

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 24 May 2018

Members: Sarah Baalham, Chris Carrigan, Nicola Fear, Jon Fistein, Kirsty Irvine (Chair), Eve Sariyannidou.

In attendance: Helen Buckles, Jane Cleave, Dave Cronin, Louise Dunn, Stuart Richardson, James Smith (Observer), Aaron White, Vicki Williams.

Apologies: Joanne Bailey, Anomika Bedi.

1	<p>Declaration of interests</p> <p>Jon Fistein noted a personal link to University of Cambridge NIC-321968-S4Q6L and would not be part of the discussion but would remain in the meeting for the discussion of that application.</p> <p>Review of previous minutes and actions</p> <p>The outcomes of the 17 May 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting.</p> <p>The minutes of the 10 May 2018 and 17 May 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>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>Institute of Cancer Research: National cohort study of mortality and cancer incidence in patients with cytogenetic and paediatric endocrine disorders (Presenter: Dave Cronin) NIC-147749-3SSRF</u></p> <p>Application: This was an extension and renewal application to permit the retention and reuse of Personal Demographics Data (PDS), Cancer Registration Data and Office for National Statistics (ONS) Mortality Data provided via the Medical Research Information Service (MRIS) or predecessor service providers. The application had been presented to IGARD on the 8 February 2018 when they had been unable to recommend for approval pending clarification who was accessing the data, confirmation that ethics approval was still valid, a clearer explanation of the history of the study from its inception to present day and the applicant's privacy notice should meet NHS Digital's nine minimum criteria.</p> <p>NHS Digital noted that section 3 of the application should be updated to reflect data held and being requested.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the study and that the application had been updated to reflect most of the comments previously made. IGARD noted section 3 of the application was blank due to a technical issue and that it should be updated to clearly reflect the data held and being requested by the applicant.</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. IGARD noted that the documentation provided, including a copy of the applicant's constitution, was not adequate.</p>

It was noted that the applicant had been advised to merge the four original studies into the one application, however, section 5 did not accurately describe this and it should be clearly described how the 4 original cohorts related to the purpose and processing under the application. IGARD also noted that section 3 should also clearly identify the original cohorts whose data was being requested.

IGARD queried the four original study titles and how they related to the current generic study title. NHS Digital confirmed that the reference numbers correlated across the studies and years and they were content that relevant support for the study was in place. NHS Digital also noted that they had spoken with HRA CAG and they were content s.251 support covered the two cohorts outlined within the application. IGARD suggested for audit purposes that NHS Digital produce a document recording this conversation and outlining the HRA CAG s.251 support for the two cohorts described in the application. IGARD also suggested that for transparency that section 5 of the application be updated to clarify how the current four study titles related to the original study title.

IGARD suggested that the special condition wording within section 6 of the application be removed and 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 within a reasonable period after obtaining the personal data, but at the latest within one month."

IGARD noted that a duplicate special condition was included in section 5b and suggested that the special condition in section 6: "All organisations party to this agreement must comply with the Data Sharing Framework Contract requirements, including those regarding the use (and purposes of that use) by "Personnel" (as defined within the Data Sharing Framework Contract i.e. employees, agents and contractors of the Data Recipient who may have access to that data)" be removed.

IGARD suggested that a special condition be included within the application that on renewal the application would be expected to provide a copy of their current ethics approval letter.

Outcome: recommendation to approve subject to the following conditions:

1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met.
2. To clearly describe the data held and data requested within section 3 of the application.
3. Section 3 should clearly identify the original cohorts whose data is requested and within section 5 clearly describe how the four original cohorts relate to the purpose and the processing activities under this application.
4. To produce a supporting document outlining HRA CAG s251 support for the two cohorts outlined in the application.

The following amendments were requested:

1. To include a special condition that on renewal the applicant will be required to produce a copy of their current ethics approval.
2. To clarify within section 5 the study titles and how the current four studies relate to the original study title.
3. 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

