

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

### Minutes of meeting held 29 November 2018

**Members:** Anomika Bedi, Kirsty Irvine (Chair), Eve Sariyannidou

**In attendance:** Dave Cronin, Louise Dunn, Rachel Farrand, Karen Myers, Kimberley Watson, Vicki Williams.

**Observers:** Priscilla McGuire

**Apologies:** Sarah Baalham, Joanne Bailey, Nicola Fear.

1	<p><b>Declaration of interests:</b></p> <p>Eve Sariyannidou noted professional links to HQIP [NIC-120848-R6V4C - University of Warwick] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 22 November 2018 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings.</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>Clinical Practice Research Datalink (CPRD): ELAPSE Study – Air pollution (Presenter: Kimberley Watson) NIC-113074-D9M1C</u></p> <p><b>Application:</b> This was a new application for pseudonymised Medical Research Information Service (MRIS) data to assess associations between long-term average concentrations of particular matter, nitrogen dioxide, sulphur dioxide, black carbon and ozone and the risk of death and disease incidence in England.</p> <p>The application was been previously considered on the 8<sup>th</sup> November 2018 when IGARD had been unable to recommended pending; clarification why St George's University of London are not also considered a Data Controller and provide relevant justification; to further explain that the US funder, The US Health Effects Institute, will not influence the design of the study or have sight of the record level data and to explain the connection between the funder and the funding recipient as outlined in supporting document 4 and to confirm that funding is in place and provide relevant evidence; aligning the named legal entities listed as the Data Controller(s) and Data Processor(s) within the application with contractual documents held by NHS Digital and as per the entities listed in the HRA CAG s251 support provided as a supporting document; to clarify why NHS Digital are not considered a Data Processor and provide relevant justification; to clarify that the postcodes provided by the GP is the patient postcode only; to provide further details of pathways of dissemination of the outputs including any specific examples of public / patient engagement; to update section 5(a) from 'nominal codes' to 'nominal pollution codes'; to remove any reference in the application to 'anonymised' and replace with 'pseudonymised'; to remove reference to 'patient' from the step 1 statement in section 5(b).</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect most of the comments previously made save for further explanation of the funding directed to the University of Utrecht and how it linked to the project described in the application.</p>

	<p>IGARD noted previously that NHS Digital were not considered as a Data Processor and asked for further clarification as to why NHS Digital were not considered a joint Data Processor when carrying out the role of trusted third party, and suggested that if they were then the application should be amended to reflect this.</p> <p>IGARD suggested that any reference to anonymised data in the application be updated to 'pseudonymised data'.</p> <p>IGARD noted that the abstract should be amended to reflect recent discussions between NHS Digital and IGARD including (but not limited to) setting out the legal basis and the relevant Article 6 and 9 of the GDPR for Imperial College London to disseminate data to NHS Digital.</p> <p>IGARD queried if the revised Clinical Practice Research Database is available to all researchers or just Imperial College London and St George's University London, NHS Digital confirmed that it will be available to all researchers who meet the relevant requirements. IGARD asked that section 5 (Purpose, Methods, Outputs) of the application be revised to confirm this information.</p> <p>IGARD queried who the other parties that were involved with the application, noting the application outlined that CPRD were requested data for two European Union funded projects and Imperial College London and Utrecht University and St George's are key members of the consortia and asked that section 5 of the application be updated to clearly identify the two EU funded projects and the roles of the three organisations in these projects..</p> <p><b>Outcome:</b> recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. To remove any reference in the application to 'anonymised' and replace with 'pseudonymised'.</li> <li>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</li> <li>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.</li> <li>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.</li> </ol> <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.2	<p><u>The Clinical Practice Research Datalink (CPRD) (Presenter: Kimberley Watson)</u></p> <p>NHS Digital provided an overview including the legal basis, Data Controllership and legal status of CPRD.</p> <p>NHS Digital noted that CPRD were not a legal entity but part of MHRA (Medicines and Healthcare Products Regulatory Agency) which in turn is part of the Department of Health. IGARD suggested that consideration be given for each application presented to IGARD if the Department of Health or MHRA should be listed as the Data Controller, noting that they could not also be listed as a Data Processor but could be a Data Controller who processed data. NHS Digital confirmed in-meeting that MHRA were an executive agency and that the Department of Health are the legal entity and should be listed as the Data Controller or joint</p>

