

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

### Minutes of meeting held 22 November 2018

**Members:** Nicola Fear, Kirsty Irvine (Chair), Eve Sariyannidou

**In attendance:** Helen Buckles (Item 2.1), Dave Cronin, Louise Dunn, Dan Goodwin (Items 2.4 – 2.6), James Humphries-Hart, Karen Myers, Kimberley Watson, Vicki Williams.

**Observers:** Maria Clark

**Apologies:** Sarah Baalham, Joanne Bailey, Anomika Bedi,

1	<p><b>Declaration of interests:</b></p> <p>Nicola Fear noted a professional link with the University of Oxford [NIC-147957-4444C] and would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of that application.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 15 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	<b>Data applications</b>
2.1	<p><u>NHS Coventry and Rugby CCG: DSfC – NHS Coventry and Rugby – STP – Comm (Presenter: James Humphries-Hart) NIC-238282-X0B6H</u></p> <p><b>Application:</b> This was a new application for pseudonymised Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT). The purpose is for 4 Clinical Commissioning Group's to commission as a Sustainable Transformation Partnership, which is responsible for implementing large parts the 5 Year Forward View set out by NHS England.</p> <p><b>Discussion:</b> IGARD noted that there was reference in the application to 'Data Controller' and that as there were three, this should be amended throughout to 'Data Controllers' to accurately reflect this.</p> <p>IGARD noted that there was reference to 'Iron Mountain' in the supporting documents and queried why they were not also listed as a storage location. IGARD asked that either Iron Mountain be added as a storage location or that the privacy notice be updated to remove reference to Iron Mountain.</p> <p>IGARD noted that NHS Arden and Greater East Midlands Commissioning Support Unit had listed within the application a number of storage and processing locations and suggested that NHS Digital may wish to satisfy itself that the processing meets the necessity test under GDPR.</p>

	<p><b>ACTION:</b> NHS Digital to provide update on existing action re the analysis carried out to ensure multiple processors / multiple processing addresses meets the necessity test and provide an update as necessary to IGARD</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update the application throughout with the appropriate use of plurals.</li> <li>2. To either update the application to list Iron Mountain as a storage location or for the applicant to update their privacy notice to remove reference to Iron Mountain, whichever reflects the factual situation.</li> </ol>
2.2	<p><u>London School of Economics and Political Science: Effects of competition and incentives on productivity, quality and efficiency of NHS providers (Presenter: Kimberley Watson) NIC-354497-V2J9P</u></p> <p><b>Application:</b> This was an amendment and renewal application for pseudonymised Hospital Episode Statistic (HES) and Patient Reported Outcome Measures (PROMs) data to analyse the impact of on-going NHS reforms implemented between 2000 and present day. The reforms were primarily associated with the introduction of two Acts of Parliament (the National Health Service Act 2006 and the Health and Social Care Act 2012) that changed both the organisational and payment structures of the NHS.</p> <p>The application was been previously considered on the 6<sup>th</sup> September 2018 when IGARD had been unable to recommended pending; clarification of the roles of the University of Kent and the University of York and provide further explanation why they are not considered joint Data Controllers; to provide an explanation of the 'Honorary Associate' role and scope; to clarify who LSE Health is; explanation of the involvement of the Health Foundation and the alignment of the purpose of the funding with the purpose of the application; to update the abstract to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to public task and public interest including appropriate justification under GDPR to the reference of University of London within the abstract; for each of the four purposes outlined in the application to clearly describe within section 5 the requirement for the additional data sets and data years; to provide confirmation that no record level data will be shared with third parties unless fully justified within the application; and confirmation within section 5 if the data will be moved on the existing server to the new storage location or if the data will be moved to a new server at the new storage location and to provide confirmation that appropriate security steps have been undertaken by the applicant for which NHS Digital are content.</p> <p>NHS Digital noted that the DPA expiry date was incorrect.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect most of the comments previously made.</p> <p>IGARD queried what the Health Foundation were providing funding for and were advised by NHS Digital that this was to cover a small part of the research for the testing of new technology. IGARD then queried how this funding for new technology fits into the four components of work as outlined in the application and asked for further clarification on this.</p> <p>NHS Digital advised IGARD that the applicant asked for data for the ten-year period from 1996 – 2006 as part of the original request, however as outlined in section 3(b) (Additional Data Access Requested) there have been some data quality issues and therefore this data has been requested again. IGARD asked that detailed justification for requesting this data was updated in section 5(a) (Processing Activities) including the reference within the 'data minimisation' table in section 3(b) explaining the data production process.</p>

