

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

### Minutes of meeting held 18 July 2019

**In attendance (IGARD Members):** Maria Clark, Eve Sariyannidou, Geoffrey Schrecker (Deputy Chair), Maurice Smith.

**In attendance (NHS Digital):** Michael Barnes, Victoria Byrne-Watts, James Humphries-Hart, Dickie Langley, Karen Myers, Emma Summers, Kimberley Watson, Vicki Williams.

**Not in attendance (IGARD Members):** Sarah Baalham, Anomika Bedi, Nicola Fear, Kirsty Irvine (Chair), Priscilla McGuire.

1	<p><b>Declaration of interests:</b></p> <p>There were no declarations of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The outcomes of the 11<sup>th</sup> July 2019 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting.</p> <p>The minutes of the 11<sup>th</sup> July 2019 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>Theatres Data Set – Briefing Paper (Presenters: Michael Barnes / Emma Summers)</u></p> <p>The briefing paper was to inform IGARD about the National Clinical Improvement Programme (NCIP) Theatres Dataset Collection, which is a discovery collection commissioned by NHS Improvement (NHSI) to support the NCIP digital product implementation.</p> <p>A mandatory request has been received from NHSI instructing NHS Digital (NHSD) to collect the NCIP Theatres Dataset for the duration of the discovery submission window (between July and December 2019). NHS Digital is requested not to disseminate theatre data collected during the discovery phase to any other party except with express permission of NHS Improvement.</p> <p>The discovery project is intended to assess the value of the theatres dataset to both improve the accuracy of the NCIP digital products and to Inform the subsequent development of a National Theatre Data Set, including understanding data items and definitions routinely recorded within theatre systems and potential barriers, burden and costs associated with submission to NHS Digital.</p> <p><b>Outcome Summary:</b> Noting that this briefing is still a “work-in-progress” provided the following comments below. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing note to a future meeting.</p> <ol style="list-style-type: none"><li>1. IGARD suggested that before an application for this dataset comes to IGARD the Direction should have been formally approved by NHS Digital EMT.</li><li>2. IGARD suggested that NHSI should be considered as the sole Data Controller and that NHS Digital should be considered as a Data Processor.</li><li>3. To clarify the legal basis for NHS Digital and NHSI to receive and process data under the General Data Protection Regulation (GDPR).</li></ol>

	<ol style="list-style-type: none"> <li>4. To provide a clearer narrative how data processing meets the relevant transparency arrangements under GDPR for example (but not limited to) via an updated Privacy Notice on the NHSI website.</li> <li>5. Provide further narrative as to how this meets the duty of confidentiality and suggested removing reference to the ICO anonymisation code of practice since it had been adopted pursuant to legislation that has been repealed.</li> <li>6. To update wording to replace “anonymised” with “pseudonymised” and to remove reference to “personal data”.</li> <li>7. IGARD asked for clarification as to why some identifiable data items are excluded.</li> <li>8. To provide a rationale as to why the focus is on senior clinicians to the exclusion of other important medical staff identifiers.</li> <li>9. To explore with the pilot sites and provide narrative with regard to the content of the senior clinician’s contracts and how the sensitive outcomes will be handled.</li> <li>10. To clarify why the National Data Opt-out does not apply to the hospitals flowing data to NHS Digital.</li> </ol>
2.2	<p><u>University of York: United Kingdom Childhood Cancer Study (UKCCS) (Presenter: Victoria Byrne-Watts) NIC-147884-R7CBN</u></p> <p><b>Application:</b> This was an amendment application for identifiable Medical Research Information Service (MRIS) and Hospital Episode Statistics (HES) data to a build on a long-running study set-up in the 1990’s aiming to investigate a range of questions relating to the long-term health and healthcare needs of childhood cancer survivors. Diagnostic-specific comparisons between cases and controls will be used to examine a wide range of factors, including known and suggested therapy-related associations, as well as second cancers and late mortality. In addition, secondary care activity patterns will be examined to investigate whether those of childhood cancer survivors ever return to background levels.</p> <p><b>Discussion:</b> IGARD noted that supporting document 1, the study protocol was provided and queried whether this was specific to the application presented; and did not relate to the historical United Kingdom Childhood Cancer Study (UKCCS) study that was set-up in the 1990’s; NHS Digital noted that the protocol provided was dated 2018 however IGARD asked that confirmation was provided in section 5 (Purpose / Methods / Outputs).</p> <p>IGARD queried if any other organisations were involved in any capacity of this study, noting none were referenced on the study website, and asked that for transparency that further confirmation was provided in section 5.</p> <p>IGARD noted that MRIS data already held by the applicant had been requested again via this application and asked that further justification of this was provided since under the GDPR legal basis it may be seen as excessive processing, and also suggested that the relevant TPP (GP System Supplier) issues around data opt outs were identified. IGARD also queried the applicants continued holding of data for the purpose of linkage and asked that section 5(b) (Processing Activities) was updated with a further explanation.</p> <p>IGARD noted that supporting document 4, the Health Research Authority Research Ethics Committee (REC) letter stated that approval was for NHS sites only and since it was not clear if non-NHS sites were included within the datasets collected which REC did not cover, asked that confirmation was provided that there were no non-NHS sites involved in the collection of data.</p> <p>IGARD queried the reference to ‘cancer survivor’ throughout the application and asked that this was replaced with an alternative formulation and in a neutral language.</p>

