

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

### Minutes of meeting held 21<sup>st</sup> December 2017

**Members:** Anomika Bedi, Chris Carrigan (Chair), Nicola Fear, Jon Fistein, Eve Sariyiannidou.

**In attendance:** Garry Coleman, Arjun Dhillon, Jen Donald, Rachel Farrand, Victoria May, Stuart Richardson, Kimberley Watson, Vicki Williams.

**Apologies:** Sarah Baalham, Joanne Bailey, Kirsty Irvine,

1	<p><b>Declaration of interests</b></p> <p>Eve Sariyiannidou noted her past professional links to University of Bristol (NIC-13133-B7B3K) but noted no specific connection with application or staff involved.</p> <p>Anomika Bedi noted her past professional links to NICE (NIC-123200-J0L4T LSHTM) as a lay member but noted no specific connection with the application or staff involved.</p> <p>Jon Fistein noted his past professional links to University of Cambridge as a past employee (NIC-38314-C3P0Z) but noted no specific connection with the application or staff involved.</p> <p>Nicola Fear noted her professional links to NIC-13133-B7B3K University of Bristol, working on both the study and data and would not be part of the discussion for that particular application.</p> <p><b>Review of previous minutes and actions</b></p> <p>The minutes of the 14 December 2017 IGARD meeting were reviewed and subject to a number of minor changes were agreed as an accurate record of the meeting.</p> <p>Action updates were provided (see Appendix A).</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<b>Data applications</b>
2.1	<p><u>Device Access UK Ltd (Presenter: Jen Donald) NIC-05429-H7X6R</u></p> <p><b>Application:</b> This was an application to continue to receive pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC), Outpatients (OP), Accident &amp; Emergency (A&amp;E) and Critical Care (CC) data plus additional 2017/18 monthly data set releases for HES APC, OPC, A&amp;E and CC.</p> <p>The application was most recently discussed at the 6 July 2017 meeting when IGARD had recommended for approval for 6 months with more information requested about the principles used to determine what data can be used for which projects and the governance arrangements in place to decide this and more specific information about the projects for which the data is being used and each projects specific data requirements. In addition more information about what efforts had been made to increase the NHS client base would be expected at renewal.</p> <p><b>Discussion:</b> IGARD noted the efforts made by the applicant to provide further clarity on points previously raised.</p> <p>IGARD queried the supporting document detailing the Device Access Data Access Review Group (DADARG) board membership and noted that it did not accurately reflect the information provided in section 5 of the application. The supporting document should be updated to correctly reference the membership that three of the five members were external to</p>

	<p>Device UK Limited. IGARD queried if only commercial company proposals for devices would be presented to the DADARG board and asked for confirmation that all proposals (commercial and NHS) would be presented to the board and this be reflected in section 5 of the application.</p> <p>IGARD noted that the statement in the application that NHS Digital data should not be used for sales or marketing in section 1 should be added to section 5. It was also suggested that Device Access UK update their fair processing information on their website to clearly state that individuals will not be identified and that a statement in section 5 of the application that the applicant cannot link data within this application to other datasets be explicitly stated.</p> <p>IGARD also suggested that the renewal application would be expected to provide further evidence of their process for approvals and any benefits achieved for health and social care from their projects.</p> <p>Outcome: Recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> <li>• SD3 should be updated to clarify the DADARG membership and to accurately reflect the information in the application summary.</li> <li>• Confirmation within section 5 of the application that all proposals will go through the DADARG board for consideration</li> <li>• A statement in section 1 with regard to data not being used for sales or marketing should be explicitly stated in section 5c of the application</li> <li>• A statement that the applicant cannot link to other datasets should be explicitly stated in section 5 of the application</li> <li>• Wording on the applicant's website should be updated to state that the data held does not directly identify individuals</li> </ul> <p>The following advice was given:</p> <ul style="list-style-type: none"> <li>• IGARD advised when the application returns to IGARD for renewal, the applicant should provide evidence of their process for approvals and any benefits achieved from their projects</li> </ul>
2.2	<p><u>University of Bristol – (Presenter: Jen Donald) NIC-13133-B7B3K</u></p> <p>Nicola Fear was not present for the discussion of this application due to a conflict of interests.</p> <p><b>Application:</b> This was an application to renew and amend two existing Data Sharing Agreements (DSA) for bespoke extracts of Hospital Episode Statistics (HES) Admitted Patient Care (APC), Critical Care (CC), Outpatient (OP) and Accident &amp; Emergency (A&amp;E) data as well as Office for National Statistics (ONS) Cancer registration and death data.</p> <p>ALSPAC is a transgenerational prospective birth cohort study that recruited women during pregnancy in the early 1990's and is designed to investigate influences on health, wellbeing, epigenetic, biological, psychological, social and environmental exposures and a similar range of health, social and development outcomes.</p> <p><b>Discussion:</b> IGARD queried the consent material received and noted that earlier versions of the consent forms from when the cohort reached the age of 16 in 2004 should be provided.</p> <p>NHS Digital confirmed that only the children from the original cohort had been re-consented however it was noted that the legal basis for the dissemination of data was not clear and asked for clarification as to why S251 detail was included. It was suggested that NHS Digital redraft the application to remove reference to S251 projects and cohorts and that section 5 be</p>

