Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 20 August 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Louise Dunn	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics (Observer: Items 2.1-2.3)
Kimberley Watson	Data Access Request Service (DARS)
Vicky Byrne-Watts	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 13th August 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	Imperial College London: Community-based VIrtual Electronic Wards for remote monitoring in suspected cases of COVID-19 (coronavirus): C-VIEW Study (Presenter: Kimberley Watson / Vicky Byrne-Watts) NIC-396113-N9L4L **Application:** This was a new application for identifiable GPES Data for Pandemic Planning and Research (GDPPR) and Emergency Care Data Set (ECDS) for the purpose of a study designed to test the effectiveness of the new care pathway of virtual wards for healthcare delivery for individuals suspected of COVID-19. Virtual wards can be established to manage patients remotely, freeing up staff, avoiding overwhelming hospitals, and reducing patient anxiety by allowing recovery at home. Healthcare professionals in virtual wards can track vital signs of those suspected of COVID-19, in near real-time, receiving alerts for clinical deterioration. Pulse oximeters combined with digital innovation (i.e. mobile applications) allow for systems to recognise early deterioration in vital parameters and self-reported symptoms, supporting clinical decision making. NHS Digital noted that both Imperial College London (ICL) and NHS England were joint Data Controllers and that ICL would be the sole Data Processor. NHS Digital noted that reference to 'North of England' as one of the pilot sites should be removed, as this was an error. **Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 18th August 2020. IGARD also noted that this application had also been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 19th August 2020. IGARD noted that this application was for the new Virtual Ward data set and that they were not providing assurance on the validity and legal basis analysis for the underlying datasets collected. IGARD suggested that relevant analysis was undertaken of the consent being relied upon, in particular the consent materials for the participant to take part in the data gathering via the electronic app, to ensure that when the Health Service (Control of Patient Information Regulations) 2002 (COPI) expires, the legal bases underpinning data collection and dissemination was sound. IGARD noted the update with regard to the joint Data Controllership and suggested that the application be updated throughout to reflect ICL as a joint Data Controller. In addition, IGARD supported the removal of 'North of England' as a pilot site, since this was incorrect. NHS Digital noted that the Information Governance (IG) directorate had indicated that the legal basis was COPI Reg 3(b)(1) "…*confidential patient information may be processed with a view to* ***recognising trends*** *in such [communicable] diseases and risks [to public health]…*", however IGARD suggested that COPI Reg 3(1)(d)(i) "…*confidential patient information may be processed with a view to* ***monitoring and managing*** *outbreaks of communicable disease…"* may be more appropriate and that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) be updated. IGARD noted the analysis that had been undertaken by NHS Digital's Chief Medical Officer (CMO) and by ICL's own internal research governance department with regard to whether this application was a "service evaluation". However since the questions to be answered in section 5(c) (Special Outputs Expected, including target dates) were more supportive of a research study, IGARD suggested that these were updated to align with a service evaluation, along with written confirmation from NHS Digital's CMO that this was a service evaluation study. Alternatively, IGARD suggested that written confirmation from the Health Research Authority (HRA) that this activity was not deemed research would be helpful. Any documentation should

	be uploaded to NHS Digital's customer relationship management (CRM) system as future supporting documentation. NHS Digital noted that section 3(b) (Additional Data Access Requested) would need to be updated to correctly reference the data being disseminated. IGARD were supportive of the amendments and asked that the ECDS be removed and that Personal Demographic Service (PDS) data be inserted. In addition, and referencing NHS Digital's DARS Standard for Data Minimisation (which is reflected also in the Profession Advisory Group (PAG) comment), IGARD suggested that the table in section 3(b) be updated to make clear that the GDPPR data had been minimised to the virtual ward cohort only and suggested that further information be provided on the '*special code clusters*'. IGARD noted that patient objections would not apply, however suggested that a statement be inserted in section 5(a) (Objective for Processing) clarifying that Type 1 objections had been applied to the underlying GDPPR dataset. IGARD noted in section 5(a) that "…*The role of Imperial College is to access data collected from pilot sites for retrospective analysis and they have also developed a trial protocol and minimum dataset requirements for collecting prospective data*…" and suggested that this be updated to include real world figures. IGARD noted in section 5(a) that "…*The COVID-19 National Incident Response Board (NIRB) have approved the three pilots in London, Slough and South Tees*…" however since no published minutes had been provided for the Board's decision, asked that a copy of the minutes or notes from the specific meeting that outlined the support for the virtual wards be provided, and a copy uploaded to CRM as a future supporting document. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that both NHS England and ICL update their privacy notices to include, but not be limited to, the processing outlined in this application. In addition, IGARD noted that the special condition in section 6 (Special Conditions) which stated "*NHS England / Imperial College London must update their privacy notice to be compliant with the ICO criteria*…" should be updated to reference that a "*GDPR compliant*" privacy notice would be provided within 1 month of signing the Data Sharing Agreement (DSA). IGARD noted that no public engagement had been set out in this application. and noting the importance of the work being undertaken and that University College London (UCL) were undertaking a qualitative assessment, suggested that further consideration be given to those groups that had been excluded from the study. Noting that this work could lead to a possible national roll-out, any exclusion of certain groups may exacerbate health inequalities and so any possible mitigating steps should be considered. IGARD noted the comments made by PAG and that these had in the main been addressed in the review of this application and the advice given. **Outcome:** recommendation to approve subject to conditions 1. In respect of this application being for service evaluation: a. To provide written confirmation of NHS Digital's CMO's analysis undertaken to evidence that this was service evaluation not research, or to seek and provide written confirmation from HRA re the same; b. To upload a copy of the relevant written assurance to CRM; c. To update any questions to be answered in section 5 which were more supportive of a research study than a service evaluation. 2. In respect of data minimisation:

