

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

## Minutes of meeting held 22 February 2018

**Members:** Joanne Bailey, Nicola Fear, Jon Fistein, Kirsty Irvine (Chair), Eve Sariyiannidou.

**In attendance:** Dave Cronin, Louise Dunn, Dickie Langley, Katie Shepherd (Observer), Kimberley Watson, Anna Weaver (Observer), Vicki Williams.

**Apologies:** Sarah Baalham, Anomika Bedi, Chris Carrigan.

1	<p><b>Welcome and introduction</b></p> <p>The Chair welcomed Katie Shepherd and Anna Weaver as observers to the meeting.</p> <p><b>Declaration of interests</b></p> <p>Jon Fistein noted his professional links to University of Sheffield (NIC-129819-V5P5Z) and would not be part of the discussion. It was agreed that Jon would remain in the meeting for the discussion of that application.</p> <p>Jon Fistein declared a conflict of interest in relation to NIC-352291-Y7B1S University of Leeds due to his work with the University of Leeds and professional relationship with the particular applicants. It was agreed Jon would leave the meeting for the discussion of that application.</p> <p><b>Review of previous minutes and actions</b></p> <p>The minutes of the 15 February IGARD meeting were reviewed and subject to a number of minor changes were agreed as an accurate record of the meeting.</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<p><b>Data applications</b></p>
2.1	<p><u>London North West Healthcare NHS Trust – Colonoscopic Surveillance for Familial Risk of Colorectal Cancer (Presenter: Dave Cronin) NIC-148406-2YXPR</u></p> <p><b>Application:</b> This was an extension and renewal application to permit the retention, reuse and further receipt of Personal Demographics data, Cancer Registration data and Office for National Statistics (ONS) data that had been previously provided via NHS Digital's Medical Research Information Service (MRIS) or predecessors. The data is linked to a cohort of patients under the care and / or surveillance of the Family Cancer Clinic at St Mark's Hospital and is used to ensure the Clinic has complete ascertainment of cancer deaths from records it routinely collects as part of its surveillance programme.</p> <p>NHS Digital noted that the Data Sharing Framework Contract for the applicant had expired and also noted that the updated fair processing notice for the applicant had been published.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study.</p> <p>IGARD queried the honorary contract and it was confirmed by NHS Digital that the individual was employed by Imperial College London and was an Honorary Consultant Physician at London North West NHS Trust and also an NHS Consultant Physician at Imperial College Healthcare NHS Trust. However, IGARD noted that the Honorary Consultant Physician should enter into a new honorary contract with London North West Healthcare NHS Trust if the substantive employer (Imperial College London) ceased to a Data Processor named in the agreement, and that a clause be included that the substantive employer of the person under the honorary contract will take appropriate action in the event of a breach, with a copy of the honorary contract provided to NHS Digital.</p>

IGARD queried why the applicant had not requested 'address' since s251 support had given permission to get the latest address for the cohort, however NHS Digital noted the system limitations within MRIS to provide address within the current product disseminated, and the applicant may request a list clean which was supported by s251 in the future.

Given the importance of the study, IGARD queried the lack of substantive yielded benefits within section 5d 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 noted the data retention period and suggested that justification be given as to why the data should be retained until 2028, noting that the last two sentences within the data retention period section 8a should be removed.

IGARD queried the cohort size, noting different figures were used throughout the application and supporting document, NHS Digital confirmed for the purpose of this application that the cohort size and number flagged on the system was 2110, as reflected in section 3, and that the cohort was not accepting new members, but may add to cohort numbers under a future agreement.

IGARD asked for further clarification in section 5 that the legal basis for dissemination of the ONS data is section 42(4) where the applicant is a type of organisation and suggested that the standard ONS wording be included within section 5b of the application.

IGARD noted that the applicant's version 14 IG Toolkit scores had not yet been reviewed and asked NHS Digital to ensure that the standard special condition wording around this would be included in the data sharing agreement

IGARD also noted that section 5 of the application would not be easily understood by a lay audience and suggested the applicant may wish to use Plain English. A typo within the application title was noted for amendment and references to 'commissioning letter' be removed from the application.

