

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 23 August 2018

Members: Sarah Baalham, Anomika Bedi, Nicola Fear, Jon Fistein, Kirsty Irvine (Chair)

In attendance: Dave Cronin, Rachel Farrand, Karen Myers, Jon Smith, Joanne Treddenick, Kimberley Watson

Apologies: Joanne Bailey, Eve Sariyiannidou

1	<p>Declaration of interests</p> <p>Jon Fistein noted professional links to the University of Cambridge (NIC-28744-S4F8H and NIC-34907-D9R3N) 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 outcomes of the 9th August 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meetings.</p> <p>The minutes of the 2nd and 9th August IGARD meeting were reviewed out of committee by IGARD following conclusion of the meetings and were agreed as an accurate record of the meetings.</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	<p><u>Civil Registrations Data – Briefing Paper (Presenters: Joanne Treddenick and Dave Cronin)</u></p> <p>NHS Digital is transitioning from disseminating data under delegated authority from the Office of National Statistics (ONS). To date, data has been disseminated based upon the Statistics and Registrations Act 2007 (SRSA) and this moves to dissemination based upon the Health and Social Care Act 2012 (H&SCA). The purpose of the paper was to provide further information to IGARD.</p> <p>IGARD noted the contents of the briefing paper</p>
3	<p>Data applications</p>
3.1	<p><u>The Royal Marsden NHS Foundation Trust: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Kimberley Watson) NIC-190996-C4P9G</u></p> <p>Application: This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset. The independent Cancer Taskforce set out a vision for improving services, care and outcomes for everyone with Cancer. Cancer Alliances, which have been set up across England, are key to driving the change needed across the country to achieve the Taskforce's vision providing the opportunity for a different way of working to improve and transform Cancer services.</p> <p>The application was previously considered on the 9th August 2018 when IGARD had been unable to recommend and had advised that; the applicant should consider whether NHS England or other parties involved should also be Data Controllers; to explicitly list the parties in the relevant Cancer Alliance and the governance and contractual arrangements as between the Cancer Alliance actors; clarify how the members of the Cancer Alliance will access the data;</p>

clarify the interplay between CCGs and Cancer Alliances and any possible duplication of access to the data; clarify how the controls on access to data will be implemented and enforced.

Discussion: IGARD noted that it was still unclear within the application who the Data Controller was and asked that this be made explicitly clear within the abstract and section 5 that The Royal Marsden NHS Foundation Trust was Data Controller and that any reference that the Cancer Alliance(s) being a Data Controller was removed from the application.

It was also suggested for clarity that where there are any references to the “Royal Marsden Partners” it also clearly states that The Royal Marsden NHS Foundation Trust is the Data Controller.

IGARD queried if record level data would be shared with anyone outside The Royal Marsden NHS Foundation Trust and if so asked that clear justification for this be provided.

IGARD noted that NHS Digital had included a reference within the abstract to the applicant’s legal basis under the General Data Protection Regulation (GDPR) Article 6(1)(e) and 9(2)(j), however IGARD suggested that a clear justification for the choice of each Article should be given.

IGARD noted that the wording in section 4 Fair Processing should be updated to read “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”

IGARD queried whether the data disseminated was restricted to the data of cancer patients in North West and South West London as this was identified as the scope of the operation of this Cancer Alliance and when confirmed asked for this to be clarified within section 3(b) and section 5.

IGARD suggested that it should be made clear on page 14 that access to the CWT system data was “restricted” to a particular class of individuals.

IGARD suggested amending introductory wording in the Special Conditions to clarify that The Royal Marsden NHS Foundation Trust is responsible for ensuring that the Cancer Alliance members adhere to the conditions of supply and controls on use.

To also amend points 3 and 5 of the Special Conditions to make it clear that the restrictions imposed apply to “any organisations within the Cancer Alliance”.

IGARD suggested that any reference to Cancer Alliance should be specific to this application and not to Cancer Alliances generally, and this should be made clear in the application and specifically in section 5.

IGARD observed that this type of application was proposed as a template application and suggested that IGARD review several applications prepared under the template first, (and IGARD agreement obtained) before it moves to dissemination by NHS Digital internal review only.

Outcome: recommendation to approve subject to the following conditions:

1. To explicitly state within the abstract and section 5 that the Royal Marsden NHS Foundation Trust is the Data Controller and remove any reference to (or inference that) the Cancer Alliance(s) being a Data Controller.
2. To clarify if record level data will be shared outside the Royal Marsden NHS Foundation Trust and, if so, why and with whom. If record level data is to be shared outside the Royal Marsden Foundation Trust, then appropriate justification for this should be provided.

3. To provide further narrative in the abstract explaining the rationale for the GDPR Article 6(1)(e) and Article 9(2)(j) lawful basis relied on by the Data Controller to process data for the purposes set out in this application.

