Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 12 September 2019

In attendance (IGARD Members): Sarah Baalham, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Maurice Smith.

In attendance (NHS Digital): Paul Croft, Louise Dunn, James Humphries-Hart, Dickie Langley, Karen Myers, Emma Summers, Vicki Williams.

Not in attendance (IGARD Members): Anomika Bedi, Priscilla McGuire, Eve Sariyiannidou, Geoffrey Schrecker.

Observers: Ibrahim Ali, Dan Goodwin, Jackie Gray, Denise Pine.

1	**Declaration of interests:** Maria Clark noted professional links to the Data Protection Officer at the University of Sheffield *[NIC-261216-Q1L2Q University of Sheffield]*, but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 29th August 2019 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	<u>NHS Horsham and Mid Sussex CCG: DSfC - NHS Horsham & Mid Sussex CCG; RS, IV. (Presenter: James Humphries-Hart) NIC-91871-D2W1N</u> **Application:** This was an renewal application for identifiable Secondary Use Service for Commissioners (SUS) and an amendment to add identifiable Mental Health Service Dataset (MHSDS) for the purpose of Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do and 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. NHS Digital advised IGARD that the data minimisation columns within the tables in section 3 (Datasets Held / Requested) had not been populated and would need amending to reflect the data minimisation that was outlined in section 5(b) (Processing Activities). NHS Digital also advised IGARD that section 3(c) (Patient Objections) would need a further update to correctly state that patient objections were 'mixed'. **Discussion:** IGARD noted the two updates from NHS Digital in relation to the amendment to the data minimisation columns in section 3; and the patient objections update to section 3(c) and supported both amendments outlined. IGARD noted the addition of the Mental Health Services Data Set to the application and queried what the specific expected outputs and benefits were that would flow directly from this additional data; and asked that section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) were revised to outline how the data will enrich analysis and benefit the processing. IGARD also asked that NHS Digital provide them with a review of progress made and the benefits achieved by the applicant 6 months from the receipt of the data under this application. **Outcome Summary:** recommendation to approve subject to the following condition:

	1. To revise section 5(c) and section 5(d) to outline the specific expected outputs and benefits flowing directly from the addition of the Mental Health Services Data Set. The following amendments were requested: 1. To amend the tables in section 3 to reference the data minimisation outlined in section 5(b). 2. To amend section 3(c) to correctly reference 'mixed' patient objections. It was agreed the condition would be approved OOC by IGARD Members. **ACTION:** NHS Digital to provide to IGARD a review of the progress made and benefits achieved by the applicant 6 months from receipt of data.
2.2	Imperial College London: TOGETHER Study (Presenter: Louise Dunn) NIC-157873-F6F8K **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for a study (Imperial and The LOndon GEneral Practice-based InvesTigation of Cardiovascular HEalth and Risk Factors (TOGETHER) among diverse populations) aiming to understand the burden of cardiovascular risk factors across different ethnic groups. The direct and in-direct burden of cardiovascular disease (CVD) on the NHS and UK economy is estimated to be around £9 and £19 billion each year respectively. With the presence of racially and diverse communities, prevention tools and strategies derived from population studies need to consider these groups to ensure services provided by the NHS are more appropriate to the population they serve. NHS Digital advised IGARD that they had advised the applicant seek advice from the Health Research Authority Confidentiality Advisory Group (HRA CAG) in relation to s251 support; and were advised by CAG that support was not required because the data was pseudonymised and there was therefore no breach in confidentiality. **Discussion:** IGARD noted the update from NHS Digital on the s251 advice from CAG; and commended the applicant for taking NHS Digital's advice in following this up. IGARD noted that conflicting information was provided throughout the application and the protocol provided as a supporting document, in relation to the cohort age group and asked for clarification if the group was aged 40-74 (as part of the NHS Health Check) or those aged 30-90 who are outside the age range for NHS Health Checks; along with a further explanation of how the cohort numbers were agreed in section 3(b) (Additional Data Access Requested). IGARD also asked that following clarification of the cohort age group, that confirmation was provided that ethics approval and other relevant support for the application was still applicable for the data requested and processing set out in the application. IGARD noted the reference within the application to "consent form" and advised, that to avoid any confusion in terminology, this should be amended throughout to "participation agreement" (or similar). IGARD noted the information provided in section 5 (Purpose / Methods / Outputs) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader; and also queried the reference to cardiovascular disease being a "burden" and asked that further consideration was given to the patient audience and how this type of language could be perceived. IGARD queried information provided in section 5(c) (Specific Outputs Expected) that relate to 'processing' and asked that the relevant paragraphs were correctly moved into section 5(b) (Processing Activities).

