

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 28 June 2018

Members: Sarah Baalham, Joanne Bailey, Nicola Fear (items 2.1 – 2.4), Jon Fistein, Kirsty Irvine (Chair).

In attendance: Helen Buckles, Garry Coleman, Dave Cronin, Louise Dunn, Arjun Dhillon, Dickie Langley, Karen Myers, Dave Roberts, James Smith, Kimberley Watson, Vicki Williams.

Apologies: Anomika Bedi, Chris Carrigan, Eve Sariyannidou

1	<p>Declaration of interests</p> <p>Joanne Bailey noted a personal link to the commissioning work being undertaken (i5 Health NIC-14709-Z2H2R) but noted no specific connection with the application or staff involved.</p> <p>Jon Fistein noted a professional link to Public Health England (NIC-201243-R7L2M) 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 21 June 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting.</p> <p>The minutes of the 21 June 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 meeting.</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>University of Oxford: Patient outcomes and NHS costs following primary hip and knee replacement surgery (Presenter: Dave Cronin) NIC-172121-G0Z1H</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Patient Reported Outcome Measures (PROMS) data. The data would be reused for two additional projects that were not within the scope of the previous Agreement. The UTMoSt Study will compare risk-benefit and costs of unicompartmental (compared to total) knee replacement for patients with multiple co-morbidities: a non-randomised study, and different novel approaches to minimise confounding. In the second project, the UK SAFE Study, follow-up care is provided to ensure that problems with replaced joints are identified as early as possible before serious damage occurs.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the work being undertaken.</p> <p>IGARD noted that the role of the University of Leeds was not clear within the application and suggested that the application summary and section 5 be updated to clarify the role of the University of Leeds and what data they may have access to.</p> <p>It was also suggested the applicant's privacy notice should be updated to reference the University of Leeds and their processing of data, as may be appropriate, and IGARD suggested that the fair processing notice be written in a language suitable for a lay audience and the intended audience, since it currently contained information more suited to the research</p>

	<p>community. IGARD also noted that the website link provided in the application was broken and suggested that it be updated.</p> <p>IGARD noted that the application stated that ethics approval was not required, however since ethics approval is in fact required for this application that the application be updated with appropriate standard ethics approval wording within section 7 of the application.</p> <p>IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested and as per recent discussions between NHS Digital and IGARD. .</p> <p>IGARD also suggested that NHS Digital consult with the IG Advisor to IGARD to ensure reference and supporting statements relating to Article 5(1)(b) GDPR (Purpose Limitation Principle) be updated within the abstract. The revision to the abstract should also include reference to the public interest condition under the DPA 2018</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018. 2. To further amend the abstract in consultation with the IG Advisor to IGARD to ensure the appropriate reference and supporting statements relating to Article 5(1)(b) GDPR (Purpose Limitation Principle). 3. Section 5 (and the abstract) of the application should be updated to clarify the role and involvement of the University of Leeds and any data they may have access to, as well as updating the Fair Processing Notice to reference the University of Leeds and their processing of data, as may be appropriate. 4. To include the standard ethics approval wording within the application. <p>The following advice was given</p> <ol style="list-style-type: none"> 1. IGARD suggested the applicant review their fair processing notice and website in a language suitable for the lay reader and intended audience.
2.2	<p><u>The Brain Tumour Charity (TBTC): BRIAN (Brain Tumour Information and Analysis Network) is an online information system that will enable patients to make better-informed decisions about their treatment and accelerate research to find a cure. (Presenters: Helen Buckles / Garry Coleman) NIC-158754-R5T3V</u></p> <p>Application: This was a new application requesting pseudonymised Hospital Episode Statistics (HES) Outpatients (OP), HES Accident and Emergency (A&E), HES Admitted Patient Care (APC) and HES Critical Care (CC) data. The aim of TBTC is to establish a research database, BRIAN, which can be used to facilitate research from third parties with suitable permissions, and to enable cohort data to be included. Only anonymous data (for example, organisational level data or lookup tables for ICD10 codes) will be linked to the HES data.</p> <p>NHS Digital noted that the legal basis under General Data Protection Regulations (GDPR) was still to be finalised.</p>

Discussion: IGARD welcomed the application and noted the importance and value of the work being undertaken.