	<p>updated to more accurately reflect the projects undertaken, confirm the legal basis for the cohort which are currently confirmed by consent and that the processing activities be updated.</p> <p>IGARD suggested that applicant update their DPA registration to more clearly state that data is processed about patients or healthcare users.</p> <p><b>Outcome:</b> Recommendation deferred, pending</p> <ul style="list-style-type: none"> <li>• The application should be redrafted to more accurately reflect the cohorts, the processing activities and the projects that are covered by consent, as the legal basis.</li> <li>• The applicant to provide a copy of all previous earlier consent materials from when the cohort consented at age of 16</li> </ul>
2.3	<p><u>Compufile Systems Ltd – ESPRIT Tool (Presenter: Rachel Farrand) NIC-01207-V9G9P</u></p> <p><b>Application:</b> This was an application to continue to receive Hospital Episode Statistics (HES) Critical Care (CC), Outpatients (OP) and Admitted Patient Care (APC) data for use in the ESPRIT tool.</p> <p>The application was most recently discussed at the 14 December 2017 when IGARD deferred making a recommendation pending confirmation that the data would not be used to support services associated with financial or incentive programmes and evidence that a formal governance procedure was in place.</p> <p><b>Discussion:</b> IGARD noted the application had been updated to reflect comments previously raised. IGARD noted that in line with good practice, Compufile Systems Limited may wish to develop their oversight board to include lay or patient representation.</p> <p>It was noted that objectives 1, 2 and 3 on the new customer approval process were not included and the applicant may wish to update the process with details of the purposes of the request.</p> <p><b>Outcome:</b> Recommendation to approve</p> <p>The following advice was given:</p> <ul style="list-style-type: none"> <li>• IGARD advised that the new customer approval process should include details of the purposes of the request to ensure objectives 1, 2 or 3 (as highlighted in the application) are to be met</li> <li>• IGARD advised that the applicant may wish to develop their oversight board to include lay representation</li> </ul>
2.4	<p><u>London School of Hygiene &amp; Tropical Medicine (LSHTM) – Vitamin D and Longevity (VIDAL) Trial: randomised feasibility study (Presenter: Rachel Farrand) NIC-123200-J0L4T</u></p> <p><b>Application:</b> This was a new application for Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Critical Care (CC) data, MRIS patient tracking for cancer registrations, Office for National Statistics (ONS) mortality data and cohort event notification for the purposes of the VIDAL study.</p> <p><b>Discussion:</b> IGARD queried the data controllership and NHS Digital confirmed that LSHTM were the sole data controller. IGARD asked if recruitment was ongoing and it was confirmed that recruitment had stopped, however IGARD noted that for future trials the applicant may wish to review their current consent materials.</p> <p>IGARD noted that fair processing on the applicant's website did not fully meet the nine minimum criteria and that NHS Digital work with LSHTM before data can flow. IGARD noted in</p>