	a. To update the table in 3b to make clear that the GDPPR data has been minimised to the virtual ward cohort; b. To clarify the specific code clusters. The following amendments were requested: 1. To update the application throughout to reflect ICL is joint Data Controller. 2. To update sections 1 and 5 to correctly reference the correct limb under COPI ie Reg 3(1)(d)(i). 3. In respect of section 3b: a. To remove the request for ECDS. b. To add the request for PDS. 4. To update section 5(a) to reference real world figures in respect of retrospective analysis and prospective data. 5. To update section 5(a) to clarify that type 1 objections have been applied to the underlying GDPPR dataset. 6. To update the special condition wording in section 6 that a "GDPR compliant" privacy notice would be provided within 1 month of signing the DSA. 7. In respect of NIRB: a. To provide a copy of the minutes or notes from the specific meeting that outlined the support for the virtual wards; b. To upload a copy to CRM. The following advice was given: 1. IGARD suggested that NHS England and ICL update their privacy notices to include, but not limited, the processing outlined in this application. 2. IGARD suggested that further consideration be given to those groups of people that had been excluded from the study. Such exclusion from a possible nation-wide roll out may exacerbate health inequalities and any possible mitigating steps should be considered. 3. In respect of the PAG comments: a. IGARD noted the data minimisation comment raised, which had been addressed in condition point 2 above; b. IGARD noted the comment with regard to transparency, which had been addressed in advice point 1 above. It was agreed the conditions would be approved OOC by IGARD Members
2.2	<u>NHS England (QH): OpenSAFELY and High Cost Drugs Linkage (Presenter: Kimberley Watson / Vicky Byrne-Watts) NIC-397618-T8L8Z</u> **Application:** This was a new application for pseudonymised Community-Local Provider Flows, for the purpose of supporting NHS England's Coronavirus (COVID-19) research platform work. OpenSAFELY is a new secure analytics platform for electronic health records in the NHS, created to deliver urgent results during the global COVID-19 emergency. It is now successfully delivering analyses across more than 24 million patients' full pseudonymised primary care NHS records. The purposes for processing are to identify medical conditions and medications that affect the risk or impact of COVID-19 infection on individuals; this will assist with identifying risk factors associated with poor patient outcomes as well as information to monitor and predict demand on health services.