IGARD noted that NHS Digital had not included 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 be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested and as per recent discussions between NHS Digital and IGARD. IGARD also suggested that it be also be clearly outlined at the start of section 5a the legitimate interest relied upon as related to the purpose of the research.

IGARD noted that special condition 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" be deleted since section 4 of the fair processing notice included this text and new special condition wording: "One month after the dissemination of the data, NHS Digital will check and record confirmation that that the applicant has published a privacy notice that is compliant with the GDPR notice requirements" be inserted.

IGARD noted that the purpose of the current application could be clearer and suggested that section 5 be reordered to clearly describe the current purpose, rather than any intended future purposes, which should also link to the applicant's legitimate interest basis for processing. IGARD noted the summary will be initially commissioned by the charity however it was suggested that the abstract remove reference to 'research commissioned by charity' since it was not part of this agreement or application.

IGARD also noted that the sentence within section 5a "all outputs **received** will be aggregated data with small numbers suppressed" be amended to "all outputs **produced** by the applicant will be aggregated data with small numbers suppressed" along with deleting the duplicate sentence at the end of the same paragraph.

IGARD noted the inclusion of IT infrastructure organisations however it was not clear within section 5 their roles and responsibilities including any access to data, who owned the servers the data was held on and who maintained the software. It was also suggested that it be clear within section 5 that no employees of Bluecube Technology Solutions Ltd will access to any data. It was also noted that Pulsant was listed as a storage location and stated their view that it may be more appropriate to also list this organisation as an additional data processor. 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

IGARD noted the typo within the abstract and suggested that the legal basis be updated to s261(9)(2)(b). Section 5a should also be updated to correct the typo referencing linkage to clearly state that it will **not** increase the likelihood of reidentification.

IGARD noted that the utility of the database needed to be clearly established to justify the number of data years requested.. IGARD discussed with NHS Digital the suggestion that the length of the Data Sharing Agreement be limited to 12 months in order for the applicant to establish the processes around the use of the database and embed the proposed governance processes. IGARD suggested that, upon renewal, the applicant should clearly outline the roles of the Advisory Board and Data Management Board, the relationship between the two Boards, the terms of reference governing both Boards and any additional governance process in place.

IGARD noted that data was “primarily sourced from NHS Digital” but it was not clear within section 5 if this was the only data being utilised by the applicant and that any additional data being used should be clearly explained within the application

Outcome: recommendation to approve subject to the following condition:

1. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, and the advice of the IG Adviser to IGARD, including (but not limited to) the GDPR legitimate interests requirements.

The following amendments were requested:

1. The special condition 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.” to be deleted (as superseded by wording in section 4 of the DSA) and replaced with a new special condition “Within one month of receiving the data from NHS Digital, the University of Sheffield must provide evidence to NHS Digital that a privacy notice has been published (or otherwise made available), in compliance with the GDPR notice requirements”
2. To provide clear justification for the number of data years requested and as required for the utility of the database.
3. To amend section 5 of the application to clearly describe the purpose at hand (rather than any future intended projects) and link such purpose to the applicant’s relevant legitimate interests basis for processing.
4. To amend the sentence in section 5a “all outputs **received** will be aggregated data with small numbers suppressed” to “all outputs **produced** by the applicant will be aggregated data with small numbers suppressed’, and remove the duplicate sentence at the end of the paragraph.
5. Giving a clear explanation within section 5 of the application the roles and responsibilities of the IT infrastructure outlined within the application, including any access to data, who owns the server, who maintains the software and confirming that no employees of Bluecube Technology Solutions Ltd will have any access to data.
6. To clarify reference to ‘data primarily sourced from NHS Digital’ and explain any additional sources of data.
7. To update the abstract to remove reference to the “research commissioned by the charity” since this is not part of this application or agreement.
8. To amend section 5a so the reference to linkage reads “**not**” increasing the likelihood of reidentification.
9. The DSA end date be changed to 12 months.

