

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 1 March 2018

Members: Anomika Bedi, Chris Carrigan (Chair), Nicola Fear, Kirsty Irvine, Eve Sariyiannidou.

In attendance: Dave Cronin, Jen Donald, Duncan Easton, Kimberley Watson, Vicki Williams.

Apologies: Sarah Baalham, Joanne Bailey, Jon Fistein.

1	<p>Welcome and introduction</p> <p>The Chair thanked all those attending today, noting that Nicola Fear was joining the meeting via telephone.</p> <p>Declaration of interests</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 22 February IGARD meeting were reviewed and subject to a number of minor changes were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	<p>Data applications</p>
2.1	<p><u>University of Oxford: MR1164 - The Asymptomatic Carotid Surgery Trial (ACST-2) (Presenter: Jen Donald) NIC-10123-M5K5H</u></p> <p>Application: This was a renewal application to retain and continue to receive identifiable mortality data linked to Asymptomatic Carotid Surgery Trial (ACST-2) cohort. The trial started recruitment in 2007/08, continuing to recruit until 2019 and the aim of ACST-2 is to compare the long-term benefits of carotid surgery with carotid stenting. The longitudinal study benefits will help inform clinicians and patients of the long-term effects of the surgeries to help them make informed treatment decisions.</p> <p>NHS Digital had noted to the applicant that further benefits and outputs would be required on renewal.</p> <p>Discussion: NHS Digital noted that they had been proactively working with the applicant with regard to their consent material. IGARD noted this was a clinical trial and the applicant was using informed consent and the applicant should consult with relevant guidance recently issued by the Information Commissioner's Office (ICO) but noted that significant progress should have been made by the 25 May 2018, with language appropriate to the audience. IGARD also noted that consent issues could not be addressed by fair processing</p> <p>IGARD noted that the renewal application would be expected to provide further evidence of the benefits achieved for health and social care should be provided at renewal and that the applicant should engage widely with stakeholders and the public.</p> <p>IGARD suggested that funding be clarified when the application returns, and it be confirmed if funding was provided by the British Heart Foundation. IGARD also noted that the legal basis was incorrectly referenced within the application and should be updated.</p>

	<p>IGARD suggested that NHS Digital may wish to update its special condition wording to ensure “appropriate” encryption was applied for data held by the applicant.</p> <p>IGARD queried if unsuppressed data would be shared internationally and NHS Digital confirmed that it was not and only aggregated data with small numbers suppressed would be shared with partners.</p> <p>Outcome: recommendation deferred, pending:</p> <ul style="list-style-type: none"> • An updated application be presented to IGARD with information about the steps taken to amend the consent materials to the General Data Protection Regulation (GDPR) standard and to re-consent the cohort. • The applicant should work with DARS Information Governance staff to ensure the correct legal basis for data dissemination is listed within the application. <p>IGARD noted that on renewal, IGARD would expect to see further information with regard to benefits.</p>
2.2	<p><u>University College London: MR104B - Regional Heart Study (Female Cohort) (Presenter: Dave Cronin) NIC-148101-R7RSL</u></p> <p>Application: This was a renewal application for Medical Research Information Service (MRIS) data for use in the British Women’s heart and health study and to permit the retention of Personal Demographics data (PDS), Cancer Registration data and Office for National Statistics (ONS) data. The extension for a period of 6 months was an interim step to enable retention of data and for the study team to seek an appropriate legal basis to support expanding the study to include non-cardiovascular conditions of relevant to post-menopausal women. The study aims to determine the contribution of both established and new risk factors to the considerable variation in ischaemic heart disease and stroke in Great Britain and it is a cohort study of cardiovascular disease in women aged over 60 years.</p> <p>NHS Digital noted that the Data Sharing Agreement (DSA) had expired and that after consideration by NHS Digital a short-term extension with special conditions had been issued to the applicant.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the study.</p> <p>IGARD noted NHS Digital’s concern with regard to onward data sharing and 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 continued retention of data and that NHS Digital should satisfy itself that the audit report recommendations had been fully implemented. IGARD suggested that NHS Digital work with the applicant to implement an appropriate sub-licencing model and that section 5 of the application be explicit that sub-licencing is in place to ensure appropriate controls were in place.</p> <p>IGARD noted that the applicant wished to continue to hold and process the data but noted that informed consent did not provide adequate legal basis. IGARD suggested the applicant redraft their consent material to meet the General Data Protection Regulation (GDPR) standard of consent, including a clear process for re-consenting the cohort, as well as setting up a process for recording and monitoring consent. IGARD noted that an alternative legal basis be explored and the applicant should consult the guidance recently issued by the Information Commissioner’s Office (ICO).</p> <p>IGARD noted that the title of the application ‘Regional Heart Study (Female Cohort)’ did not match the study content in section 5 nor the Health Research Authority Confidentiality Advisory Group (HRA CAG) support and suggested section 5 clearly explain what data is being requested</p>