	Discussion: IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 18th August 2020. Noting NHS Digital's DARS standard for Data Minimisation and the data requested was for high cost drugs, IGARD suggested that section 3(b) (Additional Data Access Requested) be updated to clearly articulate how the data was minimised, for example, to only those patients with a positive COVID-19 test. If it was not possible to minimise the high cost drugs to only those drugs of interest to the research, that a justification be provided in section 5 (Purpose / Methods / Outputs) detailing why the entire data set for high cost drugs was flowing, since this data would, for example, include drugs for treating cancer. IGARD noted that the table in section 3(b) should be updated to correctly reference the 'sensitivity' category if relevant. Noting that the application was flowing pseudonymised data, IGARD suggested that a clear narrative be provided as to why the Health Service (Control of Patient Information Regulations) 2002 (COPI) was being relied upon, since COPI applies to flows of confidential patient information. IGARD noted that section 5 of the application and the supporting documentation provided as part of the review contained contradictory text in relation to the data flowing and suggested that a clear narrative of the data flows, the data access and the data locations at all stages under this application be provided. In addition the narrative should also clearly outline where the data was flowing to and from, for transparency of process. NHS Digital noted that NHS England held the 'SALT key', which is a industry standard cryptographic hashing technique, however the only reference to 'SALT' in section 5 was "*The DSCROs* have already been provided with the dataset schema required and the pseudonymisation salt...*" and suggested that an explanation be provided with regard to the use of and approach of using SALT. IGARD were also unclear as to whether one or two data flows were flowing back to the two Data Processors: Egton Medical Information Systems Ltd (EMIS) and The Phoenix Partnership Ltd (TPP) UK, and asked that a clear statement be included in section 5 as to the nature of the data flowing, since OpenSAFELY is one platform. Noting that the data remains with the electronic health records (EHR) vendor (EMIS / TPP), IGARD asked for clarification as to why NHS England had been listed in section 2 (Storage Locations) for locations in Leeds and London, and should the data not remain in the EHR vendor systems, to provide relevant narrative. IGARD noted in supporting document (SD) 3.2, '*Honorary Contract Holders DAA EMIS'*, that Amazon Web Services (AWS) was a sub-processor for EMIS and suggested that AWS be included in section 1(c) (Data Processors) as an additional Data Processor. IGARD noted in section 3(c) (Patient Objections) that patient objections would not apply to the data provided under the 'COPI Notice', however suggested that a clear statement be included in both section 3(c) and section 5 that in addition type 1 objections would not apply. IGARD noted a number of acronyms in section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader for such technical jargon such as "*SQL*", "*GitHub*" and "*level 1, level 2*". IGARD noted that a Data Protection Impact Assessment (DPIA) had been undertaken but a copy had not been provided, and suggested that it be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. Noting the valuable research being undertaken by this study which may have potentially direct and indirect impact on citizens across the nation, particularly those that were vulnerable and

	extremely clinically vulnerable, for example those who had been and still were shielding, IGARD suggested that consideration be given to patient and public involvement (PPI). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and noted NHS England's statutory obligation and the General Data Protection Regulation (GDPR) Article 14, the "right to be informed". *Data Services for Commissioners Regional Offices **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the data flows and section 5 a. To provide a clear narrative of the data flows, data access and data location at all stages under this application; b. To clearly outline where the data is flowing from and to; c. To align the application and supporting documentation to remove any contradictory text in relation to the data flows. The following amendments were requested: 1. In respect of data minimisation: a. To update section 3(b) to clearly articulate how the data is minimised eg only those patients with a positive CV19 result; b. If it is not possible to minimise the high cost drugs to only those drugs of interest, to provide a justification in section 5 of why the entire data set is flowing. 2. In respect of section 3(b) a. To update the "sensitivity" category, if relevant; b. To provide an explanation as to why COPI is being relied on for an application for pseudonymised data. 3. To update sections 3 and 5 that type 1 objections will not apply. 4. To clarify in section 5 the data flowing back to EMIS and TPP eg one data flow or two. 5. To set out in section 5 any oversight that is being undertaken for the use of data by EMIS and TPP. 6. To amend section 1(c) to include AWS as a Data Processor. 7. To provide an explanation in section 5 regarding the use of and approach of using SALT. **8.** To amend section 5 to ensure that all acronyms upon first use be defined and further explained, as may be necessary for a lay reader. 9. To amend section 5 to ensure the use of technical jargon is used only where necessary such as "SQL" and "level 1, level 2". 10. In respect of the DPIA a. To provide a copy of the DPIA, and b. To upload a copy to CRM. 11. To clarify why NHS England is listed as a storage location in section 2, if in fact the data remains with the EHR vendors. The following advice was given: 1. Given the valuable research being undertaken with potentially direct and significant impact on citizens – particularly clinically vulnerable and extremely clinically vulnerable citizens – IGARD suggested that consideration be given to PPI. It was agreed the conditions would be approved OOC by IGARD Members.
2.3	<u>Imperial College London: MR1108: CT colonography, colonoscopy, or barium enema for diagnosis of colorectal cancer in older symptomatic patients: SIGGAR1 (Special Interest</u>

