

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 4 April 2019

Members: Sarah Baalham, Anomika Bedi, Maria Clark (Acting Chair), Nicola Fear, Priscilla McGuire, Eve Sariyannidou.

In attendance: Stuart Blake, Dave Cronin, Louise Dunn, Rachel Farrand, Karen Myers, Vicki Williams.

Apologies: Joanne Bailey, Kirsty Irvine, Geoffrey Schrecker, Maurice Smith.

1	<p>Declaration of interests:</p> <p>Nicola Fear noted a professional links with University College London [NIC-234656-C3J1D] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest</p> <p>Nicola Fear noted a professional links with King's College London [NIC-274251-H0G6M] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest</p> <p>Priscilla McGuire noted professional links to NHS Improvement [NIC-213403-P3R8Q] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Eve Sariyannidou noted professional links to HQIP [NIC-355855-R4G6G Royal College of Anaesthetists] 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 March 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	Data applications
2.1	<p><u>Royal College of Anaesthetists (RCoA): MR1386 - National Emergency Laparotomy Audit (Presenter: Stuart Blake) NIC-355855-R4G6G</u></p> <p>Application: This was an amendment, extension and renewal application for identifiable Medical Research Information Service (MRIS) and Hospital Episode Statistics (HES) data for a national clinical audit commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical and Patient Outcomes Programme (NCAPOP) to enable the improvement of the quality of care of patients undergoing emergency laparotomy by providing high quality comparative information of the clinical practice and outcomes of all NHS providers of emergency laparotomy in England and Wales.</p> <p>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 queried the various parties involved and the roles of NHS England, the Royal College of Surgeons of England (RCS) and The Royal College of Anaesthetists (RCoA) and asked for clarity as to why they were not considered joint Data Controllers; and if they were, that the application was amended throughout to reflect this.</p>

IGARD queried the role of HQIP and were advised by NHS Digital that they had requested the audit. IGARD asked for further clarity of how HQIP's discretion and contribution to the purpose, design and execution of the audit was substantive to establish its role as a data controller.

IGARD noted that the application had previously been reviewed by its predecessor the Data Access Advisory Group (DAAG) in 2015 and that substantial amendments had been made since, that were not reflected in the current s251 support; and suggested that an amendment application should be submitted to the Health Research Authority Confidentiality Advisory Group (HRA CAG).

IGARD queried the reference in supporting document 18, the RCoA Memorandum of Understanding to the 'NIAA Health Services Research Centre' and asked for further clarity on their role in the audit; and also its role in terms of supervising any subcontracted workers.

IGARD noted the reference in section 6 (Special Conditions) to the "*Royal College of Anaesthetists (RCOA) contracted employees*" and asked that this was updated to say "*contracted workers*" noting that some employees may not be substantive. IGARD queried if any individuals were seconded into the RCoA or if the RCoA sub-contracted this work to another organisation and asked that this was clarified.

IGARD noted that the standard wording in section 4 (Privacy Notice) read "*all data required by the Data Controller under this agreement...*" and should be amended to read "*Data processed under this agreement...*" and to also remove "*...but at least within one month*" from the end of the sentence.

IGARD noted that section 5(a) (Objective for Processing) should be updated to include clearer examples for processing and how the applicant has been using the data. IGARD also suggested that the applicant provide further details, on renewal, of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement.

Outcome: Unable to recommend for approval

1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis.
2. To clarify why NHS England, Royal College of Surgeons of England (RCS) and The Royal College of Anaesthetists (RCOA) are not considered joint data controllers and, if they are, to amend the application throughout to reflect this.
3. To clarify how HQIP's discretion and contribution to the purpose, design and execution of the audit is substantive to establish its role as a data controller.
4. Given the substantial amendments in this application are not reflected in the current s.251 support, an amendment application should be submitted to HRA CAG.