	<p>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 within a reasonable period after obtaining the personal data, but at the latest within one month.”</p> <ol style="list-style-type: none"> 4. To remove from Section 6 the special condition ““All organisations party to this agreement must comply with the Data Sharing Framework Contract requirements, including those regarding the use (and purposes of that use) by “Personnel” (as defined within the Data Sharing Framework Contract i.e. employees, agents and contractors of the Data Recipient who may have access to that data)” as this is a duplication referenced in 5b. 5. To remove the fair processing special condition. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.2	<p><u>AHSN Precedent / Template: access to HES / HDIS (Presenter: Helen Buckles)</u></p> <p>Application: This was a template / precedent application from the Academic Health Science Network (AHSN) and did not relate to a specific AHSN. Currently there are 15 AHSN’s in England and each AHSN works within its own region alongside a Sustainable and Transformation Partnership (STP) to respond to health priorities. Hosted AHSN’s (hosted by another organisation i.e. a Trust) will be requesting either pseudonymised non-sensitive HDIS access for one year or Hospital Episodes Statistics (HES) extract data access for 3 years.</p> <p>NHS Digital noted a previous AHSN application had been presented to IGARD on the 15 March 2018 they were seeking advice to establish a precedent whereby IGARD did not need to review additional applications from AHSN’s unless they have a show stopper (i.e. breached), they are a hosted organisation, commercial exploitation is included as a purpose which would not apply if commercial use aim was an additional purpose by the AHSN.</p> <p>Discussion: IGARD welcomed the template application but noted that NHS Digital should include within the abstract the applicant’s legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9 and suggested that a clear justification for each choice indicated 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.</p> <p>It was also suggested that section 5 of the template be revised to clearly state the legal basis for each example given for the hosted AHSN’s. NHS Digital noted that the template presented would form a precedent for AHSN’s to access data via HES or HDIS and were seeking clarification and principals to be set, however IGARD noted that examples given in section 5 were generic and that more information should be provided including the legal basis for each one given.</p> <p>IGARD noted the new fair processing notice requirements and that new standard wording for use with pseudonymised data be used within the fair processing section: “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 within a reasonable period after obtaining the personal data, but at the latest within one month.”</p> <p>IGARD noted that the template still included reference to ‘non-sensitive’ and that the application be updated.</p> <p>NHS Digital stated that a number of applicants were waiting for the precedent template application to be approved, however IGARD suggested that these applicants should use the</p>

	<p>current template and submit via IGARD so that comment and general advice could be given on each template application submitted which in turn would aid the development of standards and precedents.</p> <p>IGARD noted that precedent setting applications may be considered as part of the ongoing IGARD transition project and that a number of standards needed to be in place before precedent templates could be agreed at IGARD meetings since precedents are specific examples of activities that display adherence to standards.</p> <p>Outcome: IGARD welcomed the template application for advice and encouraged NHS Digital to bring further live AHSN application to IGARD.</p>
2.3	<p><u>University HDIS Precedent/Template: access to HDIS system to support health related studies at the University of Sheffield School of Health and Related Research (ScHARR) (Presenter: Dave Cronin) NIC-198583-B7H8Q</u></p> <p>Application: This was a template / precedent setting application from the University of Sheffield. Many universities are interested in using Hospital Episode Statistics (HES) data in order to establish feasibility for research or for economic modelling. NHS Digital had been working with the University to set up an agreement for the University to use the HDIS system to provide access to HES data in a controlled way to support Life Sciences Services.</p> <p>NHS Digital were seeking advice to establish a precedent whereby IGARD did not need to review additional applications from universities for HDIS access unless the purposes of HDIS access falls outside the precedent application or they have breached their data sharing agreement (DSA). Each application would only have access to the HDIS system for a maximum period of 3 years.</p> <p>Discussion: IGARD welcomed the template application but noted that NHS Digital should include within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9 and suggested that a clear justification for each choice indicated 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. NHS Digital noted that the template presented would form a precedent for Universities to access HES data and were seeking clarification and principals to be set, however IGARD noted that examples given in section 5 were generic and that more information should be provided including the legal basis for each example given.</p> <p>IGARD noted the new fair processing notice requirements and that new standard wording for use with pseudonymised data be used within the fair processing section: "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 within a reasonable period after obtaining the personal data, but at the latest within one month."</p> <p>IGARD suggested that minimum standards be established for the governance structure aspect of the precedent template application and as noted previously on these types of applications and this be included in section 5 of the template.</p> <p>It was also suggested that the precedent template application be updated to include standard wording with regard to what is considered a commercial activity and what is not, and that they are allowed under the economic model. IGARD noted that universities have a range of activities and that not all fall under public task under public interest as some universities may have commercial underpinning i.e. product testing, economic modelling and that a generic general commercial statement was not accurate.</p>

