

## Independent Group Advising on the Release of Data (IGARD)

### Minutes of meeting held 14 February 2019

**Members:** Joanne Bailey, Maria Clark, Kirsty Irvine (Chair), Priscilla Maguire, Eve Sariyiannidou.

**In attendance:** Stuart Blake, Dave Cronin, Louise Dunn, Karen Myers, Vicki Williams.

**Apologies:** Sarah Baalham, Anomika Bedi, Nicola Fear.

**Observers:** Dr Ohtera (Items 2.1-2.4) and Dr Sasaki (Items 2.1-2.4) (Otaru University of Commerce, on behalf of the Cabinet Office Japan), Jonathan Smith (Items 2.2-2.3).

1	<p><b>Declaration of interests:</b></p> <p>There were no declarations of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 7<sup>th</sup> February 2019 IGARD meeting were reviewed and agreed as an accurate record of the meeting.</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<p><b>Data applications</b></p>
2.1	<p><u>NHS England (Quarry House): Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Louise Dunn) NIC-204575-V7X8H</u></p> <p><b>Application:</b> This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to both monitor and improve performance against the Cancer Waiting Time standards and to inform wider cancer pathway improvements.</p> <p><b>Discussion:</b> IGARD queried the reference to 'patient postcodes' under the Mitigating Risk of Re-identification heading in section 5(a) (Objective for Processing) and were advised by NHS Digital that there would be no access to patient postcodes as this is not part of the Cancer Waiting Times Monitoring Dataset. IGARD asked that for clarity section 5(a) be amended to insert a full stop after 'geographic breakdowns' and remove the rest of the sentence referring to patient postcodes.</p> <p>IGARD noted the audit pathways and examples given and suggested that reference to 'audit work' should be amended to 'clinical audit work' to indicate this was clinical audit work undertaken by the direct care team.</p> <p>IGARD queried what levels of data were shared, with which parties and for what purposes and suggested that it be made explicitly clear within section 1 (Abstract) and section 5 (Purpose / Methods / Outputs).</p> <p>IGARD suggested that any amendments made for clarity also be made to any further CWT applications going forward.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"><li>1. To amend section 5(a) to insert a full stop after 'geographic breakdowns' and remove the rest of the sentence.</li></ol>

	<ol style="list-style-type: none"> <li>2. To amend any reference within the application from 'audit work' to 'local clinical audit work'.</li> <li>3. To make it explicitly clear within the abstract and section 5 what levels of data are shared, with which parties and for what purposes.</li> </ol>
2.2	<p><u>Queen Mary University of London: A STUDY TO INVESTIGATE THE ASSOCIATION BETWEEN SELECTIVE UPTAKE OF CERVICAL CANCER SCREENING AND ALL CAUSE MORTALITY (Presenter: Stuart Blake) NIC-15741-J6Y4L</u></p> <p><b>Application:</b> This was a new application for Civil Registration Mortality Data on a sample of deaths of women for use in the study 'to investigate the association between selective uptake of cervical cancer screening and all-cause mortality' which has been designed to understand whether women who suffer health problems or have riskier lifestyles are less likely to attend cervical screening, using a sample of women who died between 1992 and 2012 aged between 20 and 69 in 1992.</p> <p>The application was been previously considered on the 1<sup>st</sup> November 2018 when IGARD had deferred pending: to use consistent terminology throughout the application that the cohort is limited to women aged between 20 and 69 in 1992 and between time period 1992 and 2012; to update the abstract, section 3 and section 5 to clearly explain the cohort including its size; to provide further narrative in the abstract explaining the lawful basis relied upon for the data flows between NHAIS and NHS Digital and NHS Digital and NHAIS, as set out in the application, and clarify in section 5 why NHAIS are not considered a joint Data Controller; to provide further detail within the abstract and section 5 on the references to phases 1 and 2 outlined within section 5 and explain how the applicant will identify the cases and identify the control / comparison group; to provide more detail of the expected benefits within section 5 of the application with a clear pathway of dissemination; to provide evidence of how the applicant has dealt with the specifics of support detailed in the HRA CAG support letter, and in particular how they will deal with patient notifications; the application should be updated to confirm that funding is in place and provide relevant evidence from Cancer Research UK; to delete the reference to 'The files shared between NHS Digital and NHAIS for identification of cohorts consists of personal identifiers and a PseudoID only. They DO NOT include mortality or screening data.' from within section 5; to amend the term 'sub-cohort' to be clear this refers to a different category within the same cohort; to update section 5 when referencing '..cause of death specified above...' to clarify what this is, as outlined in the protocol.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect most of the comments previously made and thanked the presenter for the helpful comparison document.</p> <p>IGARD noted that deferral point 8 appeared to have been overlooked and NHS Digital agreed that this deletion should be made ( "<i>The files shared between NHS Digital and NHAIS for identification of cohorts consists of personal identifiers and a PseudoID only. They DO NOT include mortality or screening data.</i>" be deleted from within section 5).</p> <p>IGARD were informed that Public Health England (PHE) had commissioned NHS Digital to run NHAIS and suggested that PHE be added as a joint Data Controller and any necessary amendments be made to the application to reflect this, since the NHAIS data flows were a core aspect in phase two and PHE were already the data controller for the NHAIS data.</p> <p>IGARD queried the reference in section 5 to 'riskier lifestyles' and noted that this may be open to misinterpretation and asked that this either be explained or be removed; after some discussion, NHS Digital determined that the phrase was not relevant to the data being sought and thus agreed that removing it would be the appropriate course of action.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p>

