Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 23 May 2019

In attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Maria Clark, Kirsty Irvine (Chair) (2.1–2.5), Geoffrey Smith (Acting Chair) (2.6–2.7).

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

Observer (NHS Digital): Denise Pine

Not in attendance (IGARD Members): Nicola Fear, Priscilla McGuire, Eve Sariyiannidou, Maurice Smith.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 16th May 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	Programme Level Data Sharing Agreements – Briefing Paper (Presenters: Kimberley Watson) The briefing paper was to inform IGARD of work undertaken by the Data Access Request Service (DARS) to develop guidance for organisations making applications for 'programme level' Data Sharing Agreements. A 'Programme Level Agreement' grants a level of autonomy to one or more organisations to determine what projects will use the data under the Agreement without seeking approval from NHS Digital for each specific project; and is an Agreement in which NHS Digital does not approve the use of data for specific projects but instead approves the use of the data for unspecified projects for the purpose of a specified aim. IGARD welcomed the briefing paper and suggested that NHS Digital may wish to consider drafting a Precedent with templated wording for programme level projects for consideration at a future IGARD meeting. In addition, a number of the principles articulated in the briefing paper could be incorporated into a new public facing Standard on Programme Level Data Sharing Agreements. IGARD suggested that this might also address the issue of audit plans for Programme Level Agreements and the identification of further Specific Risk Criteria for high risk applications.
2.2	University of Leicester: Cardio-oncology: A high resolution national electronic health record investigation of the interplay between cancer and heart disease (Presenter: Kimberley Watson) NIC-143888-H0W2N **Application:** This was a new application to allow the access, processing and linkage of identifiable Hospital Episode Statistics (HES) and Civil Registrations data already disseminated under a separate Data Sharing Agreement (DSA) for the VICORI programme;

	which is broken down into four work packages, to undertake health care record population research into the interplay between heart disease and cancer. The application was previously unable to be recommended on the 2nd May 2019 when IGARD gave the following points of advice: in the context of the original application and involvement of HQIP, can Barts Health NHS Trust, Public Health England and University of Leicester be considered Data Controllers for this purpose; to provide clarification in section 5 why the other parties outlined in the protocol are not considered as Data Controllers and in addition a clear case to be made for those Data Controllers listed and an explanation of the criteria applied, based on the protocol document provided; to provide clarification of the roles of the other organisation involved as outlined in the protocol; to provide clarification of the role of Health Data Insight as referred to in supporting document 2.6 and provide further information on who they are; to provide written evidence that the HRA CAG conditions have been met; to update the table in section 3 to refer to s251; to provide a copy of the governance principles for the oversight committee as referred to in section 5(a); IGARD suggested that depending on the analysis of data controllership, this application may be suitable to be merged with the original application (NIC-359940-W1R7B); or that both applications could be reviewed by IGARD together but classed as a standalone applications. **Discussion:** IGARD noted that the application and supporting documents had been updated to address all of the comments previously made. IGARD had a lengthy discussion on the purpose of this application, which was to allow the access, processing and linkage of data disseminated under a different Data Sharing Agreement (DSA) and queried the relationship of the other DSA with this application. IGARD asked that for transparency, NHS Digital clearly noted within section 5(b) (Processing Activities) the NIC number for the previous DSA that this application covered and refer to any other relevant DSA relating to the data disseminated under this DSA so that the fuller picture of the initial audit and additional research with audit data was clearly articulated. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To amend section 5(b) to note the relevant NIC numbers and previous agreements that this application covers and refer to any other relevant data sharing agreements relating to the data used under this agreement so that the fuller picture of the initial audit and additional research with audit data is clearly articulated. It was agreed the conditions be approved OOC by IGARD Members.
2.3	<u>Nuffield Trust: Nuffield Trust Primary DSA (Presenter: Dave Cronin) NIC-226261-M2T0Q</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Emergency Care Data Set (ECDS) and Community Services Data Set (CSDS), for a new Data Sharing Agreement (DSA) to replace several existing active Agreements, involving the same data which is supplied once and reused under the respective Agreements. There are six priority areas which include, Health and Social Care finance and reform, NHS workforce, Older people and complex care, Quality of care, New models of health care delivery and children and young people; the work of the Trust is organised into a number of programmes which address these priorities. **Discussion:** IGARD queried how the previous DSAs would roll forward into this application and how the previous DSAs will end and asked for further clarity on this, including how this will be managed without dislocation of the data.

