Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 11 July 2019

In attendance (IGARD Members): Anomika Bedi, Maria Clark (Alternate Deputy Chair), Priscilla McGuire, Eve Sariyiannidou.

In attendance (NHS Digital): Victoria Byrne-Watts, Dave Cronin, Dickie Langley, Karen Myers, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Nicola Fear, Kirsty Irvine (Chair), Geoffrey Schrecker, Maurice Smith.

1	**Declaration of interests:** Maria Clark noted professional links to the Royal College of Surgeons [NIC-161422-Q0K1M Royal Liverpool University Hospital] 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 4th July 2019 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 B).
2	**Data applications**
2.1	NHS North Kirklees CCG**:** DSfC - NHS North Kirklees CCG - RS and IV (Presenter: Dickie Langley) NIC-191964-Y3Z1L **Application:** This was an amendment application for identifiable Secondary Use Service (SUS+) data for the additional 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. **Discussion:** IGARD noted information provided in section 5(b) (Processing Activities) under 'Risk Stratification' that stated *"Patients who are normally registered and/or resident within NHS North Kirklees CCG (including historical activity where the patient was previously registered or resident in another commissioner)"* and asked for further clarification that the data being disseminated was for those who lived in the CCG's area and / or those who were registered in the CCG's area. IGARD asked that the information provided in section 5(b) under 'Segregation' be updated to also clarify that where there were two datasets relating to opt outs, one where opt-outs had been applied and one where opt-outs had not been applied to confirm that those datasets would be held separately to reduce the likelihood of re-identification of those who had opted out. IGARD noted information provided in supporting document 1, the data flow diagram that described that the backing-data sets would be flowing from the provider to the Controlled Environment for Finance (CEfF) (in the North of England Commissioning Support Unit) as well as the SUS data flowing from NHS Digital to CEfF and asked that section 5(b) was updated to also clearly reflect this. **Outcome Summary:** recommendation to approve The following amendments were requested:

	1. To update section 5 to provide further clarity that the data being disseminated is for those people who live in the CCG's area or who are registered in the CCG's area. 2. To update section 5(b) ('Segregation') to clarify that there are two datasets, one for where opt-out has been applied and one where opt out has not been applied and confirm that these datasets will be held separately to reduce the likelihood of re-identification of those who have opted out. 3. To update section 5(b) ('Invoice Validation') to clarify that backing-data sets are flowing from the provider to CEfF as well as the SUS data flowing from NHS Digital to CEfF.
2.2	<u>NHS North East Lincolnshire CCG: DSfC - NHS North East Lincolnshire CCG; IV & Comm. (Presenter: Dickie Langley) NIC-59807-V1B8W</u> **Application:** This was an amendment application for pseudonymised Secondary Use 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), Diagnostic Imaging Data Set (DIDS), Community Services Data Set (CSDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs) for the additional 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 to provide intelligence to support the commissioning of health services. NHS Digital advised that the application and supporting document 1, the data flow diagram were inconsistent; and that the diagram would need updating to remove the reference to 'consented data'. **Discussion:** IGARD noted the update from NHS Digital on the inconsistencies in the application and supporting document 1; and supported the amendment to the data flow diagram to remove the reference to 'consented data'. IGARD also queried information in section 5(b) (Processing Activities) that stated the SUS records would flow to the provider and asked that the data flow diagram was updated to reflect this and that the risk stratification element was also removed from the application. IGARD noted the information in section 5(b) that SUS records would be sent back to the Commissioner and the provider as part validation and asked that this section was updated to provide further clarity. IGARD noted information provided in supporting document 1, that described that the backing-data sets would be flowing from the provider to the Controlled Environment for Finance (CEfF) (in the North of England Commissioning Support Unit) as well as the SUS data flowing from NHS Digital to CEfF and asked that section 5(b) was updated to also clearly reflect this. IGARD queried the sentence in section 5(b) that states *"The data to be released from NHS Digital will not be national data."* and asked that this was removed as further information was contained later on in the application identifying the dataset in more detail. IGARD noted information provided in section 5(b) under 'For the purpose of Commissioning' that stated *"Patients who are normally registered and/or resident within East riding of Yorkshire CCG (including historical activity where the patient was previously registered or resident in another commissioner)"* and asked for further clarification that the data being disseminated was for those who lived in the CCG's area and / or those who were registered in the CCG's area. **Outcome Summary:** recommendation to approve