	Group in Gastrointestinal and Abdominal radiology). Plus SOCCER (Symptoms of Colorectal Cancer Evaluation Research). (Presenter: Louise Dunn) NIC-291981-Y7J2F **Application:** This was an amendment application which had come for advice on the consent materials and whether these are sufficient enough for the 'consent' to meet the common law duty of confidentiality. The study follows on from an earlier study on bowel cancer symptoms, with the aim of providing evidence that is needed to show whether flexible sigmoidoscopy (a technique which examines only the last [distal] part of the colon) is an effective and safe alternative to whole colon examinations for many people; which may change how doctors diagnose bowel cancer in their patients based on their symptoms. **Discussion:** IGARD noted that this was a long running study and that the applicant would be permitted to continue to hold and processing already disseminated data, and that a short term 6 month extension had been approved via the NHS Digital precedent: 'Short Term Extensions and Renewals'. The application had previously been considered on the 30th January 2020 when IGARD had deferred making a recommendation. In respect of those members of the cohort who were already covered by the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support, IGARD were supportive of NHS Digital's analysis that the s251 support was up to date and valid, and that the common law duty of confidentiality had been addressed adequately for those patients in this cohort. **Consent Materials Review:** In respect of those members of the cohort that were covered by the consent materials, IGARD were supportive of NHS Digital's analysis that this cohort did not have adequate patient information or detailed consent processes describing the linkages taking place, but that the website had been updated with regard to what was happening. IGARD noted that the consent was not compatible with the proposed processing and considered a number of remedial options. Since the consent was incompatible in such a far reaching way IGARD considered that even direct communication with the consented cohort would not be a sound approach. Given the time elapsed, IGARD would be supportive of the applicant either seeking s251 support for the whole consented cohort, however if this was not possible, that the applicant reconsent the current cohort and then apply for s251 for those deceased cohort members or cohort members who do not respond to the re-consent request. **Application review:** IGARD did not review nor give any comments on the application presented and noted that NHS Digital had extended, under precedent, the application to the end of March 2021. **Outcome:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed.
2.4	University of York: Does the transition from paediatric to adult healthcare lead to increased healthcare usage for young people with a life limiting condition? A quasiexperimental study (Presenter: Louise Dunn) NIC-331607-P4J8H **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for the purpose of research to determine whether there is an increase in healthcare use (particularly emergency healthcare use) when children with life limiting conditions transition from children to adult services.

	The main group of interest to the research is a cohort of children and young people aged 12-23 with life limiting conditions. The research aims to determine the effect of transition on healthcare use, particularly emergency healthcare use and to estimate the costs of any change in healthcare use at the transition. The application was been previously considered on the 30th January 2020 when IGARD had deferred pending: to clearly align the table in section 3(b) with the narrative in section 1 in respect of what is happening with the comparator groups; to clarify the years that the data is being obtained, to justify the quantum of data requested and to confirm the years (age range of cohort participants); in accordance with section 3, to update section 5 with further clarity on the cohort, the study years and when the "study period" runs from; to clarify in section 3 the statement that the data requested is low risk; to update section 1 and section 5(a) with further information of the *"life limiting"* conditions referred to (for example, the number of conditions that will be captured in the cohort); to update section 5(a) with further information on the *"wider research"* referred to and (in the absence of a study protocol) the other parties involved; to update section 5(a) with further information on the "Martin House Research Centre", what their role is and if any other organisations are involved; to update section 5(a) with further clarity of how the data requested and processing proposed will translate into improved care for young people; to update section 5(a) with further information on the data minimisation efforts undertaken in respect of each aspect of the cohort/comparators; to update section 5(b) to ensure the use of technical phrases is used only where necessary; and where it is necessary, to be also written in language suitable for a lay reader; to update section 5(c) to align with the benefits in section 5(d) and the purpose of process outlined in section 5(a); to provide further information in section 5(c) outlining how the benefits and outputs of the study will benefit **national** children's hospices and national transitional care for young people (in light of national data being requested); to provide definitive written confirmation that Ethics Approval is not required or otherwise that any internal/University-specific processes have been followed. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted their previous deferral point 1 with regard to '*comparator group*' and deferral point 8 with regard to '*data minimisation*' and suggested that in addition to the information provided, that a brief narrative be included in section 5 (Purpose / Output / Methods) detailing how the comparator group had been created. IGARD noted their previous deferral point 5 with regard to the '*wider research*' and in addition suggested that section 5 be updated to reference that Clinical Practice Research Datalink (CPRD) process 'pseudonymised' data. IGARD noted their previous deferral point 6 with regard to '*Martin House*' and suggested that it be made clear in section 5 that both Martin House Research Centre and Martin House Children's Hospice were **not** involved in any activity that could lead them to be considered a joint Data Controller. IGARD noted reference to s251 in table 3(b) (Additional Data Access Requested) and suggested this be removed, since it was not relevant. IGARD queried reference to "…G*ender will be coded as male, female or not known….*" being requested and asked that the datasets requested in the application aligned with the specific NHS Digital data that can flow, for example 'sex' vs 'gender'. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** recommendation to approve

