

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 12 April 2018

Members: Joanne Bailey, Chris Carrigan (Chair), Nicola Fear, Kirsty Irvine, Eve Sariyiannidou.

In attendance: Jane Cleave (items 2.6 & 2.7), Dave Cronin, Gaynor Dalton (items 2.1-2.3), Rachel Farrand, James Humphries-Hart, Aaron White, Vicki Williams.

Apologies: Sarah Baalham, Anomika Bedi, Jon Fistein

1	<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 5 April 2018 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: Dave Cronin) NIC-10123-M5K5H</u></p> <p>Application: This was an MRIS application to retain and continue to receive identifiable mortality data linked to Asymptomatic Carotid Surgery Trial (ACST-2) cohort. The application had been previously deferred by IGARD on the 1 March 2018 pending steps taken to amend the consent material to GDPR standards and to re-consent the cohort and the applicant working with DARS IG to ensure the correct legal basis for data dissemination is listed within the application.</p> <p>NHS Digital noted that this was a short-term extension.</p> <p>NHS Digital also noted that DARS IG were yet to provide the correct legal basis for data dissemination for inclusion in the application.</p> <p>Discussion: IGARD welcomed the application and noted the application had been updated to reflect the comments previously raised.</p> <p>IGARD noted that clinical trials were regulated by the Clinical Trials legislation which sets informed consent as a requirement, but compliance with the GDPR is also a precondition. IGARD also noted that NHS Digital advised that it had drawn to the attention of the research community, during the course of its GDPR road shows in 2017, that consent would be the only permissible legal basis in the context of processing data for a clinical trial. IGARD suggested that NHS Digital work with the applicant to assess whether the consent materials meet the required standards of consent and in line with the upcoming application of the GDPR</p> <p>IGARD noted that the applicant would be retaining and continuing to process data under this application and suggested that given that the applicant's previous DSA had expired, NHS Digital might wish to consider putting a short-term extension in place for a limited time period to enable the applicant to continue to retain and process data for purposes within this application / DSA. IGARD asked that it be explicitly stated in section 5 of the application that cancer data has not been disseminated to the applicant nor would be under this application / DSA. IGARD also noted that only aggregated data would be shared and that NHS Digital update the application to be clear throughout section 5.</p>

	<p>IGARD noted that the application referenced the HRA detailed guidance “B – study approved and recruiting new participants after 25 May 2018”, however IGARD suggested that the applicant may wish to also consider: “C – Study approved and participants are still in the study after 25 May 2018”</p> <p>Outcome: Recommendation to approve subject to the following condition for an extension only and for a limited period for the applicant to retain the data but not otherwise process:</p> <ul style="list-style-type: none"> • Clarifying explicitly within section 5 of the application that cancer data has not been disseminated previously, nor under this application <p>The following advice was given:</p> <ul style="list-style-type: none"> • IGARD suggested that at renewal the application clearly articulate the lawful basis for processing both under data protection legislation and the common law of confidentiality. <p>It was agreed that the condition would be approved OOC by the IGARD Chair.</p>
2.2	<p><u>University of Liverpool: MR1025 - The Roy Castle Lung Cancer Research Programme, Liverpool Lung Project (Presenter: Dave Cronin) NIC-147982-J7KGV</u></p> <p>Application: This was an MRIS application to extend a current agreement to retain data already held for the cohort; renew the agreement to receive additional years of data of Hospital Episodes Statistics (HES) Admitted Patient Care, Outpatients, Accident & Emergency data and Office for National Statistic (ONS) data; amend the agreement to receive Cancer Registrations data for this cohort; amend the agreement to include and receive ICD 10th revision coded cause of death for the cohort. The application had been previously deferred by IGARD on the 20 July 2017 pending provision of relevant consent materials from the beginning of the recruitment onwards; providing further information about the view taken by HRA CAG and previously by ONS that the consent material provided an appropriate legal basis for data sharing.</p> <p>Discussion: IGARD welcomed the application and the importance of the work being undertaken. IGARD noted the application had been updated to reflect the comments previously raised.</p> <p>IGARD noted that the consent materials did not appear to meet the GDPR consent standard. IGARD also noted that this was not a clinical trial and that the applicant may choose to update their current consent and re-consent or consider an alternative legal basis, in order to be compliant with the GDPR. IGARD suggested that on renewal the applicant should clearly articulate the lawful basis for processing the data under GDPR</p> <p>IGARD noted the feedback from HRA CAG and ONS and suggested that the applicant work with NHS Digital and DARS IG to consider their consent materials in the context of the common law duty of confidence to identify any gaps which are not incompatible with the original purpose of the study and which may be mitigated by fair processing information.</p> <p>IGARD queried reference to the DNA being anonymous. IGARD noted that genetic data is personal data under GDPR.</p> <p>IGARD queried if the applicant was receiving new data under this application in addition to data already held since it was not referenced in section 3b of the application and NHS Digital confirmed that they applicant would not be receiving data under this application.</p> <p>Outcome: recommendation to approve for an extension only and for a limited period for the applicant to retain the data but not otherwise process:</p> <p>The following advice was given:</p>

