Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 4 February 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair (Chair: item 2.2 and item 3.5)
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member (Acting Chair: item 3.4)
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:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS) (Observer: item 3.4)
Liz Gaffney	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 1 - 3.3)
Karen Myers	IGARD Secretariat
Charlotte Skinner	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Access Request Service (DARS)

1	**Declaration of interests:** There were no declarations of interest.

	Review of previous minutes and actions: The minutes of the 28th January 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Papers**
2.1	<u>British Spine Registry - Briefing Paper (Presenter: Tom Wright)</u> The briefing paper and relevant supporting documents were provided to IGARD for review, including; the over-arching Briefing Paper for Clinical Registries (04.02.2020), Databases and Audits; the Clinical Registry Annexe (v1.3); and the transparency materials. The purpose was to inform IGARD about the British Spine Registry (BSR), which was established in May 2012, with the aim of improving patient safety and monitor the results of spinal surgery. The registry collects large volumes of clinical and patient outcome data for all who undergo particular operations. The information collected in this registry is analysed to increase the clinical understanding of an operation's success. The BSR was set up by the British Association of Spine Surgeons (BASS) to monitor the outcomes of spinal procedures, collecting valuable and insightful data, to better understand procedures and techniques and a patient's experience and quality of life. BASS aims to improve spinal care throughout the UK by encouraging research, audit and good clinical practice. It also aims to educate patients about spinal problems, the available treatments, expectations and quality of life. IGARD welcomed the overarching briefing on Clinical Registries and relevant supporting documentation, specifically in relation to the British Spine Registry. IGARD had no additional comments with regard to the overarching briefing note presented. NHS Digital advised IGARD that although BASS were a Data Controller, they currently had not submitted or had an entry on the Data Security and Protection Toolkit (DSPT). NHS Digital confirmed that they had received an explanation from NHS England advising that this was not deemed necessary, due to BASS only receiving fully anonymised data and not patient level data. IGARD noted and advised that NHS Digital should discuss this issue further with the NHS Digital Security Advisor and / or the DSPT Team. IGARD noted that within section 7 of the Clinical Registry Annexe, that the tick box relating to *"Direct Care"* had been ticked; and asked that as this was incorrect, this box was deselected. IGARD noted that within version 2 of the BSR patient information leaflet (PIL) dated '2018', there were statements that limited what can be done with the data, for example; that the data would not be shared with any third party; that the data would only be used for data analysis; and that the data would only be shared with Clinicians involved with the care of the participants. IGARD queried how many participants had received this particular PIL, as this was not clear within any of the documents provided. IGARD noted that that these limiting statements were a key area of risk, in terms of the common law duty of confidentiality (CLDOC) in respect of the processing undertaken by NHS Digital. In addition, IGARD noted that the transparency information on the BSR website, did also not address the UK General Data Protection Regulation (GDPR) legal basis and advised that this should also be updated accordingly. IGARD noted that the description of the 'Data Processor', Amplitude Clinical Solutions Ltd on the BSR website, appeared to be more aligned with a Data Controller; and asked for