	<p>NHS Digital noted that a number of applicants were waiting for the precedent template application to be approved, however IGARD suggested that these applicants should use the current template and submit via IGARD so that comment and general advice could be given on each template application submitted, which in turn would aid the development of standards and precedents.</p> <p>IGARD noted that precedent setting applications may be considered as part of the ongoing IGARD transition project and that a number of standards needed to be in place before precedent templates could be agreed at IGARD meetings since precedents are specific examples of activities that display adherence to standards.</p> <p>Outcome: IGARD welcomed the template application for advice and encouraged NHS Digital to bring a live HDIS University application to IGARD.</p>
2.4	<p><u>Temporary National Repository: An amendment to the consolidated NHSE temporary National Repository (tNR) application to request extensions to existing flows and additional datasets (Presenter: Stuart Richardson) NIC-92346-T4Z0F</u></p> <p>Application: This was an amendment application and request for additional data from Improving Access to Psychological Therapies (IAPT) additional payment data, IAPT pilot wave 2, Emergency Care dataset, Children and Young People's Health Service (CYPHs), Community Services Dataset (CDS), Maternity Services Dataset (MSDS), Diagnostic Imaging Dataset (DIDs), and National Hip Fracture Database (NHFD). The application had been presented to IGARD on the 18 October 2017 when it was unable to recommend for approval pending clarification of references to the Master Patient Index, clarifying references to CCG DSA's, clearly explain what data will not be linked and roles or organisations involved, referring to outputs being aggregated with small numbers suppressed and clarification of statements with regard to additional datasets.</p> <p>NHS Digital noted that tNR was now known as the National Commissioning Data Repository (NCDR).</p> <p>NHS Digital noted that 'assuring transformation' data had not been included within the data flow diagram provided.</p> <p>NHS Digital also noted that IAPT wave 1 would be continuing along with IAPT wave 2 and that this was not clearly outlined in the application.</p> <p>NHS Digital also noted that the application included reference to NHS Arden & GEM CSU which was incorrect.</p> <p>NHS Digital noted that DARS IG had confirmed that the legal basis to disseminate the data should also include reference to s261(5)(d).</p> <p>Discussion: IGARD noted that clarification should be sought within section 5 what IAPT wave 1 was continuing alongside IAPT wave 2. IGARD also suggested that all references to NHS Arden and GEM CSU be removed from the application, since they were not part of this application and also noted DARS IG advice to include s261(5)(d) within section 3 of the application as the legal basis to disseminate data. IGARD noted that the data flow diagram should be updated to include the 'assuring transformation' data but also suggested the diagram be updated to include 'IAPT' data flows.</p> <p>IGARD queried why the tNR had moved to a new name that implied permanency and noted the large-scale repositories being held by NCDR and NHS Digital for holding data. NHS Digital noted that the NCDR was still a temporary repository for data and until DSP was in place.</p> <p>IGARD noted the applicant was receiving pseudonymised data which under GDPR was classed as personal data and as such new standard wording for use with pseudonymised data be used:</p>

<p>“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 within a reasonable period after obtaining the personal data, but at the latest within one month.” 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 queried reference to the Health Foundation and suggested that further information be included within section 5 of the application including the role of the Health Foundation within the project.</p> <p>IGARD noted that the special condition listed a number of organisations but suggested that Lima Network Limited be included within this list, since they would be accessing data.</p> <p>IGARD also suggested that repeated text “Physical and mental health are closely linked – people with severe and prolonged mental illness are at risk of dying on average 15 to 20 years earlier than other people – one of the greatest health inequalities in England” as it is duplicated within section 5</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. 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 within a reasonable period after obtaining the personal data, but at the latest within one month.” <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove the ICO web link in the Fair Processing section. 2. To remove the special condition about Fair Processing, since this has been superseded by updated wording in the Fair Processing section. 3. To remove reference to NHS Arden & GEM CSU since they are not part of this application 4. To include the legal basis s261(5(d)) within section 3 and as advised by DARS IG. 5. To clarify within section 5 that the IAPT wave 1 would be continuing along with IAPT wave 2. 6. To amend the data flow diagram to include reference to ‘assuring transformation’ and ‘IAPT’ data. 7. To amend the special condition listing Lima Networks Limited who would be accessing the data. 8. To provide further information about the Health Foundation and their role within this project. 9. To remove repeated text “Physical and mental health are closely linked – people with severe and prolonged mental illness are at risk of dying on average 15 to 20 years earlier than other people – one of the greatest health inequalities in England” as it is duplicated within section 5. <p>It was agreed the condition would be approved OOC by IGARD Members</p>