	<p>particular that the privacy notice did not accurately reflect that identifiers will be sent to NHS Digital and that the fair processing in general should be consolidated into one area.</p> <p>IGARD noted that an erroneous sentence in section 5 with regard to appropriate controls in place should be removed from the application and that the expire date for the applicant's DPA be updated to accurately reflect that it expires in 2018</p> <p><b>Outcome:</b> Recommendation to approve subject to the following condition:</p> <ul style="list-style-type: none"> <li>The fair processing information for LSHTM is updated to meet the nine minimum criteria for privacy notices before data can flow, in particular that identifiers will be sent to NHS Digital and the fair processing information consolidated into one place.</li> </ul> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> <li>IGARD noted that LSHTM DPA registration had expired and the date should be updated</li> <li>A reference in section 5b of the application to appropriate controls should be deleted.</li> </ul> <p>It was agreed the above condition would be reviewed out of committee by the IGARD Chair.</p>
2.5	<p><u>Barts Health NHS Trust – NICOR Commissioning through Evaluation (CtE) Registries / Audits: Left Atrial Appendage Occlusion (LAAO), Mitral Valve Repair (Mitraclip), and Patent Foramen Ovale Closure (PFOC) (Presenter: Kimberley Watson) NIC-151212-B5Z3R</u></p> <p><b>Application:</b> This was an application for the National Institute of Cardiovascular Outcomes Research (NICOR) hosted at Barts Health NHS Trust for Hospital Episode Statistics (HES) Admitted Patient Care (APC) and HES / Office for National Statistics (ONS) linked data.</p> <p>The HES and ONS mortality data is requested for use in an audit of patients who have undergone percutaneous mitral valve leaflet repair for mitral regurgitation using MitraClip, LAAO and PFOC procedures. The work aims to gather more data on the safety and effectiveness of these three complex cardiology procedures which are not currently routinely funded by the NHS with the data gathered from centres undertaking these procedures to be analysed in inform future commissioning intentions.</p> <p><b>Discussion:</b> IGARD welcomed the applications and noted that importance of the study.</p> <p>IGARD noted that a data flow diagram would have been helpful to ascertain the legal basis for each data flow, how each organisation was involved and clearly explains each flow of data requested. The S251 support did not appear to cover the involvement and processing activities of The Newcastle Upon Tyne Hospitals NHS FT (NUTH) and the York Health Economic Consortium and further clarity was required. IGARD also noted that the Data Controller and Data Processor organisational responsibilities were not clear and that this would need to be clarified.</p> <p>IGARD noted that fair processing did not fully meet the nine minimum criteria, in particular the privacy notice should accurately reflect the organisation involved in the audit, the processing activities involved and the data sharing between the relevant organisations.</p> <p>IGARD noted the data retention period for the applicant and suggested that justification be given as to why the data should be retained until 2031.</p> <p><b>Outcome:</b> Recommendation deferred, pending</p> <ul style="list-style-type: none"> <li>Organisational responsibilities with regard to Data Controller and Data Processor were unclear and further clarification was required.</li> <li>S251 support did not appear to cover the involvement and processing activities of NUTH and the York Health Economic Consortium</li> </ul>