	clarification as to whether they should be considered a joint Data Controller, in line with any analysis undertaken of the facts, as per the NHS Digital Standard for Data Controllers / Data Processors. IGARD queried the contradictory information within the supporting documents provided that stated both 31 days **and** 180 days when referring to keeping the data without consent; and asked that further clarity of which date was correct and the legal basis for holding the data for the period of time stated. IGARD looked forward to receiving an updated suite of documents with regard to BSR at a future IGARD business as usual (BAU) meeting and **before** any first of type applications are submitted.
2.2	Ambulance Data Set Pilot - Briefing Paper (v0.5) The briefing paper was to inform IGARD about the Ambulance Data Set (ADS) pilot, which is being led by NHS England and NHS Improvement, who have commissioned NHS Digital to develop a dataset via a work package under a Provision of Services Agreement (POSA). The pilot is to implement the processing of emergency and urgent care related data collected by English Ambulances Services to NHS Digital with key operational data items in "*near real-time*" and other key data items to be linked to the Emergency Care Dataset (ECDS). A two stage approach has been developed to pilot operational (Computer Aided Despatch – CAD) and then clinical data (Electronic Patient Record – EPR) collection and transfer. The project will produce interim and full impact assessments and options appraisals on both the operational and clinical components. A successful pilot will result in a data set that produces "*dashboard*" type operational information available in 15-minute intervals from data receipt. The direction is limited in scope to the pilot activity and as such is known as a "discovery Direction". IGARD noted that this briefing paper had been presented at the IGARD – NHS Digital COVID-19 Response meeting on the 7th January 2021, where a number of observations had been made. IGARD welcomed the updated briefing paper and confirmed they had no further comments to make and look forward to receiving applications in due course along with a copy of this briefing paper (first couple of applications only) as a supporting document.
3	**Data Applications**
3.1	University College London (UCL): Family, household and environmental risk factors for hospital admissions in childhood (Presenter: Vicky Byrne-Watts) NIC-234656-C3J1D (v2.12) **Application:** This was an amendment application, to link additional data to the existing birth cohort, via the Office for National Statistics. This additional data includes linking mothers and babies in the birth cohort to longitudinal environmental exposure using postcode histories in the Personal Demographics Service (PDS). In addition, the DSA has been updated to reflect one UCL PhD student will access the pseudonymised data. The purpose is for a project, examining environmental and household risk factors for preventable hospital admissions in children, and whether children whose parents were born abroad face barriers to accessing preventive primary and community health services, which in turn leads to the need for hospital admission.

	Discussion: IGARD noted the statement in section 5(a) (Objective for Processing) *"To allow NHS Digital to apply patient objections to the data, as approved by IGARD."*, and asked that this incorrect statement was removed since IGARD did not approve patient objections. IGARD noted that the reference throughout section 5(a) to *"HES IDs"*, and asked that this was either expanded to provide further clarity; or that a supportive explanation was provided for the acronym upon first use. IGARD queried the reference in section 5(b) (Processing Activities) to the '*ONS policy for safeguarding data whilst managing Admin Data Research Network projects*' document; and asked that the reference to this document was either removed, or that a publicly accessible link was provided to the document. IGARD noted the references in section 5(d) (Benefits) to "*cost savings*" for the NHS, and asked that this was updated throughout to either removes these references, as this information was not necessarily accurate; or to reorder, to ensure the benefits to the patients were prioritised. IGARD noted that section 5(d) (iii) (Yielded Benefits) had not yet been populated, and asked that this was updated to reflect the work that has been undertaken and the benefits accrued, since the application was last seen by NHS Digital; or to provide a brief and up to date explanation as to why there were no yielded benefits to date. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to either expand, or provide a supportive explanation for, the *"HESID"* acronym upon first use. 2. To remove reference to IGARD approving patient objections in section 5(a). 3. To update section 5(b) to remove the reference to the ONS "*document"* or to provide a publicly accessible link. 4. To update section 5(d) to remove references to cost saving, or reorder to ensure the benefits to the patients are prioritised. 5. To amend section 5(d) (iii) to populate the yielded benefits accrued, or to provide a brief explanation as to why there are no yielded benefits to date.
3.2	<u>University of Oxford: The short and long-term cardiovascular consequences of critical illness: The C3 Study (Presenter: Vicky Byrne-Watts) NIC-352725-V1X2R (v0.13)</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration data. The purpose is for a study, designed to find out which patients are at risk of heart attacks / strokes up to several years after discharge from an Intensive Care Unit (ICU); and whether treatments and events occurring in ICU contribute to this risk. This study will provide new knowledge about the associations between baseline cardiovascular risk, the disease resulting in ICU admission and therapies / events on ICU with subsequent major adverse cardiovascular events (MACE) events, to allow the ongoing risk of these events to be determined. This may identify modifiable risk factors and allow for preventative treatments, improving the health outcomes of this vulnerable group of patients. **Discussion:** IGARD noted and commended the applicant and NHS Digital on the quality of the application submitted for review. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and queried if this was correct, for example, was the data being backed-up to a different storage

