

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 10 January 2019

Members: Sarah Baalham, Joanne Bailey, Maria Clark, Nicola Fear (2.3 (part onwards), Kirsty Irvine (Chair), Priscilla Maguire.

In attendance: Stuart Blake, Dave Cronin, Rachel Farrand, Karen Myers, Kimberley Watson, Vicki Williams.

Apologies: Anomika Bedi, Eve Sariyannidou.

1	<p>Declaration of interests:</p> <p>Nicola Fear and Maria Clark noted a professional link with staff involved with NIC-121849-W0T5C University of Birmingham and would not be part of the discussion. It was agreed Nicola and Maria would not remain in the meeting for the discussion of this application.</p> <p>Joanne Bailey noted professional links to the University of Cambridge (NIC-147829-5K4QP and NIC-147750-8GS7S), but noted no specific connection with the applications 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 20th December 2018 IGARD meeting were reviewed and agreed as an accurate record of the meeting</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>NHS Coastal West Sussex CCG: DSfC – NHS Coastal West Sussex CCG – RS & IV (Presenter: Kimberley Watson) NIC-91799-G0T9X</u></p> <p>Application: This was a renewal application for identifiable Secondary Use Service (SUS) for Commissioners data for Risk Stratification 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 Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do.</p> <p>NHS Digital noted that section 8(a) (Data Retention) needed amending to ensure the data retention period was aligned to the indicative Data Sharing Agreement (DSA) expiry date.</p> <p>NHS Digital also noted that supporting document 1, the data flow diagram needed updating to ensure the narrative text explaining the data flows was accurately recorded.</p> <p>Discussion: IGARD noted that the links provided in section 4 (Privacy Notice) and section 1(a) (Abstract) were incorrect and should be removed.</p> <p>IGARD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) register had been updated for this application and that the s251 support expiry date was now the 30th September 2020; and suggested that the applicant may wish to consider updating their fair processing notice to reflect this.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none">1. To amend section 8(a) to align the data retention period with the indicative DSA expiry date.

	<ol style="list-style-type: none"> 2. To ensure the narrative text explaining data flows maps to the data flow diagram provided as a supporting document. 3. To remove the link to the appendix within Section 4 and abstract. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant consider updating their fair processing notice to reflect the updated expiry date of the S251 support.
2.2	<p><u>St George's, University of London: Spatio-Temporal Exposure Assessment Methods for estimating the health effects of air pollution (Presenter: Rachel Farrand) NIC-127189-R2K8F</u></p> <p>Application: This was a new application for Hospital Episode Statistics (HES) data for a study estimating the health effects of outdoor air pollution which has been associated with increased risks of admission to hospital and death. The study aims to evaluate and integrate the different models of measuring pollution effects, by time and location, and use the resulting predicted pollution concentration in a joint analyses of long and short-term exposures for a limited number of health endpoints as a 'proof of concept'.</p> <p>NHS Digital noted that the Data Protection Act (DPA) expiry date was noted as the 17th December 2018 and confirmed it has since been renewed and this should be amended to the 17th December 2019.</p> <p>Discussion: IGARD noted additional Data Protection Act 2018 (DPA) registration details were incorrect within section 1 (Abstract) of the application and asked that these were updated across all parties.</p> <p>IGARD noted the reference to St George's Hospital Medical School within section 1(c) (Data Processors) and asked that this be removed or for further clarity to be provided clearly explaining their involvement.</p> <p>IGARD noted that section 3(b) (Additional Data Access Requested) stated that unsuppressed data was being requested and asked that further clarity be provided in section 5 (Purpose / Methods / Outputs) clarifying why this was being requested.</p> <p>IGARD noted that there was reference to 'anonymous' in the identifiability column in section 3(b) and asked that this was removed since this was incorrect.</p> <p>IGARD noted that there was reference to 'pseudonymised data' in section 3(c) (Patient Objections) and asked this was removed since the data is identifiable.</p> <p>IGARD noted that section 5(a) (Objective for Processing) should be updated to include clearer examples for processing and how the applicant had been using the data. IGARD also suggested that on renewal the applicant provide further details of pathways for disseminating the outputs of the study to patients and the wider public including specific examples of public / patient engagement.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the DPA registration details across all parties. 2. To remove reference to St George's Hospital Medical School or to clearly explain their involvement. 3. To clarify within section 5 why unsuppressed data is being requested. 4. To remove reference to 'anonymous' from the identifiability column in section 3(b). 5. To remove reference to 'pseudonymised data' from section 3(c) since the data is aggregate.