**ACTION:** IGARD suggested NHS Digital may wish to consider the naming conventions of support documents.

**Outcome:** recommendation to approve subject to the following conditions

- To provide substantive details in the yielded benefits section 5d(iii), including examples of public / patient engagement.
- To clarify in section 5 of the application that the legal basis for the dissemination of the ONS data is section 42(4) where the applicant is a type of organisation listed in the section and to remove references to a 'commissioning letter'.
- To add a special condition that the Honorary Consultant Physician will enter in to a new honorary contract with the LNWHNT, which will include a clause that the substantive employer of the person under the honorary contract will take appropriate action in the event of a breach and that the honorary contract will need to be in place and a copy be provided to NHS Digital when Imperial College London (the substantive employer) ceases to be a data processor named in the Agreement.
- To provide clear justification for the retention period of 2028 and to remove the last two sentences of Section 8a.

The following amendments were requested:

- Section 5b be updated with ONS standard wording: all processing of ONS data will be in line with the ONS standard conditions.

	<ul style="list-style-type: none"> <li>The standard special condition wording should be added regarding the need for version 14 IG toolkit to be reviewed as satisfactory.</li> </ul> <p>It was agreed the conditions would be approved OOC by IGARD.</p>
2.2	<p><u>University of Sheffield – Life and Bladder Cancer: The Yorkshire Cancer Research Bladder Cancer Patient Reported Outcomes Survey (Presenter: Dickie Langley) NIC-129819-V5P5Z</u></p> <p><b>Application:</b> This new application for Medical Research Information Service (MRIS) list cleaning report comes as part of a study of Life and Bladder cancer (LBAC). Its primary aims are to describe the health-related quality of life of a group of two separate cohorts of patients living with bladder cancer diagnosed in Yorkshire, Humber, North Derbyshire and South Tees to gain a deeper understanding of the variation in patient reported outcome measures (PROMs) and to identify areas of unmet need, with one cohort being longitudinal (over 10 years) and one cross-sectional (over a single year).</p> <p>The study team will develop a questionnaire that records these measures in patients with bladder cancer during and after treatment, surveying all new and existing patients within Yorkshire and the Humber to compare outcomes across the region, across the spectrum of disease states and treatments, and over the first 12 months since diagnosis. The team will then use the information to understand the outcomes within the population, to identify gaps in care and barriers to care improvement, and to shape clinical care delivery.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study.</p> <p>For the longitudinal research cohort, IGARD queried the consent material provided, noting that the cohort were newly diagnosed and may not expect their information to be forwarded to another organisation and that the study team would have their up to date address details that there currently did not appear to be a legal basis for the identifiers to flow to NHS Digital for list cleaning. IGARD noted the consent materials were dated 2017 and suggested that NHS Digital should carefully consider if the consent materials were in line with the requirements of the upcoming implementation of GDPR, and in particular consider how participants could withdraw their consent. IGARD noted that the processing for this cohort were not adequately described and for transparency this should be included in section 5 and which would be easily understood by a lay audience.</p> <p>IGARD suggested for the cross-sectional research cohort that the applicant review their fair processing against the ICO's Privacy Notice Code of Practice to ensure it meets best practice standards and that a clear statement should be added to the application summary that NHS Digital was satisfied that the applicant's fair processing meets the NHS Digital nine minimum criteria for privacy notices (to be known as NHS Digital's fair processing criteria) and suggested the fair processing information reference NHS Digital's involvement and provide additional contact details such as email and / or postal address for the cohort to opt out. IGARD also noted the support documents provided to and from HRA CAG with regard to non-respondents and suggested that a clear statement be included in section 5 that the applicant would not access the data of non-respondents after two reminders had been sent to the participant.</p> <p>IGARD noted that should the application be 'split' that NHS Digital should note within section 5 of the application that this agreement does not include any dissemination of data for the longitudinal research cohort.</p> <p>IGARD noted that for both cohorts explicit detail for the role of the Chief Investigator, including his substantive employer and role across both the University of Leeds and University of Sheffield be included in section 5 and queried why the University of Leeds was not listed as a joint Data Controller since they are running the study along with the University of Sheffield.</p>