	location, since other University of Oxford applications had this facility; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate. IGARD queried reference to "*gender*" in section 5(b) (Processing Activities), and asked that the datasets requested in the application aligned with the specific NHS Digital data that can flow, for example requesting 'sex' rather than 'gender' if "sex" is what is captured in the dataset. IGARD noted the statement in section 5(a) (Objective for Processing) *"The dissemination of the aggregated results of this study pose no risk to the public"*, and asked that this statement was reviewed, and modified as appropriate to reflect that this was in the applicant's opinion after due consideration. IGARD noted reference to the word *"survivor"* in section 5 (Purpose / Methods / Outputs), and suggested that the applicant may wish to consider reviewing the use of this word, when used as a description of patients who have been in an intensive care unit (ICU). IGARD suggested that the applicant reviewed their patient facing materials to ensure they did not give the impression that they would retrospectively review data received, in the event that a patient exercised the National Data Opt-out subsequent to the data flowing. **Outcome:** recommendation to approve The following amendments were requested: 1. To consider if there are any additional storage locations and to amend section 2(b) if appropriate. 2. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example requesting 'sex' rather than 'gender' if "sex" is what is captured in the dataset. 3. To review the statement in section 5(a) in respect of there being *"no risk"*, and to modify to reflect that this is in the applicant's opinion after due consideration. The following advice was given: 1. IGARD suggested that the applicant reviewed their patient facing materials to ensure they do not give the impression that they will retrospectively review data received, in the event that a patient exercised the National Data Opt-out subsequent to the data flowing. 2. IGARD suggested that the applicant may wish to consider reviewing the use of the word *"survivor"* when used as a description of patients who have been in ICU.
3.3	<u>University of Oxford: CPinBOSS Study - Cerebral Palsy in the British Orthopaedic Surgery Surveillance Study (Presenter: Vicky Byrne-Watts) NIC-324368-Q0H5T (v0.12)</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data; for the purpose of a study, aiming to identifying the total number of patients with cerebral palsy, that are eligible for Single Event Multi Level Surgery (SEMLS), for example, the incidence of children with cerebral palsy who fulfil the criteria for this type of surgery; and to look at the variation in the surgeons' criteria in selecting children for surgery by analysing the children's clinical characteristics. SEMLS is a surgical intervention that involves a minimum of two surgical procedures (bony or soft tissue) undertaken at a minimum of two different levels (e.g. hip and knee or thigh and calf) with the objective to improve walking function within cerebral palsy patients. There are