The following amendments were requested:

1. To update the application so that any reference to the “Royal Marsden Partners” also makes clear that the Royal Marsden NHS Foundation Trust is the Data Controller.
2. 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”.
3. To clarify in section 3(b) and section 5 that the data disseminated is restricted to cancer patients in North West and South West London (which is identified as the scope of operation of this Cancer Alliance).
4. To amend the wording on page 14 (second paragraph) from “Access to the CWT system data is provided to Cancer Alliance employees...” to “Access to the CWT system data **is restricted** to Cancer Alliance employees....”.
5. To amend the introductory wording in section 6, Special Conditions from “...the Cancer Alliance will...” to “...the Royal Marsden NHS Foundation Trust will ensure that the Cancer Alliance members will...”.
6. To amend points 3 and 5 within the Special Condition to say “any organisation within the Cancer Alliance”.
7. To ensure that the application, and in particular section 5, specifically relates to this Cancer Alliance and not Cancer Alliances generally.

The following advice was given:

1. IGARD observed that this was proposed as a template application and suggested that IGARD review several applications prepared under the template first, (and IGARD agreement obtained) before it moves to NHS Digital internal review.

It was agreed that the conditions would be agreed OOC by the IGARD Chair.

3.2

University College London (UCL) - Evaluating variation in special educational needs provision for children with Down syndrome and associations with emergency use of hospital care.
(Presenter: Kimberley Watson) NIC-50975-X6N3J

Application: This was a new application for month and year of death to be provided use PDS which will be linked to a cohort of 119,000 derived from the Public Health England (PHE) National Down Syndrome Cytogenetic Register (NDSCR) and the PHE already-held Hospital Episode Statistic (HES) data. The study will look at variation across England in health, social care and education services for children with Down Syndrome and determine the impact on emergency use of hospital care.

The application was previously considered on the 2nd August 2018 when IGARD had deferred making a recommendation pending; clarification of the legal basis under GDPR for the linkage of HES data; clarification of the legal basis under GDPR for the flow of identifiable data; clarification of the control cohort and the legal basis for PHE to sample childhood data; to update the abstract sections on Article 6 and 9 of GDPR; to amend section 4 with standard wording.

NHS Digital advised that previous queries raised by IGARD had been addressed in supporting document 6.

	<p>Discussion: IGARD noted that the legal basis relied on for each flow of data was not clearly justified in the application and supporting document 4 the data flow diagram, and these should be updated to identify the legal basis relied on for each flow of data.</p> <p>IGARD queried whether the application had current CAG approval and asked that evidence was provided to support this.</p> <p>Outcome: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The legal basis relied on for each flow of data should be justified to IGARD's satisfaction. This should be done by updating the application (and in particular supporting document 4 - the data flow diagram) to identify in detail the legal basis relied on for each flow of data. 2. To provide evidence of the renewal of the CAG approval. <p>It was agreed that the condition would be agreed OOC by the IGARD members.</p>
3.3	<p><u>Clinical Practice Research Datalink (CPRD): BisCK Study (Risks and Benefits of bisphosphonate use in patients with chronic kidney disease) (Presenter: Kimberley Watson) NIC-113017-L9R3N</u></p> <p>Application: This was a new application requesting trusted third-party data linkage facility for the UK Renal Registry data (part of the Renal Association) and CPRD data. The bridge file of Hospital Episode Statistics (HES) to Diagnostic Imaging Datasets (DIDs) data will be used to assess the association between the use of oral bisphosphonates (anti-osteoporosis medication) and the progression (stage worsening or entering renal replacement therapy / transplant) of kidney disease in NHS patients with moderate or severe chronic kidney disease).</p> <p>The application was previously considered on the 2nd August 2018 when IGARD had deferred making a recommendation pending; to provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section; to clarify the legal basis to disseminate data for CPRD; provide evidence that a s.251 support is in place for the cohort described; CPRD to update their Fair Processing Notice to meet the NHS Digital's fair processing criteria for privacy notices including accurate description of the processing activities; University of Oxford to provide a Fair Processing Notice to meet NHS Digital's fair processing criteria for privacy notices including removing links to other fair processing notices referenced on their website; the Fair Processing section to be amended to include the new standard wording; to update the legal basis within section 3(b) to section s.261(7).</p> <p>Discussion: IGARD noted that funding was in place for this study as outlined in the application and suggested that the application be updated to clearly state this and provide evidence such as a funding letter.</p> <p>IGARD queried whether CPRD was the appropriate legal entity to enter into the Data Sharing Agreement (DSA) and associated Data Sharing Framework Contract (DSFC). It was also queried if the Data Controller (for the data requested) is appropriately described as CPRD (as opposed to, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) or the Department of Health and Social Care (DHSC)). IGARD suggested that NHS Digital satisfied themselves on this topic and provided confirmation to IGARD of their satisfaction and rationale.</p> <p>IGARD noted that the application stated that ethics approval was not required and requested that the application be updated to explain why ethics approval is not required. This should be done within section 7 of the application.</p> <p>Outcome:</p>

1. The application should be amended to confirm that funding is in place and refer to the relevant evidence.
2. To provide confirmation that NHS Digital is satisfied that (i) CPRD is the appropriate legal entity to enter into the DSA and associated DSFC and (ii) the Data Controller (for the data requested) is appropriately described as CPRD (as opposed to, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) or the Department of Health and Social Care (DHSC)).