	<p>including background to the original study, when it commenced and how it related to the title of the application.</p> <p>IGARD noted that the expiry date for one of the Approved Researchers had expired and should be updated, and that the supporting document provided did not accurately reflect the application and suggested that section 9 be updated with the correct detail.</p> <p>IGARD were unclear if the London School of Hygiene and Tropical Medicine and University of Bristol had destroyed previously held data and sought confirmation.</p> <p>Outcome: unable to recommend for approval</p> <ul style="list-style-type: none"> • The consent materials did not appear to provide a legal basis on which to continue to process data. • Section 5 of the application to be updated to explicitly state that there is sublicensing, and NHS Digital should work with the applicant to implement an appropriate sub-licensing model • Confirmation that both University of Bristol and London School of Hygiene and Tropical Medicine have destroyed previously held data. • The title of the application and content of the application do not match in terms of the relevant study and section 5 of the application should clearly explain which study the data is requested for. • The list of Approved Researchers in section 9 should be updated to reflect the supporting documentation provided and to take into account the fact that the approved research status for one individual has expired. <p>IGARD noted the importance of this research 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 continued retention of data while work was undertaken to address the queries raised by IGARD.</p>
2.3	<p><u>University College London: MR104C - Regional Heart Study (S251 cohort) (Presenter: Dave Cronin) NIC-174486-Q8J1B</u></p> <p>The application was withdrawn by the presenter.</p> <p>IGARD noted the importance of this research 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 continued retention of data while work was undertaken by NHS Digital.</p>
2.4	<p><u>Renal Registry: The Renal Association, UK Renal Registry - audit application (Presenter: Kimberley Watson) NIC-94250-L8W8T</u></p> <p>Application: This was a new application for Hospital Episode Statistics (HES) Admitted Patient Care, Office for National Statistics (ONS) data, HES outpatients and HES critical care data for the purposes of audit. The HES and ONS data provided will be used to strengthen national audit of renewal services for those with kidney disease or injury.</p> <p>Discussion: IGARD noted that the applicant's fair processing did not meet NHS Digital's nine minimum criteria for privacy notices, specifically listing all identifiers sent to NHS Digital, updating the opt out information to correctly state this refers to any information and that opting out will not affect the care received, and removing references to the use of data for research</p>

data and misleading statement that anonymous data is used for research. IGARD noted that a clear statement should then be added to the application summary that NHS Digital was satisfied that the applicant's fair processing meets the NHS Digital nine minimum criteria for privacy notices (to be known as NHS Digital's fair processing criteria) before data can flow.

IGARD noted that the application did not align to the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support document provided for consideration and that section 5 should be updated to explicitly list the identifiers flowing to NHS Digital, which would prevent any breach to the data sharing agreement. IGARD noted that research use of the data was not covered by the s251 support and that the application be updated to explicitly state that research use of the data is not part of this application. IGARD queried a reference to the researchers accessing the data and that section 5 be explicit that the researchers are only accessing audit data and not the data disseminated by NHS Digital. IGARD also suggested that the bullet points in section 5a be re-ordered to be clearer to a lay reader when published as part of the data release register.

IGARD queried which specialist health body was being referred to for the receipt of ONS data and suggested a clearer explanation as to how s42(4A) applied to this application as the legal basis for the receipt of the ONS data.