	major differences between the Trusts that perform SEMLS in terms of patient selection and the choice of the specific surgical interventions. **Discussion:** IGARD noted the importance of the research being undertaken and welcomed the application. IGARD noted that national data had been requested for the study, and queried why national data was required since it was not clear within the application. IGARD asked that further justification was provided and in addition, queried whether, this could be filtered, for example by participating NHS Trust, since only 19 Trusts had been identified in the application. IGARD noted in section 5(b) (Processing Activities) the extensive range of data fields listed, for record level data of Hospital Episode Statistics Admitted Patient Care, and queried why, for example, ethnicity data was required since it was not clear in the application, and asked that further clarity was provided. IGARD also asked that confirmation was provided in section 5 (Purpose / Methods / Outputs) of how the data fields listed in section 5(b) were being utilised for non-identifying **case ascertainment**, as referenced throughout section 5. In addition, in respect of case ascertainment, IGARD queried the apparent inconsistent narrative in section 5 , that referred to *"Live data-links that would be established to identify potential missed or duplicate cases"*; and asked that this was reviewed and updated as appropriate. IGARD also queried how case ascertainment, purely on case number counts, was compatible with the narrative, which may suggest there may be re-identification activity by the lead surgeon or others, since it was unclear how a duplicate could be spotted if it had not been identified as a duplicate. IGARD asked that section 5 was updated to provide a clear explanation; or that if this was case ascertainment purely on numbers, to explain how this process was practical and manageable for the NHS Trusts receiving the data. IGARD noted that section 5(d) (Benefits) appeared to infer that there was a larger study, and asked that section 5(d) was updated to expand on the information provided and to provide an explanation of how this study fitted in with any larger study, as this had not been clearly articulated in the application. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and queried if this was correct, for example, was the data being backed-up to a different storage location. since other University of Oxford applications had this facility. IGARD asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate. IGARD suggested that, noting that much of the language within the public facing content of the application had been carried over from a scientific protocol; that a careful review was undertaken of the language used, for example, changing the reference from *"…how patients with Cerebral Palsy are surgically managed..."*, to refer to the *"condition"* being managed. Separate to this application, IGARD suggested NHS Digital may wish to raise with the applicant the wider issue of what the legal basis was for the broader activity referred to within the applicant, particularly patient details collected on the database and how they do this, and then follow that patient, without consent; and to upload any evidence on to NHS Digital's customer relationship management system (CRM) for future reference. IGARD advised NHS Digital that they were able to offer support to the applicant out of committee in order to support the study.

	Noting that this application was to be deferred, IGARD advised that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** Recommendation to defer, pending: The following advice was given: 1. In respect of the data requested: a) To provide justification of why **national** data is required, for example, could this this be filtered by participating NHS Trust. b) To clarify why the extensive range data fields, for example ethnicity data, is required. c) To provide further confirmation of how the data fields listed in section 5(b) are being utilised for non-identifying **case ascertainment**. 2. In respect of the case ascertainment statement in section 5: a) To update the apparently inconsistent narrative in section 5 that refers to live data links, and the ability to spot duplications. b) To update section 5 to provide a clear explanation of how case ascertainment, purely on case number counts, is compatible with the narrative, which may suggest there may be re-identification activity by lead surgeon or others. c) If this is case ascertainment purely on numbers to explain how this process is practical and manageable for the NHS Trusts receiving the data. 3. To update section 5(d) to expand the information provided that infers there is a larger study, and to provide an explanation of how this study fits in with any larger study. 4. To clarify if there are any additional storage locations and to amend section 2(b) if appropriate. The following advice was given: 1. IGARD suggested that, noting that much of the language within the public facing content of the application has been carried over from a scientific protocol, that a careful review was undertaken of the language used, for example, changing the reference from *"…how patients with Cerebral Palsy are surgically managed..."*, to refer to the *"condition"* being managed. 2. Separate to this application, IGARD suggested NHS Digital may wish to raise with the applicant the wider issue of what the legal basis is for the broader activity referred to within the applicant, particularly patient details collected on the database and how they do this, and then follow that patient, without consent; and to upload any evidence on to CRM. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3.4	<u>University of Bristol: University of Bristol - Longitudinal Linkage Collaboration (Consent) (Presenter: Louise Dunn) NIC-420168-K4N1F (v0.8)</u> **Application:** This was a new application for a pseudonymised Hospital Episode Statistics to Mental Health Minimum Data Set Bridge File, Cancer Registration, Civil Registration, Community Service Data Set (CSDS), COVID-19 Hospitalization in England Surveillance System, Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3), Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), Demographics, Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (GDPPR), Hospital Episode Statistics (HES), Improving Access to Psychological Therapies Data Set (IAPT), Medicines dispensed in Primary Care (NHS Business Services Authority data), Mental Health Minimum Data Set (MHMDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS),