	The following amendments were requested: 1. To update section 5(b) to remove the sentence *"The data to be released from NHS Digital will not be national data."*. 2. To update section 5 to provide further clarity that the data being disseminated is for those people who live in the CCG's area or who are registered in the CCG's area. 3. To update section 5(b) ('Invoice Validation') to clarify that backing-data sets are flowing from the provider to CEfF as well as the SUS data flowing from NHS Digital to CEfF. 4. To provide further clarity in section 5(b) (Point 8) that SUS records will be sent back to the Commissioner from the provider as part of the validation. 5. To amend the data flow diagram to show the SUS records flowing to the provider; to remove the Risk Stratification element and to remove the reference to consented data.
2.3	<u>National Institute for Health Research (NIHR) Bioresource: MR1393 - Join Dementia Research (Presenter: Victoria Byrne-Watts) NIC-366913-C2V5F</u> **Application:** This was a renewal and amendment application for Medical Research Information Service (MRIS) data for a UK-wide service that allows people to register their interest in participating in dementia research and be matched to suitable studies via website and database and is a key element of the Prime Minister's Challenge on Dementia 2020. **Discussion (Consent Materials):** IGARD welcomed the application which came for advice on the consent materials. IGARD had a lengthy discussion on the consent materials in relation to the General Data Protection Regulation (GDPR) and these were not deemed to meet the GDPR consent requirements both in terms of content as well as process. IGARD suggested that the applicant should seek further advice from their Data Protection Officer (DPO) and discuss with them the options for the way forward which might also include approaching the Information Commissioners Office (ICO). IGARD also asked that when this application returned for a full review the applicant would need to provide clear, substantive answers based on the consent materials provided to the DPO and the ICO and to present a clear case to NHS Digital, including a clear narrative substantiating and making a clear case on their legal basis as the consent materials were not deemed compliant with the GDPR standards and the window of opportunity had lapsed to either uplift the consent materials or change legal basis. . IGARD also noted that a list clean had been requested and advised that the consent materials did not currently cover this. Under GDPR each purpose for processing the data would need to be clearly outlined in the consent materials. **Discussion (Application):** IGARD queried the reference in section 1 (Abstract) to "reasonable expectations" under the Common Law Duty of Confidentiality heading and asked that this was removed as it was not relevant. IGARD noted the reference in section 1 to the Health and Social Care Act s261(7) being the legal basis for dissemination and asked that this be expanded and updated as appropriate. IGARD queried the reference in section 1 under Patient Objections that states *"Will not apply as s251 support is not in place. Consent is in place to meet the Common Law Duty of Confidentiality."* and asked for the exact position to be specified. It was noted that s251 support would only be used if consent was not being relied on (and such an application would have had to have been made). IGARD noted that section 3(a) (Data Access Already Given) was incomplete and asked that this was updated with to reflect the data already received.