IGARD suggested that the DPA registration for Quality Health Ltd should be updated to refer to processing data about patients rather than 'our patients', that it more clearly state that data is processed about patients or health care users, and that the relevant section be updated that it 'may' be about survey respondents. IGARD also suggested that the University of Sheffield update their DPA registration to clearly state that data is processed about patients or health care users.

IGARD suggested spelling out acronyms upon first use within section 5 of the application and to explain the acronym HRQL and to correctly reference the study acronym LBAC (Life and Bladder Cancer) throughout the application.

**Outcome:** The cross-sectional research cohort was recommended for approval subject to the following conditions:

- The fair processing notice for the applicant be updated to meet NHS Digital's nine minimum criteria (to be known as NHS Digital's fair processing criteria) for privacy notices, specifically providing additional contact details (email and/or postal address) for the cohort to opt out and expressly referring to the NHS Digital's involvement, and before data can flow.
- References to not accessing the data of non-respondents should be included within section 5b of the application in line with the HRA CAG final approval.
- Clarifying why the University of Leeds is not listed as a joint Data Controller, as both the University of Leeds and the University of Sheffield are running the study and the Chief Investigator is a substantive employee of Leeds University.
- To clarify within section 5 that this application does not include any dissemination of data for the longitudinal research cohort.

The following amendments were requested:

- Quality Health Ltd to remove reference to 'our' patients from their DPA registration and within the relevant section update that it 'may' be about survey respondents.
- IGARD suggested that the University of Sheffield and Quality Health Ltd update their DPA registration to more clearly state that data is processed about patients or healthcare users.
- To explain the acronym HRQL in section 5 of the application and to correctly reference the LBAC across the whole application.

It was agreed the conditions would be approved OOC by IGARD members

**Outcome:** unable to recommend for approval the longitudinal research cohort

- There does not appear to be a legal basis in consent for the identifiers to flow to NHS Digital for list cleaning.
- It is not clear why the University of Leeds is not listed as a joint Data Controller, as both the University of Leeds and the University of Sheffield are running the study and the Chief Investigator is a substantive employee of Leeds University.
- Section 5 of the application should adequately describe the processing for this cohort.
- The consent materials to provide contact details (including email and/or postal address) for the cohort to withdraw consent.

The following amendments were requested:

- Quality Health Ltd remove reference to 'our' patients from their DPA registration and within the relevant section update that it 'may' be about survey respondents.
- IGARD suggested that the University of Sheffield and Quality Health Ltd update their DPA registration to more clearly state that data is processed about patients or healthcare users.
- To explain the acronym HRQL in section 5 of the application and to correctly reference the LBAC across the whole application.