IGARD queried if The Renal Association should be listed a Data Processor since they are the legal entity, noting that the renal registry function was part of The Renal Association. IGARD also suggested that confirmation be sought that the individuals accessing the data were substantive employees of The Renal Association, working within the renal registry function and that standard wording be included in section 5 with regard to access controls to access the data.

IGARD noted that the applicant had made efforts to minimise data requested and suggested reference to the anonymous nature of data within section 5 be removed from the application. IGARD also noted that the applicant should spell out acronyms upon first use in section 5 of the application and update reference to UKRDC including their role which could be understood by the lay reader when published as part of the data release register.

IGARD noted that the data flow diagram provided reference Personal Demographics data (PDS) data being received by the applicant from NHS Digital, however this was not in the application and suggested that since PDS was not part of the application that that data flow diagram be updated and remove reference to PDS data.

Outcome: Recommendation to approve subject to the following conditions:

- Section 5 should be updated to clearly list the identifiers flowing to NHS Digital, aligning with s.251 support.
- Section 5 of the application be updated to explicitly state that the research use of data is not part of the application as it is not covered by s.251 support
- The first three bullet points within section 5a should be re-ordered.
- A reference to researchers accessing data should be explicit that they are accessing audit data only and not data disseminated by NHS Digital.
- A clearer explanation as to how s.42(4) applies in this application as is the legal basis for the receipt of ONS data.
- To update the data flow diagram to include only flows relevant to this application.
- Confirmation that the individuals accessing the data are substantive employees of The Renal Association working within the renal registry function.

	<ul style="list-style-type: none"> The fair processing notice for the applicant be updated to meet NHS Digital's nine minimum criteria (to be known as NHS Digital's fair processing criteria) for privacy notices including listing all the identifiers sent to NHS Digital, updating the opt out information to correct state this refers to any information and that opting out will not affect the care received, and removing references to the use of data for research data and the misleading statement that anonymous data is used for research, before data can flow. <p>The following amendments were requested:</p> <ul style="list-style-type: none"> To clarify in section 5 of the application the acronym UKRDC that appears in the s.251 letter which supports the processing activities under this application. To correctly reference The Renal Association as a Data Processor. A clear statement should be added to the application summary that NHS Digital are satisfied that the applicant's fair processing meets the NHS Digital nine minimum criteria for privacy notices (to be known as NHS Digital's fair processing criteria). Reference to anonymous nature of data within section 5b of the application be removed. <p>It was agreed the conditions be approved OOC by IGARD Members.</p>
2.5	<p><u>Wilmington Healthcare: Niemann Pick Type C Patient Finder (Presenter: Kimberley Watson) NIC-34548-M7R3H</u></p> <p>Application: This was a new application requesting Hospital Episode Statistics (HES) data to identify episodes within the HES datasets which have been coded with combinations of ICD-10 codes that suggest clinical features compatible with a diagnosis of Niemann-Pick Type C.</p> <p>The application had previously been considered by IGARD on the 18 January 2018 when IGARD were unable to recommend for approval pending clarification of the Data Controller and Data Processor organisations; providing evidence the applicant has adequately addressed the condition of the s251 support outlined by Health Research Authority Confidentiality Advisory Group (HRA CAG); the fair processing to be updated to meet NHS Digital's minimum criteria; updating the funder organisation and their role; and providing description of the tool.</p> <p>NHS Digital noted that the address where the data is being processed was different to the Data Processor's address but was still part of University College London Hospital (UCLH), however NHS Digital noted that no data would flow to the applicant until NHS Digital had confirmed that UCLH's IG toolkit covered that location.</p> <p>Discussion: IGARD noted the application had been updated to reflect some of the comments previously raised, however a number of key points raised previously were still outstanding.</p> <p>IGARD noted that an updated fair processing notice had been provided by the Data Processor and that information was also available on the Niemann Pick website, however the Data Controller should provide a fair processing notice which meets NHS Digital's nine minimum criteria for fair processing notices which specifically describes the study and organisations involved in the study, their role and the full scope of the processing activities, and the purposes of the project. IGARD noted that a clear statement should then be added to the application summary that NHS Digital was satisfied that the applicant's fair processing meets the NHS Digital nine minimum criteria for privacy notices (to be known as NHS Digital's fair processing criteria) before data can flow.</p> <p>IGARD noted that within the HRA CAG letters it was not clear if the applicant had addressed the conditions previously raised as no evidence was provided and that this should be provided. HRA CAG had queried the project's exit strategy and whether the project would end when the letter was sent to the GP as, at this point, it was up to the GP to decide whether they wished to contact</p>

