Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 30th January 2020

In attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Maria Clark, Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance (NHS Digital): Dave Cronin, Louise Dunn, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Nicola Fear, Geoffrey Schrecker, Maurice Smith.

Observers: Liz Gaffney (NHS Digital)

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 23rd January 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	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. NHS Digital advised IGARD that the University of York had also requested data from the Clinical Practice Research Datalink (CPRD) for this research, and that this would provide more granularity of the primary care data; and that the NHS Digital data would provide secondary care data. **Discussion:** IGARD noted the update from NHS Digital in relation to the CPRD data request from the University of York. IGARD also noted that this was a useful and valuable study. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD noted the information provided in section 1(Abstract) that outlined details of the cohort and comparator group's and asked that section 3(b) (Additional Data Access Requested) was updated to correctly align with the narrative outlined in section 1. IGARD also queried the years that the data was being obtained and asked for further clarity of this since there was reference within the documentation provided to the study period being 2000-2019 and 2006-2019 , for further justification of the quantum of data requested since it was not clear if date

	was being requested for those reaching at least 43 years of age, and that confirmation of the age range of the cohort participants was also clarified in section 1 and section 3(b) since it was not clear if they were requesting data for those aged 23 years and under or those aged 23 years in the 2019 financial year. IGARD also asked that in accordance with section 3 (Datasets Held / Requested), that section 5 (Purpose / Methods / Outputs) was updated with further clarity and a clear narrative with regards to the cohort and comparator groups, the study years, when the 'study period' runs from and the data minimisation efforts undertaken. Also to clarify the statement that the data requested is low risk. IGARD queried the reference within the application to *"life limiting"* conditions and asked what this referred to, for example, was it the number of conditions that would be captured in the cohort; and asked that section 1 and section 5(a) (Objective for Processing) were updated with further information for transparency and for families to know if they were included or not; and to also note that this may impact on data minimisation. It was noted that section 5(a) did not clearly specify the data minimisation efforts undertaken in respect of each aspect of the cohort / comparators; and asked that this section was clearly updated to reflect this. In addition, IGARD asked for clarify of how the data requested and processing proposed would translate into improved care for young people, such as bespoke transition services. IGARD noted the references in section 5(a) that stated *"The research falls within the wider research of the Martin House Research Centre at the University of York…"* and asked that in the absence of a study protocol, that this was updated to provide further information on what the wider research was and to provide details on the other parties / organisations that were involved. In addition, to provide further information in section 5(a) of the role of the Martin House Research Centre. IGARD queried the outputs detailed in section 5(c) (Specific Outputs Expected) and asked that this was updated to aligned with the benefits outlined in section 5(d) (Benefits) and the purpose of process outlined that was detailed in section 5(a). IGARD noted and commended the efforts to involve the local children's hospice, as outlined in section 5(c); and asked that further information was provided outlining how the benefits and outputs of the study would benefit **national** children's hospices and national transitional care for young people, in light of national data being requested. IGARD noted the information provided in supporting document 2, the e-mail correspondence *"Advice on need for NHS Research Ethics Committee (REC) approval"* from the University of York, where it stated that it was of the opinion that REC approval was not required; and asked that definitive written confirmation was provided, that Ethics Approval was not required or otherwise that any internal / University-specific processes had been followed. IGARD noted the information provided in section 5(b) (Processing Activities) that stated *"…each individual. Gender will be coded as male, female or not known. Individuals with more than one recorded gender will be assigned the most commonly recorded gender."* and advised that categories should be clear and that if a significant number of records had no gender recorded this could possibly impact on addressing health inequalities. IGARD noted reference to a number of technical phrases and words within section 5(b) (Processing Activities) and suggested that it be updated to ensure that technical language was used only where necessary; and where necessary that it also had an explanation in language suitable for a lay reader. **Outcome Summary:** Recommendation to defer, pending:

	1. 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). 2. 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. 3. To clarify in section 3 the statement that the data requested is low risk. 4. 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). 5. 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. 6. 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. 7. To update section 5(a) with further clarity of how the data requested and processing proposed will translate into improved care for young people. 8. To update section 5(a) with further information on the data minimisation efforts undertaken in respect of each aspect of the cohort/comparators. 9. 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. 10. To update section 5(c) to align with the benefits in section 5(d) and the purpose of process outlined in section 5(a). 11. 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). 12. To provide definitive written confirmation that Ethics Approval is not required or otherwise that any internal/University-specific processes have been followed.
2.2	University of Surrey and RCGP: Secondary data linked to the Royal College of General Practitioners (RCGP) Research and Surveillance Centre's (RSC) primary care sentinel data for the purposes of infectious and respiratory diseases surveillance in England (Presenter: Louise Dunn) NIC-21083-B6C5J **Application:** This was a new application for identifiable Hospital Episodes Statistics (HES) and Civil Registrations data for the use in studies, done in parallel with Public Health England surveillance, focussing on the impact of influenza and other infections. The data will support a robust database and reporting system using up to-data primary and secondary care data at individual patient level that can be easily queried in order to answer a wide range of research questions covering; Upper respiratory infections (URTI), Lower respiratory infections (LRTI) (pneumonia and acute bronchitis), Asthma and Chronic Obstructive Pulmonary Disease (COPD). **Discussion:** IGARD noted the importance of the first two limbs of the study, to monitor influenza and research influenza vaccine effectiveness. IGARD noted and endorsed NHS Digital's review that the University of Surrey and the Royal College of General Practitioners (RCGP) that the applicants did **not** meet NHS Digital's Standard for privacy notices IGARD had a lengthy discussion on the issue of data controllership, in particular noting the statement in supporting document 6, the '*Research and Surveillance Project Agreement*' between the University of Surrey and the RCGP, that stated the purpose as being to "*to*

	undertake the following activities to meet the requirements of the key PHE contract". IGARD also noted that PHE were able to utilise Regulation 3 Health Service (Control of Patient Information) Regulations 2002 to set aside the duty of confidence. Since legislation establishes that PHE cannot delegate its Data Controllership as a public authority in performance of its statutory duties and noting that Data Controllership is also established by the relevant facts, and in light of the information provided within supporting document 6 provided with the application, it was suggested that PHE was added as a Data Controller, since the supporting documents provided established that the surveillance and efficacy testing was required to be carried out in order to fulfil PHE's statutory duty. IGARD also asked that, on the basis of the information provided in relation to PHE's role, that the University of Surrey's role as a Data Controller was reconsidered, since it appeared that the University of Surrey were acting under the instruction of PHE. IGARD also noted that the Chief Investigator of the study had moved to the University of Oxford, from the University of Surrey, and asked that the role of the University of Oxford as a joint Data Controller was also reviewed, since PHE gives authority under its regulations to the Chief Investigatory only and as such it was unclear of the legal gateway for the University of Surrey to be involved in the first place. Noting that the RCGP were already considered a Data Controller, IGARD also asked that their role was reviewed in terms of Data Controller and Data Processor and that the facts be established. Once the facts had been clearly established with regard to the Data Controllers and Data Processors for this application, IGARD suggested that section 5 (Purpose / Methods / Outputs) was updated throughout to reflect the correct facts once established with a clear narrative. IGARD also asked that the application was updated to reflect that the ability of PHE to utilise Regulation 3 Health Service (Control of Patient Information) Regulations 2002 to set aside the duty of confidence clearly limits the processing to surveillance and monitoring of vaccine efficacy and that an alternative legal basis would need to be articulated for the proposed third purpose which related to more general research. Also, to clarify why PHE does not need to seek s.251 support as a matter of process. IGARD queried the references within the application of the study being part of a wider programme of work; and asked for a clear narrative of the study, the wider programme and to clearly articulate who is in the cohort for each of these. **Outcome Summary:** Unable to recommend for approval 1. In respect of data controllership: a) To add Public Health England (PHE) as a Data Controller as the supporting documents provided establish that the surveillance and efficacy testing is required to be carried out in order to fulfil a statutory duty on PHE. b) To reconsider the role of the University of Surrey as a Data Controller on the basis of the information provided. c) To review the role of the University of Oxford as a Data Controller. d) To review the role of the RCGP in terms of Data Controller and Data Processor. e) To update section 5 throughout to reflect the correct data controllership facts. 2. To provide further information of the study as part of a wider programme of work, what is the study, what is the wider programme, and who is in the cohort for of each. 3. To update the application to reflect that the ability of PHE to utilise Regulation 3 Health Service (Control of Patient Information) Regulations 2002 to set aside the duty of confidence clearly limits the processing to surveillance and monitoring of vaccine