	<p>Data Controller, dependent on the application presented. IGARD suggested that a clear narrative be included within section 5 setting out who CPRD are, how they link to MHRA and the Department of Health and the facts of who is processing the data in each instance.</p> <p>IGARD suggested that CPRD may wish to refer to the (Information Commissioners Office) ICO guidance on 'what is personal data' to clearly identify the type of data within each application.</p> <p>IGARD thanked NHS Digital for their presentation.</p>
2.3	<p><u>Intensive Care National Audit &amp; Research Centre (ICNARC): Renal Replacement Anticoagulant Management (RRAM) (Presenter: Kimberley Watson) NIC-184951-D1G8R</u></p> <p><b>Application:</b> This was a new application for one off extracts of Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Civil Registration (death) data sets for the Renal Replacement Anticoagulation Management (RRAM) study which has been designed to utilise routinely collected data to compare the clinical and cost effectiveness of changing to citrate anticoagulation for continuous renal replacement therapy (CRRT) in adult intensive care units (ICO).</p> <p>The application was been previously considered on the 1<sup>st</sup> November 2018 when IGARD had been unable to recommended pending; ICNARC to clarify its role and that of the Chief Investigator and the University of Oxford and what discretion each has in the overall project and therefore consider whether University of Oxford be considered a joint Data Controller, and that the applicant may wish to utilise the ICO guidance with regard to identifying Data Controllers; to provide an explanation within why the Renal Association are not considered a joint Data Controller and that the applicant may wish to utilise the ICO guidance with regard to identifying Data Controllers.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect most of the comments previously made save for clarification around the role of Chief Investigator and why they were not considered to be carrying out the role of Data Controller.</p> <p>IGARD noted that ICNARC had responsibility for the day to day management and running of the study and that the Chief Investigator, based at the University of Oxford was not part of the research team nor accessing the data provided by NHS Digital. However IGARD repeated their request for further clarification on the responsibilities and powers of the Chief Investigator and the discretion they had in the overall project – given what might be usually expected of someone carrying out that role – and, in light of that, for the applicant to consider whether the University of Oxford should be considered a joint Data Controller since they were the employer of the Chief Investigator.</p> <p>IGARD queried what the GDPR legal basis was for the Renal Association to flow the data to NHS Digital and asked that the abstract be updated to clarify this.</p> <p><b>Outcome:</b> Recommendation to defer, pending:</p> <ol style="list-style-type: none"> <li>1. The applicant to clarify the responsibilities and powers of the Chief Investigator (as an employee of the University of Oxford) and what discretion they have in the overall project and therefore consider whether University of Oxford be considered a joint Data Controller.</li> <li>2. To update the abstract to list the GDPR legal basis for the Renal Association to flow the data to NHS Digital.</li> </ol>
2.4	<p><u>University of Warwick: Safety and feasibility evaluation of tourniquets for total knee replacement (SAFE-TKR) (Presenter: Rachel Farrand) NIC-120848-R6V4C</u></p>