The following advice was given:

1. IGARD suggested at renewal that the application should clearly outline roles of the Advisory Board and Data Management Board, the relationship between the two entities, the terms of reference governing the boards and any additional governance processes in place.

It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority

Application: This was a renewal application requesting an additional year of pseudo Hospital Episode Statistics (HES) and Secondary Uses Service (SUS) data as well as the final 2016-17 M13 HES data. i5 Health evaluates the economic impact of Non-Medical Prescribing (NMP), the prescribing of drugs by health practitioners other than Doctors. i5 Health analyses relevant activity data to identify utilisation of NMP practitioners in various healthcare settings, to enable them to measure the impact NMP has, or, if introduced more widely, will have on different health economies.

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 and as per recent discussions between NHS Digital and IGARD, including reference to the public interest condition under DPA 2018.

IGARD requested that special condition 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" be deleted since section 4 of the fair processing notice included this text and new special condition wording: "One month after the dissemination of the data, NHS Digital will check and record confirmation that that the applicant has published a privacy notice that is compliant with the GDPR notice requirements" be inserted.

It was noted that since i5 Health were listed as a commercial organisation, that for transparency, section 5e be updated to include a brief summary of the nature of their commercial activities.

IGARD noted that the LIA undertaken by the applicant be assessed by NHS Digital and confirmation be included in the abstract or a supporting document that they have deemed it satisfactorily.

IGARD noted that the applicant was requesting more years for the data already disseminated and suggested that section 5 be updated to clearly explain the data minimisation efforts undertaken with the appropriate controls in place.

Outcome: recommendation to approve

The following amendments were requested:

1. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD.
2. The special condition 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." to be deleted (as superseded by wording in section 4 of the DSA) and replaced with a new special condition "Within one month of receiving the data from NHS Digital, the University of Sheffield must provide evidence to NHS Digital that a privacy notice has been published (or otherwise made available), in compliance with the GDPR notice requirements"

	<ol style="list-style-type: none"> 3. Confirmation in the abstract or a supporting document that NHS Digital have assessed the LIA and deemed it satisfactory. 4. To include within section 5e the nature of i5's commercial business model, for transparency. 5. To explain within section 5 the data minimisation efforts undertaken by the applicant and the appropriate controls in place.
2.4	<p><u>University College London: British Regional Heart Study (BRHS) - data linkage of established cohort to NHS Digital datasets (HES, MHMDS, DIDS) (Presenter: Kimberley Watson / Louise Dunn) NIC-28591-H5Q3X</u></p> <p>Application: This was a new application requesting pseudonymised Hospital Episode Statistics (HES) Outpatient (OP), HES Accident & Emergency (A&E), HES Critical Care (CC), HES Admitted Patient Care (APC), Mental Health Minimum Data Set, Diagnostic Imaging Dataset (DIDs) data and Bridge Files. The BRHS is a cohort study of cardiovascular disease (CVD) and other common chronic diseases and comprises of men aged 75-94 who joined the study in 1978. The additional data requested will be used to inform and develop a larger programme of research on the prevention of CVD, heart failure and CVD related ageing conditions including dementia, frailty, physical disability.</p> <p>NHS Digital noted that a number of supporting documents had been provided that were not relevant to this application.</p> <p>Discussion: IGARD noted that the men within this study were not informed via the study material of the continued mortality or morbidity follow up and that as it is important that studies ensure participants are fully informed, it was suggested the privacy notice could be used as a way to address the reasonable expectations of study participants.</p> <p>IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested and as per recent discussions between NHS Digital and IGARD, including reference to the public interest condition under DPA 2018. IGARD also suggested that the abstract should clearly signpost the legal basis for each element of the application and removing reference to legitimate interest, since it was not relevant within this application.</p> <p>IGARD noted that the data linkage was adequately addressed in section 5 and that this be included within the abstract.</p> <p>IGARD noted that a number of points had been raised following assessment of the applicant's fair processing notice by NHS Digital and that the applicant was currently updating their privacy notice before publishing to their website. It suggested that NHS Digital diarise that within one month of the dissemination of data, NHS Digital check the applicant has met their obligation under General Data Protection Regulations (GDPR) to update their privacy notice.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To clarify within the abstract the data linkage outlined in section 5. 2. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018.