	Personal Social Services Adult Social Care Survey and Personal Social Services Survey of Adult Carers. The UK Chief Scientific Advisor has established a programme of National Core Studies (NCS) for Covid-19 research as a coordinated, long-term, national research initiative. This will consider Covid-19 in terms of a viral pandemic and in terms of the health and social impacts of behavioural restrictions designed to mitigate the harms of the pandemic. The NCS has six different sub-programmes which are addressing major Covid-19 research areas; one of these is the Longitudinal Health and Well-being NCS which is designed to use data from longitudinal studies to address the impact of Covid-19 and of associated viral suppression measures on health and well-being. The LLC is the central hub component of the Longitudinal Health and Well-being NCS. This application is seeking approval to include the data of participants initially from the following University College London studies, 1) National Study of Health and Development (NSHD) and 2) Southall & Brent Revisited (SABRE). **Discussion:** IGARD welcomed the application which came for advice on the consent material and the description of the data, and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted that this application had **last** been seen at the IGARD – NHS Digital COVID-19 Response meeting on the 2nd February 2021. IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 3rd February 2021. IGARD noted the comments made by PAG and that PAG did not support the application in its current form. In respect of the consent materials, IGARD made the following comments: IGARD queried the information provided in supporting document 13, the Longitudinal Linkage Collaboration (LLC) NHS Digital Data Flow Diagram (version 1.1), that did not align with the information provided in supporting document 12, the study protocol (version 1); and asked that for transparency, it was made explicitly clear to the cohort what the role of the LLC was. In addition, IGARD also asked that the data and description of the data that flowed into the LCC was clarified to the cohort members. NHS Digital advised IGARD that the University of Bristol was leading on the development and onward sharing of the fair processing materials; and that they were relying on the individual study teams to communicate and share the materials with the study cohorts. IGARD noted the update from NHS Digital and were supportive of the proposed approach, in that individual studies, should ensure their cohorts were fully informed with regards to transparency. IGARD noted the statement in supporting document 1b, the MRC National Survey of Health and Development (NSHD) Participant Information Sheet (version 3), that *"Research data are stored separately from personal data (such as name and address) and can be linked through anonymised files that are accessible only to restricted members of the NSHD Study team."*, and asked if this was compatible with the processing outlined in the application. IGARD noted the information in supporting document 1b, to the NSHD Data Sharing Committee, which controls who has access to the NSHD data and queried if the Committee had reviewed and were content with the arrangements outlined in this application. IGARD also asked if a supporting document could be provided to demonstrate this had been done. IGARD noted the information in supporting document 2a, the Southall And Brent Revisited Study patient information sheet, that stated *"...we may share SABRE study data with other*

	research groups in the future...", and queried a seeming contradiction with information later in the document that stated *"The data we obtain will be stored securely at UCL, and used only for the purposes of the study by researchers employed by UCL."* Given that the latter statement is under the heading *"Your medical and health-related records"* which refers to NHS Digital, IGARD expressed a concern that it was incompatible with the information provided in the application. In respect of the data, IGARD made the following comments: Noting the data flow diagram was incorrect during the review of the consent materials, IGARD asked that this was updated to ensure it correctly aligned with both the application and the study protocol. IGARD noted that supporting document 4, the 'LLC: Anonymisation in Context Briefing Note', had been provided with further information in respect of the data, and discussed it at length. However it was IGARD's view that this was pseudonymised data, and that it was **not** anonymous. IGARD understood the argument that contractual and contextual controls would be employed so as to render the data anonymous in relation to researchers, but did not believe this was a concept within UK General Data Protection Regulation (GDPR) and felt for the argument to have force, it would need to be bolstered by regulatory guidance. Agreeing with this line of argument would also set a precedent for deeming pseudonymised data as anonymised depending on security and access controls in place, and have ramifications for many other NHS Digital disseminations. IGARD also requested sight of the advice from NHS Digital's Privacy, Transparency and Ethics (PTE) to the Data Access Request Service (DARS), in regard to the description of the data in the application and that this be in place before the application returned to IGARD for review. IGARD noted that Velindre University NHS Trust was listed as a Data Processor due to the fact it hosted the NHS Wales Informatics Service (NWIS), which was undertaking data linkage; however, advised that the security arrangements of the Trust did not seem to have been assessed and that the application be updated accordingly. **Outcome:** IGARD welcomed the application which came for advice on consent and the description of the data, and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD highlighted the following significant areas of risk: 1. The consent does not appear to be compatible with the processing outlined in the application. 2. If the data is classed as anonymous, through contractual and contextual controls alone, whether it adequately satisfies the UK GDPR. 3. There is a risk of setting a precedent in terms of handling, what could be considered anonymous data, and possible ramifications of onward sharing by other organisations wishing to handle disseminated pseudonymised NHS Digital data using this strategy. The following comments were made: 1. In respect of the consent: a) To make it explicitly clear to the cohort members what the role of the LLC is. b) To clarify to the cohort members the data and description of the data that flows into the LLC. c) That individual studies, ensure their cohort's are fully informed with regards to transparency.