The following amendment was requested:

1. To complete the ethics approval wording in section 7 explaining why ethics approval is not required.

It was agreed that the conditions would be agreed OOC by the IGARD Chair.

3.4	<p><u>University of Cambridge: ADDITION: Anglo-Danish-Dutch study of Intensive Treatment of people with newly diagnosed diabetes in primary care - ten year follow up (Presenter: Kimberley Watson) NIC-28744-S4F8H</u></p> <p>Application: This was an amendment application to amend a previously approved Data Sharing Agreement for an MRIS List Clean, to request HES data and add a storage location (OASIS). The data is being requested for the ADDITION-ten year follow-up study which is part of the larger ADDITION-Europe trial. The ADDITION-Europe trial is a four centre trial – Cambridge, Leicester, Denmark and the Netherlands (with Cambridge being the lead Trial centre) assessing the effectiveness and cost effectiveness of intensive treatment of multiple risk factors among people with screen-detected type 2 diabetes.</p> <p>Discussion: IGARD noted that the applicant was requesting data from 2000/2001 and queried why data was required for this period as the application states that the first cohort of patients for this study were recruited in 2002. IGARD suggested that section 3(b) was amended to remove the 2000/2001 data.</p> <p>IGARD queried how only 10 years of data for each cohort year will be processed and asked for further clarification.</p> <p>IGARD suggested that section 5(a) should be amended to provide further clarity on the timeline of the study and what has happened so far.</p> <p>IGARD asked for further clarification in the abstract that Oasis will (i) store the data and (ii) carry out no other processing other than making the data available to the University of Cambridge.</p> <p>IGARD advised that NHS Digital may wish to consider consulting with its legal advisers about the best way to achieve the effective application of the agreement from the desired date.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove the line within section 3(b) requesting data for 2000/2001 2. To clarify how only 10 years of data for each cohort year will be processed. 3. To amend section 5(a) to provide further clarity with a timeline of what has happened with the study so far. 4. To clarify in the abstract that Oasis will store the data and carry out no other processing other than making the data available to the University of Cambridge. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. NHS Digital may wish to consider consulting with its legal advisers about the best way to achieve the effective application of the agreement from the desired date.
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<p>3.5</p>	<p><u>University of Cambridge: MR1417 - ADDITION-Plus study: Ten-year follow-up of a randomised controlled trial of an individually-tailored behaviour change intervention among people with recently diagnosed type 2 diabetes under intensive UK general practice care (Presenter: Kimberley Watson) NIC-34907-D9R3N</u></p> <p>Application: This was a new application for Medical Research Information Service (MRIS) List Cleaning service is to cross reference the applicants contacts database with those in the list clean (239 participants) provided to ensure University of Cambridge participant records are up to date and to allow follow-up of participants who have moved since last follow-up.</p> <p>Discussion: IGARD queried information in section 5(a) that suggests there has already been a list clean of the 239 referred to in the application and suggested clarifying further the timeline for the list cleaning already carried out and proposed to be carried out under this agreement.</p> <p>Outcome: recommendation to approve</p> <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To clarify within section 5(a) what the timeline has been for the list cleaning already carried out and proposed to be carried out under this agreement
<p>3.6</p>	<p><u>University of Leicester: Critically ill children and young people: do national Differences in access to Emergency Paediatric Intensive Care and care during Transport affect clinical outcomes and patient experience? The DEPICT study (Presenter: Rachel Farrand) NIC-120105-F0K2L</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data and Office for National Statistics (ONS) mortality data. Critically ill children who are admitted to district general hospitals can require specialist transport to a paediatric intensive care unit (PICU). There is considerable variation in the care provided prior to admission to paediatric intensive care. The objective of the DEPICT study is to study the association between timelines of access to paediatric intensive care and 30-day mortality.</p> <p>The application was previously considered on the 12th July 2018 when IGARD had deferred making a recommendation pending; amendment of the statement ‘data flows posing an additional risk to individual’s health data’, in the abstract under the necessity test, to state ‘data processing which would be more intrusive to the data subjects.’; a clearer explanation within section 5 the roles and responsibilities of Great Ormond Street Hospital including any access to data; a clear explanation within section 5 the roles and responsibilities of HQIP and the University of Leeds including their role in the design and performance of the project and any data they may have access to; to clarify the legal basis for NHS Digital to receive data from University of Leeds and ICNARC under GDPR; to amend the sentence in 5a “University of Leicester will not release any record level data to third party organisations” to reflect that record level data will be disseminated to University of Leeds, ICNARC and Great Ormond Street Hospital; the applicant to work with NHS Digital on a fair processing notice; to clarify reference to ‘returned’ data to the University of Leicester within section 5(b); to clarify the subsection within s.42(4) for the receipt of ONS data within section 3(b) and 5(a) of the application; to include a special condition that only the University of Leicester can hold and process the data; to explain within section 8 why two study protocols were provided with the application; to clarify the number of data years requested and update the correct periods within section 3(b) and 5(b); any reference to ‘the agreement’ within section 5 must be updated to refer to ‘this agreement’; to amend references within the application from ‘section 6’ to state ‘Article 6’.</p>