	<ol style="list-style-type: none"> 3. To update the abstract to clearly signpost the legal basis for each element of the application (including relabelling the heading “BHRS Consent”) and removing reference to legitimate interests. 4. To remove the supporting documents from the on line holder not relevant to this application or agreement and to update the abstract to link the ‘appendices’ referenced to supporting document 1.1. <p>The following advice was given</p> <ol style="list-style-type: none"> 1. IGARD suggested that NHS Digital check within one month of the data being disseminated that the applicant has met their obligation under GDPR to update their privacy notice.
2.5	<p><u>RAND Europe: Outcome evaluation of Offender Liaison and Diversion (L&D) Trial Schemes (Presenter: Louise Dunn) NIC-66034-M7B8W</u></p> <p>Application: This was a new application requesting bespoke linkage of Hospital Episodes Statistics (HES), Accident and Emergency (A&E), Mental Health Minimum Data Sets (MHMDS) and Improving Access to Psychological Therapies (IAPT) data set to a cohort of service users. The application had been previously considered on the 7 June 2018 when IGARD had deferred making a recommendation pending: confirmation if recruitment to the study had closed; if recruitment had closed to clarify the legal basis to receive and process data; to update wording throughout the application what had happened prior to the 25th May; and update the explanation of the datasets outlined in section 5.</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 and as per recent discussions between NHS Digital and IGARD, including reference to the public interest condition under DPA2018.</p> <p>IGARD noted that supporting document 11 (Rand Europe LD website privacy notice) provided with the application referenced the University of Warwick and ARCS Ltd and suggested that section 5 be updated to clearly outline the roles and responsibilities of the two organisations including any access to the data.</p> <p>IGARD also noted within supporting document 11 that ‘public task’ was referenced and suggested that this be removed, since it was not relevant to the application.</p> <p>IGARD noted that the consent material provided for consideration with this application did not mention that the cohort could withdraw from the study or how to withdraw from the study, and given the profile of the cohort and that they are not likely to access the patient information leaflet or privacy noticed, had noted HRA CAG’s decision.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018. 2. Supporting document 11 ‘Rand Europe LD website Privacy Notice’ be updated to remove reference to ‘public task’.

	<p>3. Giving a clear explanation within section 5 the roles and responsibilities of University of Warwick and ARCS Ltd as outlined within supporting 11, including any access to data.</p>
2.6	<p><u>University of Sheffield: Survival outcomes and HES-based Charlson Comorbidity Scores for women recruited to the Bridging the Age Gap in Breast Cancer study (Presenter: Dickie Langley) NIC-94749-Y1R8N</u></p> <p>Application: This was a new application requesting Hospital Episodes Statistics (HES) Admitted Patient Care (APC) and Medical Research Information Service (MRIS) data.</p> <p>The Bridging the Age Gap in Breast Cancer study is a multicentre cohort study collecting prospective data on older women with breast cancer from multiple UK sites. The study, which commenced in January 2013, is using statistical and modelling techniques to determine the age, comorbidity, frailty and disease characteristics of women over 70 with early breast cancer to provide guidance on 2 primary questions.</p> <p>NHS Digital noted this was a NIHR funded application however section 5 was not a direct copy of the NIHR application summary.</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 noted that Civil Registrations data was the new name for ONS Mortality data once under NHS Digital controllership. 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 and as per recent discussions between NHS Digital and IGARD, including reference to the public interest condition under DPA 2018 and research purpose limitation Article 5(1)(b).</p> <p>IGARD noted that the abstract wording referencing common law duty of confidentiality and consent be updated and that the data flow diagram provided with the application remove reference to consent as the legal basis</p> <p>IGARD requested that the special condition 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" be deleted since section 4 of the application now included this text. IGARD and NHS Digital agreed that new special condition wording: "One month after the dissemination of the data, NHS Digital will check and record confirmation that the applicant has published a privacy notice that is compliant with the GDPR notice requirements" would be inserted.</p> <p>IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that it be updated to include the name of the Data Controller, level and type of data processed and how participants can withdraw from the study.</p> <p>IGARD noted that the applicant would be sending out another newsletter to participants in 2019 and suggested that supporting document 4.1 (Patient information sheet version 1 20-10-</p>