2.5	<p><u>Group of 3 CCG¹s: for the purpose for Commissioning only (Presenter: Stuart Richardson) GA18-CM-AMD</u></p> <p>Application: this was a new application for pseudonymised sensitive Secondary Uses Service (SUS) and Local Provider Flow Data to provide intelligence to support the commissioning of health services and adding NHS Midlands & Lancashire CSU as a data processor. 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 CCG area</p> <p>Discussion: IGARD advised that NHS England should continue to work with CCG's to support their transition to General Data Protection Regulations (GDPR) and noted that due to the public interest and continued running of NHS services the data should continue to flow. IGARD suggested that a time limited special condition of 3 months be included in section 6. The applicant should clearly describe the relevant sections under Article 6 and 9 and GDPR and provide a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met</p> <p>IGARD suggested that the special condition wording within section 6 of the application be removed and suggested that new standard wording for use with pseudonymised data be used within the fair processing section: "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."</p> <p>IGARD suggested that the fair processing special condition wording be removed from the application, since it was not relevant.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To add a special condition to section 6 that within 3 months the application clearly describes the relevant sections under Article 6 and 9 of GDPR and provides a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. 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 within a reasonable period after obtaining the personal data, but at the latest within one month." 3. To remove the fair processing special condition.
2.6	<p><u>North Hampshire CCG: to receive pseudonymised SUS+ data for the purposes of commission using CHKS Limited as data processor (Presenter: James Humphries-Hart) NIC-54781-M2F2K</u></p> <p>Application: this was a new application for the CCG to receive pseudonymised Secondary Uses Service (SUS+) for the purposes of commission using CHKS Limited as an additional data processor. The data is 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 CCG area.</p>

¹ NHS Coventry and Rugby CCG NIC-147835-C8J9S; NHS Warwickshire North CCG NIC-147842-F2B6C; NHS South Warwickshire CCG NIC-147943-C4Q5

	<p>Discussion: IGARD advised that NHS England should continue to work with CCG's to support their transition to General Data Protection Regulations (GDPR) and noted that due to the public interest and continued running of NHS services the data should continue to flow. IGARD suggested that a time limited special condition of 3 months be included in section 6. The applicant should clearly describe the relevant sections under Article 6 and 9 and GDPR and provide a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met</p> <p>IGARD suggested that the special condition wording within section 6 of the application be removed and suggested that new standard wording for use with pseudonymised data be used within the fair processing section: "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."</p> <p>IGARD suggested that further information be included in section 5 of the application of the role of CHKS Limited.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To add a special condition to section 6 that within 3 months the application clearly describes the relevant sections under Article 6 and 9 of GDPR and provides a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. 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 within a reasonable period after obtaining the personal data, but at the latest within one month." 3. To provide further clarity within section 5 of CHKS Ltd and their role.
2.7	<p><u>University of Cambridge: EPIC – European Prospective Investigation into Cancer in Norfolk (Presenter: Louise Dunn) NIC-321968-S4Q6L</u></p> <p>Application: this was an amendment application to receive additional back years of Hospital Episode Statistics (HES) data, going forward monthly MRIS reports and to request Mental Health Minimum Data Sets (MHMDS) to follow up on approximately 30,000 men and women aged 40-79 resident in Norfolk at the time of recruitment. EPIC is a long-standing research project established to examine the relationship between lifestyle, in particular diet and physical activity, biological factors and health outcomes. EPIC is an international ten country collaboration coordinated by the Internal Agency for Research in Cancer in Lyon which is part of the World Health Organisation.</p> <p>NHS Digital noted that article 6 and 9 justification was not included within the application abstract.</p> <p>Discussion: IGARD welcomed the application and supported the work being undertaken by the researchers.</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</p>