The following amendments were requested:

1. To provide clarity on the role of the NIAA Health Services Research Centre as referred to in supporting document 18 and clarify its role in terms of supervising any subcontracted workers.
2. To update the special condition in section 6 to amend the reference to 'contracted employees' to 'contracted workers'.
3. To provide clarification if individuals are seconded into the Royal College of Anaesthetists or if the Royal College of Anaesthetists sub-contract this work to another organisation.
4. To update section 4 and insert a special condition in section 6 with the standard wording "Data processed under this application is pseudonymised and therefore is

	<p>considered as personal data under the GDPR. All data controllers shall provide a privacy notice that is compliant with the GDPR notice requirements”.</p> <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.
2.2	<p><u>University College London: Family, household and environmental risk factors for hospital admissions in childhood (Presenter: Rachel Farrand) NIC-234656-C3J1D</u></p> <p>Application: This was a new application to access a birth cohort, which includes identifiable Hospital Episode Statistics (HES) Admitted Patient Care (APC) data already disseminated under NIC-10094-P6P4B for a project building on previous results to examine environmental and household risk factors for preventable hospital admissions in children, and whether children whose parents were born abroad face barriers to accessing preventive primary and community health services, which in turn leads to the need for hospital admission.</p> <p>NHS Digital noted that ‘Edinburgh’ should be included within section 1 (Abstract) when referencing the ‘university’.</p> <p>Discussion: IGARD noted the references throughout the application to <i>“knowledge of English”</i> and <i>“English proficiency”</i> and asked for further information on the meaning of these terms and that consistent language was used throughout. IGARD also asked for confirmation of the data set used for this information and whether this was a self-assessed competency.</p> <p>IGARD queried the role of the Office of National Statistics (ONS) and asked that section 1 (Abstract) was updated outlining this; and a further explanation as to why they were not considered a joint Data Controller.</p> <p>IGARD queried the information provided in supporting document 7, the draft privacy notice. IGARD noted the sensitive nature of the research and for those involved to be cautious to ensure that it is treated as such, and asked that draft privacy notice be updated to further reflect the information provided in the application; and suggested the applicant considered changing the word ‘risk’ to ‘chance’ to eliminate any possible negative connotations, since it was clear that this project was not looking to lay blame for hospital admissions on certain members of society.</p> <p>IGARD noted that supporting document 9, the ‘ONS policy for safeguarding data whilst managing Admin Data Research Network projects’ was produced prior to General Data Protection Regulation (GDPR) and suggested there may be a more recent version available which may include information post the introduction of the GDPR.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To provide further information or clarity on the meaning of the term ‘knowledge of English’ / ‘proficiency of English’, ensure consistent language is used throughout with regards these terms and confirm the data set used for this information and whether this is in fact a self-assessed competency. 2. To update section 1 to clarify the role of ONS and why they are not considered a joint Data Controller. 3. To update the draft privacy notice to further reflect the information provided in the application and consider changing the word ‘risk’ to ‘chance’ to take away possible negative connotations. <p>The following advice was given:</p>