	<p><b>Application:</b> This was a new application for Hospital Episode Statistics (HES) Admitted Patient Care (APC) and HES Outpatient data for the purpose of establishing the evidence of blood clots in the legs, lungs and brain in patients undergoing knee replacement surgery with a tourniquet.</p> <p>The application was been previously considered on the 13<sup>th</sup> September 2018 when IGARD had been unable to recommended pending; to update the application to reflect that the National Joint Registry are a joint Data Controller; to provide the legal basis under GDPR for the flow of data from the National Joint Registry to NHS Digital; to clarify the involvement of University Hospitals Coventry and Warwickshire NHS Trust as outlined in the study protocol, including their role and responsibilities and any access to data under the different components of the study; to clarify the three components of the larger study outlined within the protocol and to clarify this application / data sharing agreement only covers one component, and to clearly state that this is an observational study and not a trial; to clarify if any further data minimisation can be undertaken by the applicant; to remove reference to the University of Leicester from the abstract since they are not relevant to this application.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect the comments previously made, however IGARD noted that Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task is the appropriate legal basis .</p> <p><b>Outcome:</b> Unable to recommend for approval</p> <ol style="list-style-type: none"> <li>1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis.</li> </ol>
2.5	<p><u>Barts Health NHS Trust: Continuation of order NIC-147204-CGWY5 MR1283: DARE (Diabetes Alliance for Research in England) - NE London Diabetes Research Network Locality (Presenter: Rachel Farrand) NIC-291938-R6V3V</u></p> <p><b>Application:</b> This was a renewal application for identifiable Medical Research Information Service (MRIS) data. The Diabetes Alliance for Research in England (DARE) study was established in order to understand the cause of diabetes and its complications such as heart disease, diabetic eye disease and diabetes kidney disease, and to improve treatment and prevention of these important illnesses, the DARE study team need to find both the genes and also non-inherited factors that make some people more likely to get diabetes and the medical problems related to diabetes. This research study is a nationwide collaboration between patients and professionals to provide a platform to enable further study into the causes and complications of diabetes.</p> <p><b>Discussion:</b> IGARD queried what the outputs and benefits were of the study and how they link to health and social care. IGARD suggested that section 5 (Purpose, Methods, Outputs) be updated to clearly define outputs and benefits, including any examples of public / patient engagement.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>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</li> </ol> <p>It was agreed the condition would be approved OOC by the IGARD Chair.</p>
2.6	<p><u>UK Biobank: MR1109 – UK Biobank – Renewal / Extension (Presenter: Dave Cronin) NIC-08472-V9S6K</u></p>

**Application:** This was an extension and renewal application for identifiable Mental Health and Learning Disabilities Data Set (MHLDDS), Medical Research Information Service (MRIS), Diagnostic Imaging Dataset (DIDs), bridge file Hospital Episode Statistics (HES) to Mental Health Minimum Data Set (MHMDS) and bridge file Hospital Episode Statistics (HES) to Diagnostic Imaging Dataset (DIDs). The purpose is to create a prospective epidemiological resource of the 500,000 people aged 45-69 and set up and manage a major international research resource for health-related research.

The application was been previously considered on the 15<sup>th</sup> November 2018 when IGARD had been unable to recommended pending; to provide further confirmation of the legal basis relied on for processing NHS Digital Data, as set out in the application, and clarification of how this aligns with the legal bases outlined in the applicant's published privacy notice; clarification of the GDPR legal bases for the processing of data provided from other sources would be welcomed; to clarify how the action raised by DAAG in 2015 with regard to providing a case study has been addressed; to confirm that funding is continuing or now in place and provide the relevant evidence; to confirm that any funder will not have influence on the outcomes nor suppress any outcomes of research; to clearly state the applicant's fair processing notice "does not" meet NHS Digital's fair processing criteria for privacy notices.

**Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made.

IGARD queried the legal basis relied on for processing NHS Digital Data, as set out in the application, and clarification of how this aligns with the legal bases outlined in the applicant's published privacy notice on their website and what is intimated in the Access Procedures Policy (as expanded below). IGARD suggested that the different purposes for which the applicant was processing the data in the clinical setting be clearly outlined, including clearly identifying the legal bases that relates to each separate purpose within a clinical setting and to update within the data flow diagram.

IGARD noted the permissions listed under the Access Procedures in the supporting document provided appeared to presume consent was the legal basis for processing the data and asked that it be clear how the legal basis relied upon within the application aligns to the Access Procedures Policy.

IGARD suggested that NHS Digital may wish to consider how the NHS Digital Data Sharing Framework Contract (DSFC) with UK Biobank overrides the incorporated by reference documents listed on the UK Biobank website which clearly state that peoples from overseas can access their data, however NHS Digital gave assurances that the DSFC took precedent over any other document or contract that the applicant may have signed with other organisations or individuals with regard to NHS Digital data.

**Outcome:** Unable to recommend for approval

1. To clearly outline the different purposes for which UK Biobank are processing data in the clinical setting and clearly identify the legal bases that relates to each separate purpose within a clinical setting.
2. To align the lawful basis for the applicant with the permissions listed under the Access Procedures supporting document (which appears to presume consent is the legal basis for processing).