	IGARD noted the application referred to a 10 year follow up and reference in section 5(b) to funding and asked that this was removed as it was not relevant. IGARD queried the reference in section 5(b) to *"It is proposed that there will be a plan to follow the cohort extracted from EMIS over the next 10 years with linkage to HES…"* and asked that section 1 (Abstract) and section 5(b) were updated to clarify that the data requested within this application was for a specific point in time; and that should the applicant request further HES data that this would be subject to an amendment application being submitted to NHS Digital and the necessary approval being provided. IGARD also asked that section 5(c) and 5(d) (Benefits) were updated to ensure that the information provided related to the processing outlined and the data received in this specific application. IGARD also queried if the benefits could be realised from the type of data that was being requested; and asked for further clarity on this. IGARD noted the information provided in section 5(a) (Objective for Processing) that stated *"Regeneron (the funder) have no scientific input into this study and no influence over the outputs."* and asked that this was replicated as a special condition in section 6 (Special Conditions). IGARD queried what patient-focussed transparency materials were available, for example leaflets, posters etc, and asked that the applicant provide these to NHS Digital; noting that the draft transparency materials had been provided for the Practice Manager but were not focussed on the patient cohort audience. **Outcome Summary:** Recommendation to defer, pending: 1. To provide clarity throughout the application if the cohort age group are those aged 40-74 (as part of the NHS Health Check) or those aged 30-90; and to provide a further explanation within section 3(b) of how the cohort numbers were agreed. 2. Following clarification of the cohort age group, to ensure that ethics approval and other relevant support is still applicable. 3. Throughout the application to amend the reference from "consent form" to "participation agreement" (or similar). 4. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example when referring to "burden"). 5. To remove the relevant paragraphs referencing 'processing' from section 5(c) and include within section 5(b). 6. To remove the reference to 'funding' from section 5(b). 7. To update section 1 and section 5(b) to clarify that the data is requested for a specific point in time and that should the applicant request further HES data that this will be subject to an amendment application to NHS Digital (and the necessary approvals being provided). 8. To update section 5(c) and section 5(d) to ensure the information provided relates to the processing outlined and the data received in this specific application. 9. To clarify that all stated benefits can be realised from the type of data requested in this application. 10. To amend the application to state that the funder will have no scientific input into this study and no influence over the outputs; and to also include this as a special condition in section 6. 11. The applicant to provide to NHS Digital patient-focussed transparency material, for example a leaflet and poster (noting that draft transparency materials have been provided for the Practice Managers but not focussed on the patient cohort).