	<p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement and how the results will be disseminated to the wider public.
2.3	<p><u>University of Cambridge: MR480 - MRC Study of Cognitive Function and Ageing MR490 – Alpha Study (Liverpool) (Presenter: Rachel Farrand) NIC-147829-5K4QP</u></p> <p>Application: This was an amendment application for identifiable Medical Research Information Service (MRIS) to bring together two study cohorts to form one cohort and to receive further data for the combined cohort. The studies are longitudinal population based epidemiological studies based in six areas of the UK and have recruited over 18,000 people and conducted in excess of 48,000 interviews over a period of more than 25 years. These studies have provided sound evidence generated by high quality population-based research to advance understanding of health and health changes with age.</p> <p>The application was been previously considered on the 20th September 2018 when IGARD had been unable to recommended pending: to further clarify in section 5 what the relationship is between the two studies referred to within the application; further information to be included in section 5 about the two cohorts and how they were identified; to provide further information in section 5 of the purpose of the CFAS study and the studies that sit under it, including what is covered by this particular application; to clarify within section 5 who is the Data Controller; to update section 4 with the standard wording “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month”; to provide more examples of measurable and yielded benefits within section 5 of the application with a clear timescale for outputs; to explain that the studies are being brought together for administrative ease, to explain the background of the historic DSAs and to clearly outline in the application how the datasets will be managed going forward.</p> <p>Discussion: IGARD noted that the application had been updated to reflect all of the comments previously made.</p> <p>IGARD queried if the derived pseudonymised data was being shared onwardly and asked for clarification of this, and to clarify if the derived pseudonymised data related to living persons. IGARD also asked that section 5(a) (Objective for Processing) include an amendment clarifying that there will be no attempt to re-identify by recipients of derived data.</p> <p>IGARD noted the reference to the 47 consented participant sub-cohort who appeared to have given consent and asked what the legal basis was for their inclusion in the application since they did not appear to be covered under the s251 support documents provided which clearly stated that the s251 support extended to non-consented participants.</p> <p>IGARD queried if the University of Cambridge had provided a copy of relevant identifiers to NHS Digital and asked that this be clearly stated within section 5 (Purpose / Methods / Outputs).</p> <p>IGARD noted the standard wording in section 4 (Privacy Notice) reads “All data required by the Data Controller under this agreement...” and should be amended to read “Data processed under this agreement...”.</p>

	<p>Outcome: recommendation to approve subject to the following conditions for the main cohort of the study only (not including the sub-cohort of 47 participants who appear to have given consent and consequently do not appear to be covered by the s251 support):</p> <ol style="list-style-type: none"> 1. To clarify the subjects of the derived pseudonymised data being sharing onwardly; and if the data relates to living persons, to include an amendment in section 5 clarifying that there will be no attempt to re-identify by recipients of derived data. 2. To remove reference to the 47 consented participant sub-cohort who do not appear to be covered under the s251 support documents provided. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To clearly state within section 5 that the University of Cambridge has already provided a copy of relevant identifiers to NHS Digital. 2. To amend the standard wording within section 4 to read: "Data processed under this agreement..."
2.4	<p><u>Queen Mary University of London: Long-term Anastrozole vs. Tamoxifen Treatment Effects (LATTE) NIC-37666-Z1C3M</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data for an observational study aiming to collect long-term safety and efficacy data on anastrozole and tamoxifen, drugs that were taken by post-menopausal women. The study aims to collect further follow-up information on a maximum of 2200 UK eligible patients, to provide additional efficacy and safety data on time to recurrence of breast cancer and death after recurrence.</p> <p>Discussion: IGARD noted that the Common Law Duty of Confidentiality section within section 1(a) (Abstract) references NHS Digital in respect of the disclosure, and asked that this be removed.</p> <p>IGARD queried if funding was ongoing and asked that section 5 (Purpose / Methods / Outputs) of the application be updated to state that the funder will not have influence on the outcomes nor suppress any of the findings of the research.</p> <p>IGARD queried if NHS Digital had reviewed the data minimisation undertaken by the applicant and were satisfied that this aligned with the Health Research Authority Confidentiality Advisory Group (HRA CAG) outcome letter provided as supporting documents; and asked that section 1(a) (Abstract) was amended to confirm this.</p> <p>IGARD noted the standard wording in section 4 (Privacy Notice) reads "All data required by the Data Controller under this agreement..." and should be amended to read "Data processed under this agreement..."</p> <p>IGARD noted that supporting document 9, the ethics approval document was from 2009 and asked that NHS Digital's CRM holder was updated to include a copy of the updated ethics approval document for future reference.</p> <p>IGARD noted that section 5(a) (Objective for Processing) should be updated to include clear examples for processing and how the applicant had 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 wider public including specific examples of public / patient engagement, particularly given the "main target audience" outlined in the application is patients with early stage breast cancer and on renewal.</p> <p>IGARD also suggested that on renewal the data flow diagram be updated to include the legal basis for the flow of confidential information.</p>