	<p>1. IGARD suggested that there could be an updated version of supporting document 9, the 'ONS policy for safeguarding data whilst managing Admin Data Research Network projects' which may include information post the introduction of the GDPR.</p>
2.3	<p><u>NHS Improvement: NHS Improvement - National Clinical Improvement Programme (NCIP) (Presenter: Louise Dunn) NIC-213403-P3R8Q</u></p> <p>Application: This was a new application, to use data held under Monitor's main agreement NIC-15814-C6W9R, for pseudonymised Diagnostic Imaging Dataset (DIDs), Secondary Uses Service (SUS), Hospital Episode Statistics (HES), Civil Registration and Patient Reported Outcome Measures (PROMs) data for a programme aiming to support clinicians with learning and continuous self-development with respect to the services they deliver.</p> <p>The programme will provide both team and clinical-level activity and metrics about the whole of a clinician's practice, and links to relevant service delivery research and other evidence, delivered through a secure online portal. NHS consultants in England will use to source their personal and unit-level outcome data in the context of national benchmarks. This information will support quality improvement activities, with the ultimate aim of delivering improved patient care.</p> <p>NHS Digital noted the reference in section 5 to the sub-licence being provided and advised this would be removed from the document as it was not relevant.</p> <p>Discussion: IGARD noted that an application with the same request had recently been recommended for approval by IGARD and asked that the same security assurances assurance wording relating to the use of cloud storage were applied and included within the application. IGARD also asked for clarification as to whether the storage location for Microsoft Azure was England and Wales.</p> <p>IGARD noted a number of a references in the application to 'Consultants' and whether they were NHS employed consultants working for the NHS, and asked for further clarity in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) on the definition of this.</p> <p>IGARD queried the level of data that Consultants will have access to on the dashboard and asked that section 1 and section 5 was updated clarifying this.</p> <p>IGARD queried the references in the application to 'unit level activity' and asked for further clarity in section 1 and section 5 on what is meant by this; and whether this refers to the Consultant's own activity only; and the level and type of data that the Consultant will have access to.</p> <p>IGARD noted the references to 'designated organisation' when referring to NHS Trusts and asked for further clarity on the meaning of this; and the implications if the designated organisation was not an NHS Trust.</p> <p>IGARD noted sub-licensing arrangements were in place and suggested that section 5(a) (Objective for Processing) was amended to reflect the arrangements of the sub-licensing agreement. IGARD also noted the update provided by NHS Digital to the sub-licence reference in section 5 and supported the amendment to remove this.</p> <p>IGARD queried if the data held was restricted to care and treatment activity in English hospitals only and asked that confirmation was provided.</p> <p>IGARD noted the inclusion of the Competition and Markets Authority (CMA) and The Royal National Orthopaedic Hospital NHS Trust as Data Processors under this application and asked for further clarity on their roles.</p>

<p>IGARD queried whether Advanced 365 Limited was only listed as a storage location and asked for further clarity on this; and if so that a special condition was added to section 6 (Special Conditions) stating that Advanced 365 Ltd will not access data held under this agreement.</p> <p>IGARD queried if a Direction was available for the National Clinical Improvement Programme (NCIP) and were advised by NHS Digital that this was still in draft form and currently being progressed by NHS Improvement. IGARD asked that a special condition was inserted in section 6 (Special Conditions) that the application and the Data Sharing Agreement (DSA) would be amended to reflect the published Direction.</p> <p>IGARD queried the correct legal basis that was being used under Article 9 of the General Data Protection Regulation (GDPR) and asked that if necessary this was reviewed and amended from Article 9(2)(j) to Article 9(2)(h).</p> <p>IGARD noted the first output in section 5(c) (Specific Outputs Expected) “<i>Developing the Carter Model Hospital, GIRFT and NCIP product.</i>” and asked for further clarity on this.</p> <p>Outcome: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To insert appropriate security assurance wording relating to the use of cloud storage. 2. To provide clarification in section 1 and section 5 on the definition of ‘Consultants’. 3. To provide further clarity in section 1 and section 5 on what is meant by ‘unit level activity’, whether this refers to the Consultant’s own activity only and the level and the type of data the Consultant with have access to. 4. To provide further clarity in section 1 and section 5 what is meant by ‘designated organisation’ with reference to NHS Trust and the implications if the designated organisation is not a Trust. 5. To update section 5 to reflect the sub-licensing arrangements as outlined in the sub-licensing agreement. 6. To update section 1 and section 5 to provide clarity on the level of data that Consultants will have access to on the dashboard. 7. To provide confirmation that the data held is restricted to care and treatment activity in English hospitals only. 8. To clarify the role of CMA and The Royal National Orthopaedic Hospital NHS Trust as Data Processors under this application. 9. To clarify whether Advanced 365 Ltd is only listed as a storage location and if so to insert a special condition in section 6 stating that Advanced 365 Limited will not access data held under this agreement. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To insert a special condition in section 6 that the application and the DSA would be amended to reflect the published Direction. 2. To review the correct legal basis under Article 9 and amend from Article 9(2)(j) to Article 9(2)(h), if necessary. 3. To provide confirmation as to whether the storage location for Microsoft Azure is England and Wales. 4. To provide further clarity on the first output referenced in section 5(c) relating to Carter Model Hospital. 5. To remove reference to the sub-licence being provided separately from section 5 since it is not relevant. <p>It was agreed the condition be approved OOC by IGARD Members.</p>

Erasmus University Rotterdam: Synergy between PCI with TAXUS and Cardiac Surgery: SYNTAX Extended Survival (SYNTAXES) (Presenter: Louise Dunn) NIC-230360-H3Y3C

Application: This was a new application for pseudonymised Civil Registrations data for a study that represents the extension to a 10-year of the planned final follow-up of the SYNTAX trail which was a multi-centre international investigation in which 1,800 patients were randomly assigned to drug-eluting stent-based percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG).