	d) The MRC National Survey of Health and Development PIS version 3 is clear that linking files are accessible **only** to restricted members of the NSHD Study team and this seems incompatible with the processing outlined in the application. e) Noting the NSHD Data Sharing Committee as outlined in the PIS version 3, controls who has access to the data, to provide documentary evidence they have reviewed the application and are content with the arrangements. f) The Southall And Brent Revisited Study PIS states that the data obtained from NHS Digital will be used only for the purposes of the study by researchers employed by UCL, and this seems incompatible with the application. 2. In respect of the data: a) To provide a justification as to why the applicant is confident that data can be both anonymous and pseudonymous at the same time. b) IGARD requested the University of Bristol's analysis of why they consider this data to be non-personal data. c) IGARD requested sight of NHS Digital advice to DARS, with regard to the description of the data. d) To update the data flow diagram to ensure it aligns with the application and study protocol. e) The security arrangements of Velindre University NHS Trust do not seem to have been assessed.
3.5	<u>Department for Work and Pensions: (Presenter: Charlotte Skinner) NIC-350562-G6K9H</u> **Application:** This was a request for advice on the consent materials, for the 'Thrive into Work Health-led Employment Trial', which is testing a new type of job support, for people who have a health condition and / or disability, and are out of work and would like a job. The West Midlands Combined Authority is working with NHS England, the Department of Health and Social Care, and the Department for Work and Pensions to look at how to help people get back into work and continue working. **Discussion:** IGARD welcomed the consent materials which came for advice, and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted the potential conflicting information within the plain English patient information sheet, in respect of how long the data would be held for, and asked that the consent materials were made clear on this point, for example, updating the privacy notice, in line with NHS Digital's NHS Digital's Standard for privacy notices. IGARD asked that section 5 (Purpose / Methods / Outputs) was amended, to ensure that it was written in plain English, for example reference to "*fuzzy matched*", and was in a style suitable for a lay reader; or to update to provide appropriate lay summaries throughout. IGARD queried the information in section 3 (Patient Objections) that patient objections would be upheld, and asked that this was updated to correctly state that patient objections should not be upheld as this is a consented cohort. **Outcome:** IGARD welcomed the consent materials which came for advice, and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD were of the opinion, with the limited information available, that the consent was compatible with the processing outlined in the draft documentation provided. The following comments were made:

	1. The materials should be clear as to how long personal data will be held for, for example, updating the privacy notice, in line with NHS Digital's NHS Digital's Standard for privacy notices. 2. To amend section 5 to ensure it is written in Plain English and in a style suitable for a lay reader (or to provide appropriate lay summaries throughout). 3. To update section 3 to be clear that patient objections should not be applied. 4. To update the application throughout to ensure consistency with the trial run dates. 5. To remove from section 5(a) reference to '*there are no moral or ethical issues*".
4	<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-82493-P8Y3N v2.2 University of Essex • NIC-06605-X1L9Z v10.4 University Hospitals Birmingham NHS FT • NIC-291981-Y7J2F v5.2 Imperial College London • NIC-148130-46N08 v4.2 – University of Oxford IGARD welcomed the four 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.
5	<u>IG Covid-19 Release Register December 2020</u> IGARD noted that the IG Covid-19 Release Register December 2020 had been circulated and reviewed out of committee by members, and discussed and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate.
6	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 2nd February 2021 can be found attached to these minutes as Appendix C.
7	<u>AOB:</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 29/01/21