	<p>2012) be updated that withdrawing or opting out of the study will not affect the care received or any future care. It was also suggested that the updated privacy notice be disseminated with the next iteration of the newsletter and that it be written in a language suitable for the lay reader. IGARD also suggested that the applicant may wish to consider the audience of their newsletter and include information relevant to the participant.</p> <p>Outcome: The application was recommended for approval from such time as ONS data has moved to NHS Digital controllership and subject to the following condition</p> <ol style="list-style-type: none"> 1. To clarify the legal basis for the processing of Civil Registrations Data, and before data can flow. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018 and research purpose limitation Article 5(1)(b). 2. To update the abstract to amend references to consent and common law duty of confidentiality. 3. The data flow diagram to be updated to remove reference to consent as the legal basis. 4. The special condition 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." to be deleted (as superseded by wording in section 4 of the DSA) and replaced with a new special condition "Within one month of receiving the data from NHS Digital, the University of Sheffield must provide evidence to NHS Digital that a privacy notice has been published (or otherwise made available), in compliance with the GDPR notice requirements" 5. The applicant update their Fair Processing Notice to meet the NHS Digital's fair processing criteria for privacy notices including the name of the Data Controller, level and type of data processed and how participants can withdraw from the study. 6. Supporting document 4.1 'Patient information sheet version 1 20-10-2012' be updated that withdrawing or opting out of the study will not affect the care received or any future care. <p>The following advice was given</p> <ol style="list-style-type: none"> 1. IGARD suggested that the updated Privacy Notice be disseminated to participants with the next iteration of the newsletter and that it be written language suitable for the lay reader
2.7	<p><u>Changes to Data Minimisation Controls Briefing Paper (Presenter: Dickie Langley)</u></p> <p>The briefing note was previously presented to IGARD on the 21st June and noted that currently, Data Access Requests for commissioning data, including both pseudonymised (general commissioning) and identifiable (Risk Stratification and Invoice Validation) have data minimisation controls attached which state: "CCG of residence and registration for the CCG".</p> <p>IGARD noted the contents of the briefing note and suggested that the Deputy Caldicott Guardian review the briefing note and provide comments back to NHS Digital DARS team.</p>

2.8	<p><u>NHS Health Check Briefing Note (Presenter: Dave Roberts / James Smith)</u></p> <p>The briefing note was to inform of a request from Public Health England (PHE) to share general practice data on the NHS Health Check for adults aged 40-74 years (referred hereafter to as the 'NHS Health Check'). The data have not previously been collected by NHS Digital, however in June 2018 NHS Digital will extract data for the NHS Health Check and will be a one off retrospective collection of data for the period 1 April 2009 – 31 March 2018.</p> <p>IGARD noted the contents of the briefing note and welcomed the approach undertaken.</p>
2.9	<p><u>Public Health England (PHE): NHS Health Checks data (Presenter: Dave Roberts / James Smith) NIC-201243-R7L2M</u></p> <p>Application: This was a new application requesting a one-off pseudonymised dataset extract for the period 01/04/2009 - 31/03/2018 for the purpose of PHE to undertake vital programme monitoring to allow the agency and wider system to understand the benefits of NHS Health Checks for patients and establish whether the programme provides value for money for health and care economy.</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 and as per recent discussions between NHS Digital and IGARD, including to 'no less intrusive to the data subject' wording under Article 9(2)(h).</p> <p>IGARD noted that schedule 1 part 1 had been referenced within the abstract, however suggested that NHS Digital work with the IG Advisor to IGARD to correctly list the DPA 2018 schedule 1 Part 1 references against each of the Article 9 legal basis cited and clearly describe how the schedule conditions are met. It was also suggested that the abstract of the application be updated to link the purpose of the data disseminated to PHE's statutory functions and that section 5 be amended to clearly describe the cohort and health check data, since this was published.</p> <p>IGARD noted that the IG Advisor to IGARD had noted that the legal basis table in the application was incorrect and be updated to correctly list the legal basis s261(5)(d) for disseminating data.</p> <p>IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 be updated to clearly state that the application privacy notice 'does not' meet the criteria.</p> <p>IGARD noted the large number of processing locations outlined in the application and although appreciated PHE was a large organisation asked if NHS Digital's security advisor was content. It was suggested that the security advisor provide contentment to the remote access arrangements in place and that data could not be downloaded in any other location other than those outlined in the storage section of the application.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including (but not limited to) reference to 'no less intrusive to the data subject' wording under Article 9(2)(h).