	<ul style="list-style-type: none"> • IGARD suggested that at renewal the application clearly articulate the lawful basis for processing under GDPR. • IGARD suggested that NHS Digital should consider the consent materials in the context of the common law duty of confidence to identify any gaps which are not incompatible with the original purpose of the study and may be mitigated by fair processing information. <p>It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority</p>
2.3	<p><u>Cardiff University: MR1274 - FOLFERA - A randomised phase II study of Irinotecan, 5-Fluorouracil and Folinic Acid (FOLFIRI) with or without the addition of an endothelin receptor antagonist in patients with metastatic colorectal cancer after failure of Oxaliplatin-containing chemotherapy (Presenter: Dave Cronin) NIC-148209-JZFSK</u></p> <p>Application: This was an MRIS application for mortality data for a cohort of participants in the FOLFIRI study, a randomised phase II study of Irinotecan, 5-Fluorouracil and Folinic Acid (FOLFIRI) with or without the addition of an endothelin receptor antagonist in patients with metastatic colorectal cancer after failure of Oxaliplatin-containing chemotherapy.</p> <p>NHS Digital noted that a number of supporting document references were not included in section 7 of the application and that these had now been included.</p> <p>Discussion: IGARD noted that the requirements of informed consent under the relevant clinical trials legislation had been met and the materials provided were reasonably specific and met the reasonable expectations. IGARD were unclear about the correct cohort size and suggested that the applicant clarify the cohort size within the application.</p> <p>IGARD suggested that Cardiff University update their DPA registration to clearly state that data is processed about patients or health care users.</p> <p>IGARD also suggested that on renewal the applicant would be expected to provide further examples of how they had maximised the benefits of dissemination of the outputs to a wider audience.</p> <p>Outcome: recommendation to approve.</p> <p>The following amendment was requested:</p> <ul style="list-style-type: none"> • Clarifying within the application the correct cohort size. <p>The following advice was given:</p> <ul style="list-style-type: none"> • Cardiff University should update their DPA registration to more clearly state that data is processed about patients or healthcare users. • IGARD suggested that on renewal the applicant would be expected to provide further examples of how they have maximised the benefit of dissemination of outputs.
2.4	<p><u>University College London: Healthcare transitions for young people (Presenter: Rachel Farrand) NIC-330769-C9Y8Y</u></p> <p>Application: This was an application to continue to retain and process Hospital Episode Statistics (HES) Admitted Patient Care, Outpatients, Critical Care and Accident & Emergency data, linked to Office for National Statistics (ONS) data. The aim of the research is to investigate the effect of transitioning from paediatric to adult care on indicators of illness management relating to health service usage.</p>

Discussion: It was noted that historic phrasing was being used in section 4, Fair Processing and may be out of date by the time the applicant's sign their contract / DSA with NHS Digital. It was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements." IGARD also suggested the special condition referencing fair processing notices be removed, since it was not relevant to this application.

IGARD suggested that the University College London update their DPA registration to clearly state that data is processed about patients or health care users and remove reference to 'patients of partner hospitals'.

Outcome: recommendation to approve

The following amendments were requested:

- The Fair Processing section to be amended to include the new standard wording: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements."
- To remove the special condition referencing fair processing notices, since it is not relevant to this application.

The following advice was given:

- University College London should update their DPA registration to more clearly state that data is processed about patients or healthcare users.

2.5 University Hospitals Coventry & Warwickshire NHS Trust: What factors lead to palliative care patients being admitted to acute hospitals; can we design services to improve their support at home? (Presenter: Rachel Farrand) NIC-113611-X2Y3H

Application: This was a new application for a one-off extract of pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care and HES Accident & Emergency Data. The application was previously deferred by IGARD on the 5 April 2018 pending clarification of the individuals involved in data processing, where the data processing was being undertaken, adding the University of Warwick as a Data Processor, clarifying the substantive employment details, adding a special condition that processing will only be undertaken at the Hospital location, clarifying how phase 1 and 2 interlink, how the data for phase 1 will be used for phase 2, clarifying any linkages, to ensure ethical approval in place should the Hospital be processing data under phase 2, updating section 5 for the lay reader, providing a copy of the letter of permission for research, clarifying the funding in place for 2018/19, and referencing within section 3b what the basis for processing data is under GDPR.