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-50975-X6N3J	University College London	29/10/2020	1. In respect of the National Data Opt-outs: a. To clarify whether NDO's have been applied at each stage where s251 support has been relied upon, or b. If NDO's have not been applied, to explain why not.	IGARD members	IGARD Chair, under Chair's Authority	

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

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

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-423553-H8D6H NHS Brighton and Hove CCG, NHS East Sussex CCG, NHS West Sussex CCG

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 3rd February 2021

Application & application version number: DARS-NIC-420168-K4N1F-v0.8 **Organisation name: University of Bristol** **Profession Advisory Group Agenda item: 2**
PAG welcomed and supported the underlining research intent. PAG discussed potential conflict of interest and concluded that none existed. The application is complex on a research, technical, legal and IG levels. To help move the research forward PAG suggest exploration in the following areas: 1. The application was not clear in its separation between its immediate needs and future ambitions (especially with regards to creating anonymous datasets). Perhaps applying for immediate needs will make this simpler. 2. PAG asked why any immediate research questions could not be completed in the NHS Digital TRE. Can NHS Digital support the work Bristol want to complete? 3. The Paper was not clear about the size of the population that will be linked more immediately. 4. PAG welcomed the paper on anonymisation (SD4) but felt it was not within it's remit to judge and approve its argument; PAG believes this needs to be discussed more formally within NHS Digital and related information governance groups. In its current form PAG do not support the application.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Liz Gaffney	Head of Data Access	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Pam Soorma	Secretariat	NHS Digital
Louise Dunn	Senior Data Approvals Officer	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, 2nd February 2021

In attendance (IGARD Members):	Prof Nicola Fear (IGARD Specialist Research Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Nicola Bootland (DARS)
	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:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2.1	NIC-422971-B8P2V NHS England / Imperial College London **Background:** this was a new application requesting GPES Data for Pandemic Planning & Research (GDPPR) data for the purpose of examining inequalities in breast cancer screening during the COVID-19 pandemic. The data will be used for service evaluation, not research purposes. The application had already been reviewed by the Profession Advisory Group (PAG) on the 20th January 2021 who had raised a number of queries which had been addressed by way of any update in section 1 and would be presented to the IGARD business as usual (BAU) meeting on Thursday, 11th February 2021. **IGARD Observations:**

	IGARD members noted this was potentially valuable and useful work and were supportive of the concept outlined. IGARD members noted the update from NHS Digital and that the application was to be presented to the IGARD business as usual (BAU) Meeting on Thursday, 11th February 2021. 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. To support DARS and the applicant prior to submission of any papers for the IGARD BAU meeting, IGARD members provided the following high-level comments: • Noting that the Cancer Trusted Research Environment (TRE) contains more than just data about confirmed cancer diagnoses (as per the draft response to PAG), to provide further justification as to why the applicant cannot consider the use of the Cancer TRE. • Similarly, a more detailed explanation was required why the NHS England OpenSafely platform could not be utilised. • To cross reference with the purpose outlined in application NIC-384608 to check if the data disseminated under that purpose could be utilized for the purpose outlined in the application, since they both appeared to relate to service evaluation. • Noted that DARS would discuss with the Privacy, Ethics & Transparency Directorate (formerly the Information Governance (IG) Directorate) the Data Controllership queries raised and how these fit under Regulation 3 of COPI, and to amend the application throughout to reflect the IG advice received. IGARD thought that the legal gateway for Imperial should be straightforward. • Noting reference within section 5 to "…*COVID-19 recovery*…" to be clear what it meant by this terminology for the lay reader for example recovery of the health service following its emergency footing. • IGARD members noted reference to a PhD student in section 5 and noted that since the data would be disseminated under emergency legislation that any PhD processing and outputs flowing from use of this data would have to be linked to the COVID-19 response to the pandemic only. **Significant risk areas:** data handling principles (minimising flows of data were possible).
2.2	<u>NIC-420168-K4N1F University of Bristol</u> **Background:** these was a verbal update to the updates that had been previously provided at the COVID-19 response meetings on the 8th December, 15th December 2020 and 15th January 2021, plus COVID-19 slot on the business as usual (BAU) meeting on the 21st January 2021. The application was to be considered at the BAU meeting on Thursday, 4th February. **IGARD Observations:** IGARD members noted this was potentially valuable and useful work. IGARD members noted the update from NHS Digital and that the application was to be presented to the IGARD business as usual (BAU) Meeting on Thursday, 4th February 2021.