<p>to satisfy the relevant tests associated with the legal basis suggested. IGARD noted that the documentation provided, including a copy of the applicant's constitution, was not adequate.</p> <p>IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5b of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement.</p> <p>IGARD queried the cohort sizes outlined in the application and supporting documentation noting that the application requested data on 30,000 individuals, however, the protocol referenced a baseline cohort figure of 25,000. IGARD noted that EPIC was ongoing with the 5th phase of data collection and suggested that clarification be sought on the correct cohort figure and how this corrected cohort figure affected the 5th phase of data collection.</p> <p>IGARD queried if the data being requested was for a list clean to identify new contact details for the 5th phase of data collection and suggested for transparency that clarification be sought and included in section 5 of the application.</p> <p>IGARD noted that a duplicate special condition was included in section 5b and suggested that the special condition in section 6: "All organisations party to this agreement must comply with the Data Sharing Framework Contract requirements, including those regarding the use (and purposes of that use) by "Personnel" (as defined within the Data Sharing Framework Contract i.e. employees, agents and contractors of the Data Recipient who may have access to that data)" be removed.</p> <p>IGARD suggested that the special condition wording within section 6 of the application be removed and suggested that new standard wording for use with pseudonymised data be used within the fair processing section: "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."</p> <p>IGARD also suggested that the special condition wording within section 6 referencing Mental Health Minimum Data Set be included in section 5 of the application.</p> <p>Outcome: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application. 3. To confirm the EPIC cohort size and how the corrected cohort figure affects the 5th phase of data collection. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. 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 within a reasonable period after obtaining the personal data, but at the latest within one month." 2. To remove from Section 6 the special condition "All organisations party to this agreement must comply with the Data Sharing Framework Contract requirements, including those regarding the use (and purposes of that use) by "Personnel" (as defined within the Data

	<p>Sharing Framework Contract i.e. employees, agents and contractors of the Data Recipient who may have access to that data)” as this is a duplication referenced in 5b.</p> <ol style="list-style-type: none"> 3. To remove the special condition about Fair Processing, since this has been superseded by updated wording in the Fair Processing section. 4. To include in section 5 the special condition: Mental Health Minimum data set. 5. To clarify if the data requested is for a list clean to identify new contact details for phase 5 of the project. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.8	<p><u>Monitor: DIDs, IAPT monthly, additional HES/SUS consultant level field, ONS-HES and CMA as a data processor (Presenter: Louise Dunn) NIC-15814-C6W9R</u></p> <p>Application: this was an amendment application from NHS Trust Development Authority (TDA) and Monitor, as data controllers in common, to add to their current agreement Cancer Waiting Time (CWT) data. Previously CWT data was received via an agreement with NHS England, however the route for CWT data is changing with data being received direct from NHS Digital.</p> <p>NHS Digital noted that article 6 and 9 justification was not included within the application abstract.</p> <p>NHS Digital noted that ONS data was still to move to NHS Digital controllership, under the new name of Civil Registrations Data.</p> <p>Discussion: IGARD raised a question with regard to the additional data sets and why for the collection of CWT data the applicant had not used the same process and analysis as undertaken for the collection of PLICS data. IGARD suggested that a clear description for the process of collection and analysis be provided in section 5 of the application.</p> <p>IGARD queried Civil Registrations data and NHS digital confirmed that this was the new name for ONS Mortality data once under NHS Digital controllership. IGARD suggested that this be clearly explained in section 5 of the application. IGARD queried the legal basis for processing of the Civil Registrations data since the relevant legal basis (S42(4)) was not listed and that the legal basis for processing this data be updated within section 3 of the application and before data flowed.</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.</p> <p>IGARD suggested that confirmation be sought who was accessing the data and the level of data accessed for Cancer Waiting Times and that standard wording be included in section 5 with regard to access controls to access the data and that only those staff accessing the data had appropriate agreements in place with NHS Digital. IGARD also queried who could access the flexible analytical tool iView Plus and suggested that it be clearly described in section 5 of the application the type of data and what the data was held by the tool, with appropriate access controls in place.</p> <p>IGARD were not clear of the type or level of data being accessed by both the Data Controller and Data Processors as currently outlined in the abstract and section 5, and suggested that it be clearly outlined in both sections, including what type and level of data the Competitions & Markets Authority were accessing. IGARD also suggested that the Competitions & Markets</p>

Authority be included in the list of organisations outlined in section 5b to ensure they could access the data.

IGARD suggested that the special condition wording within section 6 of the application be removed and suggested that new standard wording for use with pseudonymised data be used within the fair processing section: "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 within a reasonable period after obtaining the personal data, but at the latest within one month."

IGARD suggested that the special condition within section 6 with regard to Mental Health Minimum data sets be included in section 5.