	efficacy and that an alternative legal basis would need to be articulated for the proposed third purpose which relates to more general research. 4. To update the application to clarify why PHE does not need to seek s.251 support as a matter of process.
2.3	<u>NHS East Berkshire CCG: DSfC - NHS East Berkshire CCG - Comm, RS & IV (Presenter: Louise Dunn) NIC-186893-W6V1H</u> **Application:** This was a renewal application for pseudonymised Local Provider Flows data and pseudonymised / identifiable Secondary Use Service (SUS) for Commissioners data. The application was also an amendment application to 1) add Graphnet Health Limited as a Data Processor for the purpose of Risk Stratification; 2) to add Microsoft UK as a Data Processor (as they provide Cloud services to Graphnet Health Limited); and 3) to remove NHS East Berkshire CCG as a Data Processor. The purpose is for Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do, Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. NHS Digital advised IGARD that the applicant's Privacy Notice did not contain information stating that the Risk Stratification was a form of profiling; and that NHS Digital were working closely with them to address this issue. **Discussion:** IGARD noted the update from NHS Digital in relation to the Privacy Notice not addressing the Risk Stratification being a form of profiling. IGARD also noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices for privacy notices and asked that a revised Privacy Notice was provided ensuring that it was compliant with the notice requirements under the General Data Protection Regulation (GDPR), particularly with reference to profiling and automated decision-making. IGARD queried the information outlined in section 5(b) (Processing Activities) on the role of Graphnet Healthcare Ltd and asked that a clear narrative was provided outlining their involvement. IGARD also asked for a further explanation as to why this was not considered parallel / excessive processing, noting the similar role of NHS South, Central and West Commissioning Support Unit (CSU). IGARD noted the inconsistencies with regard to commissioning between the information outlined in the application and information in supporting document 1, the Data Flow Diagram (DFD) in relation to the parties involved; and asked that either section 5(a) (Objective for Processing) was updated to reflect the information within the DFD or the DFD was updated to reflect the information outlined in section 5(a). **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide a clear narrative with regards to the involvement of Graphnet Healthcare Ltd and to explain why this is not considered parallel/excessive processing. 2. To either update section 5(a) to reflect the parties outlined within the data flow diagram; or to update the data flow diagram to reflect the facts outlined in section 5(a). The following amendment was requested: 1. The applicant to provide a revised Privacy Notice and to ensure that it is compliant with the notice requirements under the GDPR, particularly with reference to profiling and automated decision-making.

	It was agreed the conditions would be approved Out of Committee (OOC) by the IGARD Chair.
2.4	<u>Health IQ Ltd: Health iQ - Benchmarking and reporting (Presenter: Dave Cronin) NIC-15293-R6V2H</u> **Application:** This was a renewal application for pseudonymised Hospital Episodes Statistics (HES) data; an extension to extend the years of data permitted to be retained on the Vantage online tool; and an amendment to store and process data using a Cloud facility. The purpose of the application is to support the Vantage online tool that produces dashboards and reports to support the delivery of healthcare and the delivery of key healthcare strategic priorities; which include the NHS Five-Year Forward View, Quality, Innovation, Productivity and Prevention (QIPP) targets and Joint Strategic Needs Assessment (JSNA) targets. Potential users of the reports are NHS (Prover Trusts, GP's etc), Commissioning Support Units (CSU's), Governmental organisations, Social Care, Charities and Life Science organisations. NHS Digital advised IGARD that the applicant's current Data Sharing Agreement (DSA) was due to expire on the 31st January 2020. **Discussion:** IGARD noted the update from NHS Digital in relation to the DSA expiry date. IGARD also noted that there were four elements to bear in mind with regard to the consideration of this application: extension, renewal, cloud storage and additional years of data and that the NHS Digital Commercial Standard was clear that the benefit to the public more be proportionately balanced against the commercial interests and benefit accruing to the applicant. The last time this application had been brought to IGARD for review was in November 2018, and following this, in early 2019 NHS Digital published the (5e) Commercial Purpose Standard and the (10) Sub-Licencing and Onward Sharing of Data Standard. IGARD queried why the application had not been uplifted to meet these current published NHS Digital Standards and advised that any future versions of this application would need to be updated and that the amendments should align with the published NHS Digital Standards. In addition, IGARD also asked section 5 was updated clarifying how the elements of the Standards had been addressed. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD queried why the additional years of data that the applicant wished to retain was required and asked that clear justification was provided clarifying this. In addition that further justification be provided with regard to the data minimisation efforts undertaken as part of the request for additional years of data. IGARD noted the references within section 5 (Purpose / Methods / Outputs) of the application that stated *"This allows the user to be more specific when analysing data, so can pick a targeted group of patients..."* and asked that further clarification was provided outlining how this would provide more robust analysis. IGARD noted the applicant had selected Legitimate Interests as a legal basis and asked that it be clearly articulated within section 1 (Abstract) and section 5 how this specifically related to the purpose of the proposed processing outlined in the application and provide detailed consideration of how the proposed processing linked to the three limbs of the Legitimate Interest Assessment (LIA).

