

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 7 March 2019

Members: Sarah Baalham, Joanne Bailey, Nicola Fear, Kirsty Irvine (Chair), Priscilla McGuire.

In attendance: Louise Dunn, Rachel Farrand, James Humphries-Hart, Karen Myers, Vicki Williams.

Apologies: Anomika Bedi, Maria Clark, Eve Sariyannidou.

1	<p>Declaration of interests:</p> <p>Nicola Fear noted a professional link with Kings College London [NIC-199726-F4V3C] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 28th February 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix B).</p>
2	<p>Data applications</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-204571-R1F4T</u></p> <p>Application: 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>Discussion: IGARD noted that section 3(b) (Additional Data Access Requested) had geographical area information missing from the data minimisation column and asked that this was updated to include the relevant information.</p> <p>IGARD noted the second special condition in section 6 (Special Conditions) “<i>comply with the requirements of NHS Digital Code of Practice on Confidential Information, the Caldicott Principles and other relevant statutory requirements and guidance to protect confidentiality</i>” was no longer relevant and asked that this be removed.</p> <p>ACTION: IGARD noted that NHS Digital’s review of NHS England’s Fair Processing Notice was not included within section 1 (Abstract) of the application and asked that a copy of this was shared with IGARD and for it to be included in future applications, or separately as a supporting document.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none">1. To update the data minimisation column in section 3(b) to include the relevant geographical area.2. To remove the second special condition in section 6 since it is no longer relevant.

King's College London: The National Early Inflammatory Arthritis Audit Data Linkage Request (Presenter: Louise Dunn) NIC-199726-F4V3C

Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for an audit looking to improve the quality of care for people living with inflammatory arthritis by assessing the performance of rheumatology units against NICE Quality Standards. There is compelling evidence that early intensive treatment greatly improves the outcome of these disabling diseases, which predominantly affect people of working age.

NHS Digital noted that section 5(c) (Specific Outputs Expected) contained acronyms that were not fully spelt out upon first use and advised that this would be updated accordingly.

Discussion: IGARD noted that the Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task is the appropriate legal basis.

IGARD noted that under the Common Law Duty of Confidentiality legal basis within section 1 (Abstract) there was reference to "in this case NHS Digital" and asked that this was removed.

IGARD queried the reference to a research database within some of the supporting documents and asked that section 5 (Purpose / Methods / Outputs) was updated to make it clear that the application does not permit the use of NHS Digital Data for the creation of a research database.

IGARD queried why the British Society of Rheumatology were listed as a data processor as they do not store or process the data and are therefore not acting in this role in this application and asked that they were therefore removed as a data processor.

IGARD noted that section 7 (Ethics Approval) states that the applicant's Health Research Authority Confidentiality Advisory Group (HRA CAG) Annual Review was due in April 2018 and asked that this section was updated to refer to the most recent submission and for this document to be uploaded to NHS Digital's Customer Relationship Management system.

IGARD noted that Kings College London hold identifiers with study identifiers and asked for further clarification that the study data disseminated should be described as pseudonymised.

IGARD noted that the Data Protection Act (DPA) 2018 conditions within section 1 (Abstract) stated that the condition was met if the processing is 'carried out by or under the responsibility a health professional'. A named Medical Director was specifically referred to but IGARD asked that this be updated to make it clear that the processing was carried out *under the responsibility* of a health care professional in order to fully satisfy the requirements of the DPA 2018 schedule condition.

IGARD queried the reference in point 6 and 7 within section 5(b) (Processing Activities) to 'IMD rank' and asked that this was updated with a further explanation as to what this is.

IGARD queried the statement in point 2, within section 5(b) "*NHS Digital will share the specified products...*" and asked that this was updated to provide a definition of "specified products". IGARD also noted the reference to "*NHS Digital will share no other identifiable information...*" and asked that this be removed.

IGARD queried the statement "*Data flow includes patient level information at Data Entry...*" and asked this was removed from section 5(b).

Outcome: Unable to recommend for approval

1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis.