Outcome: recommendation to approve from such time as ONS data has moved to NHS Digital controllership and subject to the following conditions:

1. To clarify the legal basis for the processing of Civil Registrations Data, and before data can flow.
2. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met.
3. To clarify who has access to and the level of data accessed for Cancer Waiting Times including the appropriate controls in place for those staff accessing the data and the agreements in place with NHS Digital.
4. To clarify who has access to the flexible analytical tool iView Plus and clarification of the what data and the type of data held within the tool.
5. To clearly describe why the process for the collection and analysis of PLICS data has not been used in the Cancer Waiting Time data.
6. To clearly describe the type and level of data both the Data Controllers and Data Processors are accessing, including the Competition & Markets Authority.

The following amendments were requested:

1. To clarify within section 5 that ONS Mortality data is being renamed Civil Registrations Data once under NHS Digital controllership.
2. 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 within a reasonable period after obtaining the personal data, but at the latest within one month."
3. To remove the special condition about Fair Processing, since this has been superseded by updated wording in the Fair Processing section.
4. To include in section 5 the special condition: Mental Health Minimum data set.
5. To include the Competition & Markets Authority within the list of organisations outlined within section 5b.

It was agreed the conditions would be approved OOC by IGARD Members

2.9	<p><u>Imperial College London: frequency of follow up for patients with low, intermediate and high risk colorectal adenomas (Presenter: Louise Dunn) NIC-147827-NC2TC</u></p> <p>Application: this was an amendment application to add Nuffield Department of Population Health (University of Oxford) as a data processor and add an additional purpose to the agreement. The Intermediate Adenoma (IA) study was set up in 2006 and run by the Cancer Screening and Prevention Research Group (CSPRG) at Imperial College London. CSPRG has been awarded further funding from National Institute Health Research Health Technology Assessment (NIHR-HTA) to expand the remit of the additional study to investigate the ideal frequency of follow up for patients with adenoma detected at initial investigation using the same databased.</p> <p>NHS Digital noted that article 6 and 9 justification was not included within the application abstract.</p> <p>NHS Digital noted that they had not provided as part of the supporting documentation a copy of the MRP evidence.</p> <p>Discussion: 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.</p> <p>IGARD noted that within the supporting documentation no evidence had been provided for MRP or ARP. NHS Digital noted that all researchers had APR and were listed in section 9 of the application, however IGARD noted that evidence should be provided for both MRP status and ARP current approved researchers.</p> <p>IGARD queried what access staff at the University of Oxford had to the data and suggested that it be explicitly stated in section 5 of the application who was accessing the data and the level of data accessed by the University of Oxford and that standard wording be included in section 5 with regard to access controls to access the data and that only appropriate staff would have access to the data. IGARD also suggested that clarification be sought of the data minimisation efforts undertaken by the applicant with the appropriate controls in place.</p> <p>IGARD suggested that the special condition wording within section 6 of the application be removed and suggested that new standard wording for use with pseudonymised data be used within the fair processing section: "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 within a reasonable period after obtaining the personal data, but at the latest within one month." IGARD also noted that Imperial College London would need to amend their Fair Processing Notice to include reference to the University of Oxford who were processing data as part of this study.</p> <p>IGARD noted that a duplicate special condition was included in section 5b and suggested that the special condition in section 6: "All organisations party to this agreement must comply with the Data Sharing Framework Contract requirements, including those regarding the use (and purposes of that use) by "Personnel" (as defined within the Data Sharing Framework Contract i.e. employees, agents and contractors of the Data Recipient who may have access to that data)" be removed.</p> <p>IGARD noted that the data retention period noted in the application was different to the one outlined in the HRA CAG application form provided, and suggested that the data retention period date be updated so that the data retention period dates aligned.</p>
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<p>IGARD noted that the data flow diagram provided referenced Scotland and that the protocol provided referenced England and Wales with no mention of Scotland. IGARD suggested that since no data was being provided for Wales or Scotland that the references on the data flow diagram be clarified within section 5.</p> <p>IGARD noted that the application stated that ethics approval was not required, however since ethics approval is required for this application that the application be updated with appropriate standard ethics approval wording.</p> <p>IGARD noted a noted a spelling mistake and suggested that 'college' be updated.</p> <p>IGARD suggested that on renewal the application would be expected to provide further dissemination routes for the outputs including relevant patients' groups, in addition to dissemination to researchers and journals.</p> <p>Outcome: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. To provide evidence of the MRP status. 3. To provide APR current approved researcher evidence. 4. To clarify within section 5 what data University of Oxford can access, the data minimisation efforts undertaken and the appropriate controls in place. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. 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 within a reasonable period after obtaining the personal data, but at the latest within one month." 2. To remove the special condition about Fair Processing, since this has been superseded by updated wording in the Fair Processing section. 3. To remove from Section 6 the special condition ""All organisations party to this agreement must comply with the Data Sharing Framework Contract requirements, including those regarding the use (and purposes of that use) by "Personnel" (as defined within the Data Sharing Framework Contract i.e. employees, agents and contractors of the Data Recipient who may have access to that data)" as this is a duplication referenced in 5b. 4. Imperial College London to update their Fair Processing Notice to include reference to University of Oxford who are processing data as part of this study. 5. To clarify within section 5 references in the data flow diagram to Scotland or Wales. 6. To update the data retention period within the application to align with the HRA CAG application form. 7. A typo within section 5b referring to 'collage' be updated to correctly reference 'college'. 8. To include the standard ethics approval wording within the application. <p>The following advice was given:</p>