	The following amendments were requested: 1. To update section 5 to refer to CPRD processing "pseudonymised" data. 2. To make clear in section 5 that Martin House Research Centre and Martin House Children's Hospice are not involved in any activity which could lead them to being considered a joint Data Controller. 3. To provide a brief narrative description in section 5 of how the comparator group were created. 4. To remove from section 3(b) reference to s251 since it is not relevant. 5. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example 'sex' vs 'gender'.
2.5	<u>University of Bristol: REducing unwarranted variation in the Delivery of high qUality hip fraCture services in England and Wales; the REDUCE study (Work package 1) (Presenter: Louise Dunn) NIC-334549-B1Y6X</u> **Application:** This was a new application for a one-off extract of pseudonymised Hospital Episode Statistics (HES), Civil Registration, HES Civil Registration (death) bridge file, for the purpose of a study investigating sources of variation in the delivery of hip fracture care and its effects on patient outcomes for the REDUCE study. The REDUCE study is a 3-5 year funded programme of work which commenced on the 1 October 2019 and consists of three work packages. This application is for work package 1. Work package 1 will link audit and publicly available data sources, detailing how fracture services are delivered at each hospital. This will include for example, how busy the hospital's emergency department is each year and how often patients are delayed before being found a bed, how many orthopaedic surgeons, orthogeriatricians and specialist fracture nurses each hospital employs, whether weekend orthogeriatrician cover is routine, how frequently anaesthetics for hip fracture are given by senior anaesthetists, how much post-operative physiotherapy is usually delivered, what access to rehabilitation beds is available, whether services have routine multi-disciplinary clinical governance meetings, whether bone density scanning equipment is available on site, and much more. The research group will determine which components of these hospital services account for poor patient outcomes, and which services successfully lead to good patient outcomes. NHS Digital noted that Health Research Authority Confidentiality Advisory Group (HRA CAG) approval was in place until October 2020 and a copy of the CAG register had been uploaded to the NHS Digital customer relationship management (CRM) as a future supporting document. **Discussion:** IGARD noted in section 5 (Purpose / Methods / Outputs) that hospital summary reports would be produced outlining the strengths and vulnerabilities of the Hospital Trusts and would be used for selected qualitative interviews. However, noting that some Trusts may be identified as 'low performing' that careful discussion be undertaken with the Trusts to establish if there was any explanation for the variations, such as population or patient profiles. IGARD noted in section 5(a) (Objective for Processing) that "…*the research team will cost NHS resources used in the year post hip fracture using ICD10…*" and asked that a narrative be provided in the public facing section as to why ICD10 codes were being requested. IGARD noted in section 2 (Storage Locations) three sites listed for the University of Bristol, however, in section 5(b) (Processing Activities) storage was noted as "...*its secure storage*…" in the singular, and suggested that either section 2 or section 5 be updated to reconcile the storage arrangements for the University.

	IGARD noted in section 5(a) reference to HES Admitted Patient care (APC) for the period 2006-2020, however section 3(b) (Additional Data Access Requested) requested data from 2013/14 to latest available. Since the dates did not tally, IGARD suggested that either section 3(b) or section 5(a) be updated to reconcile the data years requested for HES APC. IGARD noted in section 5(c) (Specific Outputs Expected, including target dates) reference to "…*the data produced by this study will inform Public Health England (PHE) for whom elimination of health inequalities is a priority target*…" and suggested the narrative be amended or removed, since it is not PHE's role to 'direct'. IGARD queried the benefits outlined in the section 5(d) (Benefits) and noted the declarative statements used, such as "…*findings **will** inform future commissioning*…", rather than the "…*findings **may** inform future commissioning*…" 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 statement "…*Reports will be made publicly available, making patients more 'in control', by being informed of their local hospital performance*…", and suggested the applicant reword the section since a patient with a broken hip may not necessarily be 'in control' of the hospital they are attending in the first instance after fracturing their hip. **Outcome:** recommendation to approve The following amendments were requested: 1. To provide a narrative in section 5 of why the ICD10 code data is being requested. 2. To update section 2 or section 5 to reconcile the storage arrangements for the University of Bristol. 3. To update section 3(b) or section 5 to reconcile the HES APC data years requested. 4. To revise the wording in section 5(c) or remove reference to PHE. 5. To revise the language in section 5(d), including reference to "will" and ensure that the benefits are realistic and achievable. 6. To reword section 5(d) to reflect that patients would not be "in control". The following advice was given: 1. IGARD noted that the Hospital Trust summary report would be used for selected qualitative interviews, but suggested that careful discussions be undertaken with the Trusts who may be identified as being "low performing" to establish if there was any explanation for the variations such as population or patient profiles.
3	<u>Returning Applications</u> 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.
4	<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 18th August can be found attached to these minutes as Appendix C. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
5	AOB: 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.
5.1	NIC-172334-W0G2L - Imperial College London NHS Digital noted that the application had been approved under a previous version via SIRO precedent for 1 year, and therefore the conditions remained outstanding on the version which had been approved by IGARD on the 13 February 2020. IGARD noted that when the application returned for independent review, the conditions would still be 'live' and to have been updated to be in line with NHS Digital's DARS standards.
5.2	NIC-381078-Y9C5K - Health Data Research UK NHS Digital noted that the application had been recommended for approval at the meeting on the 23 July 2020. Noting that at the time, discussion had taken place to include up to 16 Data Controllers, IGARD agreed with NHS Digital's approach that the application should not be brought back each time a new Data Controller was added, but asked that for transparency of process, an update be provided at IGARD detailing the summary of variables for each new Data Controller so that it could be included within published minutes.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 14/08/20