	<p>IGARD noted that section 5 incorrectly referenced 'Public Interest' as the legal basis under the General Data Protection Regulation (GDPR) and asked that this was updated to correctly reflect 'Public Task' as the correct legal basis.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1 To provide confirmation within section 5 that the protocol provided is specific to this application and does not relate to the historical UKCCS study.</li> <li>2 To provide confirmation in section 5 that no other organisations are involved in any capacity with this study.</li> <li>3 To provide further justification why MRIS data already held by the applicant needs to be resupplied to the applicant again and to identify the relevant TPP issues.</li> <li>4 To confirm that there are no non-NHS sites involved in the collection of data.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1 To review the term 'cancer survivor' throughout the application and to replace this with an alternative formulation.</li> <li>2 To update section 5 to reflect that the legal basis under GDPR is Public Task <b>not</b> Public Interest.</li> <li>3 To provide a further explanation in section 5(b) of the continued holding of data for the purpose of linkage.</li> </ol> <p>It was agreed the conditions would be approved OOC by IGARD members</p>
2.3	<p><u>University of Cambridge: National Trends in Coronary Artery Disease Imaging (Presenter: James Humphries-Hart) NIC-258780-S9H7G</u></p> <p><b>Application:</b> This was a new application for a Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistics (HES) and Civil Registrations data for the purpose of better understanding the impact of national guidelines on the investigation of stable chest pain, both on resource utilisation of the different imaging modalities, and the resultant downstream morbidity and mortality. Such knowledge will determine if the findings from such trials are being actualised in the routine clinical environment. Analysis of the imaging trends and their outcomes will inform future clinical practice, and further research in this area.</p> <p><b>Discussion:</b> IGARD noted reference to the ICO anonymisation code of practice which was out of date and queried why small numbers suppression was not appropriate, noting that there was no explanation within the application clarifying and asked that a clear justification was provided.</p> <p>IGARD noted that supporting document 1, the study protocol detailed the involvement of the University of Edinburgh and the Royal Brompton Hospital in the study design and outputs and was part of the study team but were not listed in the application as joint Data Controllers; and asked for further clarification why they were not considered Data Controllers in light of the information provided.</p> <p>IGARD noted that section 5(c) should be updated to provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1 To provide a clear justification why small numbers suppression is not appropriate.</li> <li>2 To provide further clarification why the University of Edinburgh and the Royal Brompton Hospital are not considered Data Controllers given they are involved in the study design, outputs, described in the protocol and part of the study team.</li> </ol>