	<ol style="list-style-type: none"> <li>1. To add Public Health England as a joint Data Controller and make any necessary amendments to the application to reflect this.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To delete the reference to 'The files shared between NHS Digital and NHAIS for identification of cohorts consists of personal identifiers and a PseudoID only. They DO NOT include mortality or screening data.' from within section 5.</li> <li>2. To remove reference to the term "riskier lifestyles" in section 5.</li> </ol> <p>It was agreed the condition would be approved OOC by the IGARD Chair.</p>
2.3	<p><u>King's College London: Modelling small-area rates of self-harm in London (Presenter: Stuart Blake) NIC-174740-C0H0L</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a project entitled 'Understanding variations in self-harm rates between deprived areas in London' and forms the final part of a PhD project. The study aims to 1) Describe the distribution of self-harm hospital admission rates across small-areas of Greater London over time and compare them to the distribution of all admissions to identify any self-harm specific spatial patterning; 2) Explore the impact of using different definitions of self-harm, for exemplifying including injuries and poisonings coded as of undetermined intent or accidental, on associations with self-harm rates and the geographical patterning of self-harm rates; 3) Test the validity of a model using area and population level exposures to predict areas with high and low rates of self-harm.</p> <p>NHS Digital advised that funding will continue for the duration of the study and provided a supporting document to IGARD in advance of the meeting documenting this.</p> <p>NHS Digital advised that following further discussions with the applicant that further data minimisation efforts had been implemented which reduced the amount of data requested by the applicant.</p> <p><b>Discussion:</b> IGARD noted that funding was continuing as outlined in the supporting document provided. IGARD thanked the presenter and the applicant for the helpful additional supporting material provided in advance of the meeting.</p> <p>IGARD noted and commended the data minimisation efforts undertaken by the applicant and asked that the data minimisation column in section 3(b) (Additional Data Access Requested) was updated to reflect recent discussions with the applicant with regard to data minimisation.</p> <p>IGARD noted the reference to the Care Act within section 1 (Abstract) and asked that this be removed as it is not relevant.</p> <p>IGARD noted that the abstract was inconsistent with the information provided in section 3(c) (Patent Objections) that stated that patient objections had not been applied and asked that the abstract be updated to reflect the correct information.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update the abstract to delete the reference relating to the Care Act.</li> <li>2. To update the abstract to align with section 3(c) that patient objections are not applied.</li> <li>3. To amend the data minimisation column in section 3(b) to reflect recent discussions with regard to the data minimisation efforts undertaken.</li> </ol>
2.4	<p><u>The Nuffield Trust For Research And Policy Studies In Health Services: Rapid Service Evaluation (RSET) (Presenter: Dave Cronin) NIC-194629-S4F9X</u></p>