	<p>1. IGARD advised that on renewal, IGARD would expect the applicant to provide further dissemination routes for the outputs including relevant patient groups.</p> <p>It was agreed the conditions would be approved OOC by the IGARD Members</p>
<p>2.10</p>	<p><u>Leeds Teaching Hospitals: impact of ethnicity on outcomes of living kidney donors and risk predictions models: UK national cohort study (Presenter: Rachel Farrand) NIC-183621-W0V7W</u></p> <p>Application: this was a new application for a one-off extract of pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) data from 1997/98 to 2016/17 along with the latest available for 2017/18 for a research study into the long-term outcome of Living Donor Kidney Transplantation (LDKT) in the UK.</p> <p>NHS Digital noted that article 6 and 9 justification was not included within the application abstract.</p> <p>Discussion: IGARD welcomed the application and noted the valuable work being undertaken.</p> <p>IGARD were unclear of the relationship between NHS Digital, University of Manchester and University of Leeds outlined in the application. NHS Digital noted that the PhD student worked for the NHS Digital but was undertaking their master's degree at University of Manchester. IGARD suggested that it be clarified why the University of Manchester and NHS Digital were not listed as joint Data Controllers along with the University of Leeds, even though the University of Leeds was instigating the work being undertaken.</p> <p>IGARD were also unclear who was accessing the data and where they were based, noting reference to collaboration teams and clinical team in Leeds, Birmingham and Leicester. IGARD suggested that it be explicitly stated in section 5 who was accessing the data, the level of data being accessed, where they were based and that appropriate access controls to access the data were in place. IGARD also queried who the Clinician Team were and how the University of Manchester was involved, including the PhD student referenced in the application and suggested that it be clarified in section 5 of the application. It was also suggested that it be explicitly stated in section 5 that collaborating clinicians from Leeds, Birmingham, Cardiff and Leicester would not have access to the data outlined in this application, since it was also noted in the application that no data would be accessed outside of England.</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.</p> <p>IGARD suggested that the special condition wording within section 6 of the application be removed and suggested that new standard wording for use with pseudonymised data be used within the fair processing section: "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 within a reasonable period after obtaining the personal data, but at the latest within one month."</p> <p>IGARD noted that in the protocol provided that the study was looking at pregnancy outcomes including gestation period and asked about the birth rate and queried if this was via the mother's or child's record. IGARD suggested that it be clear within section 5 why pregnancy data had been requested and that it explicitly state that this also included the baby's data. IGARD also noted that sensitive psychiatric history data was being requested and because no ethics approval was in place, asked that justification be provided as to why this data was being requested and what this data was being used for in the analysis. NHS Digital noted that the</p>

	<p>applicant had completed the online tool for REC approval and that had suggested that ethics approval was not required, IGARD suggested that NHS Digital work with the applicant to review the answers given, specifically in relation to the application stating 'no' to question set 2, questions 1 and 2, concerning recruitment based on use of NHS service.</p> <p>Outcome: recommendation to deferred pending:</p> <ol style="list-style-type: none"> 1. Clarifying why the University of Manchester and NHS Digital are not listed as a joint Data Controllers 2. Section 5 of the application should be updated to be explicit about who is accessing data, where they are based, the appropriate security measures in place, who the Clinician Team are and how the University of Manchester are involved, including the PhD student. 3. Confirmation within section 5 of the application that the collaborating clinicians from Leeds, Birmingham, Cardiff and Leicester will not access data. 4. Clarification within section 5 why data on pregnancy outcomes have been requested and to clarify if that also includes the baby's data. 5. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 6. Justification for the request of psychiatric history data and how it will be used in the analysis. 7. To review the answers given via the online ethics tool, specifically why the applicant responded 'no' to question set 2 (questions 1 and 2) concerning recruitment based on use of NHS service. 8. 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 within a reasonable period after obtaining the personal data, but at the latest within one month." 9. To remove the special condition about Fair Processing, since this has been superseded by updated wording in the Fair Processing section. 10. To include the standard ethics approval wording within the application, as may be appropriate.
3	<p>AOB</p> <p>None</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> <p>19/04/18: IGARD chair to update members at May's education session.</p> <p>03/05/18: The Chair of IGARD noted that he would be contacting key stakeholders over the coming weeks.</p> <p>24/05/18: ongoing</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</p>	Open