	IGARD noted the yielded benefits outlined in section 5(d) (Benefits) but asked that these were amended to ensure any benefits accrued were clearly dated so it was clear, upon future review, when this section had been updated. **Outcome Summary:** recommendation to approve for two months for points 1 (extension), 2 (renewal), and 3 (use of Cloud storage) only. **Outcome Summary**: unable to recommend for approval for point 4 (additional years) IGARD stated this application was not suitable for NHS Digital's Precedent route; and upon return would expect to see the application uplifted to meet NHS Digital's Standards including Sub-Licencing and Onward Sharing of Data and the Commercial Purpose Standards. A robust Legitimate Interest Assessment would need to be articulated, in particular, linking it to the specific processing outlined within the application. If after two months, it is not possible to return the application to IGARD then NHS Digital must notify IGARD of any further extension including the length of extension and the date expected back to IGARD.
2.5	<u>University of Oxford: The Oxford Heart Vessels and Fat (ox-HVF) Cohort (Presenter: Dave Cronin) NIC-392669-T1F8B</u> **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES), Civil Registrations, Medical Research Information Service (MRIS) and Emergency Care Data Set (ECDS); an extension; and an amendment to 1) add a fourth cohort to the three cohorts for which data was provided under previous iterations of this Data Sharing Agreement (DSA); and 2) to add the Emergency Care Data Set. The purpose of the study is to discover new blood, genetic and imaging biomarkers that differ between patients with advanced coronary atherosclerosis and healthy individuals. The ability of these biomarkers to predict clinical outcomes in patients and controls will be evaluated by analysing prospective data. These new biomarkers could also serve as potential therapeutic targets, allowing the development of new therapeutic strategies for the prevention and treatment of cardiovascular disease. NHS Digital advised that this application had been previously recommended for approval with (seven) conditions on the 27th June 2019; and that five of the conditions had been approved by IGARD out of committee; and that the outstanding two conditions (2 and 3) had not been met within the 3 months following the meeting and as per process the application had to be submitted to a full meeting of IGARD. The outstanding conditions are: • To provide a fair processing notice, in draft and prior to publication on the study website, that is GDPR compliant (including but not limited to) clearly explaining the data controllership, the data being used, where the data is from, the processing activities undertaken, the purposes for each study, how each study interlinks, what the overarching project is and how it links to the study, to explain the cohort and to provide a mechanism for participants to withdraw consent; and • To send to all participants of the study an updated newsletter which gives details of the fair processing notice as provided on the study website with similar details as point 2, or to provide a written justification as to why a newsletter cannot be sent to participants and if not, to provide alternative means to satisfy the requirements of fair processing notice to all participants. NHS Digital also advised that new Patient Information Sheets (PIS) had been uplifted for each of the studies.