NHS Digital noted that the University Hospitals Warwickshire & Coventry NHS Trust had not been correctly referencing in section 5 of the application.

Discussion: IGARD noted the application had been updated to reflect the comments previously raised. IGARD noted that the Data Controller within section 5 be clearly referenced as University Hospitals Warwickshire & Coventry NHS Trust.

IGARD queried if a special condition should be included with regard to processing data now that University of Warwick was listed as a Data Processor, however it was agreed that the

	<p>application and Data Sharing Agreement were clear that data processing could only be undertaken at the University of Warwickshire & Coventry NHS Trust.</p> <p>IGARD suggested that the DPA registration for University Hospitals Warwickshire & Coventry NHS Trust should be updated to refer to processing data about patients rather than ‘our patients’</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> To clarify within section 5b of the application that the University Hospitals Warwickshire & Coventry NHS Trust is the Data Controller. <p>The following advice was given:</p> <ul style="list-style-type: none"> IGARD advised that the applicant should update their DPA registration to refer to processing data about patients rather than ‘our patients’.
2.6	<p><u>NHS Great Yarmouth and Waveney CCG: An amendment for Great Yarmouth and Waveney CCG to move Data Processor from North of England Commissioning Support Unit to Arden and Greater East Midlands Commissioning Support Unit for the purposes of Commissioning. (Presenter: Stuart Richardson / James Humphries-Hart) NIC-173538-J5S0W</u></p> <p>Application: This was an amendment application to use pseudonymised data: Secondary Use Service+ (SUS+), Local provider flows (for commissioning), Mental Health Minimum Data Set, Mental Health Learning Disability Data Set, Mental Health Services Data Set, Maternity Services, Improving Access to Psychological Therapies, Children & Young People’s Health Service, Community Services Data Set and Diagnostic Imaging Data Set to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is to provide intelligence to support the commissioning of health services and for the applicant to move Data Processor from North East London Commissioning Support Unit to Arden and Greater East Midlands Commissioning Support Unit for the purposes of Commissioning.</p> <p>Discussion: IGARD noted that North East London CSU had been incorrectly referenced within the application and suggested this should be updated to North of England CSU. It was also suggested that DAAG / IGARD approval dates be inserted into the table within the abstract for clarity.</p> <p>IGARD noted that Pulsant 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 and that reference to Interxion should be removed from this paragraph. 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>It was noted that historic phrasing was being used in section 4, Fair Processing and may be out of date by the time the applicant’s sign their contract / DSA with NHS Digital. It was suggested that new standard wording for use with pseudonymised data be used: “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements.” IGARD also suggested that the ICO web link in section 4 be deleted and the special condition referencing fair processing notices be removed, since it was not relevant to this application.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p>

	<ul style="list-style-type: none"> • The Fair Processing section to be amended to include the new standard wording: “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements.” • To remove the special condition referencing fair processing notices, since it is not relevant to this application. • To remove the ICO web link in the Fair Processing section. • Reference to North East London CSU within the abstract be updated to correctly reference North of England CSU. • Reference to Interxion in the paragraph: “For clarity, any access by Interxion and Pulsant Data Centre to data held under this agreement would be considered a breach of the agreement. This includes granting of access to the database[s] containing the data” should be removed. • The abstract be updated to clearly list the previous DAAG / IGARD approval date.
2.7	<p><u>Group of 2 CCG’s¹: to receive pseudonymised data to support the Sustainability Transformation Plan (STP) (Presenter: Stuart Richardson / James Humphries-Hart)</u></p> <p>Application: This was a new application to receive pseudonymised data: Secondary Use Service+ (SUS+), Local provider flows (for commissioning), Mental Health Minimum Data Set, Mental Health Learning Disability Data Set, Mental Health Services Data Set, Maternity Services, Improving Access to Psychological Therapies, Children & Young People’s Health Service, Community Services Data Set and Diagnostic Imaging Data Set to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the Sustainable Transformation Partnership (STP) area. Each CCG will receive data for the entire STP region covered by all the CCG’s in order to support each other proactively in delivering their commissioning agendas.</p> <p>NHS Digital noted that there was an error in section 3 and that the CCG’s did not hold each other’s data and that it had been updated to be ‘CCG of residence’.</p> <p>Discussion: IGARD noted the amendment to ‘CCG of residence’ and suggested that the abstract and section 5 be updated to clearly reference that the CCG’s were processing data for the geographical area.</p> <p>IGARD noted that the applicant had requested pseudonymised data however section 2 indicated that the applicant was receiving identifiable sensitive data and this reference should be removed.</p> <p>IGARD noted that Torbay & South NHS Foundation Trust and Stem Networks Limited were listed as a storage location and stated their view that it would be more appropriate to also list these organisations as additional data processors. 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>It was noted that historic phrasing was being used in section 4, Fair Processing and may be out of date by the time the applicant’s sign their contract / DSA with NHS Digital. It was suggested that new standard wording for use with pseudonymised data be used: “All data required by the</p>