	<p><b>Application:</b> This was a new application for both identifiable and pseudonymised Hospital Episode Statistics (HES) data to conduct rapid evaluations of health and care service innovations, in close partnership with those who deliver, manage and use these services. The RSET Team will enable provision of formative, as well as summative feedback to those implementing innovations in health and care services.</p> <p>The application was been previously considered on the 22<sup>nd</sup> November 2018 when IGARD had been unable to recommended pending; to provide a clear explanation within section 5 of the application articulating the roles and responsibilities of the other organisations outlined, particularly the Department of Applied Health Research at UCL, including their role in the selection, design and approval of research protocols and performance of the projects, and any data they may have access to; to confirm how the funder is involved with the project and provide confirmation that they will not have influence on the outcomes nor suppress any outcomes of research; to clarify that the Data Controller is solely responsible for directing the project.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect all of the comments previously made and had no further comments to make.</p> <p><b>Outcome:</b> recommendation to approve</p>
2.5	<p><u>University of Glasgow: Data linkage request for FAMOUS-NSTEMI study (Presenter: Dave Cronin) NIC-170589-L2W0Y</u></p> <p><b>Application:</b> This was a new application for identifiable Hospital Episode Statistics (HES) data and Civil Registrations Mortality Data for a study focusing on the diagnostic and clinical value of using Fractional Flow Reserve (FFR) to guide treatment decisions in patients with a recent heart attack and the longer-term study of patient survival and wellbeing which is crucial in supporting medical decision making.</p> <p><b>Discussion:</b> IGARD noted that the University of Glasgow was not referred to within the consent material supporting documentation provided and queried how the study participants would be informed that they are involved in the study. IGARD also noted that the consent materials submitted were a sample only and asked that they were provided with a copy of all the consent materials provided to the participants for all the parties involved, not just a sample from one hospital. It was agreed that a full suite of consent materials for this application would be provided at a future IGARD meeting for advice without prejudice to any additional issues that may arise when the application was next reviewed.</p> <p>IGARD noted that once all the consent materials were available further justification should be provided of who was the Data Controller and to include whether each of the participating hospitals should be listed as a party.</p> <p>IGARD queried whether the data subjects were only from the randomised cohort, or whether they included any people who were only on the registry and asked that the cohort was clearly defined within the application.</p> <p>IGARD queried if the 5-year follow-up noted within the application was part of the pilot or an interim step between the pilot and the study and asked for further clarity.</p> <p>IGARD asked that the sections on Article 6 and 9 of GDPR is updated in section 1 (Abstract) to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public task condition under section 8 of the DPA 2018.</p> <p><b>Outcome:</b> Unable to recommend for approval</p>

	<ol style="list-style-type: none"> <li>1. To set out how the study participants will be informed that the University of Glasgow is involved in the study and a justification of who is the Data Controller (including whether each of the participating hospitals should be listed as a party).</li> <li>2. To provide a copy of all the consent materials provided to the participants for all the parties involved, not just a sample from one hospital.</li> <li>3. To clearly define the cohort of data subjects within the application.</li> <li>4. To clarify if the 5-year follow-up was part of the pilot or an interim step between the pilot and the study.</li> <li>5. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public task condition under section 8 of the DPA 2018.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that the full suite of consent materials could be provided at a future IGARD meeting for advice without prejudice to any additional issues that may arise when the application is next reviewed.</li> </ol>
2.6	<p><u>University of Oxford: MR1086 - The Oxford Vascular Study: incidence and outcome of stroke, transient ischaemic attack (Presenter: Dave Cronin) NIC-148369-8PPWK</u></p> <p><b>Application:</b> This was an extension and renewal application for identifiable Medical Research Information Service (MRIS) data for a long-running study to determine mortality, disability, psychological morbidity, cognitive decline and cost of care following stroke, transient ischaemic attack (TIA), Acute Coronary Syndrome (ACS) and acute peripheral vascular events in patients registered in one of eight GP practices in Oxfordshire.</p> <p>NHS Digital noted the statement within section 1 (Abstract) about the applicant previously holding Hospital Episode Statistics (HES) data and advised that this data has now been destroyed.</p> <p>NHS Digital noted that the incorrect legal basis for dissemination had been noted in section 3 (Datasets Held / Requested) and had been amended.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study and noted and supported the amendments in relation to the HES data and the correct legal basis for dissemination. IGARD noted that the data minimisation table in section 3(b) (Additional Data Access Requested) needed amending to reflect the change to the legal basis.</p> <p>IGARD queried how the Patient Information Leaflet and Consent materials that were submitted as supporting documents satisfied the duty of confidentiality and noted the explicit statement within these documents that the data identifying the participants would not leave the hospital. IGARD advised that the duty of confidentiality did not appear to be met, on the basis of the supporting documents presented, and suggested that NHS Digital work with the applicant in order to find a practicable solution. Various options were discussed in the meeting, including the applicant acting solely as a data processor .</p> <p>IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 (Privacy Notice) be updated to clearly state that the application privacy notice 'does not' meet the criteria.</p> <p>IGARD noted that a data flow diagram was not provided as a supporting document and asked that one be provided to support the detail within section 5(b) (Processing Activities) of the application and to better understand the flows and to clearly explain any separation of identifiers from the clinical data and asked that section 5(b) be updated to clearly outline this and to clarify the controls that are in place.</p>