	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. **Significant risk areas:** • The consent does not appear to be compatible with the processing outlined in the application • If the data is classed as anonymous through contractual and contextual controls alone, if this adequately satisfies UK GDPR • Risk of setting a precedent in terms of handling what could be considered anonymous data and possible ramifications of onward sharing by other organisations wishing to handle disseminated pseudonymised NHS Digital data using this strategy.
2.3	<u>Cancer Data Sets from PHE to be made available in the TRE – Briefing Presentation</u> **Background:** This was a verbal update to the pre-briefing presentation that had been disseminated out of committee to members for review, had been previously discussed at the COVID-19 response meeting on the 19th January and previously discussed at the IGARD business as usual (BAU) meeting on the 21st January. Additional points following those meetings had been circulated to the presenter ahead of the verbal update at today's COVID-19 response meeting. **IGARD Observations:** IGARD welcomed the pre-briefing verbal update presentation and looked forward to receiving a briefing note (on the relevant template). Key points to be addressed in the briefing paper included, but were not limited to: • To provide a briefing note, utilising the presentation and verbal discussion information to inform the paper including, but not limited to: o All comments previously made in-meeting or via OOC email. o Providing a copy of the updated Data Provision Notice as an appendix. o To provide further clarity on the customers involved by way of specific named customers, where known, and broad "categories" of anticipated future customers. o To clarify if Cancer Alliances are receiving an additional data flow and if there are plans for them to be part of a future TRE. o With regard to transparency materials available to the public, to be clear that if a patient wishes to have their data removed from or not transferred into the TRE that they need to exercise their NCRAS opt out, since the National Data Opt Out does not apply to cancer registration data. o To clearly articulate the level(s) of data that sit(s) in the TRE. o To clarify the legal bases for each stage of the process: the legal basis to go into the TRE, the legal basis in the TRE and, if relevant the legal basis to extract out of the TRE.

	o To clarify the legal basis for the identifying data going into the TRE, noting that COPI is short lived legal gateway, whereas the Cancer TRE appears to be a long term project. o IGARD would usually expect to see the legal basis for the collection of the original datasets that are being put into the TRE and provided as an appendix to the briefing paper. Cross references to the relevant data controller websites for the original collections may suffice in this instance. o To clarify the language throughout the documentation to ensure that the wording used is clinically correct such as removing reference to "non-malignant cancers" etc. • Noting that the briefing note would be a working document and updated as new information became available, to be clear where information was not available to add text such as "*this level of detail is not available at X date*" under the relevant briefing note header, and to then provide the briefing note with applications as a supporting document and updated as and when new information became available. **Significant risk areas:** transparency materials visible to the public, in particular regarding application of NDOs; specifically, those citizens who had applied for a NDO but may be unaware that their data was being captured for this data collection and that a separate cancer registry opt out was required to give effect to their wishes.
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.