The aim of the multinational SYNTAXES study is to assess long term survival of patients who underwent CABG or PCI.

Discussion: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

IGARD queried the General Data Protection Regulation (GDPR) legal basis for the Data Controller(s), noting that data will be processed for individuals that may still be alive to establish the date of death and asked for further clarification of this.

IGARD noted the overwhelming evidence within the supporting documents that establishes the University Hospitals Southampton (UHS) NHS Foundation Trust (FT) as the Data Controller and asked for further clarity to support the data controllership of the applicant, currently the Erasmus University Medical Centre.

IGARD queried why the other principal investigators referred to in the application were not considered joint Data Controllers with the Chief Investigator of the UHS NHS FT and asked for a further explanation of this.

IGARD noted the references within the application to 'Erasmus University' and 'Erasmus University Medical Centre' and asked for further clarity on the difference between the two; and for a further explanation as to why Erasmus University is named as the Data Controller.

IGARD noted that the study had s251 support and discussed that this would only be applicable to the English cohort and would only permit the disclosure and the processing of the data by the UHS NHS Foundation Trust; and asked that evidence was provided of a legal gateway under the Duty of Confidentiality for the applicant to receive this data.

IGARD queried information provided in section 1 (Abstract) in relation to the Data Protection Officer (DPO) and asked that it was made clear that the DPO requirement per organisation was specific to the Netherlands, under Dutch Law.

IGARD queried the information provided in the data minimisation column in section 3(b) (Additional Data Access Requested) that states that *"12% of the available fields have been requested"* and asked for clarity if this relates just to the date of death or to additional data.

IGARD noted that supporting document 9, the draft privacy notice contained a number of clinical terms and asked that this was updated to be more accessible to a lay reader.

IGARD noted the special condition in section 6 (Special Conditions) *"NHS Digital will ensure that ISO certificate for Erasmus MC is successfully verified before data will flow."* and suggested that this was reviewed to ensure the obligation is on the applicant not NHS Digital.

Outcome: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

1. To provide the GDPR legal basis for the relevant data controller(s), since the data controller will process the data of individuals who may still be alive to establish the date of death.

	<ol style="list-style-type: none"> 2. Since the supporting documents provide overwhelmingly evidence that establishes UHS NHS FT as the data controller, to provide clarification to support the data controllership of the applicant (the medical centre of the Erasmus University) 3. To provide an explanation why the other principal investigators are not joint data controllers with the chief investigator UHS NHS FT. 4. What is the difference between the Erasmus University and Medical Centre and why Erasmus University is named as the Data Controller. 5. Since the s.251 is for the English cohort and permits the disclosure to and the processing of the data by the UHS NHS FT only, to provide evidence of a legal gateway under the Duty of Confidentiality for the applicant to receive the data 6. To update the abstract to be clear that the DPO requirement per organisation is specific to the Netherlands under Dutch Law. 7. To clarify the percentage field of 12% outlined in the application and whether this relates just to the Date of Death or to more data. 8. IGARD suggested the fair processing notice be updated to be more accessible to a lay reader. 9. IGARD suggested that NHS Digital review the special conditions outlined in Section 6 to ensure obligation is on the applicant, not NHS Digital.
2.5	<p><u>University of Bristol: MR141 - CAERPHILLY ISCHAEMIC HEART DISEASE STUDY</u> (Presenter: Dave Cronin) NIC-148336-V4SL1</p> <p>Application: This was an extension, renewal and amendment application for identifiable Medical Research Information Service (MRIS) for a long-running study, initially set up in the late 1970's, aiming to enhance the understanding of life course influences on the aetiology of chronic disease and physiological traits by examining life style, genetic and other exposures at various time in the life course and determine whether these predict a wide range of different outcomes.</p> <p>Discussion: NHS Digital noted that the application had had no previous independent review. IGARD noted the reference in section 1 (Abstract) to 'anonymised' data and asked that this was amended to correctly reference 'pseudonymised' data.</p> <p>IGARD noted that the original ethics approval was for the University of Cardiff and were advised by NHS Digital that this was the original location of the study prior to it moving to the University of Bristol. IGARD queried why ethics approval was not required going forward and were advised by NHS Digital that this was not required due to the data being pseudonymised. IGARD noted the points however asked that clarification was provided on the history of the project (in relation to the University of Cardiff and the University of Bristol); and confirmation as to why ethics approval was not required going forward was included in section 1 and section 5(a) (Objective for Processing).</p> <p>IGARD noted a copy of the Health Research Authority Confidentiality Advisory Group (HRA CAG) register was not currently available and asked that a copy was added to NHS Digital's Customer Relationship Management system (CRM).</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 reference from 'anonymised' data to correctly reference 'pseudonymised' data.