	<ul style="list-style-type: none"> <li>• The fair processing information is updated to meet the nine minimum criteria for privacy notices and that the privacy notice accurately reflects the organisations involved in the audit, the processing activities and the sharing of data with the relevant organisations.</li> <li>• A data flow diagram should be provided with the application which clearly explains the flow of data, the legal basis for each data flow and explains each organisation involved, including York Health Economic Consortium</li> </ul>
2.6	<p><u>Wilmington Healthcare – (Presenter: Kimberley Watson) NIC-16016-Y9H1D</u></p> <p><b>Application:</b> This was a renewal and amendment application which was most recently discussed at the 19 October 2017 meeting when IGARD recommended for approval for 3 months with more information requested about; the specific criteria used by the advisory board to determine whether a use of data is compliant with the DSA; with confirmation of what other steps the applicant had taken to expand membership of the advisory board; further information about the amount of data required with a clearer justification for why this is necessary; and the proposed website text be amended to clarify a reference to data that cannot identify an individual as this was considered misleading.</p> <p><b>Discussion:</b> IGARD noted that an amendment requested on the 19 October had not been addressed, namely: <i>IGARD noted that the extension, amendment or renewal application submitted within three months should include clarification of what specific criteria are used by the advisory board to determine whether a use of data is compliant with the DSA, with confirmation of what other steps the applicant will take to expand the membership of this advisory board such as including a data protection officer or information governance specialist, as well as recruiting one or more lay members potentially via engagement with relevant charities.</i></p> <p>IGARD noted that this application was inconsistent with applications considered earlier in the day with regard to advice given by IGARD around advisory boards, and that evidence should be provided by the applicant not NHS Digital. IGARD stressed the importance of consistency. NHS Digital noted that the decision not to seek clarification for this amendment by IGARD had been taken by the Director for Data Dissemination, under delegated authority from the SIRO.</p> <p>IGARD noted that they were unable to access the fair processing notice on the applicant's website and it was agreed that the applicant should publish an appropriate privacy notice that would meet NHS Digital's nine minimum criteria including that it is publishable, visible and accessible and that it correctly reference that pseudonymised data does not directly identify individuals.</p> <p><b>Outcome:</b> Recommendation deferred, pending:</p> <ul style="list-style-type: none"> <li>• IGARD were unable to fully consider the application because the information previously requested for the 3-month approval had not been provided for IGARD's consideration and the data sharing agreement end date should be limited to only last for three months, with an updated application to be submitted to IGARD at the end of that period, and the agreement should be limited to permit the applicant to continue to store data but not otherwise process it.</li> <li>• Providing evidence that the fair processing information for Wilmington Healthcare meets the nine minimum criteria for privacy notices, in that it is published, visible and accessible on the company's website and to correctly reference that pseudonymised data does not directly identify individuals.</li> </ul>

	<p><b>ACTION:</b> NHS Digital / IGARD to discuss at a future meeting the issue of consistency across applications presented.</p>
2.7	<p><u>Thurrock Council (Presenter: Stuart Richardson) NIC-146909-L9Q3C</u></p> <p><b>Application:</b> This was an application to use pseudonymised data to provide intelligence to support commissioning of health and social care services. The data is required to ensure that analysis of health care provision can be completed to support the needs of the health profile of the population within the Local Authority area based on the full analysis of multiple pseudonymised datasets.</p> <p><b>Discussion:</b> IGARD noted that Interxion was listed as a storage location and stated their view that it would be more appropriate to also list this organisation as an additional data processor. It was acknowledged that there was currently an open action with NHS Digital regarding storage locations and how to reflect their role as data processors.</p> <p>IGARD queried the due diligence undertaken by NHS Digital with regard to the MedeAnalytics tool and were assured. IGARD noted that it was not clear if linkage was taking place by MedeAnalytics and that it be clearly stated in section 5 that MedeAnalytics cannot link data requested in this application to any other data held, apart from the linkages permitted under this application. Section 5 of the application should be updated to confirm that the tool is used inside the organisations for pseudonymisation at source and that work is not being undertaken by MedeAnalytics. IGARD also requested clarification that only appropriate staff involved in population health management will have access to the data and that this be explicit in section 5.</p> <p>IGARD noted that HSCIC were listed as the organisation on the application form in section 14 and that this should be updated to accurately reflect Thurrock Council. IGARD suggested that the applicant update their DPA to more accurately cover the activities of population health management.</p> <p>IGARD queried the legal basis for the data releases within the template and suggested that NHS Digital satisfy itself that the correct legal basis is listed and on all subsequent templates.</p> <p><b>Outcome:</b> Recommendation to approve</p> <p>The following amendments were requested</p> <ul style="list-style-type: none"> <li>• Confirmation that the MedeAnalytics tool is used inside the organisations for pseudonymisation at source and that this work is not being undertaken by MedeAnalytics should be accurately reflected of section 5 of the application.</li> <li>• Section five of the application should be updated to more clearly state that MedeAnalytics will not link data requested in this application to any other data, apart from the linkages permitted under this application.</li> <li>• NHS Digital should satisfy itself that the correct legal basis for data releases is listed in the application and ensure this updated on the standard template application.</li> <li>• An erroneous sentence in section 5a of the application should be deleted.</li> <li>• Section 14 of the application should be updated to correct applicant's details to Thurrock Council</li> <li>• Clarification within section 5 of the application that only appropriate staff involved in population health management will access the patient level data</li> </ul> <p>The following advice was given:</p>