	<p>IGARD queried if the funding as described within the application was ongoing since the data was suspended in March 2018 and asked for clarification of this.</p> <p>IGARD noted the benefits outlined were mainly research publications and reports and since the aim of the study was to improve public health queried the outputs and benefits and asked for further specific details which reflect the study outlined in the application, including more details of practical examples.</p> <p>IGARD also noted that the revised consent materials needed to be reviewed to provide more specific information on a number of issues, including the data collected and processed, the processing activities undertaken, the context of any onward sharing, and also to use clear, concise and accessible language.</p> <p>IGARD noted that the abstract should be updated to correct the tense used.</p> <p><b>Action:</b> IGARD noted that the new consent materials were brought for advice only and would provide further comments out of committee.</p> <p><b>Outcome:</b> Unable to recommend for approval</p> <ol style="list-style-type: none"> <li>1. It was IGARD's view that the Patient Information Leaflet and Consent submitted as supporting documents do not satisfy the duty of confidentiality, in particular the explicit statement that data identifying the participants will not leave the hospital.</li> <li>2. To amend the data minimisation table to reflect the change to the legal basis.</li> <li>3. To update section 4 to clearly stated the applicant's fair processing notice 'does not' meet the NHS Digital's fair processing criteria for privacy notices</li> <li>4. To provide a data flow diagram to support the detail provided in section 5(b).</li> <li>5. To clearly outline within section 5 that any identifiers will be kept separate to clinical data and to clarify the controls that are in place.</li> <li>6. To clarify that the funding as described in the application is ongoing.</li> <li>7. To provide more specific details of how the outputs and benefits reflect the purpose of the study including details of practical examples.</li> <li>8. To update the abstract to correct the 'tense' used.</li> </ol> <p>IGARD noted the importance of the study being undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital was due to expire, and in light of this it was suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.</p>
2.7	<p><u>Cardiff University: Modelling the associations between wider health and social characteristics and diabetes related health (Presenter: Dave Cronin) NIC-158283-T2Q2D</u></p> <p><b>Application:</b> This was a new application for identifiable National Diabetes Audit Data for use in a research project, 'Investigating interrelationship between diabetes and children's educational achievement', which aims to model the association of the relationship between wider health and social characteristics and diabetes related health and better understanding the effects of educational trajectories, experiences and outcomes on diabetes management.</p> <p><b>Discussion:</b> IGARD noted that the Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task is the appropriate legal basis.</p> <p>IGARD queried the relationship between NHS Wales Informatics Service (NWIS), Cardiff University, Secure Anonymised Information Linkage (SAIL) Databank and Higher Education Statistics Agency (HESA) and asked that section 5 (Purpose / Methods / Outputs) be updated to outline this.</p>