	<p>IGARD and NHS Digital discussed the draft Honorary Research Associate contracts provided as supporting documents. IGARD noted that the documents appeared to be based on non-disclosure agreements and, inter alia, did not appear to address all the necessary data protection issues. IGARD suggested that the applicant might consider using LSE's standard honorary contract for researchers</p> <p>IGARD queried who LSE Health are and what their legal status was and asked for further clarification of this in section 5(a) and confirmation that they are not a separate legal entity.</p> <p>IGARD noted that the DPA expiry date was incorrect within the application and that this needed amending to reflect the correct date of the 20 August 2019.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> <li>1. To clarify how the Health Foundation funding for testing new technology fits into the 4 components of work outlined in the application.</li> <li>2. To provide a more detailed justification in section 5(a) for the request of data for the period 1996 to 2006 including reference to the information provided in the data minimisation table in section 3(b) explaining the data production process.</li> <li>3. Provision of suitable honorary contracts for use with the Honorary Research Associates.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To explain the legal status of LSE Health in section 5(a).</li> <li>2. To update the DPA expiry date to 20 August 2019.</li> </ol> <p>It was agreed the conditions be approved OOC by IGARD Members.</p>
2.3	<p><u>The Clinical Practice Research Datalink (CPRD) (Presenter: Kimberley Watson)</u></p> <p>Due to time constraints this item will now be discussed at the next IGARD meeting on the 29th November 2018.</p>
2.4	<p><u>Derbyshire Healthcare NHS Foundation Trust: NIC-147907-MLK7R MR1142 - Self Harm Monitoring Project - Mortality Following Self-Harm (Presenter: Dave Cronin) NIC-147907-MLK7R</u></p> <p><b>Application:</b> This was a renewal and extension of a previously Data Sharing Agreement (DSA) to permit the retention and reuse of Personal Demographics data and mortality data that had been provided via NHS Digital's Medical Research Information Service (MRIS). This was one of three linked Data Sharing Agreements (NIC-147916-DPQ3Q and NIC-147957-4444C) whereby three organisations were involved in the multi-centre study of self-harm permitting them to share identifiable data with NHS Digital and pseudonymised data with each other.</p> <p>NHS Digital noted that there was a special condition linked to this application requiring publication of a fair processing notice on or linked to its website which met NHS Digital's requirements and that this condition had not been met.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study.</p> <p>IGARD queried whether the duty of confidentiality had been met and asked that the applicant provide a detailed IG assessment that confirms that the duty of confidentiality has been met.</p> <p>IGARD noted that the application stated that ethics approval was not required, and suggested that the application be updated with appropriate standard ethics approval wording within section 7 of the application. IGARD noted that documentation provided for REC approval was</p>