	<ul style="list-style-type: none"> <li>IGARD advised that the DPA registrations within the application should be updated to accurately cover the activities of population health management including references to our patients</li> </ul>
2.8	<p><u>Kirklees Metropolitan Council (Presenter: Stuart Richardson) NIC-159523-F1C1P</u></p> <p><b>Application:</b> This was a new application to enable the Integrated Commissioning Executive (ICE) (Kirklees Council., NHS North Kirklees CCG and NHS Greater Huddersfield CCG) to understand how services and the trajectory of service users interact around social care provision and hospital utilisation, by linking pseudonymised social care data with pseudonymised Secondary Use Service (SUS) data</p> <p><b>Discussion:</b> IGARD queried the relationship between PI Limited and Equinix LD5 DC and suggested that NHS Digital satisfy itself with the relationship and the data processing arrangements in place. IGARD suggested that both PI Limited and Kirklees MBC update their DPA to more accurately the data under this data sharing agreement.</p> <p><b>Outcome:</b> Recommendation to approve</p> <p>The following advice was given:</p> <ul style="list-style-type: none"> <li>IGARD advised that PI Limited and Kirklees Metropolitan Borough Council should update their DPA registration to accurately reflect the data under this data sharing agreement</li> <li>IGARD advised NHS Digital should satisfy themselves with regard the relationship between the two organisations: PI Limited and Equinix LD5 DC and the data processing arrangements in place</li> </ul>
2.9	<p><u>Group of 7 CCG <sup>1</sup> applications – (Presenter: Stuart Richardson) GA12-SCW-AMD</u></p> <p><b>Application:</b> This was an amendment application for the CCGs to receive pseudonymised datasets on the Sustainable Transformation Partnership (STP) footprint to allow collaborative working. The CCG's will also receive pseudonymised datasets and link with GP data and social care data for the purpose of commissioning across the STP.</p> <p><b>Discussion:</b> IGARD noted the use of a large number of acronyms within section five of the application and emphasised the importance of writing this section in a way that could be understood by the general public as this text would feature on NHS Digital's data release register.</p> <p>IGARD queried the data flow diagram presented and suggested that the key be updated to more accurately reflect the data flows. NHS Digital were assured with the black box arrangements in place and it was suggested that this assurance be forwarded to IGARD for information.</p> <p>IGARD noted the anti-terrorism initiatives and requested further detail to be added to the application for clarity in section 5 (17c) that the CCG's are looking at the impact of terror on services.</p> <p><b>Outcome:</b> Recommendation to approve</p> <p>The following amendments were requested</p> <ul style="list-style-type: none"> <li>The data flow diagram key should be updated to accurately reflect the data details.</li> </ul>

<sup>1</sup> NHS Aylesbury Vale CCG NIC-49690-C6R1L; NHS Chiltern CCG NIC-49736-W5L3J; NHS Oxfordshire CCG NIC-116582-F2F2J; NHS Newbury and District CCG NIC-49697-J0V7M; NHS North and West Reading CCG NIC-49707-L6M3G; NHS South Reading CCG NIC-49714-T1W5W; NHS Wokingham CCG NIC-49731-X9N2K