	<p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend the abstract to remove reference to “NHS Digital” under ‘common law duty of confidentiality r.e disclosure’. 2. To confirm within section 5 that the funder will not have influence on the outcomes nor suppress any of the findings of the research. 3. To amend the abstract to confirm that NHS Digital have reviewed the data minimisation undertaken by the applicant and are satisfied and that this aligns with the CAG outcome letter provided. 4. To amend the standard wording within section 4 to read: “Data processed under this agreement...”. 5. To update the CRM holder to include a copy of the updated ethics approval document and for future reference. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement, particularly given the “main target audience” outlined in the application is patients with early stage breast cancer. 2. IGARD suggested that on renewal that the data flow diagram be updated to include the legal basis for the flow of confidential information.
2.5	<p><u>University of Birmingham: Long term impact of giving antibiotics before skin incision versus after cord clamping on children born by caesarean section: longitudinal study based on UK electronic health records (Presenter: Dave Cronin) NIC-121849-W0T5C</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data to determine whether there is an association between the change in antibiotic prophylaxis in caesarean delivery and the incidence of subsequent admission of the child for a number of diseases.</p> <p>The application was been previously considered on the 6th December 2018 when IGARD had deferred making a recommendation pending: to provide a clear description of the control group and the cohort within section 5(a), and for each, to clearly describe what data is gathered on the mothers, what data is gathered on the babies and to clearly describe how the data is gathered, including the years of data sought and a clear justification for the years of data for both mothers and babies in both the control group and cohort; to clearly describe and provide a justification for the number of years of data being requested for the mother prior to birth, which could be from 2005 (even if the birth is in 2018), and the data being gathered after birth (56 days); to clearly define which other health conditions are being captured since only eczema / asthma are expressly outlined; to clearly describe how this study is different from other similar clinical trials with published findings, drawing out the fact that this study is focused on health outcomes for both babies and mothers; to provide evidence of funding; to clearly describe within section 5 how the data linkages align with those data linkages set out in the protocol document provided; to clearly outline up to what age or time period will the mother and / or baby be followed.</p> <p>NHS Digital noted that the Data Sharing Agreement (DSA) start date was the 12th December 2018 and this, along with the end date would need amending.</p> <p>NHS Digital also noted reference to ‘our’ within section 5 and noted that this had been updated.</p>