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-141410-W6H4Y	University College London	09/07/20	1. To provide written confirmation that the Ethics support is continuing, for example, that the appropriate Ethics Annual Reviews have been submitted and are up to date, and that any required steps to update the Ethics Review Panel of the amendments to the study have been taken.	IGARD Members	Quorum of IGARD Members	**In relation to amendment point 6** – *"Exercising the NDO would not stop their health data being made available for any non-clinical uses for similar projects in the future", since this is a use of pseudonymised data. we would suggest the applicant seeks advice from the relevant data protection staff within their institution."*
NIC-365492-H6D6V	NHS Blood and Transplant	18/06/20	1. To provide any quantitative data available for the numerous categories of s251 support, for example numbers of patients allocated to various categories or numbers per Trauma Centre. 2. To clearly articulate what objective criteria is applied to ensure the appropriate and consistent use of the s251 support; and to clarify that all efforts have been taken to obtain informed consent before applying s251.	IGARD Members	Quorum of IGARD members	*"IGARD have requested that in relation to condition 4b (To make it explicitly clear within the application that NHS Digital data is not being shared and the territory of use is England and Wales.), because it is not explicitly clear that the US centres cannot use the data (only that the agreement*

			3. To update section 5 to provide further information of who makes the judgement on subjective criteria and what checks and balances are undertaken when relying on subjective criteria (for example, to ascertain whether a patient could be classed as *"distressed".* 4. In respect of the US study: a) To provide confirmation and a clear description of the interplay between this study and the US study. b) To make it explicitly clear within the application that NHS Digital data is not being shared and the territory of use is England and Wales.			*doesn't cover them - but that is a different statement). We would request that this is stipulated in a special condition in section 6. If section 6 is updated then we are content that all conditions are met."*
NIC-114652-L3R2T	NHS Blood and Transplant	18/06/20	1. In respect of the US study: a) To provide confirmation of the interplay between this study and the US study. b) To make it explicitly clear within section 5 of the application that NHS Digital data is not being shared and that the territory of use is England and Wales. 2. In respect of the transfer of data between the different processing locations for the data management and statistics limbs of the data processing: a) To confirm why NHS Digital data is requested on a quarterly basis. b) How is the NHS Digital data being transferred. 3. To provide a further explanation of the statement in the Patient Information Sheet,	IGARD members	Quorum of IGARD members	With reference to condition 1b this is stipulated in a special condition in section 6.

			that states *"We would like to continue to monitor you for safety"*. 4. To ensure that the consent enables the required flows of patient data if they are obtaining the final mortality data after 12-months has elapsed, since the recruitment to the trial.			
NIC-12828-M0K2D	Imperial College London	25/06/20	1. In respect of the 2 years overlap of the ECDS and HES A&E data, to either provide a detailed justification of having 2 full years of (largely) duplicated data, or to produce a shorter timeframe to carry out the requisite checks, with the option to request further data for comparison purposes if necessary.	IGARD members	Quorum of IGARD Members	N/A
NIC-381972-Q5F0V	University College London	25/06/20	1. In respect of the Licence which has expired: a) To provide evidence of the renewed Licence which clearly covers the expanded use purpose and cohort. b) To amend the Licence special condition in section 6, to reflect the expanded use and purpose. 2. In respect of the Ethics Approval: a) To provide a copy of the Ethics Approval specifically addressing the expanded purpose as described in the application and the expanded cohort. b) To upload a copy of the Ethics approval to NHS Digital's CRM system. 3. To provide an appropriate justification of why the full cohort linking the data of 18 million children and young people is required, and why less data, for example	IGARD members	Quorum of IGARD members	N/A