2.3	<p><u>University College London Institute of Education (UCL IoE) – MR1362: Extension of NIC-349413-F1J1N - Next Steps Cohort Study (Presenter: Kimberley Watson) NIC-15226-X7Z9R</u></p> <p><b>Application:</b> This was an amendment application to review the National Centre for Social Research (NatCen) as a data processor as their role in the study had come to an end and an extension to retain Medical Research Information Service (MRIS) list cleaning report. The Next Steps longitudinal study of young people in England has followed the lives of 15,620 people born in 1989/90, since year 9 of secondary school collecting information such as education, employment, health and wellbeing, relationships and family life, housing and finances.</p> <p><b>Discussion:</b> IGARD noted that this application had been previously reviewed by its predecessor DAAG when a query had been raised with regard the NHS Number and s251 support. It was noted that a clear statement should be added to the application summary that NHS Digital was satisfied that the applicant's fair processing notice meets the NHS Digital nine minimum criteria (to be known as NHS Digital's fair processing criteria) and suggested adding reference to NHS number.</p> <p>IGARD noted an erroneous mention of the HES analysis guide which was not relevant to this application and should be removed.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition</p> <ul style="list-style-type: none"> <li>The fair processing notice for the applicant be updated to meet NHS Digital's nine minimum criteria (to be known as NHS Digital's fair processing criteria) for privacy notices, specifically adding in reference to NHS number, and before data can flow.</li> </ul> <p>The following amendment was requested:</p> <ul style="list-style-type: none"> <li>Removing reference that outputs will be suppressed in line with the HES Analysis Guide from section 5 of the application.</li> </ul> <p>It was agreed that the condition would be approved OOC by the IGARD Chair.</p>
2.4	<p><u>University of Leeds - Bariatric surgery and colorectal cancer risk – Bespoke Data Linkage (Presenter: Louise Dunn) NIC-352291-Y7B1S</u></p> <p>It was noted that due to a conflict of interest Jon Fistein was not present for the discussion of this application.</p> <p><b>Application:</b> This was an application to extend an agreement for non-sensitive Hospital Episode Statistics (HES) Admitted Patient Care data. Previously NHS Digital had linked bariatric / obesity HES cohort to a cancer cohort which flowed from Public Health England under s251 approval (NIC-352291-Y7B1S) and this application was to link this cohort to the HES Admitted Patient Care and Linked HES / ONS Mortality Datasets and extracts of the study dataset. The application had been previously considered by IGARD on the 15 February when it had been unable to make a recommendation as there was not a quorum of members present but made the following comments: providing evidence that s251 support was still in place, providing clarity of the use of ONS data, clearly stating that the University would not link data, and adding a special condition that all data should be encrypted.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect comments previously made and NHS Digital noted that the summary section of the application would be updated to include the minutes from the 15 February 2018.</p> <p>IGARD noted that there was no new request for data to flow from Public Health England (PHE) to NHS Digital. The s251 support originally supported this flow of data and that if no longer</p>

	<p>required, and NHS Digital had destroyed the flowed data, that the applicant contact HRA CAG to confirm that s251 support was no longer required and update section 5 of the application.</p> <p>IGARD queried reference to ONS/Mortality/HES data sets and suggested that section 5 be updated to refer to this data as 'derived mortality data'. IGARD also suggested that the abstract be updated to be clear that all the steps referred to had been completed.</p> <p>IGARD noted that the University of Leeds was listed twice as a Data Controller and the duplicate information should be removed from Section 1.</p> <p><b>ACTION:</b> IGARD suggested that NHS Digital may wish to update its special condition wording with regard to "appropriate" encryption.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition</p> <ul style="list-style-type: none"> <li>To clarify within section 5 of the application that a s.251 support is no longer required for this application as there is no new request for data to flow from PHE to NHS Digital and that the data NHS Digital received under the original s.251 support has since been destroyed.</li> </ul> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> <li>That the duplicate Data Controller details for University of Leeds be removed from section 1b of the application.</li> <li>To amend references to ONS/Mortality/HES data in section 5 as this is derived data.</li> </ul> <p>The following advice was given:</p> <ul style="list-style-type: none"> <li>IGARD suggested that NHS Digital might wish to consider auditing the organisation in relation to this application/agreement.</li> </ul> <p>It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority.</p> <p>It was agreed that the condition would be approved OOC by the IGARD Chair.</p>
2.5	<p><u>National Institute for Cardiovascular Outcomes Research (NICOR) – National Heart Failure Audit 2016-17 Report (Presenter: Kimberley Watson) NIC-42272-S9J3L</u></p> <p><b>Application:</b> This was a renewal application for a Hospital Episode Statistics (HES) Admitted Patient Care tabulation without small numbers suppressed of an additional year of data. The National Heart Failure Audit is a national clinical audit which monitors the care and treatment of hospitalised heart failure patients in England and Wales, commissioned by Healthcare Quality Improvement Partnership (HQIP) and managed by Barts Health NHS Trust. The Audit collects data on patients with an unscheduled admission to hospital in England and Wales who are discharged with a primary diagnosis of heart failure and was established in 2007, collecting over 200,000 records of heart failure-coded hospital episodes.</p> <p><b>Discussion:</b> IGARD noted that the yielded benefits listed within section 5d were too generic and that specific examples of benefits to patients be provided in order to be transparent for the general public when this was published within NHS Digital's data release register.</p> <p>IGARD queried why the applicant requested unsuppressed data in order to provide tables with small numbers suppressed, and that further clarity be added to section 5 of the application.</p> <p>IGARD suggested that acronyms, such as NICOR, be spelt out on first use within section 5 to be easily understood by a lay audience.</p> <p><b>Outcome:</b> recommendation to approval subject to the following condition:</p>