	<ul style="list-style-type: none"> <li>Section five should be amended to explain any un-expanded acronyms in point 18.</li> <li>To be clear in section 5 (17c) of the application that the CCG's are looking at the impact of a terror on services</li> </ul>
2.10	<p><u>Group of 6 CCG <sup>2</sup>applications (Presenter: Stuart Richardson) GA07-NEL-STP</u></p> <p><b>Application:</b> This was an amendment application for the CCG's to receive pseudonymised data based on the Sustainable Transformation Partnership (STP) footprint to allow collaborative working. The CCG's will use pseudonymised data to provide intelligence to support the commissioning of health services.</p> <p><b>Discussion:</b> IGARD noted that Interxion was listed as a storage location and stated their view that it would be more appropriate to also list this organisation as an additional data processor. It was acknowledged that there was currently an open action with NHS Digital regarding storage locations and how to reflect their role as data processors.</p> <p>IGARD noted the use of a large number of acronyms within section five of the application and emphasised the importance of writing this section in a way that could be understood by the general public as this text would feature on NHS Digital's data release register.</p> <p>IGARD noted the anti-terrorism initiatives and requested further detail to be added to the application for clarity in section 5 (17c) that the CCG's are looking at the impact of terror on services.</p> <p><b>Outcome:</b> Recommendation to approve</p> <p>The following amendments were requested</p> <ul style="list-style-type: none"> <li>Section five should be amended to explain any un-expanded acronyms in point 18</li> <li>To be clear in section 5 (17c) of the application that the CCG's are looking at the impact of a terror on services</li> </ul>
2.11	<p><u>University College London – healthcare transitions for young people (Presenter: Rachel Farrand) NIC-330769-C9Y8Y</u></p> <p><b>Application:</b> This was an amendment application to request additional data for a project on health care transitions for young people. The application was most recently discussed at the 28 September 2017 meeting when IGARD had not recommended the application for approval for the following reasons: clearer justification for the amount of data requested and how the use of the additional data is required in order to lead to additional benefits to health and social care; more information about the benefits achieved to date with the data already held; more information about the planned outputs and how these will be disseminated in a way that will help ensure benefits; to be clear in the application that linkage of data is not permitted; an amendment to the application with regard to the expiry date for the commissioning letter covering the use of Office for National Statistics (ONS) data; and a special condition should be added that the ONS data of death data currently held by the applicant must be securely destroyed within two months.</p> <p><b>Discussion:</b> The potential importance of work in this area was noted and IGARD expressed their support for the aims of the study. IGARD noted that an amendment requested on the 28 September had not been addressed, namely: <i>A clearer justification is required for the amount of data requested and how the use of this amount of additional data is required in order to lead to additional benefits to health or social care. More information was also requested about the</i></p>

<sup>2</sup> Bexley CCG NIC-43529-B7P0P; Bromley CCG NIC-43760-C3C8W; Greenwich CCG NIC-43418-W0V0N; Lambeth CCG NIC-106180-L3C4J; Lewisham CCG NIC-43469-Z6P1G; Southwark CCG NIC-43513-G0K8W



	<p><i>benefits achieved to date with the data already held.</i> IGARD did not consider that the application provided a sufficient justification for the amount of additional data requested and it was agreed that a clearer explanation was needed of how the use of this volume of additional data would result in additional benefits to health or social care.</p> <p>IGARD also queried if a random sample could be used, however NHS Digital noted that this may not give the applicant sufficient data to analyse. IGARD also requested an update about any benefits that had been achieved to date using the data already held by the applicant for this purpose.</p> <p><b>Outcome:</b> Recommendation deferred, pending:</p> <ul style="list-style-type: none"> <li>IGARD were unable to fully consider the application because the information had not been provided for IGARD's consideration, namely: a clearer justification is required for the amount of data requested and how the use of this amount of additional data is required in order to lead to additional benefits to health or social care. More information was also requested about the benefits achieved to date with the data already held</li> </ul>
2.12	<p><u>University of Nottingham – QResearch Data Linkage Project (Presenter: Rachel Farrand / Garry Coleman) NIC-376367-M5V9H</u></p> <p>Application: This was a renewal application to request additional years of pseudonymised Hospital Episodes Statistics (HES) data to link to the existing QResearch databased so that it can be used for medical research. The QResearch database consists of the coded pseudonymised electronic health records from primary care patients registered with approximately 1000 general practices (GP) throughout the UK.</p> <p><b>Discussion:</b> IGARD noted the application and did not raise any substantive concerns or comments.</p> <p><b>Outcome:</b> Recommendation to approve</p>
2.13	<p><u>University of Cambridge – Mortality data for OCCAMS cohort (Presenter: Victoria May) NIC-38314-C3P0Z</u></p> <p><b>Application:</b> This was an application for Office for National Statistics (ONS) mortality data for use in the Oesophageal Cancer Clinical and Molecular Stratification (OCCAMS) research study. The main focus of the OCCAMS study is to develop a model that can be used to better assess therapeutic options for future patients with this specific condition with a key aim identifying markers that indicate the likely pathway and rate of progression of the condition in individuals so that care plans can be appropriately tailored.</p> <p>NHS Digital confirmed that special conditions within the data sharing agreement including security had been updated into section 5 of the application.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the OCCAMS study.</p> <p>IGARD queried the role of Oxford University and it was explained that they were the original storage for the data and that the applicant used them for their study data, however it was confirmed that NHS Digital data would be stored at Oxford University and associated with the application.</p> <p>IGARD queried version 9 consent form presented and asked if versions 1 to 8 had been used to consent for this study, however NHS Digital noted that only version 9 had been used to consent for this study and that version 10 would be used for all future recruits to the study.</p>