			smaller geographical strata, won't suffice (refer to NHS Digital Data Minimisation Standard and GDPR).			
NIC-384781-J8H2K	NHS Wakefield CCG	06/08/20	1. To make clear throughout the application in respect of the re-identification of patients, if this is the re-identification of a 'group of individuals' or an 'individual(s)'.	IGARD Chair	IGARD Chair	N/A
NIC-387297-J5L7M	NHS North Lincolnshire	06/08/20	1. To make clear throughout the application in respect of the re-identification of patients, if this is the re-identification of a 'group of individuals' or an 'individual(s)'.	IGARD Chair	IGARD Chair	N/A
NIC-387358-H3Z2J	NHS Birmingham and Solihull CCG	06/08/20	1. To make clear throughout the application in respect of the re-identification of patients, if this is the re-identification of a 'group of individuals' or an 'individual(s)'.	IGARD Chair	IGARD Chair	N/A

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

In addition, a number of applications were approved under class action (addition of Liaison Financial Service and Cloud storage):

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 19th August 2020

Application: DARS-NIC-396113-N9L4L-v0.2 **Organisation name: NHS England** **Profession Advisory Group Agenda item: 4**
PAG members noted there is a potential conflict of interest from the Chair Arjun Dhillon on this application, as he is a GP Principal in one of the geographical areas of the potential study. PAG recognised the importance and innovative nature of the work, but noted that the GDPPR was not being minimised to either the cohort, or the cohort and subset of the population to match. PAG recommend that the data be minimised to appropriate patients enrolled to the new service delivery model of interest. Patients should be informed that their data will be used in this way. If a matched cohort is required or wider data within the geography of interest this should be justified within the application. We note that researchers have minimised the data by code cluster. The application therefore needs to address this point. If satisfactorily addressed, then PAG support the application. PAG members note the importance of the application and its work for addressing a potential service at the time of a pandemic. PAG support the application if the above issues are addressed. Please note this is not a professional endorsement from BMA or RCGP of the novel service, as this is beyond the scope of PAG.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC 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, 18 August 2020

In attendance (IGARD Members):	Prof. Nicola Fear (Specialist Academic Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Geoff Schrecker (Special GP Member)
In attendance (NHS Digital):	Prof. Jonathan Benger (Clinical Director – item 3.4)
	Vicky Byrne-Watts (DARS – items 3.2-3.4)
	Dave Cronin (DARS – item 3.1)
	Liz Gaffney (DARS – Item 2)
	Rachel Habergham (Product Development – item 3.4)
	Karen Myers (IGARD Secretariat – Observer)
	Heather Pinches (DARS – item 3.1)
	Kimberley Watson (DARS)
	Vicki Williams (IGARD Secretariat)
In attendance (external):	Emily Cross (IBM (external) – item 2 only)
	Stephen Pettitt (IBM (external) – item 2 only)

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:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2	<u>IBM update</u> IGARD members were given a brief update to the IBM work underway in NHS Digital including improvements to the customer experience and current projects. It was agreed that this would be a weekly update to the COVID-19 response meeting.

	IGARD members thanked IBM and NHS Digital for the update and suggested that IGARD should be included early in any process or drafting changes including, but not limited to, application checklists, standards and precedents.
3.1	NIC-396423-H4Z6Z University of Oxford **Background:** This is a new application to utilise the Permission to Contact Service. This is the first application from the University to use COVID-19 Permission to Contact data (CV19 PtC). The trial will enable the University to assess how well people of all ages (approximately 5,260 volunteers) can be protected from COVID-19 with a new vaccine and will generate valuable information on safety aspects of the vaccine and its ability to generate good immune responses against the virus NHS Digital noted that this was the first application for the CV19 PtC data. In addition NHS Digital noted that since submission of the documentation for review, they had received an updated protocol version 10 which had been approved by the Research Ethics Committee (REC) on the 12th August 2020. **IGARD Observations:** IGARD members discussed future steps and were assured by NHS Digital that work was ongoing with the applicant to address any ongoing issues and to support the drafting of consent materials which would support any future proposed processing or linkage in future applications to NHS Digital. IGARD members noted that section 5(e) (Is the purpose of this application in anyway commercial?) should be expanded to include, but not limited to; • specifically naming the pharmaceutical company involved in the production of the vaccine, • to amend the sentence "…*in this instance, the benefit to the global population outweighs the commercial interest of the pharmaceutical company*" to the commercial benefit being "*proportionate*" to the potentially significant benefit accruing to health and social care in England and Wales, • that the application had been through the CV-19 prioritisation process and supported, and • describing any "*benefit in kind*" or indirect financial benefit that might be provided by NHS Digital to the pharmaceutical company (eg benefiting from the existence of the PtC service to recruit volunteers) alongside the direct commercial benefits accruing from commercialisation of the vaccine. IGARD members noted the update from NHS Digital with regard to the updated protocol version 10 and that REC approval had been granted, and suggested a copy of all documentation be uploaded to NHS Digital's Customer Relationship Management (CRM) system for any future audit. NHS Digital noted that the application would be approved under the SIRO precedent for the COVID-19 work being undertaken, and given the time pressures, IGARD members were supportive of this approach in this instance.
3.2	NIC-397618-T8L8Z NHS England (Quarry House)