2.3	The University of Manchester: MR727 - Toxicity from anti-TNF therapy (Presenter: Louise Dunn) NIC-148353-G88Q7 **Application:** This was an extension, renewal application for identifiable Medical Research Information Service (MRIS) and an amendment to add an additional Data Controller for a long-term observational study to monitor the safety of new biologic and targeted therapies prescribed for rheumatoid arthritis in routine healthcare, specifically to understand if these new drugs increase the risks of developing cancer or premature death above the expected risks in a population with similar disease characteristics not receiving these therapies. **Discussion:** IGARD queried if the British Society of Rheumatology had a Privacy Notice that was specific to its role as a Data Controller and asked that NHS Digital satisfy itself of this, as well as ensuring that it was accessible to the public. IGARD suggested that the sentence in 5(a) (Objective for Processing) that stated: *"The risk of potential harm, in terms of moral or ethical issues, to the public by the dissemination of data from the study is minimal."* was removed since it was not necessary to include in the application. IGARD noted the role of the pharmaceutical companies in funding the study, and asked that the application was amended to clearly state that the funder would not have any scientific input into this study and no influence on the outputs; and asked that this was also replicated as a special condition in section 6 (Special Conditions). IGARD queried information outlined in section 5(c) (Specific Outputs Expected) that referred to future outputs and benefits linked to data not in this agreement; and asked that the applicant ensure that outputs and benefits reflect the data flowing under this agreement and not just for such time when the applicant may receive HES data in the future. IGARD also queried how the outputs for the participants of the study would be disseminated and asked that section 5(c) was updated with a plan for an explanation of this, for example via a newsletter (referred to in the supporting document's provided). IGARD noted the information provided in the Patient Information Sheet that stated *"Your participation will not interfere with the standard of care you receive."* and suggested that future iterations be updated to make it expressly clear that "non-participation" would not affect the standard of care received. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. NHS Digital to be satisfied the British Society of Rheumatology has a Privacy Notice specific to its role as Data Controller and that is accessible to the public. 2. To remove from section 5(a) reference to '*there are no moral or ethical issues*". 3. To amend the application to state that the pharmaceutical funder will have no scientific input into this study and no influence over the outputs; and to add this as a special condition in section 6. 4. To update section 5(c) to ensure the outputs and benefits outlined reflect the data flowing under this agreement and not just for such time when the applicant may receive HES data in the future. 5. To update section 5(c) to set out the plan for an explanation of the outputs for the participants, for example via the newsletter referred to in the supporting documents. The following advice was given:

	1. IGARD suggested that future iterations of the Patient Information Sheet be updated to make it expressly clear that "non-participation" will not affect the standard of care received.
2.4	<u>Cardiff University: Modelling the associations between wider health and social characteristics and diabetes related health (Presenter: Louise Dunn) NIC-158283-T2Q2D</u> **Application:** This was an amendment application to permit NHS Digital to disclose the names of the data subjects as part of the National Diabetes Audit (NDA) following the amendment of s251 support. The data is 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. The application was been previously considered on the 14th February 2019 when IGARD had been unable to recommended due to Healthcare Quality Improvement Partnership (HQIP) not providing adequate evidence to substantiate that public task is the appropriate legal basis. **Discussion:** IGARD noted that they were previously unable to recommend due to the inadequate evidence to support HQIP's legal basis and were advised by NHS Digital that they had taken the decision to disseminate data. NHS Digital noted that HQIP no longer handled the NDA data which was now done by NHS Digital under Direction and in light of this, IGARD asked that reference to HQIP was removed from the application including (but not limited to) the legal basis in section 1 (Abstract). IGARD suggested that the sentence in 5(a) (Objective for Processing) that stated: *"Cardiff University has determined that there are no moral or ethical issues from dissemination of data for this purpose."* was removed since it was not relevant. IGARD queried if a copy of the Health Research Authority Confidentiality Advisory Group (HRA CAG) register was available to support the s251 support and asked that NHS Digital updated their Customer Relationship Management (CRM) holder with a copy, if available. IGARD noted that section 1(c) (Data Processors) incorrectly listed the North West Informatics Service (NWIS) and asked that this was amended with the correct information. IGARD noted that the applicant's privacy notice did not meet NHS Digital's fair processing notice criteria and given the nature of the work being undertaken, suggested that when NHS Digital discuss the Privacy Notice with the applicant, the applicant may wish to analyse the processing undertaken to consider if profiling or automated decision making was taking place. **Outcome Summary:** recommendation to approve 1 To remove reference to HQIP from the application including (but not limited to) the legal basis in section 1, in light of HQIP no longer handling the National Diabetes Audit (NDA) data. 2 To remove from section 5(a) reference to '*there are no moral or ethical issues*". 3 To update the CRM holder with a copy of the CAG register (if available). 4 To update section 1(c) to amend the reference to the 'North West Informatics Service (NWIS)'. The following advice was given:

	1 IGARD suggested that when NHS Digital discuss the Fair Processing Notice with the applicant, they suggest the applicant analyses the processing to consider if profiling or automated decision making is taking place.
2.5	University of Sheffield: The PJI Study: Do Invasive Dental Procedures Cause Prosthetic Joint Infections (PJI)? (Presenter: Dickie Langley) NIC-261216-Q1L2Q **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data for a study looking at the link between Invasive Dental Procedures (IDP) and Prosthetic Joint Infections (PJI). The primary objective is to perform a case-crossover design study to quantify the incidence of IDP in the 3 months immediately preceding an LPJI diagnosis and compare this with the incidence of IDP in earlier 3-month periods for the same patient, before the Late peri-Prosthetic Joint Infections (LPJI) diagnosis. In addition, as a secondary objective the study will include a case-control design study comparing the frequency of courses of dental treatment that DO (cases) and DO NOT (controls) involve an IDP in the 3 months immediately preceding a LPJI. NHS Digital advised IGARD that they had undertaken an analysis the involvement of the University of Sheffield and that they considered them to be the sole Data Controller. **Discussion:** IGARD welcomed the application and noted the importance and potential far-reaching impact of the study. IGARD considered the data controllership and agreed with NHS Digital's analysis that the University of Sheffield had been correctly identified as the sole Data Controller for this study. IGARD noted that the table in section 3(b) (Additional Data Access Requested) cited s261(7) as the correct legal basis and asked that this was updated to include an additional statutory basis to support this. IGARD queried how the findings of the study would be applicable to the public in the UK, since the application predominately outlined how the findings would be applicable to the USA and asked that section 5(b) (Processing Activities) and section 5(c) (Specific Outputs Expected) were updated to clarify this; as well as providing further details of the plans for dissemination to the relevant interested public in the UK, for example recipients, or prospective recipients, of joint replacements. IGARD noted the benefits outlined in the application and queried if any UK cost analysis had been undertaken, in addition to the USA cost analysis information provided, including the possible reduction of antibiotic use, and asked that further details of this were included in section 5(d) (Benefits). IGARD queried the information provided in section 5(a) (Objective for Processing) and asked that the introduction to this section was updated to ensure it highlighted the specific objective for processing that was relevant to the UK. IGARD noted the role of the pharmaceutical companies in funding the study and asked that the application was amended to explicitly state that the funder would not have any scientific input into this study and no influence on the outputs; and asked that this was also replicated as a special condition in section 6 (Special Conditions). IGARD and NHS Digital noted that section 5(d) needed updating further to confirm that the additional collaborators, researchers and funder would not have influence on the outcomes nor suppress any of the findings of the research; and that this should also be replicated as a special condition in section 6 (Special Conditions).

	Outcome Summary: recommendation to approve 1. To update the table in section 3(b) to include an additional statutory basis to support the s261(7) citation. 2. To update section 5(b) and 5(c) to clarify how the findings of the study will be applicable to the public in the UK and plans for dissemination to the relevant interested public in the UK (for example recipients, or prospective recipients, of joint replacements). 3. To provide further details in section 5(d) of any UK cost analysis undertaken and the possible reduction of antibiotic use. 4. To ensure that the introduction of 5(a) highlights the specific objective for processing, relevant to the UK. 5. To confirm within section 5(d) that the additional collaborators, researchers and funder will not have influence on the outcomes nor suppress any of the findings of the research; and to replicate this within section 6 as a special condition.
2.6	<u>NHS Midlands and Lancashire CSU: (Presenter: James Humphries-Hart) NIC-317048-N8P0R</u> **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), Civil Registries Data (CRD), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs) data to provide intelligence to support the commissioning of health services. NHS Digital noted that section 5(a) (Objective for Processing) contained two duplicate paragraphs that started *"In addition to the dissemination of Cancer Waiting Times Data via the DSCRO…"* and advised that both of these would be removed from the application as they were not relevant. **Discussion:** IGARD noted and supported the amendment suggested by NHS Digital in removing the two duplicate paragraphs in section 5(a). IGARD queried the transparency materials provided as part of the supporting documentation and suggested that NHS Digital satisfy themselves that NHS Redditch and Bromsgrove CCG had published appropriate transparency material, such as a Privacy Notice. IGARD noted the references within section 3(b) (Additional Data Access Requested) to '*identifiable*' and asked that these were amended to correctly say '*pseudonymised*'. IGARD queried the second paragraph in section 5(a) "*Sustainability and Transformation Partnerships build on collaborative work that began under the NHS Shared Planning…" and asked that this was removed as it was not relevant.* IGARD noted that section 5(a) referred to "*6 CCGs*" and asked that this was updated to correctly reference "*4 CCGs*" as outlined elsewhere in the application. **Outcome Summary:** recommendation to approve subject to the following condition: 1. NHS Digital should satisfy themselves that NHS Redditch and Bromsgrove CCG have published transparency material, such as a Privacy Notice. The following amendments were requested:

	1 To update section 3(b) to amend the references from 'identifiable' to 'pseudonymised'. 2 To remove the second paragraph in section 5(a) that starts *"Sustainability and Transformation Partnerships build on collaborative work that began under the NHS Shared Planning…"* 3 To update section 5(a) to amend the reference from 6 CCG's to correctly reference 4 CCGs. 4 To remove the last 2 paragraphs in section 5(b) as they are not relevant.
2.7	<u>Theatres Data Set – Briefing Paper (Presenters: Paul Croft / Emma Summers)</u> The briefing paper was to inform IGARD about the National Clinical Improvement Programme (NCIP) Theatres Dataset Collection, which is a discovery collection commissioned by NHS Improvement (NHSI) to support the NCIP digital product implementation. A mandatory request has been received from NHSI instructing NHS Digital (NHSD) to collect the NCIP Theatres Dataset for the duration of the discovery submission window (between July and December 2019). NHS Digital is requested not to disseminate theatre data collected during the discovery phase to any other party except with express permission of NHS Improvement. The discovery project is intended to assess the value of the theatres dataset to both improve the accuracy of the NCIP digital products and to Inform the subsequent development of a National Theatre Data Set, including understanding data items and definitions routinely recorded within theatre systems and potential barriers, burden and costs associated with submission to NHS Digital. IGARD welcomed the briefing paper, which has been previously presented on the 18th July 2019 and had been updated to reflect most of the comments previously made, and looked forward to receiving a "live" application in due course, alongside the finalised briefing paper as a supporting document. IGARD provided the following comments: 1. To update the briefing note in line with suggested comments including, but not limited to, clarifying the legal basis for NHS Digital to receive, process and disseminate data under GDPR 2. To provide a copy of the DPIA for IGARD to review OOC.
3	<u>Returning Application - NIC-139091-F3T3H NHS Bolton CCG</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. IGARD welcomed the application 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 & Assurance Report which will be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis
4 **4.1**	**AOB:** <u>Risk Stratification and Automated Decision Making</u> NHS Digital presented a paper considering some of the issues raised by Risk Stratification in the context of profiling and Automated Decision making under the General Data Protection Regulation (GDPR). IGARD commended this step and agreed that further consideration needed to be given to the issue.

4.2	There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting. As part of their oversight role, IGARD discussed the following matters: • Review: Standard 2 - Processing and Storage Locations

Independent Group Advising on Releases of Data (IGARD): Out of committee report 06/09/19

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-226185-B6C2J	University of Hull	01/08/2019	1. To provide written confirmation from the Faculty of Health Sciences Ethics Committee, University of Hull (or an authorised representative of that committee) that an ethics exemption has been granted and that permission to use the pseudonymised data has been given.	IGARD Chair	OOC by IGARD Chair	
NIC-182736-Q2K7Y	King's College London	09/05/2019	1. To include the University of Oxford as a Data Controller within Section 1(b) to reflect the narrative in the supporting documents. 2. To update the description of the cohort to: i) update the data access table in section 3(b) to explain the split between the exposed and non-exposed veterans that together form the cohort, and ii) to update both the table in section 3(b) and the application to explain the approximate 5,000 difference between the cohort noted in the table and the cohort in the protocol and elsewhere.	IGARD Chair	OOC by IGARD Chair	

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

- None