	<p>IGARD were unclear if this was a single research project or multiple projects because the wording in section 5 of the application was ambiguous. Section 5 should be explicit that this was a single study research project and further clarification was sought with regard to how this research related to other clinical trials in the same space.</p> <p>IGARD noted that outputs which supported health or social care benefits were not clearly defined within the application and asked that evidence be provided on how the planned outputs would be disseminated in a way that would support health or social care benefits, including any examples.</p> <p>IGARD suggested that NHS Digital should be content that the University of Nottingham's fair processing meets the nine minimum criteria for privacy notices.</p> <p><b>Outcome:</b> Recommendation deferred, pending:</p> <ul style="list-style-type: none"> <li>• Provide evidence on how the planned outputs would be disseminated in a way that would support health and social care benefits, noting the importance of the study.</li> <li>• Section 5 of the application should be explicit that this was a single research project and detail how this research related to other clinical trials in the same space.</li> </ul>
<b>3</b>	<p><b>Any other business</b></p> <p>No other business was raised.</p>

## Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
20/04/17	IGARD Chair to contact key stakeholder organisations regarding the benefits of uses of data to feed into the IGARD annual report.	IGARD Chair	<p>14/09/17: Ongoing. It was agreed this would be discussed during the educational session.</p> <p>07/12/17: Ongoing. It was agreed to bring the first draft to January's education session.</p> <p>21/12/17: ongoing</p>	Open
27/04/17	IGARD Chair to contact the NHS Digital Caldicott Guardian regarding GPs' data controller responsibilities for fair processing around risk stratification.	Arjun Dhillon	<p>18/05/17: Ongoing. It was agreed this would be discussed with the Deputy Caldicott Guardian.</p> <p>22/06/17: Ongoing; it was suggested the Deputy Caldicott Guardian should discuss this in more detail with Joanne Bailey.</p> <p>29/06/17: It was noted this action would be taken forward by the Deputy Caldicott Guardian, and the action owner was updated.</p> <p>20/07/17: It was agreed the Deputy Caldicott Guardian would provide an update on the current status of this.</p> <p>10/08/17: An update from NHS England had been requested.</p> <p>09/11/17: A response from NHS England had been received and this would be circulated to IGARD by email.</p> <p>07/12/17: Ongoing – draft response to IGARD with Deputy Caldicott Guardian for sign off.</p> <p>14/12/17: IGARD Secretariat Team to circulate an update to IGARD Members.</p>	Close