	Background: this was a verbal update to the application which was due to be presented to the business as usual (BAU) meeting of IGARD on Thursday, 20th August 2020. OpenSAFELY is a new secure analytics platform for electronic health records in the NHS, created to deliver urgent results during the COVID-19 pandemic. NHS England will use the OpenSAFELY platform to process community local flow Provider data to deliver specific analysis on various medications with potential to identify treatment targets or identify currently unknown risks to patients on these medications and to examine the association between the use of immunosuppression to treat immune mediated inflammatory diseases and sever COVID-19 outcomes amongst adults in England. **IGARD Observations:** IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 20th August 2020 with a copy of this minute extract appended to IGARD's published minutes IGARD Members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update, however asked that a copy of the Direction relied upon for the processing of the data for this research activity, along with relevant Information Governance (IG) analysis of the legal basis, was provided ahead Thursday's meeting.
3.3	<u>NIC-372791-X0H3Q NHS Blood & Transplant (NHSBT)</u> **Background:** this was an update to verbal presentation to the COVID-19 response meeting on the 28th July 2020. The amendment is to request the GDPPR data to support outbound calling to contact individuals who have been given a diagnosis of COVID-19 to discuss with the individual if they wish to donate Convalescent Plasma, whether the individual is eligible to donate plasma and to book an appointment. NHSBT is already in receipt of pillar 1 and pillar 2 data. This work will continue to support the REMAP-CAP and RECOVERY Trials. Previous data releases under v0 and v1 of this this agreement have been facilitated and finalised by signed letters from the NHS Digital Information Governance (IG) directorate. The initial request approved under v0 and v1, was to provide contact details for individuals who fit the criteria for collection of convalescent plasma which is being explored as a possible treatment for COVID-19. NHSBT routinely collects plasma from donors who have registered directly as part of their statutory function. **IGARD Observation:** IGARD members noted the efforts undertaken by NHS Digital and the applicant to update the application following its verbal presentation to IGARD on the 28th July 2020. IGARD members noted that the application would be presented to the Profession Advisory Group (PAG) on Wednesday, 19th August, before it was presented to the IGARD BAU meeting on Thursday, 27th August 2020. IGARD members reiterated their point that the application set out how 'Teleperformance', as a processor of confidential patient information (CPI) satisfies the requirement in Regulation 7(2) of the Health Service (Control of Patient Information Regulations) 2002 (COPI) and that the relevant NHS Digital information governance (IG) advice received be appended as a

	supporting document for both PAG and IGARD review and relevant narrative be included in section 1 (Abstract). IGARD members noted that section 3 (Patient Objections) should be updated to be clear that patient objections had been applied. Noting that NHS Digital had produced transparency materials for GPs, IGARD members suggested that a review of the overarching privacy notice for GP's be undertaken to ensure it covered the processing and purpose outlined in this application.
3.4	<u>NIC-396113-N9L4L Imperial College London (ICL)</u> **Background:** this was a verbal update to the application which was due to be presented to the business as usual (BAU) meeting of IGARD on Thursday, 20th August 2020. This is a new application looking at providing Pulse Oximetry in the home (including residential and care homes) for patients to measure their own oxygen levels. The data can be used to determine when someone should no longer stay at home and go to hospital for further treatment and early indications are that this could reduce the length of stay and improve outcomes. NHS England have agreed to pilot Virtual Wards to evaluate their effectiveness in the treatment of COVID-19. **IGARD Observations:** IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 20th August 2020, and that it was to be presented following a review by the Profession Advisory Group (PAG) on Wednesday, with a copy of this minute extract appended to IGARD's published minutes IGARD Members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital, and, in particular, Professor Benger and Rachel Habergham, for their verbal update.
4	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.