	IGARD also noted that s251 support was in place for one of the previous DSAs (NIC-384572-J7P6Y) and asked for clarity that this was no longer relevant when rolled forward into this agreement. IGARD noted the reference to the Nuffield Trust Project Planning Committee within the application and queried if there was any Information Governance (IG) expertise on this Committee, and if not, if this was something the applicant had considered, for example including the Data Protection Officer (DPO), to ensure appropriate IG oversight of their processes. IGARD noted reference to linkage to national datasets in the public domain and queried the process in place for evaluating any linkage of data in the verification process and asked for confirmation that how it was documented wouldn't increase the risk of re-identification. IGARD recognised that the Nuffield Trust may be commissioned by other organisations to do research and queried if the Nuffield Trust would maintain sole Data controllership when working with other organisations and asked that section 5(a) (Objective for Processing) was updated clarifying this. IGARD noted the information provided on the remote access arrangements and that this may not necessarily apply to 'on site' and asked for clarity that that this also applied to those employees sitting remotely, as well as those on site. IGARD queried the contractual requirements that were in place for the third-party consultants outlined in the application and asked for further details on this, since it wasn't clear if this was addressing employees and / or independent contractors. IGARD noted the special condition in section 6 (Special Conditions) that references the four pre-existing Agreements and asked that for transparency this was also replicated in section 5 (Purpose / Methods / Outputs). IGARD noted that applicant's Data Protection Act (DPA) Registration had expired and asked for confirmation that this had been updated. IGARD noted that the 'periods' column in the table in section 3(a) (Data Access already Given) had not been populated and asked that this was updated. IGARD noted that section 5(a) should be updated to include clearer examples for processing and how the applicant has been using the data. 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. IGARD queried the lack of benefits within section 5 along with yielded benefits with examples of patient and public engagement. In order to be transparent for the general public when this was published within NHS Digital's data release register IGARD suggested on renewal further information would be expected to be provided. IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice within six months. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To provide clarification in section 1 and section 6 on how the previous agreements will roll forward into this application including the ending of the previous agreements and how this will be managed without dislocation of the data.

	2. To clarify that s251 support for application NIC-384572-J7P6Y is no longer relevant when rolled forward into this agreement. 3. To clarify if there is IG expertise on the Project Planning Committee, and if not whether the applicant had considered this, for example including the DPO on this Committee. 4. To confirm the process for evaluating any linkage of data in the verification process and that how it will be documented that it doesn't increase the risk of re-identification. 5. To update section 5(a) to clarify that sole Data Controllership will be maintained when working with other organisations. 6. To clarify the remote access arrangements also apply to those employees sitting remotely, as well as those on site. 7. To provide details of the contractual requirements in place for the third-party consultants. 8. To replicate the special condition referencing the four agreements in section 5. 9. To confirm that the DPA registration has been updated. 10. To update section 3(a) to populate the 'periods' column. The following advice was given: 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement. 2. IGARD advised when the application returns to IGARD for renewal, IGARD would expect to see further information with regard to yielded benefits. 3. IGARD suggested that the applicant should work with NHS Digital on a fair processing notice that is GDPR compliant within 6 months.
2.4	<u>University of Leeds: UK Women's Cohort Study-HES new database (Presenter: Louise Dunn) NIC-109867-M8S6B</u> **Application:** This was a new application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Civil Registrations data. The study of 35,000 women was established to explore links between diet, lifestyle and chronic disease, in particular cancer. The objective is to create a new database to support analysis of a number of key research questions so that links can be explored between diet, lifestyle and health outcomes and to create a unique research data set for the UK. **Discussion:** IGARD queried the information provided on the cohort numbers, referencing 34,312 within section 3, 35,000 referenced in section 5 and 14,000 referenced in supporting document 1 (s251 application form) and asked that section 3(a) (Data Access already Given) was updated to clearly define the cohort and any exclusions to the cohort. IGARD noted that a number of other organisations were referenced in section 5(a) (Objective for Processing). NHS Digital confirmed that these organisation would have no access to NHS Digital data. IGARD asked that this was updated further to provide clarification on the roles of these organisations; or to confirm that they have no role. IGARD also noted the reference to the Leeds Institute for Data Analytics (LIDA) in section 5(a) and asked for clarification that these were all substantive employees of the University of Leeds. IGARD queried if the University of Leeds would remain the Data Controller for all honorary contracts and asked that section 5 (Purpose / Methods / Outputs) was updated to explicitly state this. IGARD also queried if the appropriate 3-way contracts including the substantive