	<p>Discussion: IGARD noted that the application had been updated to reflect all, except one, of the comments previously made: To clearly define which other health conditions are being captured since only eczema / asthma are expressly outlined.</p> <p>IGARD noted that section 1(a) (Abstract) had a helpful explanation about how further health conditions were being looked into and “worked up” and asked that section 5(a) (Objective for Processing) be updated using this text to provide a more detailed explanation.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 1 to amend the start and end dates. 2. To include within section 5(a) a more detailed explanation how further conditions are being looked into and “worked up” in the future, as clearly explained in the abstract.
2.6	<p><u>University of Cambridge: ADDITION: Anglo-Dutch-Danish study of Intensive Treatment In PeOple with screeN-detected diabetes (MR798) (Presenter: Stuart Blake) NIC-147750-8GS7S</u></p> <p>Application: This was an amendment and renewal application for identifiable Medical Research Information Service (MRIS) for a study assessing the effectiveness and cost effectiveness of screening for type-2 diabetes, and to collect follow-up information for the full screened population in Cambridge to ascertain long-term outcomes.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the study in addition to the yielded benefits provided in section 5.</p> <p>IGARD noted that the application referred to a number of cohorts and asked that it be made clear within section 1(a) (Abstract) and section 5 (Purpose / Methods / Outputs) the delineation of the cohorts that are covered by the application and in each instance clarify that reference to other cohorts were provided for background information only.</p> <p>IGARD noted the standard wording in section 4 (Privacy Notice) reads “All data required by the Data Controller under this agreement...” and should be amended to read “Data processed under this agreement...”.</p> <p>IGARD asked that a copy of the Research Ethics Approval (REC) Approval document provided as a supporting document, be added to NHS Digital's CRM holder and for future reference.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To make clear within the abstract and throughout section 5, the delineation of the cohorts covered by the application and that reference to other cohorts are provided for background information only. 2. To amend the standard wording within section 4 to read: "Data processed under this agreement..." 3. To update the CRM holder to include a copy of the REC approval document and for future reference.
2.7	<p><u>CHKS Limited: SHMI Data (Presenter: Stuart Blake) NIC-368543-C3J4B</u></p> <p>Application: This was an amendment, renewal and extension application for pseudonymised Summary Hospital-level Mortality Indicator (SHMI) data and to hold and process identifiable Hospital Episode Statistics (HES) and Civil Registrations data. The data will be used as a</p>

	<p>benchmarking service for NHS Providers and Commissioners and as a mortality profiling service for NHS Trusts.</p> <p>Discussion: IGARD noted that section 1 (Abstract) noted the HES data as being 'identifiable' and asked that this be amended to correctly state that the data was 'pseudonymised'.</p> <p>IGARD noted that section 5(a) incorrectly stated that the legal basis for processing data is covered under the Data Protection Act 2018, and asked that this reference to be removed since it was not relevant.</p> <p>IGARD noted the special conditions listed in section 6 (Special Conditions) and asked that (excluding the last one listed, and those that are not already captured with the published body of the application) they be replicated within section 5(b) (Processing Activities) for transparency.</p> <p>IGARD noted that the applicant's fair processing notice did not meet the NHS Digital criteria and suggested that NHS Digital work with applicant to ensure the transparency documentation published online meets current good practice guidelines.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend the abstract to clearly state that the HES data is pseudonymised, not identifiable. 2. To remove reference within section 5 to the Data Protection Act. 3. To replicate within section 5(b) any special conditions, excluding the last one listed, that are not already captured with the published body of the application. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that NHS Digital work with applicant to ensure the transparency documentation published online meets current good practice guidelines.
<p>3</p> <p>3.1</p>	<p>AOB</p> <p><u>NIC-113074-D9M1C - Clinical Practice Research Datalink</u></p> <p>IGARD noted that following the 29th November 2018 meeting, when IGARD had recommended for approval subject to conditions. The relevant extract is as follows:</p> <p>"IGARD recommended to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To clarify if NHS Digital are considered a Data Processor when carrying out the role of trusted third party and, if so, to add NHS Digital to the application. 2. To remove any reference in the application to 'anonymised' and replace with 'pseudonymised'. 3. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including (but not limited to) setting out the legal basis under GDPR for Imperial College London to disseminate data to NHS Digital 4. To revise the purpose of the study in section 5 to clarify that the data requested was for two European Union funded projects and Imperial College London and Utrecht University and St George's are key consulting parties, and asked that section 5 of the application be updated to clearly define the parties involved and if appropriate consider if they should be considered as joint Data Controllers. 5. To revise the purpose of the study in section 5 to confirm, inter alia, that the revised database will be available to all researchers meeting the relevant requirements, not just St George's and Imperial.