	Discussion: IGARD noted the update and purpose of the application returning to IGARD and noted the two outstanding conditions that had surpassed the three-month out of committee review deadline. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. Although the information provided in the four draft Privacy Notices for the four studies were on balance informative and much improved, asked that these were further updated to include a further paragraph on the 'data subjects rights', as outlined in the General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018 and once these had been updated, to confirm when these had been published. IGARD queried the references within the application and supporting document 2.12, the Patient Information Sheet, that listed a number of other parties / organisations and asked why only the University of Oxford was considered a sole Data Controller. IGARD asked that further information was provided on the other parties / organisations and why they were not also considered Data Controllers and as clearly set out in NHS Digital's published Standard (1b) Controllers and Standard (5a) Objective for Processing, with a clear narrative in section 5(a). IGARD noted a number of draft consent forms had been provided however it was not clear which consent forms were being used by the applicant and asked that the application was updated to clearly state which of the forms would be used going forward. IGARD noted the information within the Privacy Notice which clearly articulated the data linkage that would be taking place and asked that the draft consent materials were updated to reflect this information. IGARD noted the references within the draft consent materials to "anonymous" and "anonymisation" and asked that these terms were removed and reworded (for example using the construction "*you will not be able to be directly identified*") and that the draft consent materials were updated. IGARD noted that on review of the relevant consent materials, they may raise additional points, since it was not clear which consent form(s) were to be used. It was not clear within any of the draft consent materials **how** participants could withdraw consent from the study and unclear to IGARD which consent form(s) were being use / to be used, and asked that the draft consent materials were updated to clearly outline participants would withdraw by way of providing relevant contact details. IGARD noted that the Oxford University Hospitals NHS Foundation Trust logo was being used on the draft consent materials and asked that section 1 was updated clearly outlining their involvement in the study, as background to the history of the application. It also suggested that the applicant may wish to update their Privacy Notice to ensure the use of technical phrases is used only where necessary; and where it was necessary, to be also written in language suitable for a lay reader. IGARD also asked that a special condition was inserted in section 6 (Special Conditions), stating that the recommendation provided by IGARD on the 30th January 2020 extended **only** to the cohort recruited via the consent materials in use at that date and **not** those consent materials in draft format. IGARD advised that they would wish to review this application again when it comes up for renewal **Outcome Summary:** recommendation to approve subject to the following conditions for the existing consent materials in use and those participants already recruited:

	1. To update the four draft Privacy Notices to include a further paragraph on the 'data subjects rights' and once updated to confirm when these had been published. 2. In light of the University of Oxford being listed as the sole Data Controller, to provide further information on the other parties mentioned within the application and supporting documents and why they were not considered as joint Data Controllers. The following amendments were requested: 1. In respect of the draft consent materials: a) To be clear within the application as to which version of the consent forms will be used going forward. b) To provide further information within the consent materials on the data linkage taking place (as clearly outlined in the Privacy Notice). c) To remove any reference to "anonymous" and "anonymisation" (to reflect the explanation of the data in the revised Privacy Notice). d) To ensure it is clearly outlined how participants can withdraw consent from the study. e) To clarify the roles and involvement in the study of the other organisations and individuals referred to as 'investigators' in the study. 2. To insert a special condition in section 6, stating that the recommendation provided by IGARD on the 30th January 2020 extends **only** to the cohort recruited via the consent materials in use at that date and **not** those consent materials in draft format. 3. To update section 1 to further outline the involvement of the Oxford University Hospitals NHS FT (in light of their logo being used on the consent materials). The following advice was given: 1. IGARD suggested that the applicant may wish to update their Privacy Notice 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. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
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-139741-D9Y1C Bangor University • NIC-33234-C0V1D University of Oxford • NIC-10891-M2Y6Z CHKS Limited • NIC-147815-X5CHM NHS Blood & Transplant 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 which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.
5 **5.1**	<u>AOB:</u> <u>Standards and Precedents</u>

	NHS Digital attended IGARD to discuss with members the following Standards and Precedent: • Standard 1 – Length of Data Sharing Agreement (DSA) • Standard 10a – Transparency • Precedent X - DSA Simple Amendment IGARD provided feedback to NHS Digital on the two current standards and new precedent, and it was agreed that Standard 1 and Standard 10a would be recirculated to IGARD, once updated, for further discussion. 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.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 24/01/20

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)
None						

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 quarterly Oversight and Assurance Report.