	<p>the patient in the context of direct care. A number of queries were raised, and clarification sought as to whether the applicant had amended the information provided to clinicians to reflect all the points outlined by HRA CAG; when support to process information under this support will cease; whether follow up data is required and if this will be taking place under the consent obtained by the clinician.</p> <p>IGARD also asked about what contractual arrangements / permissions would need to be put in place between Wilmington Healthcare and NHS Digital to allow the cohort to be identified if / once the application has been approved and advised that this area should be addressed in further detail on any re-submission of the application.</p> <p>IGARD discussed the ethical issues raised and how this was addressed within the application and although this appeared to be in the public interest, asked that the application should contain references of how such ethical issues had been addressed.</p> <p>Outcome: unable to recommend for approval</p> <p>IGARD noted that some of the issues previously raised were not adequately addressed:</p> <ul style="list-style-type: none"> • Providing evidence that the applicant has adequately addressed the condition of the s.251 support outlined by HRA CAG to clarify as to when support to process information under this support will cease, whether follow-up data is required and whether this will be taking place under the consent obtained by the clinician. • Providing evidence that the applicant has adequately addressed the condition of s.251 support to amend the information provided to clinicians to reflect all the points outlined by HRA CAG. • The fair processing notice for the Data Controller (UCLH) be updated to accurately describe the study and the organisations involved, including their role and the full scope of processing activities and purposes of the project to meet NHS Digital's nine minimum criteria. • Although the study appeared to be in the public interest, it still raised ethical issues and asked that the application should contain references of how such issues had been addressed.
2.6	<p><u>Beyond Compliance: PROMs data application (Presenter: Kimberley Watson) NIC-58668-V5C0L</u></p> <p>Application: This was a new application for Patient Reports Outcomes (PROMs) measures for patients receiving an implant. Northgate Public Services have designed a data collection platform and are paid by manufactures to provide reports to Beyond Compliance who are acting as the advisory group who review the reports and provide advice to manufactures.</p> <p>Discussion: IGARD noted that cohort 1 (9,856 patients) was consented under earlier versions of consent material (supporting document 1) and it did not appear to provide an adequate legal basis for the release of data. However, IGARD noted that cohort 2 (estimated 20,000 patients) was pending consent and could be consented under the new consent material provided (supporting document 3). IGARD suggested that NHS Digital work with the applicant to ensure current consent materials (supporting document 3) are re-drafted to meet the General Data Protection Regulation (GDPR) standard of consent, including updating to state 'in pseudonymised form and will not directly identify you' in the paragraph beginning with 'Personal information is treated with high standards of confidentiality', and to remove the second paragraph on page two which begins with the sentence 'Other than for these two purposes NPS ...'</p>

