARD Secretariat)

2	**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 any 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 would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	NIC-402417-N9Z5W UCL Partners **Background:** This was a brief verbal update to the update received on the COVID-19 response meeting 6th October,13th October, 10th November, 1st December and 8th December 2020 with regard to the NHS Digital Cancer Trusted Research Environment (TRE) and an application from UCL Partners to access the Cancer TRE. The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** NHS Digital noted that work was progressing with the application(s) and parties involved in the Cancer TRE to scope specific applications including, but not limited to, discussions with regard to Data Controllership. IGARD suggested ensuring that the analysis NHS Digital undertook to reach the relevant conclusion about controllership and data minimisation methods was provided as a supporting document (or inserted in section 1 (Abstract)).

	IGARD members thanked NHS Digital for the update and looked forward to receiving more information in due course, noting the aim was for a briefing note to come to IGARD in early January and an application to come to the business as usual (BAU) meeting on Thursday, 21st January 2021.
2.2	<u>NIC-396113-N9L4L Imperial College London (ICL)</u> **Background:** This was an update following an update at the COVID-19 response meetings on the 4th August and 18th August, and an application presented to the business as usual (BAU) IGARD meeting on the 20th August 2020. Pulse Oximetry in the home (including residential and care homes) enables patients to measure their own oxygen levels. As part of the COVID-19 oximetry @home (CO@h), NHS England have identified academic partners to run a service evaluation and to support this NHS Digital will be creating a new dataset, collected from CCGs and commissioned CO@h providers. The following observations were made on the basis of the verbal briefing and single slide overview only. **IGARD Observations:** NHS Digital noted that c. four applications would be presented to future meetings of IGARD over the coming months and IGARD members supported the approach that each academic partner would have their own bespoke application, rather than the approach of one overarching application. IGARD members suggested that since GPES Data for Pandemic Research & Planning (GDPPR) data was included, that the use of a Trusted Research Environment (TRE) and proposed sub-licensing agreements be discussed with the Profession Advisory Group (PAG). As arrangements currently stand, when the CV-19 Direction (issued under the emergency National Health Service (Control of Patient Information Regulations) 2002 (COPI)) expires at some point in the future, the data would have to be destroyed. IGARD members noted that they were unclear, since they had not been provided with an updated application, if this was in fact service evaluation since it appeared that elements of the approach were research. NHS Digital noted that the cohort numbers had increased and that this CO@h had expanded wider than the original virtual wards application. Noting that it was unclear if there was a control cohort or if they were comparing different models of oximetry in the home, that the application should be clear that it was service evaluation and any reference to comparing or contrasting or finding an answer to a question, should be removed, since these would indicate the application had research elements. Noting that DARS had asked NHS Digital's Privacy, Transparency and Ethics (PTE) Directorate (formerly Information Governance Directorate) to review the application and suite of documentation, and in advance of the four applications coming to IGARD, IGARD members suggeted that PTE may wish to attend a future COVID-19 response meeting. Alternatively, IGARD Specialist members were happy to discuss out of committee any aspects of the applications, and before any applications were submitted, to ensure all aspects of the processing were clearly delineated as service evaluations. IGARD members also suggested that the applicant(s) may also wish to consider requesting all or a subset of the Pillar testing data (COVID-19 Second Generation Surveillance System,

	Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3)), which would detail if a patient had or had not got COVID-19, unless only those with confirmed COVID-19 were part of the trial, but either way it may impact on the design of the study.
2.3	<u>NIC 420168-K4N1F University of Bristol</u> **Background:** Following a briefing and education session update from the University of Bristol at the COVID-19 response meeting on the 8th December 2020, this was a new draft application for a longitudinal linkage collaboration (consent) focusing on the Avon Longitudinal Study of Parents & Children (ASLPAC) (NIC-13133-B7B3K) and Southall & Brent Revisited (SABRE) (NIC-148100-6RFK9 / NIC-148407-LRP3M / NIC-86954-Y0R2N) consented cohorts. The University of Bristol (UoB) scientific programme requires the extraction and use of the NHS Digital compiled COVID-19 relevant dataset (primary care, secondary care, community mental health care provision, COVID-19 testing and outcomes data, NHS service use interactions such as NHS 111 records, mortality, disease registry and demographics data) for the purpose of establishing the Longitudinal Linkage Collaboration (LLC). The LLC will be a new research database within a Trusted Research Environment (TRE) which intends to integrate data from >15 longitudinal population studies (LPS) with a combined total of 1–2 million UK participants and then centrally links these to a wide range of COVID-19 relevant NHS and non-health administrative records. The following observations were made on the basis of the draft application and draft supporting documentation only. **IGARD Observations:** Noting the education session last week, IGARD members asked for further clarification of the nature of the data in the hands of University of Bristol and clarification of the nature of the data in the hands of the researcher, since IGARD remained unclear that, due to the volume and richness of the data, it could be classed as "anonymous" in terms of the of the General Data Protection Regulation (GDPR). If the applicant was certain that the data was anonymous in terms GDPR, at all stages of the processing, then a clear and careful analysis, referencing the appropriate resources, should be provided (and suggested this may be in the applicant's DPIA). In addition, and when the application is presented to a future business as usual (BAU) meeting in January, NHS Digital should undertake a full review of the consent materials and that this detailed analysis be provided as a supporting document with regard to what the consent covers and if there are any inconsistencies between the scope of the consent and the proposed processing. IGARD members noted that the Longitudinal Linkage Collaboration Data Access Committee Terms of Reference (LLC DAC TOR) version 0.1 (dated 2 December 2020) had been provided and noted that *"it is the ambition of the LLC DAC to have at least two members of the public as members at all times…*" and suggested that this may in fact be referring to having **cohort** members as part of the committee and that reference to "*members of the public*" be removed. IGARD members also noted the "*ambition*" but suggested that this should not be an aspiration and that cohort committee members be in place from the start of the programme. In addition,

	reference to "*a representative of each contributing study…*" should be clarified as to whether this related to academic/university representatives for those studies. Citing the NHS Digital DARS Standard for Sub-Licencing, IGARD members queried if the sub-licence document reflected the Standard, since it seemed to be silent on the ability for NHS Digital to audit the sub-licencees. Noting that the application was still in draft, IGARD members suggested a number of updates including, but not limited to: • Providing a brief summary of the sub-licencing arrangements in section 5, which may include a link to the published DARS Standard for Sub-Licencing on the NHS Digital website. • To clarify within the application that the application is relying on consent for the GDPPR data and that any relevant special conditions in relation to this dataset be included in section 6. • To explore and refine the data minimisation data fields in relation to symptom coding. • To expressly address the number of years requested for Hospital Episode Statistics Admitted Patient Care (HES APC) and provide a justification for the c. 30 years of data request, citing NHS Digital's DARS Standard for Data Minimisation. • The application be reviewed, especially the public facing section 5, to remove any references to external documents for example, "*see appendix…*". IGARD suggested that DARS take the opportunity to discuss the draft application with the Profession Advisory Committee (PAG) in relation to the inclusion of the GDPPR data and before its presentation to a BAU meeting of IGARD. IGARD thanked both DARS and the applicant for providing the draft application and detailed supporting documents in such a short time frame and looked forward to receiving updated documentation 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.