<p>provided but confirmed that this was not relevant and that evidence be provided via the HRA tool.</p> <p>IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested and as per recent discussions between NHS Digital and IGARD. IGARD noted that the GDPR legal basis should reflect both the research and the service evaluation aspect.</p> <p>IGARD noted the University of Leeds was referred to within some of the supporting documents provided with the application and queried what the University's involvement was in relation to the application. NHS Digital confirmed that although they are referenced within the supporting documents, they had no involvement with application and would not be accessing any data. IGARD asked that a clear statement be included within section 5 (Purpose / Methods / Outputs) stating that notwithstanding the University of Leeds being mentioned in both the original REC approval and within the study protocol, the University of Leeds were not part of this project.</p> <p>IGARD noted that in the table in section 3(a) (Data Access Already Given) it notes "cohort submission" and that for consistency this should be amended to "plus submission of new cohort".</p> <p>IGARD noted that the term 'flagging' had been used in the application and asked for this statement be clarified that this is only referring to all individuals attending hospital for self-harm.</p> <p>IGARD queried some of the information outlined in section 5 of the application as this appeared to differ from information provided in supporting document 6.1, the data flow diagram and asked that the narrative text explaining data flows maps to the data flow diagram.</p> <p>IGARD also queried if any data was sent to the University of Oxford and asked for clarification within section 5 that NHS Digital do not send data relating to Derbyshire Healthcare NHS Foundation Trust to the University of Oxford.</p> <p>There was a lengthy discussion with regard to the applicant's s251 support and the efforts undertaken by NHS Digital to support the applicant and IGARD noted their support and suggested that NHS Digital encourage the applicant to submit a new application as a matter of urgency to HRA CAG.</p> <p>NHS Digital noted that supporting document 4.1 was not part of this application and would be removed from the CRM on-line folder.</p> <p><b>Outcome:</b> The application was recommended for approval subject to (i) the following conditions being met and (ii), both NIC-147957-4444C and NIC-147916-DPQ3Q being recommended for approval or receiving a positive statement of advice and any conditions set out in NIC-147957-4444C and NIC-147916-DPQ3Q being met:</p> <ol style="list-style-type: none"> <li>1. To provide a detailed IG assessment that confirms that the duty of confidentiality has been met.</li> <li>2. To provide evidence that ethics approval is not required.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD.</li> </ol>
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	<ol style="list-style-type: none"> <li>2. A clear statement be included within section 5 that notwithstanding the University of Leeds being mentioned in both the original REC approval and within the study protocol, the University of Leeds are not part of this project.</li> <li>3. To update the reference in section 3 to “cohort submission” to “plus submission of new cohort”.</li> <li>4. To provide clarification that where reference is made to flagging all individuals attending hospital that this is only referring to those attending for self-harm.</li> <li>5. To ensure the narrative text explaining data flows maps to the data flow diagram provided as a supporting document.</li> <li>6. Clarification within section 5 that NHS Digital do not send data relating to Derbyshire Healthcare NHS Foundation Trust to the University of Oxford.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that NHS Digital encourage the applicant to submit a new application as a matter of urgency to HRA CAG.</li> </ol> <p>It was agreed the conditions would be approved OOC by the IGARD Chair.</p>
2.5	<p><u>University of Oxford: MR1134 - The Oxford Monitoring System for Attempted Suicide: Mortality following Deliberate Self-harm (Presenter: Dave Cronin) NIC-147957-4444C</u></p> <p><b>Application:</b> This was a renewal and extension of a previously Data Sharing Agreement (DSA) to permit the retention and reuse of Personal Demographics data and mortality data that had been provided via NHS Digital’s Medical Research Information Service (MRIS). This was one of three linked Data Sharing Agreements (NIC-147916-DPQ3Q and NIC-147907-MLK7R) whereby three organisations were involved in the multi-centre study of self-harm permitting them to share identifiable data with NHS Digital and pseudonymised data with each other.</p> <p>The application was been previously considered on the 1<sup>st</sup> November 2018 when IGARD had been unable to recommended pending; to explicitly state in section 5 that where the data flows from the University of Oxford to the University of Manchester as set out in step 2 of the data flow diagram and where University of Oxford merges the data with the two other extracts, that the University of Oxford are the Data Controller at that stage of the process; to confirm that current funding is in place and provide relevant evidence; to provide evidence of ongoing ethics support; to update the abstract to give a clear history of the application to date and clear narrative of the three interrelated applications (NIC-147957-4444C, NIC-147916- DPQ3Q and NIC-147907-MLK7R); to update the abstract on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD regarding the University of Oxford legal basis; to clarify whether stage 1 is for audit or study research.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect most of the comments previously made.</p> <p>IGARD welcomed the application and noted the importance of the study.</p> <p>NHS Digital confirmed that the applicant has submitted an application to the Health Research Authority Confidentiality Advisory Group (HRA CAG) and IGARD noted that there appeared to be enough evidence to support the duty of confidentiality as being met.</p> <p>IGARD queried if the study had ongoing ethics support. NHS Digital explained that the applicant had advised that the relevant Research Ethics Committee (REC) would provide a letter to confirm this ongoing support but this may take some time. IGARD asked that further evidence be provided confirming this, for example in the form of a confirmatory email exchange between the applicant and a suitably authorised REC representative.</p>

	<p>IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested and as per recent discussions between NHS Digital and IGARD.</p> <p><b>Outcome:</b> unable to make a recommendation as there was not a quorum of members present but made a positive statement of advice subject to (i) the following advice being received and (ii), both NIC-147916-DPQ3Q and NIC-147907-MLK7R being recommended for approval and any conditions in respect of those applications being met:</p> <ol style="list-style-type: none"> <li>1. To provide evidence of confirmation that the study has ongoing ethics support</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD.</li> </ol>
2.6	<p><u>The University of Manchester: MR1135 - Manchester self-harm project - Mortality and suicide after self-harm- a cohort study (Presenter: Dave Cronin) NIC-147916-DPQ3Q</u></p> <p><b>Application:</b> This was a renewal and extension of a previously Data Sharing Agreement (DSA) to permit the retention and reuse of Personal Demographics data and mortality data that had been provided via NHS Digital's Medical Research Information Service (MRIS). This was one of three linked Data Sharing Agreements (NIC-147957-4444C and NIC-147907-MLK7R) whereby three organisations were involved in the multi-centre study of self-harm permitting them to share identifiable data with NHS Digital and pseudonymised data with each other.</p> <p>The application had previously been presented to IGARD on the 18<sup>th</sup> October 2018 and IGARD had recommended for approval subject to (i) the conditions being met and (ii) both NIC-147957-4444C and NIC-147907-MLK7R being recommended for approval by IGARD within 2 weeks. The conditions from the 18<sup>th</sup> October 2018 meeting are as follows: to explicitly state in section 5 that where the data flows from the University of Manchester to the University of Oxford as set out in step 2 of the data flow diagram and where University of Oxford merges the data with the two other extracts, that the University of Oxford are the Data Controller at that stage of the process and that processing is outside the scope of this application; the application should be amended to confirm that current funding is in place and provide relevant evidence; to update section 5(b) to clearly list which identifiers are sent to NHS Digital, to align with s251 support.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study.</p> <p>IGARD noted that the application had been updated to reflect all of the comments previously made.</p> <p><b>Outcome:</b> recommended for approval subject to both NIC-147957-4444C and NIC-147907-MLK7R being recommended for approval or receiving a positive statement of advice and any conditions set out in NIC-147957-4444C and NIC-147907-MLK7R being met.</p>
2.7	<p><u>The Nuffield Trust for Research and Policy Studies In Health Services: Rapid Service Evaluation (RSET) (Presenter: Dave Cronin) NIC-194629-S4F9X</u></p> <p><b>Application:</b> This was a new application for both identifying and pseudonymised Hospital Episode Statistic (HES) data to conduct rapid evaluations of health and care service innovations, in close partnership with those who deliver, manage and use these services. The RSET Team will enable provision of formative, as well as summative feedback to those implementing innovations in health and care services.</p>