	<p>IGARD suggested that NHS Digital cross reference the supporting documentation provided with the application to ensure consistency and that supporting document 9 be correctly referenced.</p> <p>IGARD noted that SunGard were listed as a storage location and stated in 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 action with NHS Digital regarding storage locations and how to reflect their role as data processors</p> <p>The outcome for the application was split as follows:</p> <p>Outcome: IGARD were unable to recommend for approval for cohort 1:</p> <ul style="list-style-type: none"> • The consent materials do not appear to provide a legal basis for the release of data. • Reference to supporting document 9 be updated and corrected within the application. <p>Outcome: Cohort 2 recommended for approval subject to the following condition:</p> <ul style="list-style-type: none"> • The current consent materials should be updated to state 'in pseudonymised form and will not directly identify you' in the paragraph beginning with 'Personal information is treated with high standards of confidentiality', and to remove the second paragraph on page two which begins with the sentence 'Other than for these two purposes NPS ...'. <p>The following amendment was requested</p> <ul style="list-style-type: none"> • Reference to supporting document 9 be updated and corrected within the application. <p>It was agreed the condition would be approved OOC by IGARD Members.</p>
<p>3</p> <p>3.1</p>	<p>AOB</p> <p>Local Authority Hospital Episode Statistic (LA HES) Template</p> <p>NHS Digital noted a new Special Condition was to be inserted into the Local Authority Template Applications to cover the Information Governance Toolkit requirements, including:</p> <ul style="list-style-type: none"> • v14.1 must be completed and submitted as self-assessed as satisfactory by 31 March 2018. • If 14.1 reviewed, it must be satisfactory. • Must have Data Security and Protection Toolkit (DSAPT) in place within 1 year of v14.1 being submitted. • Must maintain compliance with mandatory assertions of the DSAPT (or subsequent versions / successor) during lifetime of the Data Sharing Agreement. • Must inform NHS Digital immediately if any of the above criteria not met. <p>IGARD noted the update to the agreed LA HES template.</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>08/02/18: it was agreed the updated draft be brought to the March education session</p> <p>01/03/18: the March education session was cancelled, and it was agreed to take the draft annual report to the April education session.</p>	Open
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>01/03/18: Ongoing</p>	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 session on changes to how Medical Research Information Service (MRIS) reports are now shown within applications.	Garry Coleman	22/02/18: IGARD Secretariat to contact Garry Coleman to suggest presentation at the June education session. 01/03/18: ongoing	Open
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. 22/02/18: IGARD Secretariat to contact Stuart Richardson to provide an update 01/03/18: Stuart Richardson noted he and Dickie Langley had met recently with NHS England and would provide a briefing note when an updated application was presented to IGARD.	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	01/03/18: 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	22/02/18: IGARD Secretariat to contact Stuart Richardson to provide an update 01/03/18: Stuart Richardson noted that STP's group CCG's together in the main (noting some STPs only have one CCG) to form larger population patches to aim for efficiencies in healthcare provision over the wider patch. They are not legal entities but have started asking for data sharing on the non-identifiable data across the CCGs involved. This has been requested (and approved by IGARD) for a London set of CCGs already under a joint data controllership model. Other CCGs grouped as CCGs and as the legal entities are likely to request the same sort of model. Moving forwards, STPs will be	Open

			moving to being IHSs (Integrated Health Systems) and will involve lead providers, possibly under a data processor model, and involvement of the local councils etc. So we will be needing to then seek amendments to bring in data sharing across those additional organisations for the non-identifiable data. Identifiable data will need to be just shared with single CCGs as legal entities under CCG, sole data-controllership, DSAs.	
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Appendix B: Out of committee report

Independent Group Advising on Releases of Data (IGARD): Out of committee report 23/02/18

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-311182-NOL1Y	National Centre for Social Research (NatCen)	08/02/18	<ul style="list-style-type: none"> Clarification within section 5 of the application that Imperial College London and University of East Anglia will not receive data under this application. A special condition be added to the application that the patient information leaflet (SD7) will be sent to the participant cohort and they will be given one month from the date sent to reply before data can flow. 	IGARD Chair	IGARD Chair	N/A
NIC-86954-Y0R2N	University College London	08/02/18	<ul style="list-style-type: none"> Clarification that Microdata Release Panel (MRP) approval has been extended to 2022 and providing a copy of the extension MRP approval letter. 	IGARD Chair	Deputy IGARD Chair (delegated)	N/A
NIC-131964-Q6L1J	London North West Healthcare NHS Trust	15/02/18	<ul style="list-style-type: none"> The fair processing notice for the applicant be updated to meet NHS Digital's nine minimum criteria (to be known as NHS Digital's fair processing criteria) for privacy notices, specifically, references to anonymous and anonymised data to be described as pseudonymised, to clarify that the opt out process applies to the processing of all data, and the fair 	IGARD Chair	Deputy IGARD Chair (delegated)	N/A

			processing notice to be published, before data can flow			
NIC-352291-Y7B1S	University of Leeds	22/02/18	<ul style="list-style-type: none"> To clarify within section 5 of the application that a s.251 support is no longer required for this application as there is no new request for data to flow from PHE to NHS Digital and that the data NHS Digital received under the original s.251 support has since been destroyed. 	IGARD Chair of the meeting	IGARD Chair of the meeting	

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

- None notified to IGARD