<p>3.2</p>	<p>It was agreed the conditions would be approved OOC by IGARD Members.”</p> <p>NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.</p> <p>Quoracy</p> <p>Following the temporary reduction in IGARD quoracy to three members (50% of the membership), this will now increase to four members from the 1st January 2019.</p>
-------------------	--

Independent Group Advising on Releases of Data (IGARD): Out of committee report 04/01/19

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-291938-R6V3V	Barts Health NHS Trust	29/11/18	1. To update section 5 to clearly define the outputs and benefits, how they link to health and social care and including any examples of public / patient engagement	OOC by IGARD Chair	OOC by IGARD Chair	
NIC-170867-M5Q6W	Royal Liverpool and Broadgreen University Hospitals NHS Trust	06/12/18	1. To provide evidence that the applicant has submitted its annual renewal for s251 support to HRA CAG.	OOC by IGARD Chair	OOC by IGARD Chair	
NIC-216638-L9N4N	NHS Brighton and Hove CCG	13/12/18	1. The application be updated to clarify that data minimisation table is limited to local data.	OOC by IGARD Chair	OOC by IGARD Chair	
NIC-108098-D2L3V	CPRD	13/12/18	1. To provide further clarification that the opt outs include Public Health England data.	OOC by IGARD Chair	OOC by IGARD Chair	
NIC-210151-K9C7G	IQVIA Technology Services Ltd	06/12/18	1. Adding a special condition that record level data will not be made available to any organisation within the IQVIA group of companies except for IQVIA Technology Services Ltd and IQVIA Solutions UK Ltd (and to also set out this restriction in part 5 of the application). 2. Adding a special condition that only substantive employees of IQVIA Technology Services Ltd and IQVIA Solutions UK Ltd will have access to record level data (and to also	OOC by quorum of IGARD members	OOC by quorum of IGARD members	

			<p>set out this restriction in part 5 of the application).</p> <p>3. To provide further information about OneKey, particularly for transparency how the data for participating physicians is collected, stored and disseminated and evidence of the fair processing material provided to physicians participating in the OneKey dataset.</p>			
NIC-07787-Z1W1X	Oxford University Hospitals NHS Foundation Trust	13/12/18	<p>1. To provide evidence that funding is continuing.</p> <p>2. To update the abstract to clearly articulate the current situation and the steps being taken to produce a Fair Processing Notice that meets the criteria and reflects the efforts undertaken by the applicant.</p> <p>3. To provide confirmation that the named individuals in supporting document 8 (the letter from University of Oxford dated 10 June 2016 naming individuals as part of the research) are still in place and that the letter covers all the necessary individuals. If any individuals have left or joined the study team, for the University of Oxford to provide a revised letter naming the relevant individuals involved.</p> <p>4. To update section 5 to clearly define the routes to dissemination for the benefits and outputs outlined in the application and as noted by their predecessor DAAG.</p> <p>5. To clarify within section 5 the role of Public Health England (PHE) and the other Foundation Trusts referred to supporting document 3 the ARK Hospital Analysis Plan.</p>	<p>OOO by quorum of IGARD members</p>	<p>OOO by quorum of IGARD members</p>	
NIC-09519-D5G0R	Methods Analytics Ltd	13/12/18	<p>1. To clearly set out an analysis within section 5(a) of the application explaining the Legitimate Interests relied on and linked to the purpose outlined.</p>	<p>OOO by IGARD Chair</p>	<p>OOO by IGARD Chair</p>	<p>"Condition 1 – to update the wording to refer to Methods' "legitimate interests".</p>

			2. To update the abstract to reflect that NHS Digital, rather than Methods Analytics Ltd, has assessed the LIA and deemed it satisfactory.			
NIC-121483-R8P9F	University Hospitals Birmingham NHS Foundation Trust	13/12/18	<ol style="list-style-type: none"> 1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD. 2. To update section 5 to clarify why University Hospitals Birmingham NHS Foundation Trust (UHB) is not considered a Data Controller and, if not, to expressly note that UHB will be acting on the instruction of the Data Controllers (University College London and University of Birmingham) to manage and administer the study. 3. To provide further clarity on the Wellcome Trust entity given that they are described within the protocol as being part of management team and carrying out substantial work, and to consider if they should be included as a Data Controller. 4. To clarify if only singleton mother and babies are being used as part of the cohort. 	OOC by quorum of IGARD members	OOC by quorum of IGARD members	"Condition 3 - As an aside, am content with the explanation of the role of the Wellcome Trust Sanger Institute being contained in the abstract but take the view that it should be in the body of the application ... please include the explanation re WTSI in section 5."

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

1. None