	employer of the guest researcher were in place for all honorary contracts and asked that section 5 was updated clarifying this. IGARD queried what process was in place for researchers accessing the data and who was deciding the oversight for data minimisation, and asked that this was clarified ensuring the appropriate data minimisation was undertaken. IGARD also noted the data accessed by each project outlined in the application and asked that justification be provided for each one to ensure it had met the necessity test. IGARD noted the list of areas to be investigated in section 5(a) and queried point 6, the *"health experience of participants and family members"* and asked for further clarification of how the family members fitted into the study. IGARD queried which identifiers were flowing out from NHS Digital and if data minimisation was in line with and meets the linkage quality and asked for clarity of this in section 5(b) (Processing Activities). IGARD queried if the operational arrangements for making sure linkage to the public available data is not increasing the risk of re-identification and asked that this was also confirmed in section 5(b). IGARD noted the reference in section 5(c) (Specific Outputs Expected) to "researchers" and queried if these were University of Leeds researchers and asked that this be updated to be clear they were researchers from the University of Leeds. IGARD suggested that section 1 be updated with regard the duty of confidentiality to reflect recent discussions. IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "*Data processed under this application is personal data under the GDPR. All data controllers shall provide a privacy notice that is compliant with the GDPR notice requirements*" IGARD noted that section 5(a) should be updated to include clearer examples for processing and how the applicant has been using the data. 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. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To update section 3(a) to clearly define the cohort and any exclusions to the cohort. 2. To update section 5(a) further to provide clarification of the roles of the other organisations involved or to confirm that they have no role. 3. To provide clarification that LIDA are all substantive employees of the University of Leeds. 4. To explicitly state within section 5 that for all honorary contracts that the University of Leeds remains the Data Controller 5. To clarify within section 5 that for all honorary contracts that appropriate 3-way contracts including the substantive employer of the guest researcher are in place. 6. To clarify the processes for the researchers accessing the data and ensuring appropriate data minimisation. 7. To provide clarification that the data accessed by each project outlined in the application has met the necessity test. 8. To clarify how the "family members" referred to in section 5(a) fit into the study.

	9. To clarify within section 5(b) which identifiers are flowing out from NHS Digital and if minimisation is in line with and meets with linkage quality. 10. To confirm in section 5(b) that the operational arrangements for making sure linkage to the public available data is not increasing the risk of re-identification. 11. To update section 5(c) to clarify that the "researchers" referred to are University of Leeds researchers. 12. To update section 1 to update the duty of confidentiality section to reflect recent discussions. 13. To update section 4 with the standard wording "Data processed under this application is personal data under the GDPR. All data controllers shall provide a privacy notice that is compliant with the GDPR notice requirements". The following advice was given: 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement.
2.5	<u>NHS Rushcliffe CCG: DSfC - Nottinghamshire Joint Data Controller - Commissioning (Presenter: James Humphries-Hart) NIC-274291-Q5T1S</u> **Application:** This was a new application for pseudonymised Secondary Uses Services (SIS+), Local Provider Flows, Civil Registrations data, Improving Access to Psychological Therapies Data Set (IAPT), Children and Young People's Health Service (CYPHS), Maternity Services Data Set (MSDS), National Cancer Waiting Times Monitoring Data Set (CWT), Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS). The data is to support seven CCG's that have formed the Nottinghamshire Integrated Care System (ICS), to provide intelligence to support the commissioning of health services as part of NHS England's five year forward plan. **Discussion:** IGARD noted that the CCGs were accessing a whole geographical area of data in order to work together to plan services on a larger scale in order to improve the quality of services and that each CCG may take the lead on a specific item across the Nottinghamshire Integrated Care System (ICS) or a group of CCG's work together for the whole ICS, but queried the access controls in place and if there was a requirement to restrict access by role and the need of the project and asked for further clarity on this point. IGARD also queried if the access controls were not solely role based, that section 5(b) (Processing Activities) was updated clarifying this. IGARD also queried the information governance processes within the ICS to handle the data. NHS Digital noted that each CCG were the Data Controller for their own data and would access the data based on the role based access controls in place. IGARD asked that a description of how this would work in practice was provided. IGARD queried the detailed work of the ICS and asked for an overview of this; along with justification of the wide level of data access that was required. IGARD also queried the limits of data sharing and if they related to the individual CCG or extended to the ICS and asked that further clarity was provided in section 5(b). IGARD noted point 2 in section 5(b) "Nottinghamshire Health Informatics Service add derived fields and link data" and asked for further clarity on the data linkage to derived fields, what this means and what it is. IGARD queried the information in section 5(b) under the header "onward sharing for direct care" and asked that this was removed as it was not relevant.