	<p>The following amendment were requested:</p> <ol style="list-style-type: none"> <li>1 To update section 5(c) to provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement.</li> </ol> <p>It was agreed the conditions would be approved OOC by IGARD members</p>
2.4	<p><u>Imperial College London: Unit-level aggregate NDA data for young adults (16-25) with diabetes in England (Presenter: James Humphries-Hart) NIC-228637-P6N0L</u></p> <p><b>Application:</b> This was a new application for National Diabetes Audit data for a study aimed at exploring the scope, feasibility and potential scalability of group clinics for young adults with diabetes and complex health and social care needs. As part of this study, a mixed-methods evaluation will be conducted of the impact of group clinics on young adults' engagement with services, and their confidence and success in managing diabetes.</p> <p>NHS Digital advised IGARD that the National Diabetes Audit (NDA) data referred to in the application was data that sits within NHS Digital.</p> <p><b>Discussion:</b> IGARD noted the update from NHS Digital on the NDA data and asked that section 5 (Purpose/Methods/Outputs) was updated to clarify that the NDA data already sits within NHS Digital and that no additional NDA data flowed into NHS Digital from any other organisation.</p> <p>IGARD noted reference to the ICO anonymisation code of practice which was out of date and queried why small numbers suppression was not appropriate, noting that there was no explanation within the application clarifying this and asked that a clear justification was provided. IGARD noted that section 1 (Abstract) and 3(b) (Additional Data Access Requested) referred to the ICO Code of Practice and asked that this was removed, as it was not relevant.</p> <p>IGARD queried the reference within the application to the qualitative and quantitative parts of the study outlined and the role of Imperial College London (ICL) and any other organisations involved, since it was clear in the protocol provided the difference between qualitative and quantitative and that ICL was involved in both but that other organisations were only involved in the qualitative part of the analysis. IGARD suggested that a clear narrative distinguishing the two parts of the study was clarified in section 5(a) (Objective for Processing) and a further explanation as to why Imperial College London are the sole Data Controller since the conclusion reached on the qualitative and quantitative analysis and organisations involved would clarify the Data Controllership under this application.</p> <p>IGARD noted the reference 'unit-level data' in section 5(a) and asked for further clarity on the definition of this and that this was amended as necessary. IGARD also suggested that a typo be addressed in section 5(a) and suggested "qualitative" be changed to "quantitative".</p> <p>IGARD queried the target date outlined in section 5(c) (Specific Outputs Expected) and noted this did not reflect the 6-month extension that had been agreed with NHS Digital and asked that this was updated to reflect this.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1 To provide a clear justification why small numbers suppression is not appropriate.</li> <li>2 Provide a clear narrative in section 5(a) to distinguishing between the qualitative and quantitative parts of the study and why Imperial College London are the sole Data Controller.</li> </ol> <p>The following amendments were requested:</p>

	<ol style="list-style-type: none"> <li>1 To update section 5 to clarify that the NDA data already sits within NHS Digital and that no additional NDA data flows into NHS Digital.</li> <li>2 To update section 5(a) to further define the term 'unit-level data' and amend as necessary for clarity.</li> <li>3 To update the target date in section 5(c) in-line with the 6-month extension agreed with NHS Digital.</li> <li>4 To update section 1 and section 3(b) to remove the reference to the ICO Code of Practice.</li> </ol> <p>It was agreed the conditions would be approved OOC by IGARD members</p>
3	<p><u>Triage Applications (Presenters: Dickie Langley / James Humphries- Hart)</u></p> <p>NHS Digital brought a sample application to present to IGARD to support the discussion around commercial / benefits standards and how NHS Digital triages the application against the Standards.</p> <p>It was agreed that any future IGARD agenda item of this nature would include an overarching note either as a supporting document or in section 1 (Abstract) to provide a clear outline to members why the application was at IGARD.</p> <p>It was agreed that the commercial standard would be brought back to a future IGARD meeting for discussion including algorithms, how to view the commercial standard with the benefit standard and how to capture both negative and positive outcomes from a study / project.</p>
4	<p><b>AOB:</b></p> <p>There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p> <p>As part of their oversight role, IGARD discussed the following matters:</p> <ul style="list-style-type: none"> <li>• Review of DARS Dashboard</li> </ul>

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 12/07/19

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-170564-P9F0D	London School of Hygiene and Tropical Medicine	13/06/2019	<ol style="list-style-type: none"> <li>1. To clearly explain each of the data flows within section 5 (and in particular section 5(b)) of the application to reflect the data flows set out in SD9 and SD5.</li> <li>2. To provide written evidence that s251 support covers the flows of data into NHS Digital with regard to either residents of Wales or people registered with a General Practice in Wales.</li> <li>3. To explicitly state that the only identifiers flowing into NHS Digital are from UCL.</li> </ol>	Quorum of IGARD Members	Quorum of IGARD Members	

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

- None