	<ol style="list-style-type: none"> To provide clarification on the history of the project (with particular reference to the University of Cardiff and the University of Bristol) within section 1 and section 5(a) including confirmation as to why ethics approval was not required. To update the CRM holder with a copy of the CAG register.
2.6	<p><u>King's College London: Outcomes after hip fracture by duration, frequency and type of rehabilitation (Presenter; Dave Cronin) NIC-274251-H0G6M</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) for the purpose of research to determine whether poor outcomes after hip fracture surgery were less frequent among patients exposed to more frequent, longer duration, and more comprehensive rehabilitation controlling for characteristics of patients, their injuries and healthcare.</p> <p>The data will provide essential outcome data (readmission and survival at 30-days) as well as rich information on ethnic category, deprivation, comorbidities and complications for regression adjustment and subgroups in the proposed analyses. The aims will inform quality improvement initiatives to reduce unwarranted variation in rehabilitation after hip fracture.</p> <p>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 the role of Crown Informatics outlined in the application and suggested that they were included as a Data Processor; or for a brief explanation be provided in section 5 (Purpose / Methods / Outputs) as to why they are not considered a Data Processor and for confirmation that they will not have access to any data under this agreement.</p> <p>IGARD noted that the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) supporting document, provided as part of the review, noted the University of Oxford's role as 'Data Processor', however noted that they were not listed as such within this application; and asked for clarity on the University of Oxford's role.</p> <p>IGARD noted the incorrect references to 'pseudo-anonymised' in the privacy notice and asked that these were removed. IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 (Privacy Notice) be updated to clearly state that the application privacy notice 'does not' meet the criteria.</p> <p>Outcome: Unable to recommend for approval</p> <ol style="list-style-type: none"> 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"> Crown Informatics to be included as a Data Processor; or to provide a brief explanation as to why they are not considered a Data Processor in section 5; and confirm that they will not have access to any data under this agreement. To remove reference to 'pseudo-anonymised' in the Privacy Notice. Since University of Oxford are not listed as a Data Processor, to provide a further explanation to the role of the University of Oxford as outlined in the HRA CAG supporting document dated February 2017 which refers to them as Data Processor. To update section 4 to clearly stated the applicant's fair processing notice 'does not' meet the NHS Digital's fair processing criteria for privacy notices.
3	<p>AOB</p> <p>None</p>

Independent Group Advising on Releases of Data (IGARD): Out of committee report 29/03/19

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-68229-Y5J6V	King's College London	14/03/19	1. To add South London and Maudsley NHS Foundation Trust as joint data controllers and to amend the application throughout to reflect this.	IGARD Members	Quorum of IGARD Members	Still a few spots where the tense needs to change from singular to plural to incorporate two data controllers (eg the first line of section 5a). Would also suggest that the following sentence is deleted or amended as it is potentially contradictory with the statement in the next para that SLaM is a data controller: "The only roles SLaM has is to process the grant funding and also an individual employed at SLaM is a coinvestigator in the trial."

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

- None