	IGARD noted the two Data Processors listed in section 1 and asked that this was updated to provide clarity on their roles, such as Data Controllers who were also undertaking processing activities. IGARD noted the reference in section 1 (Abstract) to "The CCG has a Caldicott Guardian/Clinical Director." And asked that this was updated to say "Each CCG…". **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To clarify the access controls and the requirement to restrict access by role and the need of the project. 2. To provide an overview of the ICS working that justifies the wide level of data access required. 3. To provide a description of information governance processes within the ICS. 4. To update section 5(b) to clarify that the access controls are not solely role based. 5. To update section 5 (b) to clarify the limits of data sharing and if this relates to the individual CCG or extends to the ICS. 6. To update section 5 to remove the section relating to onward sharing for direct care. 7. To provide clarity on the data linkage to derived fields, what it means and what it is. 8. To updated Section 1 to clarify the role of the two data processors listed. 9. To update the section 1 from "the CCG" to "each CCG".
2.6	<u>Manchester University NHS FT: PATTErn: A study of Physical Activity paTTerns and major health Events in older people with implantable cardiac devices (Presenter: Louise Dunn) NIC-206314-N1N7K</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) Accident and Emergency (A&E) and Admitted Patient Care (APC) data. The data is required for a study examining the relationship between physical activity (measured by cardiac devices) and non-elective hospitalisation attendances / admissions (NEHA) in older people with cardiac devices and will be exploring physical activity trends surround NEHAs. **Discussion:** IGARD noted the information provided in section 5(a) (Objective for Processing) that stated "*Patients must be able to provide written, informed consent in the English language."* and asked that an explanation was provided with the rationale for this decision, including what impact this was deemed to have on the outputs and benefits justification. IGARD also asked that section 5(c) (Specific Outputs Expected) was updated outlining the impact of the English language only consent and that this was also replicated in section 5(d) (Benefits) along with the benefits. IGARD noted that funding from Medtronic Inc ended in April 2019 and that the funding would be taken over by the British Heart Foundation and asked that section 1 (Abstract) was updated to reflect that this funding was ongoing. IGARD queried the role of Medtronic Inc in the dataflows, as it was not clear if they were processing device only data or NHS Digital data and asked that section 1 and section 5 (Purpose / Methods/ Outputs) were updated to clearly state their role and the data they were accessing. IGARD also noted that since Medtronic Inc would not have any access provided under this Data Sharing Agreement (DSA) to any NHS digital data that section 6 (Special Conditions) was updated to include a special condition explicitly stating this.