¹ NHS Northern Eastern and Western Devon CCG - NIC-172821-S1X9K; NHS South Devon and Torbay CCG - NIC-173140-S5S8J

	<p>Data Controller under this application is pseudonymised and therefore is considered as personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements.” IGARD also suggested that the ICO web link in section 4 be deleted and the special condition referencing fair processing notices be removed, since it was not relevant to this application.</p> <p>IGARD noted that the V14 Information Governance Toolkit date for NHS Northern Eastern & Western Devon CCG was 2016 and suggested that the self-assessment would have taken place during 2017 and that the date be updated to reflect.</p> <p>IGARD acknowledged an open action with NHS Digital with regard to contractual arrangements in place, the structure, enforcement strategy and how the agreements worked together so that the data disseminated by NHS Digital would be protected</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • The Fair Processing section to be amended to include the new standard wording: “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements.” • To remove the special condition referencing fair processing notices, since it is not relevant to this application. • To remove the ICO web link in the Fair Processing section. • The table in section 2 be updated to remove reference to identifiable sensitive data being included within this application. • To clarify in the abstract and section 5 that the CCG’s are processing data for the geographical area. • The V14 IG toolkit date for NHS Northern Eastern and Western Devon CCG be updated to clearly state that self-assessment was undertaken in 2017.
<p>3</p>	<p><u>AOB</u></p> <p>HRA Guidance on GDPR</p> <p>It was suggested that IGARD members consider the HRA guidance on GDPR, published on line and provide feedback</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> <p>05/04/18: to seek clarification from the Chair if stakeholders have been approached and to bring back the draft to the May education session.</p> <p>12/04/18: The Chair noted he was yet to contact external to NHS Digital stakeholders.</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>	Open

			<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>05/04/18: IGARD Secretariat had contacted Garry Colman and were awaiting a response.</p> <p>12/04/18: ongoing</p>	
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	<p>22/02/18: IGARD Secretariat to contact Garry Coleman to suggest presentation at the June education session.</p> <p>05/04/18/18: IGARD Secretariat were awaiting a response.</p> <p>12/04/18: ongoing</p>	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	<p>22/03/18: IGARD Secretariat noted had contacted Louise Dunn and were awaiting a response.</p> <p>05/04/18/18: IGARD Secretariat were awaiting a response.</p> <p>12/04/18: ongoing</p>	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	<p>22/02/18: IGARD Secretariat to contact Stuart Richardson to provide an update</p> <p>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 moving to being IHSs (Integrated Health Systems) and will involve</p>	CLOSE

			<p>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.</p> <p>15/03/18: IGARD queried the statement in the above text: 'other CCG's groups as CCG's and as the legal entities are likely to request the same sort of model' and asked for clarification on this point.</p> <p>05/04/18: Stuart Richardson noted a typo in the information provided and it should read: 'other CCGs grouped as STPs and as the legal entities are likely to request the same sort of model'</p> <p>12/04/18: It was agreed that the action can be closed and removed from the action plan</p>	
15/03/18	Stuart Richardson to provide a briefing note clarifying the contractual arrangements in place, the structure, enforcement strategy and how the agreements worked together so that the data disseminated by NHS Digital would be protected and provide a verbal update to IGARD on the progress of this note by 5 April 2018.	Stuart Richardson	<p>05/04/18: A verbal update was provided that individual Data Sharing Framework Contracts (DSFC) were issued yet Data Sharing Agreements were joint Data Controllership and that DSFC's placed exactly the same terms and conditions upon organisations and NHS Digital believe the position to be acceptable. IGARD noted the verbal update and asked that a briefing note be provided by NHS Digital confirming the arrangements in place by the end of April 2018.</p> <p>12/04/18: ongoing</p>	Open
05/04/18	IGARD to provide detailed feedback to NHS Digital with regard to application NIC-172240-R4R0L University of Oxford	IGARD	12/04/18: the detailed feedback had been circulated to members for final comment before dissemination by 16/04/18 to the DAO via the IGARD Secretariat	Open

Appendix B: Out of committee report

Independent Group Advising on Releases of Data (IGARD): Out of committee report 06/04/18

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-08095-P4D0D	NHS North of England Commissioning Support Unit	08/03/18	<ul style="list-style-type: none">Clarification within section 5 of the application the need to retain 2010/11 and 2011/12 data.	IGARD Chair	Deputy IGARD Chair	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