	<ul style="list-style-type: none"> <li>• To provide more specific examples of yielded benefits within section 5 of the application with explicit references to benefits to patients.</li> </ul> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> <li>• To clarify within section 5 why the applicant is requesting unsuppressed data, especially as the outputs of this work will only include data with small numbers suppressed.</li> <li>• To fully spell out acronyms upon first use within section 5 of the application</li> </ul> <p>It was agreed the condition would be approved OOC by the IGARD Chair.</p>
<b>3</b>	<b>AOB - none</b>

## Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
20/04/17	IGARD Chair to contact key stakeholder organisations regarding the benefits of uses of data to feed into the IGARD annual report.	IGARD Chair	<p>14/09/17: Ongoing. It was agreed this would be discussed during the educational session.</p> <p>07/12/17: Ongoing. It was agreed to bring the first draft to January's education session.</p> <p>08/02/18: it was agreed the updated draft be brought to the March education session</p> <p>22/02/18: Ongoing.</p>	Open
18/05/17	Garry Coleman to provide information about different arrangements for data storage and backup locations, for consideration of whether the organisations involved would be considered to be processing data.	Garry Coleman	<p>15/06/17: IGARD had been advised by email that a paper about this would be submitted to an upcoming IGARD meeting.</p> <p>22/06/17: It was anticipated that this would be discussed at the 6 July 2017 IGARD meeting. IGARD asked for some information to be circulated by email prior to the meeting in order to inform members who would not be present at that particular meeting.</p> <p>27/07/17: An email had been circulated requesting further information from IGARD members.</p> <p>03/08/17: Two IGARD members had responded by email and the action remained ongoing.</p> <p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: The paper was in the process of being updated based on recently published ICO guidance.</p>	Closed



			<p>14/09/17: Ongoing. IGARD noted that given the amount of time that had passed, they would consider starting to note this on relevant applications where a data storage location was not listed as a data processor.</p> <p>21/09/17: Ongoing. IGARD asked for Dickie Langley to provide an update on Garry Coleman's open actions at the next meeting to help ensure timely progression.</p> <p>02/11/17: IGARD discussed this action with Garry Coleman and requested a written update in response to the points previously raised by IGARD. Some difficulties were acknowledged as this specific scenario did not seem to be addressed in existing ICO guidance; IGARD suggested that NHS Digital should seek legal advice and if necessary then contact the ICO directly.</p> <p>16/11/17: Ongoing. IGARD queried the progress made regarding this action and there was a suggestion that this should be discussed at an education session; however it was suggested that it would be necessary to receive an updated response from NHS Digital before this.</p> <p>22/02/18: it was agreed the action be closed and transferred to the NHSD / IGARD project plan. This action can be closed and removed from the action table</p>	
20/07/17	Garry Coleman to provide an update within two weeks on how NHS Digital manage the risk involved in CCGs using South Central and West CSU as a data processor in light of data sharing breaches and recent audits.	Garry Coleman	<p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: IGARD received a verbal update on the work that had taken place following both audits and verbal assurances that NHS Digital were content with the level of risk involved in this organisation continuing to act as a data processor. IGARD welcomed this update and requested written confirmation.</p>	Open