	IGARD noted that the applicant had answered 'yes' in section 5(e) (Is the Purpose of this Application in Anyway Commercial?) and asked that this was updated to correctly state that the study was not commercial, and that the text provided was included in section 5(a) for transparency. **ACTION:** separate to this application NHS Digital should update their Customer Relationship Management (CRM) so that the free text box should be available within section 5(e) whether an applicant answers 'yes' or 'no' IGARD suggested that a clear explanation be given as to how the benefits derived from this study would inform further work and that the applicant consider if any yielded benefits demonstrated from the study could be transferable or made more widely available, including more publicly available. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To provide an explanation on the rationale that *"Patients must be able to provide written, informed consent in the English language."* and what impact this is deemed to have on the outputs and benefits justification; and to update section 5(c) and outlining the impact of the English language only consent; and to replicate this in section 5(d) along with the benefits. The following amendments were requested: 1. To update section 1(a) to clarify that the funding as described in the application is ongoing. 2. To update section 1 and section 5 to provide clarity on the role of Medtronic Inc in the dataflows. 3. To update section 6 to include a special condition to explicitly state that Medtronic Inc will not access any data provided under the agreement. 4. To update section 5(e) to state that study is not commercial and to include the text in section 5(a). The following advice was given: 1. IGARD suggested when the application returns to IGARD for renewal that the applicant should clearly explain how they will use the benefits derived from this study to inform further work. It was agreed the conditions be approved OOC by IGARD Members.
2.7	<u>Cambridge University Hospitals NHS FT: MR1474 - UK-PBC Project - cohort datasets (Presenter: Rachel Farrand) NIC-360208-K1T4F</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) data, identifiable Diagnostic Imaging Dataset (DIDs) and Medical Research Information Service (MRIS) data for a UK-wide project that is broadly aimed at improving the understanding of Primary Biliary Cholangitis (PBC), which is a rare, chronic liver disease. The UK-PBC is divided into 3 Work strands; work strand 1 is involved in developing a comprehensive PBC cohort for complete clinical characterisation; work strand 2 is focused on the immunology behind PBC; and work strand 3 is involved in delivering clinical trials of relevance to patients, patient education and modelling costs and benefits associated with PBC treatment. This application refers to work strand 1 only. The application was been previously considered on the 21st February 2019 when IGARD

	had deferred pending: to provide a clear narrative on how this component of the project (work strand 1) fits into the wider Immune-Mediated Inflammatory Disease Biobanks in the UK project referred to in the funding letter provided as a supporting document; with reference to 1 above, to clarify the roles and responsibilities of the organisations and companies stated in the funding letter and listed within section 5a; to clearly describe how the protocol and ethics approval included with this application align with the wider Immune-Mediated Inflammatory Disease Biobanks in the UK project; to clearly explain within the abstract and section 5 what is meant by 'major life events'; to include a special condition that there will be no onward sharing of NHS Digital data; to include a special condition that the only individuals accessing the NHS Digital data are the lead investigators and their teams who are substantive employees of Cambridge University Hospital NHS FT or the University of Cambridge, the two lead organisations; to correctly update the Cambridge University Hospital NHS FT DPA expiry date; the abstract should be updated to remove "(2)" after GPDR Recital 52. **Discussion:** IGARD noted that the application had been updated to reflect all of the comments previously made and welcomed the supporting document which clearly outlined the changes that had been made to the application. IGARD queried if the individuals accessing the data were substantive employees of the University of Cambridge or the Cambridge University Hospitals NHS Foundation Trust and asked that section 5(b) (Processing Activities) and section 6 (Special Conditions) were updated to clarify this point. NHS Digital noted that the 'identifiability' column in the table in section 3(b) (Additional Data Access Requested) was not populated and advised this would be updated to correctly note that the data was identifiable. IGARD noted and supported this update to section 3(b). **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To update section 5(b) and section 6 to clarify if the individuals accessing the data are substantive employees of the University or Trust. 2. To update the information within the 'identifiability' column in section 3(b) to correctly note that the data is identifiable.
3	**AOB:** There was no further business raised, the IGARD Chair and Acting 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: • Overview Framework including a review of NHS Digital's Dashboard • Precedent and Standards Review

Independent Group Advising on Releases of Data (IGARD): Out of committee report 17/05/19

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-204520-B1V2G	NHS Wakefield CCG	14/03/2019	1. In light of fact in accordance with the Cancer Waiting Times briefing note, the primary route for CCGs to access data is via Data Services for Commissioners Regional Offices (DSCRO), to provide clarity why the CCG is accessing the data via this route and how that aligns with the advice provided in the CWT briefing note. 2. To remove the non-standard text from section 5(b) from the section that starts “As part of partnership working…” or provide clarification why these named recipients are getting data and at what level. 3. To confirm who the Health and Care Partnership Analytics Team are and provide confirmation that they are substantive employees of Wakefield CCG.	OOC by 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