	<p>IGARD noted that the cohort birth dates were inconsistent within the application and supporting documents provided and asked that these were checked and made compatible throughout the application.</p> <p>IGARD noted the wording within section 3(c) (Patient Objections) was incorrect and asked that this be removed and replaced with a reference to s251.</p> <p>IGARD noted the information provided in section 5(a) (Objective for Processing) that begin <i>“The schools and college data controller.....”</i> and <i>“Cardiff University is the sole data controller.”</i> and asked that these are moved to section 5(b) (Processing Activities), and then amend to name the relevant data controllers.</p> <p>IGARD also suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement and to consider the wider academic audience including education professionals.</p> <p>IGARD suggested that NHS Digital should satisfy itself that the organisations have the appropriate contracts in place, ensuring that the contracts are rigorous and are able to satisfy the applicant’s legal obligations under the Data Sharing Agreement (DSA).</p> <p><b>Outcome:</b> Unable to recommend for approval</p> <ol style="list-style-type: none"> <li>1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update section 5 to reflect the various relationships between NWIS, Cardiff, SAIL and HESA.</li> <li>2. To check and ensure compatible use of cohort dates throughout the application.</li> <li>3. To remove the current wording within section 3(c) and replace with reference to s251.</li> <li>4. To remove the sentences from section 5(a) that begin <i>“The schools and college data controller.....”</i> and <i>“Cardiff University is the sole data controller.”</i> and move them to section 5(b), and then amend to name the relevant data controllers.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement; and to consider the wider academic audience including education professionals.</li> <li>2. IGARD suggested that NHS Digital should satisfy itself that the organisations have the appropriate contracts in place, ensuring that the contracts are rigorous and are able to satisfy the applicant’s legal obligations under the DSA.</li> </ol>
2.8	<p><u>NHS Thameside and Glossop CCG: DSfC - NHS Tameside and Glossop CCG – IV (Presenter: Louise Dunn) NIC-180025-W6S0Z</u></p> <p><b>Application:</b> This was a renewal application for identifiable Secondary Use Service (SUS) for Commissioners Data covering invoice validation (IV) which is part of a process by which providers of care or services are paid for the work they do.</p> <p><b>Discussion:</b> IGARD noted the content of the application and supporting documents provided and had no further comments or queries.</p> <p><b>Outcome:</b> recommendation to approve</p>
2.9	<p><u>POWYS Teaching LHB: DSfC Powys Teaching LHB Comm (Louise Dunn) NIC-95658-C4F7D</u></p> <p><b>Application:</b> This was a new application for pseudonymised Secondary Use Service (SUS) for Commissioners Data to provide intelligence to support the commissioning of health services.</p>

	<p>The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the Health Board area.</p> <p>NHS Digital advised that two paragraphs currently noted in section 5(b) (Processing Activities) relating to Lima Networks UK Ltd and Blackpool Victoria Hospital not accessing data would be moved to section 6 (Special Conditions).</p> <p><b>Discussion:</b> IGARD noted and supported the amendment to move the information relating to the information on Lima Networks UK Ltd and Blackpool Victoria Hospital not accessing data being moved to section 6.</p> <p>IGARD noted that data previously being held under the Memorandum of Understanding (MOU) is now held under this agreement and asked that sections 3(a) (Data Access Already Given) and 3(b) (Additional Data Access Requested) was amended to reflect both old data under the MOU and new data requested under this application.</p> <p>IGARD noted that the standard geographical data minimisation wording was not included in section 5(b) (Processing Activities) and asked that this be updated clearly stating which parties are relevant to the application.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend the application to state that the data held under MOU is now held under this agreement and to amend sections 3(a) and 3(b) to reflect both old data under the MOU and new data.</li> <li>2. To update section 5(b) with the standard geographical data minimisation wording, clearly stating which parties are relevant to the application.</li> </ol>
3	<p><b>AOB</b></p> <p>None</p>



### Independent Group Advising on Releases of Data (IGARD): Out of committee report 08/02/19

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-204544-H5L0S	NHS England (Quarry House)	31/01/2019	1. To amend the applicant information to reflect the appropriate NHS body.	OOC by IGARD Chair	OOC by IGARD Chair	N/A
NIC-90658-F0W4R	NHS East Riding of Yorkshire CCG	24/01/2019	1. To update section 5(b) with the standard geographical data minimisation wording, clearly stating which CCG's are relevant to the application. 2. To include a special condition in section 6 that no other company within the Kier Group will have access to the data other than the Kier entity listed in the agreement. 3. To differentiate within section 5(b) the different roles undertaken by Kier Business Service Limited and Dr Foster Limited in their role as data processors, and in addition, how this also differentiates from the CCG's role as a data processor to provide clarity on what services each data processor provides.	OOC by IGARD Chair	OOC by IGARD Chair	Condition 3 wording amended to say "separate analysis".
NIC-47174-R9S4W	NHS Bury CCG	24/01/2019	1. To update section 5(b) with the standard geographical data minimisation wording, clearly stating which CCG's are relevant to the application. 2. All amendments, since they are substantial in number, to be reviewed OOC by the IGARD Chair.	OOC by IGARD Chair	OOC by IGARD Chair	N/A

In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None