	IGARD asked that the applicant provide more detail as to how the issue of mental capacity was addressed as this issue may be relevant in respect of those with dementia who were signing up to the research. IGARD asked that section 5 (Purpose / Methods / Outputs) was updated to clarify this; and explain how the applicant would determine when participants were in a position to sign-up to the research in their own right and when carers signed up for them relying on a power of attorney. IGARD also noted the importance of ensuring the use of technical language was used only where necessary and that section 5 was written in a language suitable for a lay reader. IGARD noted that the information provided in section 7 (Ethics Approval) was incomplete and asked that this was updated to correctly reflect if ethics approval was / not required. **Outcome Summary:** IGARD welcomed the application which came for advice on the consent materials and provided comments without prejudice to any additional issues that may arise when the application is fully reviewed.
2.4	<u>Beyond Compliance (Northgate Public Services (UK) Limited): Beyond Compliance - PROMs data application (Presenter: Victoria Byrne-Watts) NIC-58668-V5C0L</u> **Application:** This was a renewal and amendment application for Patient Reported Outcome Measures (PROMs) data for the purpose of service evaluation relating to the manufacturing of implants used in hip and knee replacements. The objective is for Northgate Public Services to provide the Beyond Compliance Advisory Committee and the implant manufacturer with the mechanism to assess the patient reported outcomes of patients receiving an implant (within the Beyond Compliance service) in comparison to the national average procedure-specific scores to monitor implant performance, and to flag any areas where patient outcomes report to be statistically significantly worse than the expected. **Discussion (Consent Materials):** IGARD welcomed the application which came for advice on the consent materials and noted that the purpose outlined in the application was positive in that it focussed on product safety. IGARD noted that when this application had previously been discussed at IGARD in March 2018 a condition had been placed to update their consent materials which was as far as IGARD could advise at the time, it had been requested, following the coming into force of the General Data Protection Regulation (GDPR) and end of the transition period (on the 25th May 2018), that NHS Digital should work closely with the applicant to revise their consent materials to ensure they were updated in-line with the GDPR standards. IGARD noted that since GDPR had come into force and the end of the transition period, the opportunity to uplift the consent materials to the required GDPR standards or to choose an alternative legal basis had lapsed. IGARD also advised that since the consent materials had not been updated to be GDPR compliant and the applicant was still processing data under the consent legal basis, that the Article 29 Working Party Guidelines and the ICO guidance advised that those processing personal data in such a situation would need to stop processing the data and IGARD advised NHS Digital accordingly. **Discussion (Application):** IGARD noted in section 3(a) (Data Access Already Given) that PROMs data had been previously requested and asked for further information if this was survey data only or further clarification if this contains anything else. IGARD also noted that PROMs data was only available for non-commercial purposes and that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that the purpose was commercial; and further information should be provided on how they are delivering services to the NHS.

	IGARD queried who 'Beyond Compliance' were and asked for further clarity in section 5(a) (Objective for Processing) along with details of their relationship with Northgate Public Services (UK) Limited. IGARD suggested that this section be updated with a clear outline of how the data was being processed and the service provided, such as not just looking at the safety of a medical device but also looking at how patients were living with the product, patient satisfaction and lived experience. IGARD noted that a previous version of the application had only approved the flow of data for one part of the cohort and asked for a further clear narrative in section 5(a) and 5(b) (Processing Activities) outlining this for a clear audit trail, plus including additional narrative of the other part of the cohort. IGARD noted the reference to the Healthcare Quality Improvement Partnership (HQIP) in the consent materials and asked for further clarification in section 5(b) of their role. IGARD queried the reference to the BC Index Number (Study ID) in section 5(b) and asked that this was removed as it was expressly stated in the consent materials that this field would not be disseminated by NHS Digital. **Outcome Summary:** IGARD welcomed the application which came for advice on the consent materials and provided comments without prejudice to any additional issues that may arise when the application is fully reviewed.
2.5	<u>Royal Liverpool University Hospital: A Risk-adjusted and Anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms (UK-COMPASS) (Presenter: Dave Cronin) NIC-161422-Q0K1M</u> **Application:** This was an extension and amendment application for identifiable Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistics (HES), pseudonymised Secondary Use Service (SUS) and Emergency Care Data Set (ECDS) for a study looking at the clinical and cost-effectiveness of strategies for the management of juxtarenal abdominal aortic aneurysm, including fenestrated endovascular repair. The study intends to analyse the outcomes of all patients aged 25 - 100 years, undergoing juxtarenal aneurysm treatment in England without altering their treatment, during a period of 2 years. **Discussion:** IGARD noted in supporting document 2.0, the clinical study protocol listed a number of co-investigators from the University of Liverpool and queried why the University of Liverpool were not considered a joint Data Controller. In addition, IGARD asked for further clarity as to why the University of Liverpool had been added as a Data Processor. IGARD queried the role and involvement of a number of additional co-investigators from various organisations, as listed in the study protocol. NHS Digital noted that although involved initially in the study methodology their role was an ongoing one as part of the study committee, reviewing the process of the study and giving advice, however IGARD asked for clarification that section 5 (Purpose / Methods / Outputs) was updated to explicitly state that these additional collaborators were not part of the study team. IGARD queried if the ongoing funding as described in the application was still ongoing since the funding documents provided were historical and there was no up to date evidence presented, and asked that written evidence that ongoing funding was in place was provided for clarity. IGARD queried if the National Vascular Registry (NVR) dataset was part of the initial s251 application made to the Health Research Authority Confidentiality Advisory Group (HRA CAG). NHS Digital noted they had advised the applicant as part of their annual review to advise HRA CAG that the dataset was not listed on the updated register. IGARD asked that written evidence was provided of communication between the applicant and HRA CAG whereby the