	<p>Discussion: IGARD noted that the expiry date for the current Data Protection Act 2018 registration details for Great Ormond Street had expired and needed updating in the application.</p> <p>IGARD noted that 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.</p> <p>IGARD noted that the University of Leeds and ICNARC flowed data into NHS Digital and asked for the application to be updated to reflect the legal basis entitling NHS Digital to receive this data - this should be clarified in paragraph 4 of the abstract.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the application with the current DPA registration details for Great Ormond Street Hospital. 2. To amend section 4 to read: “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” 3. To update paragraph 4 of the abstract to specify the legal basis under which NHS Digital receives data from the University of Leeds and ICNARC.
3.7	<p><u>University of York: National Audit of Cardiac Rehabilitation (NACR) (Presenter: Rachel Farrand) NIC-12881-L1H2B</u></p> <p>Application: This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data to enable the NACR to report accurately on cardiac rehabilitation so that commissioners can make informed decisions about the performance of services they fund and help inform commissioning decisions and drive up the quality of provision and outcome for patients attending cardiac rehabilitation.</p> <p>Discussion: IGARD suggested clearly defining the objectives of the audit within section 5(a) in terms accessible to a lay reader.</p> <p>IGARD noted that 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.</p> <p>IGARD queried the position with funding and were advised by NHS Digital that funding was in place, IGARD suggested updating the supporting document table in the application making specific reference to the funding confirmation.</p> <p>IGARD suggested clarifying within section 5(a) the types of rehabilitation that are being compared.</p> <p>IGARD advised that the applicant consider using content from the applicant’s website as part of the update to section 5(a).</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To clearly define the objectives of the audit within section 5(a), in terms accessible to a lay reader. 2. To amend section 4 to read: “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” 3. To update the supporting document table to make reference to the funding confirmation.

	<p>4. To clarify within section 5(a) what types of rehabilitation are being compared.</p> <p>The following advice was given:</p> <ol style="list-style-type: none">1. Consider using content from the applicant's website as part of the update to section 5(a).
4	AOB

Independent Group Advising on Releases of Data (IGARD): Out of committee report 22/08/18

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-45477-B9W1L	St George's University of London	17/05/18	<ol style="list-style-type: none"> 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. Providing documentary evidence that the researcher with access to the data has an APR researcher status. 3. The Fair Processing Notice be amended to meet the NHS Digital nine minimum criteria (to be known as NHS Digital's fair processing criteria) for privacy notices and it is also published on the data controller's website. 4. To clearly describe within section 5 the purpose of the larger research project undertaken by clinical researchers at St. George's Hospital Medical School Research Department and how it relates to the project in this application. 			
NIC-147827-NC2TC	Imperial College London	24/05/2018	<ol style="list-style-type: none"> 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 	OOC by IGARD Members	Quorum of IGARD Members	N/A

			<ol style="list-style-type: none"> 2. To provide evidence of the MRP status. 3. To provide APR current approved researcher evidence. 4. To clarify within section 5 what data University of Oxford can access, the data minimisation efforts undertaken and the appropriate controls in place. 			
NIC-148411-Q64H8	University College London	02/08/18	<ol style="list-style-type: none"> 1. Clarification that s.251 support supports the use of ONS 2. To explicitly state within section 5a how this wider programme of research relates to the British Regional Heart Study. 	OOB by IGARD Members	Quorum of IGARD Members	N/A
NIC-09637-Y8T1N	University of Oxford	26/07/18	<ol style="list-style-type: none"> 1. To be explicit in section 5 that this is a small subset study of a larger study, to explain which of the benefits relate to this particular aspect of the study and include clear headline statements explaining the subset aspect for transparency and the lay reader. 	OOB by 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