18/05/17	Garry Coleman to provide information about different arrangements for data storage and backup locations, for consideration of whether the organisations involved would be considered to be processing data.	Garry Coleman	<p>15/06/17: IGARD had been advised by email that a paper about this would be submitted to an upcoming IGARD meeting.</p> <p>22/06/17: It was anticipated that this would be discussed at the 6 July 2017 IGARD meeting. IGARD asked for some information to be circulated by email prior to the meeting in order to inform members who would not be present at that particular meeting.</p> <p>27/07/17: An email had been circulated requesting further information from IGARD members.</p> <p>03/08/17: Two IGARD members had responded by email and the action remained ongoing.</p> <p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: The paper was in the process of being updated based on recently published ICO guidance.</p> <p>14/09/17: Ongoing. IGARD noted that given the amount of time that had passed, they would consider starting to note this on relevant applications where a data storage location was not listed as a data processor.</p> <p>21/09/17: Ongoing. IGARD asked for Dickie Langley to provide an update on Garry Coleman's open actions at the next meeting to help ensure timely progression.</p> <p>02/11/17: IGARD discussed this action with Garry Coleman and requested a written update in response to the points previously raised by IGARD. Some difficulties were acknowledged as this specific scenario did not seem to be addressed in existing ICO guidance; IGARD suggested that NHS Digital should seek legal advice and if necessary then contact the ICO directly.</p>	Open
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20/07/17	Garry Coleman to provide an update within two weeks on how NHS Digital manage the risk involved in CCGs using South Central and West CSU as a data processor in light of data sharing breaches and recent audits.	Garry Coleman	<p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: IGARD received a verbal update on the work that had taken place following both audits and verbal assurances that NHS Digital were content with the level of risk involved in this organisation continuing to act as a data processor. IGARD welcomed this update and requested written confirmation.</p> <p>31/08/17: IGARD were notified that the requested written confirmation should be provided within one day.</p> <p>14/09/17: An email response had been circulated on 31 August, and IGARD noted that they were awaiting receipt of the post-audit report.</p> <p>21/12/17: ongoing</p>	Open
20/07/17	Garry Coleman to categorise different standard lengths of indicative data retention periods for general research and clinical trials, with appropriate justification.	Garry Coleman	21/12/17: ongoing	Open
31/08/17	Garry Coleman to report back on how cancer registration data was previously described as pseudonymised PDS data within older versions of applications, and present to a future education	Garry Coleman	21/12/17: ongoing	Open

	session on changes to how MRIS reports are now shown within applications.			
21/09/17	Dickie Langley to provide a briefing paper (with relevant supporting documents) regarding the legal basis for receipt of data from Department for Education, and for this to be reviewed by the IG Advisor prior to circulation to IGARD.	Dickie Langley	07/12/17: Dickie Langley noted that a briefing paper would be presented to IGARD in December / January. 14/12/17: The briefing paper was presented to IGARD on 14 <sup>th</sup> December 2017.	Close
19/10/17	Stuart Richardson to provide a briefing on the Temporary National Repository infrastructure.	Stuart Richardson	16/11/17: Stuart Richardson noted discussions were ongoing. 21/12/17: ongoing	Open
02/11/17	NHS Digital to consider the responses provided by an applicant (Imperial College London NIC-27085) in relation to the language and terminology used in patient information materials.	Louise Dunn	21/12/17: ongoing	Open
07/12/17	Dickie Langley to provide a briefing note on NHS Digital's due diligence policy and process	Dickie Langley	21/12/17: ongoing	Open
07/12/17	Stuart Richardson to provide a briefing note outlining NHS Digital's work with STP's to clarify the legal / access arrangements in place between CCG's to ensure responsibilities are clearly defined	Stuart Richardson	21/12/17: ongoing	Open
21/12/17	NHS Digital / IGARD to discuss at a future meeting the issue of consistency across applications presented.	IGARD Chair / Garry Coleman		

## Appendix B: Out of committee report

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 15/12/17

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-366216-Z9H9Q	University of Sheffield	02/11/17	<ul style="list-style-type: none"><li>• Providing a clearer justification for why up to 15 years of data are required, given that the ethics application provided only explains the need to hold 10 years of data.</li><li>• Providing a clearer justification for why data is required for all ages, such as young children given the purpose of the research focuses on alcohol and tobacco, or if appropriate then the application further minimise the dataset to remove data for younger age groups.</li></ul>	Quorum IGARD Members	Quorum IGARD Members	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