			<p>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>05/04/18: IGARD Secretariat had contacted Garry Colman and were awaiting a response.</p> <p>24/05/18: 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>24/05/18: ongoing</p>	Open
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.	Gaynor Dalton	<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>26/04/18: IGARD secretariat were awaiting a response following issue of a reminder</p>	Open

			<p>03/05/18: It was noted the issue was wider than DSfC applications and applies to all DARS applications, the action owner was amended to the Head of Data Access, Gaynor Dalton.</p> <p>10/05/18: The Director Data Dissemination noted that a briefing note would be provided to IGARD for the 24 May meeting.</p> <p>24/05/18: it was noted that a briefing note had not been provided to IGARD.</p>	
12/04/18	<p>IGARD Members to consider the HRA guidance on GDPR published on line</p> <p>IGARD Chair to provide feedback to the Caldicott Guardian</p>	<p>IGARD</p> <p>IGARD Chair</p>	<p>19/04/18: IGARD members had considered the HRA guidance and asked the IGARD Chair to provide feedback to the Caldicott Guardian.</p> <p>26/04/18: IGARD Secretariat awaiting comment following issue of a reminder.</p> <p>03/05/18: the Chair of IGARD to provide a copy of the email sent to the Caldicott Guardian to the Secretariat team</p> <p>24/05/18: ongoing</p>	Open
26/04/18	<p>Stuart Richardson to complete, for transparency, on all future CCG applications the data already held information at section 3a, including such data as may be held under a different Data Sharing Agreement / NIC number.</p>	<p>Stuart Richardson</p>	<p>24/05/18: ongoing</p>	Open
26/04/18	<p>Stuart Richardson to provide for all future CCG applications a data flow diagram detailing all previously approved data flows alongside a new data flow diagram outlining the data flows for the presented application.</p>	<p>Stuart Richardson</p>	<p>24/05/18: ongoing</p>	Open

Appendix B: Out of committee report

Independent Group Advising on Releases of Data (IGARD): Out of committee report 18/0518

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-41188-J4C7J	Herefordshire Council	26/04/18	<ol style="list-style-type: none">1. A clearer explanation be included within the abstract and Section 5 that the Local Authority was only accessing their own data.2. To remove erroneous paragraphs in the abstract and provide a clearer explanation, for transparency, of the decision-making process undertaken to determine whether or not to apply Type 2 Opt Outs.	IGARD Members	Quorum of IGARD Members	N/A
NIC-148406-2YXPR	London North West Healthcare NHS Trust	22/02/18	<ol style="list-style-type: none">1. To provide substantive details in the yielded benefits section 5d(iii), including examples of public / patient engagement.2. To clarify in section 5 of the application that the legal basis for the dissemination of the ONS data is section 42(4) where the applicant is a	IGARD Members	Quorum of IGARD Members	To note that condition 1 has been amended and noted in the 17/05/18 minutes to read:

			<p>type of organisation listed in the section and to remove references to a 'commissioning letter'.</p> <p>3. To add a special condition that the Honorary Consultant Physician will enter in to a new honorary contract with the LNWHNT, which will include a clause that the substantive employer of the person under the honorary contract will take appropriate action in the event of a breach and that the honorary contract will need to be in place and a copy be provided to NHS Digital when Imperial College London (the substantive employer) ceases to be a data processor named in the Agreement.</p> <ul style="list-style-type: none"> • To provide clear justification for the retention period of 2028 and to remove the last two sentences of Section 8a. 			<p><i>A special condition be inserted: upon renewal or amendment there should be a fuller description of patient/public involvement in the running of the study and dissemination of the outputs</i></p>
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In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None notified to IGARD