IGARD noted the importance of the research undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, and in light of this it was suggested that NHS Digital might wish to

	consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to update the application.
2.7	<p><u>South London and Maudsley NHS FT: MR808 – SLaM IG Clinical Dataset Linking Service (Presenter: Dave Cronin) NIC-292279-Z2S5T</u></p> <p><b>Application:</b> This application was for an amendment, extension and renewal for pseudonymised Medical Research Information Service (MRIS) and Hospital Episode Statistics (HES) data to enable South London and Maudsley NHS FT maintain a research resource to be used to undertake various projects investigating physical health in people with mental health issues.</p> <p><b>Discussion:</b> IGARD queried if Kings College London were considered as joint Data Controllers and noted that information provided in the supporting documents indicated this, and asked that section 5 (Purpose, Methods, Outputs) be updated to clarify why Kings College London are not considered as joint Data Controllers.</p> <p>IGARD noted that previous information sent to the Research Ethics Committee (REC) in supporting document 5.1 was incorrect and suggested that a further letter of clarification be sent to REC advising that the applicant was dealing with pseudonymised data with direct identifiers removed and, in some cases, individuals may be re-identified on request.</p> <p>IGARD queried if the substantive employees with appropriate honorary contracts in place should also have a clause included that the substantive employer will be accountable in the event of a breach of data protection laws and confidentiality and asked that the substantive employers honorary contracts be updated to explicitly reference this.</p> <p>IGARD suggested that the identifiers sent to NHS Digital should be clearly aligned with section 251 support documents provided and asked that this be explicitly stated in section 5. IGARD noted that the abstract should be amended to make clear that the applicant is a Foundation Trust and the relevant Article 6 and 9 of the GDPR be updated to reflect the public task for a Foundation Trust.</p> <p><b>Outcome:</b> Recommendation to defer, pending:</p> <ol style="list-style-type: none"> <li>1 To update section 5 to clarify why Kings College London are not considered as joint data controllers (particularly considering various statements which would indicate otherwise in the supporting documents).</li> <li>2 To send a letter of clarification to REC setting out, contrary to the earlier document provided to REC, that the applicant is dealing with pseudonymised data with direct identifiers removed and, in some cases, individuals may be re-identified on request.</li> <li>3 To update the honorary contract to explicitly reference that substantive employers will be accountable for breaches of data protection laws and confidentiality.</li> <li>4 To explicitly state in section 5 the identifiers sent to NHS Digital, to align with the s251 support.</li> <li>5 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) the justification of public task for Foundation Trusts. _</li> </ol>
3.	<p><b>AOB</b></p> <p>None</p>

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 30/11/18

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-315716-L0F4M	Imperial College London	01/11/18	<ol style="list-style-type: none"> <li>1 To clearly explain within section 5 that projects 1, 3 and 4 have now completed and that this application is for project 2, and additionally to confirm funding is in place for the continuation of project 2 and provide relevant evidence.</li> <li>2 To explicitly state within section 5 the applicable controls to ensure that data will only be accessed by the researchers for project 2 and to clarify that their access to data will be restricted so they only access that subset of data that is necessary for project 2. Furthermore to update the application to clarify that access to data for the three completed projects is restricted so that this data can only be accessed for the purpose of answering queries and that there are appropriate controls in place to achieve this.</li> <li>3 To provide further examples of measurable and yielded benefits within section 5 of the application for the completed projects 1, 3 and 4.</li> </ol>	IGARD Members	Quorum of IGARD Members	N/A

NIC-67398-K2Y3T	Imperial College London	01/11/18	<ol style="list-style-type: none"> <li>1 To provide further details of pathways of dissemination of the outputs including any specific examples and also provide a clear plan of public / patient engagement</li> <li>2 To clarify within section 5 why maternity data is required, and bearing in mind that the data is to be used by the Department of Surgery and Cancer, to clearly describe how the use of maternity data in the research being undertaken aligns with the remit of the Department of Surgery and Cancer.</li> </ol>	IGARD Members	Quorum of IGARD Members	N/A
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In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None notified to IGARD