	applicant provided an additional notification to CAG for clarification purposes that the NVR dataset was part of the applicant's initial application and the applicant understood that it is therefore part of the ongoing s251 support. IGARD noted that section 1 (Abstract) should be amended to make clear that the applicant is a Foundation Trust and the relevant Article 6 and 9 of the GDPR be updated to reflect recent discussions between NHS Digital and IGARD including, but not limited to, reference to section 43(5) NHS Act 2006 in relation to the legal basis for Foundation Trusts. IGARD queried information in section 5(d) that states *"Healthcare users **can** expect to benefit in terms of improved quality of care in the form of improved survival rates and post-operative quality of life."* and asked that this was updated to accurately reflect that "*Healthcare users would be hopeful…".* IGARD noted that NHS Digital have been asked to receive data and act as a Data Processor under instruction from the Royal Liverpool and Broadgreen University Hospital NHS Trust and asked that section 5 was updated to clarify NHS Digital's role as a trusted third party. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To clarify why the University of Liverpool are not considered a joint Data Controller; and why they have been added as a Data Processor. 2. To provide written up to date evidence that ongoing funding is in place. 3. To confirm in section 5 that the remaining collaborators referred to in the protocol are not part of the study team outlined in the application. 4. To provide written evidence of the communication between the applicant and HRA CAG confirming NVR dataset was part of the initial application and is therefore part of the ongoing s251 support. The following amendments were requested: 1. To update the abstract on Article 6 and 9 to reflect the recent discussions between NHS Digital and IGARD including, but not limited to, reference to section 43(5) NHS Act 2006 in relation to the legal basis for Foundation Trusts. 2. To review the benefit outlined in section 5(d) that states *"Healthcare users can expect…"* to accurately reflect that *"Healthcare users would be hopeful…".* 3. To clarify in section 5 that NHS Digital had been asked to receive data and act as processor to carry out its role as trusted third party and under instruction from the Royal Liverpool & Broadgreen University Hospitals NHS Trust. It was agreed the conditions would be approved OOC by IGARD members
3	**AOB:** **3.1 Clinical Registries for Commissioning (Presenter: Dickie Langley)** IGARD and NHS Digital discussed information relating to Clinical Registries for Commissioning. Clinical databases play a pivotal role in the clinical management of specialised patients. They collect information about rare diseases, conditions and treatments at a much more granular level than is possible in core Trust Patient Administration Systems (PAS). Clinical areas use the databases to inform their clinical accreditation process, support research and audit, and when performance is benchmarked with other similar organisations aids identification of areas for clinical improvement. It formulates / facilities the creation of clinical support networks (both nationally and in some instances worldwide) of clinicians who specialise in similar conditions.

	Clinical databases have a part to play in the commissioning process. In some instances, the physical content of a clinical registry is used as the main source of information for the contract planning round. 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 of DARS Dashboard • CCG Precedent – it was agreed that the CCG precedent would be updated to reflect discussions by NHS Digital and recirculated to both NHS Digital and IGARD for further comment.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 05/07/19

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-12828-M0K2D	Imperial College London	20/06/2019	1. The applicant to provide documentary evidence that s251 support is in place for both the research database and the patient re-identification service for all Trusts.	OOC by IGARD Deputy Chair	OOC by IGARD Deputy Chair	
NIC-95040-Y0P3W -	NHS Cambridgeshire and Peterborough CCG	20/06/2019	1. To remove from throughout the application reference to the linkage to consented data. 2. To update section 5(a) to provide a clearer explanation of why the applicant requires the additional datasets linkage.	OOC by quorum of IGARD members	OOC by quorum of IGARD members	
NIC-233512-B7C4W	Northgate Public Services (UK) Limited	11/04/2019	1. To provide written confirmation from HRA CAG that s251 support is not required for the dissemination of LOPATID. 2. To provide the appropriate legal basis under GDPR for the Data Controller (The Society for British Neurological Surgeons) to process the requested data.	OOC by quorum of IGARD members	OOC by quorum of IGARD members	

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

- None