<p>The application was been previously considered on the 30<sup>th</sup> August 2018 when IGARD had been unable to recommended pending; to provide an explicit statement within section 5(b) that Nuffield will carry out the work alone and giving a clear explanation, within section 5 of the application, the roles and responsibilities of the other organisations outlined within the application, including their role in the design and performance of the project and any data they may have access to and being clear the Data Controller is solely responsible for directing the project; to clarify the criteria for assessment and the scope of the three project outlines provided and to set out framework criteria for future projects and how they will fall within the same scope; to provide further information about the importance and value of the “rapid response” aspect of the project; within one month after the dissemination of the data, NHS Digital should check whether the applicant has published a privacy notice that is compliant with the GDPR notice requirements and section 4 of the application be updated to refer to the privacy notice being published within “one month” of receipt of data; to clarify the wording of the special condition ‘The Nuffield Trust shall ensure access to data disseminated with NHS Digital is strictly prohibited and must not be accessed by Wavex Technology’.</p> <p>NHS Digital noted that section 5 should be updated to correctly reference ‘aiming to complete’.</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to some of the comments previously made.</p> <p>IGARD queried the other organisations involved with the project outlined in the application and asked that a clear explanation be provided within section 5 (Purpose / Methods / Outputs) articulating the roles and responsibilities, particularly for the Department of Applied Health Research at UCL, including their role in the selection, design and approval of research protocols and performance of the projects, and any data they may have access to.</p> <p>IGARD asked that the application be updated to confirm how the funder is involved with the project and provide confirmation that they will not have any influence on the outcomes nor suppress any results.</p> <p>IGARD noted that a number of parties appeared to be involved in the design of the projects and that this was not just the Nuffield Trust and even though a statement was included within the application the actual facts presented within the application and supporting documents suggested the involvement of others. IGARD therefore queried who was responsible for directing the project and asked that it be clarified within the application that the Data Controller is solely responsible for directing the project or reconsideration given to which parties would be listed as Data Controller.</p> <p>IGARD noted that this was a 5 year project and suggested that on renewal the applicant should provide further detail of the projects undertaken including reference to the project selection criteria.</p> <p><b>Outcome:</b> Unable to recommend for approval</p> <ol style="list-style-type: none"> <li>1. To provide a clear explanation within section 5 of the application articulating the roles and responsibilities of the other organisations outlined, particularly the Department of Applied Health Research at UCL, including their role in the selection, design and approval of research protocols and performance of the projects, and any data they may have access to.</li> <li>2. To confirm how the funder is involved with the project and provide confirmation that they will not have influence on the outcomes nor suppress any outcomes of research.</li> <li>3. To clarify that the Data Controller is solely responsible for directing the project.</li> </ol> <p>The following advice was given:</p>
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	<p>1. IGARD suggested on renewal that the applicant provide details of the projects they have undertaken, by reference to the project selection criteria.</p> <p>IGARD advised that they would wish to review this application again when it comes up for renewal.</p>
2.8	<p><u>University of Oxford Legal Basis (Presenter: Dave Cronin)</u></p> <p>NHS Digital provided an overview of the University of Oxford's GDPR legal basis as per recent application submission and noted inconsistencies within the text provided and agreed to provide a final version of the University's GDPR legal basis to IGARD for consideration.</p> <p>IGARD noted the work undertaken and thanked NHS Digital for their work with the applicant.</p>
3.	<p><b>AOB</b></p> <p>None</p>



### Independent Group Advising on Releases of Data (IGARD): Out of committee report 16/11/18

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-140981-R5W6Z	University College London	01/11/2018	1. Confirmation be provided that NHS REC ethics approval is not also required	OOC by IGARD Chair	OOC by IGARD Chair	

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

- None notified to IGARD