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend the Duty of Confidentiality legal basis within the abstract to remove reference to 'in this case NHS Digital'. 2. To update section 5 to make clear that the application does not permit the use of NHS Data for the creation of a research database. 3. To remove the British Society of Rheumatology as a data processor, as they are not acting in that role in this application. 4. To amend section 7 to make reference to the applicant's most recent CAG Annual Review submission and for this document to be uploaded to the CRM holder. 5. Given that Kings College London receive identifiers with study identifiers, to clarify that the study data disseminated should be described as pseudonymised. 6. To update the abstract to make clearer that the processing is carried out under the responsibility of a health care professional in order to satisfy the requirements of the DPA 2018 schedule condition. 7. To update section 5(b) to explain what 'IMD rank' is. 8. To update section 5(b) point 2, to define the reference to "specified products". 9. To update section 5(b), point 2 to remove reference to "other" (identifiable information). 10. To update section 5(b) point 3 to remove reference to "data entry".
2.3	<p><u>Nottingham University Hospitals NHS Trust: MR1469 - Demographic, morbidity and mortality data associated with the STOP-HCV Cirrhosis Study cohort (Presenter: Rachel Farrand) NIC-72626-V4P9B</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES), Medical Research Information Service (MRIS) and Diagnostic Imaging Dataset (DIDs) data for a research study on Hepatitis C Virus (HCV) cirrhosis of the liver. The study aims to aims to establish the most effective and cost-effective treatments for patients.</p> <p>Discussion: IGARD considered the materials provided and noted that they were not fully adequate, however noted that the applicant had an excellent study website that mentioned identifiers flowing and the sponsors names; and on balance IGARD were happy that the duty of confidentiality was met.</p> <p>IGARD noted that supporting document 2, the Adult Participant Information Sheet referred to data and samples being transferred to associated researchers within / outside the European Economic Area. IGARD asked that for clarity, a special condition be added within section 6 (Special Conditions) to state that no data shall be transferred outside the permitted territory of use, the United Kingdom, as set out in the agreement.</p> <p>IGARD queried the reference in section 5(b) (Processing Activities) to 'authorised individuals' being able to access the data supplied; and were advised by NHS Digital that only one individual who was an affiliate would access the data. IGARD suggested that section 5(b) should be updated to clearly reflect this.</p> <p>IGARD noted the four points listed within section 5(c) (Specific Outputs Expected) outlining the outputs expected to be delivered over the next two years and queried exactly what items would be delivered on the dates that were listed and asked that this be amended to provide further details.</p> <p>IGARD noted that supporting document 17, a letter from Glasgow Caledonian University to NHS Digital was not dated and asked that for clarity, a copy of the covering e-mail showing the date of issue was added to NHS Digital's Customer Relationship Management system (CRM).</p> <p>Outcome: recommendation to approve</p>

	<ol style="list-style-type: none"> 1. To insert a special condition in section 6 that no data shall be transferred outside the territory of use, the United Kingdom, as noted in this agreement. 2. To update section 5 to specify that there is 'one' individual who is an affiliate. 3. To amend section 5(c) numbered paragraphs (1) – (4) to provide further detail on what items will be delivered on the dates noted. 4. To update the CRM holder with the covering email which accompanied supporting document 17 showing the date of issue.
2.4	<p><u>NHS North Cumbria CCG: DSfC - NHS North Cumbria CCG - Comm & RS (Presenter: James Humphries-Hart) NIC-134552-B5T6B</u></p> <p>Application: This was an amendment and renewal 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 Registration Data (CRD). The data required is for Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital advised the DPA Registration date noted within the application had expired and confirmed that this had been extended to 2020.</p> <p>Discussion: IGARD noted that within section 1(a) (Summary) under the 'Reason' heading, reference had been made to 'eMBED' as the Risk Stratification provider; NHS Digital advised this was an error would be removed.</p> <p>IGARD noted that the web link provided for the applicant's privacy notice was incorrect and asked that this be updated with the correct link for NHS North Cumbria CCG.</p> <p>Outcome: recommendation to approve</p> <ol style="list-style-type: none"> 1. To remove reference to 'eMBED' in the 'Reason' section in Section 1(a), since they are not part of this application. 2. To provide the correct link to the applicant's Privacy Notice within the abstract, Section (1).
3	<p>AOB</p> <p>None</p>

Independent Group Advising on Releases of Data (IGARD): Out of committee report 01/03/19

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-148071-QHNM8	Imperial College London	21/02/2019	<ol style="list-style-type: none"> To provide a copy of version 4 of the UKFSST protocol as referenced in the most recent ethics approval, since it supported the scope of the amendment. To provide a copy of the recent CAG Annual Review submission. 	IGARD Chair	OOO by the Acting IGARD Chair	
NIC-126676-G1X4M	University College London (UCL)		<ol style="list-style-type: none"> To provide documentary evidence of how the duty of confidentiality owed to the patient identifiers flowing to NHS Digital is satisfied (prima facie, the original consent form and Patient Information Sheet). 	IGARD Members	OOO by a quorum of IGARD Members.	"Section 5 of the application be revised to make clear the timing of the processing, particularly that the death data will only be requested and flow after the consent has taken place and that the application relates solely to the follow up phase of the study."

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

- None