			<p>31/08/17: IGARD were notified that the requested written confirmation should be provided within one day.</p> <p>14/09/17: An email response had been circulated on 31 August, and IGARD noted that they were awaiting receipt of the post-audit report.</p> <p>22/02/18: Ongoing</p>	
20/07/17	Garry Coleman to categorise different standard lengths of indicative data retention periods for general research and clinical trials, with appropriate justification.	Garry Coleman	22/02/18: it was agreed the action be closed and transferred to the NHSD / IGARD project plan. This action can be closed and removed from the action table	Closed
31/08/17	Garry Coleman to report back on how cancer registration data was previously described as pseudonymised PDS data within older versions of applications, and present to a future education session on changes to how Medical Research Information Service (MRIS) reports are now shown within applications.	Garry Coleman	22/02/18: IGARD Secretariat to contact Garry Coleman to suggest presentation at the June education session.	Open
19/10/17	Stuart Richardson to provide a briefing on the Temporary National Repository infrastructure.	Stuart Richardson	<p>16/11/17: Stuart Richardson noted discussions were ongoing.</p> <p>22/02/18: IGARD Secretariat to contact Stuart Richardson to provide an update</p>	Open
02/11/17	NHS Digital to consider the responses provided by an applicant (Imperial College London NIC-27085) in relation to the language and terminology used in patient information materials.	Louise Dunn	22/02/18: Ongoing.	Open
07/12/17	Dickie Langley to provide a briefing note on NHS Digital's due diligence policy and process	Garry Coleman	08/02/18: It was agreed that the action owner be changed from Dickie Langley to Garry Coleman.	Closed

			22/02/18: it was agreed the action be closed and transferred to the NHSD / IGARD project plan. This action can be closed and removed from the action table	
07/12/17	Stuart Richardson to provide a briefing note outlining NHS Digital's work with STP's to clarify the legal / access arrangements in place between CCG's to ensure responsibilities are clearly defined	Stuart Richardson	22/02/18: IGARD Secretariat to contact Stuart Richardson to provide an update	Open
21/12/17	NHS Digital / IGARD to discuss at a future meeting the issue of consistency across applications presented.	IGARD Chair / Garry Coleman	22/02/18: it was agreed the action be closed and transferred to the NHSD / IGARD project plan. This action can be closed and removed from the action table	Closed
25/01/18	Arjun Dhillon, Deputy Caldicott Guardian, was tasked to check with NHS Digital whether templates which had not been approved by IGARD but where NHS Digital had taken the decision to disseminate data would come back to IGARD for consideration or was the template now class as an approved template by NHS Digital	Arjun Dhillon	01/02/18: Arjun Dhillon noted that a template not recommended for approval by IGARD should be flagged on CRM and would speak with the Director Data Dissemination if such templates could be flagged as 'not recommended by IGARD'.  22/02/18: it was agreed the action be closed and transferred to the NHSD / IGARD project plan. This action can be closed and removed from the action table	Closed

## Appendix B: Out of committee report

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 09/02/18

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-154978	The Christie NHS Foundation Trust	07/12/17	<ul style="list-style-type: none"><li>A clearer explanation in Section 5 of the application as to why the CCG need an historic extract from 01/04/11-30/11/17 alongside data period 01/12/17-30/11/17, a clearer explanation how the data will be kept separately and clarification that there will be no attempt to re-identify the data stored.</li><li>Clarification within Section 5 of the application with regard to why data is sourced locally rather than nationally.</li></ul>	IGARD Quorum	IGARD Quorum	N/A
NIC-149923	Public Health England	18/01/18	<ul style="list-style-type: none"><li>Clarifying in section five of the application that small numbers will be suppressed before inclusion in the Microsoft Excel spreadsheet</li></ul>	IGARD Chair	IGARD Chair	N/A

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

- None notified to IGARD