	<ol style="list-style-type: none"> 2. NHS Digital work with the IG Advisor to IGARD to correctly list the DPA 2018 schedule 1 Part 1 references against each of the Article 9 legal basis cited and clearly describe how the schedule conditions are met. 3. The abstract be updated to link the purpose of the data dissemination with PHE's statutory functions. 4. The Legal basis table be updated to correctly list the legal basis s261(5)(d), as advised by the IG Advisor to IGARD. 5. To clearly the describe the cohort and health check data outlined in section 5b. 6. To update section 4 to clearly stated the applicant's fair processing notice 'does not' meet the NHS Digital's fair processing criteria for privacy notices 7. To confirm within section 5 that NHS Digital security advisor has confirmed they are content with regard the remote access arrangements in place and that data was not being downloaded in any other location than those outlined in the storage section of the application.
2.8	<p>AOB</p> <p><u>National Data Opt Out</u></p> <p>IGARD asked when the National Data Opt Outs will be upheld by NHS Digital and it was suggested that NHS Digital provide a briefing note, for consideration by IGARD and before they are upheld</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>28/06/18: The Deputy Caldicott Guardian had requested an update to the progress of the annual report from Chris Carrigan, the author of the report.</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	Garry Coleman	10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.	Open

	data processor in light of data sharing breaches and recent audits.		<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>05/04/18: IGARD Secretariat had contacted Garry Colman and were awaiting a response.</p> <p>28/06/18: IGARD Secretariat had contacted Garry Colman to provide an update and were awaiting a response.</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>28/06/18: IGARD Secretariat had contacted Garry Colman to provide an update and were awaiting a response.</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.	Garry Coleman	<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>	Open

			<p>26/04/18: IGARD secretariat were awaiting a response following issue of a reminder</p> <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> <p>28/06/18: IGARD Secretariat had contacted Garry Colman to provide an update and progress made in providing IGARD with a briefing note.</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>21/06/18: IGARD Secretariat have chased the Chair for a copy of the email.</p> <p>28/06/18: IGARD Secretariat had contacted Chris Carrigan for a copy of the email in order to disseminate to IGARD Members for information.</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</p>	<p>Stuart Richardson</p>	<p>28/06/18: IGARD noted that section 3a was being completed as requested and it was agreed this was being undertaken and the action should be close</p>	Closed

	may be held under a different Data Sharing Agreement / NIC number.			
26/04/18	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.	Stuart Richardson	28/06/18: IGARD noted that data flow diagrams were being provided as requested and it was agreed this was being undertaken and the action should be closed.	Closed
14/06/18	Chair of IGARD to contact the Deputy Caldicott Guardian requesting NHS Digital engage with CPRD with regard to measures in place to engage with participating General Practices so that both GP's and CPRD meet with obligations as Data Controllers under GDPR.	Kirsty Irvine / Arjun Dhillon	28/06/18: The Interim IGARD Chair had written to the Deputy Caldicott Guardian and was awaiting a response. It was agreed that an action be raised for the Deputy Caldicott Guardian and that this action be closed.	Closed
28/06/18	IGARD asked when the National Data Opt Outs will be upheld by NHS Digital and it was suggested that NHS Digital provide a briefing note, for consideration by IGARD and before they are upheld	Arjun Dhillon / Tim Magor		Open
28/06/18	The Deputy Caldicott Guardian to provide an update of the engagement which had taken place with CPRD with regard to measures in place to engage with participating General Practices so that both GP's and CPRD meet with obligations as Data Controllers under GDPR.	Arjun Dhillon		Open

Independent Group Advising on Releases of Data (IGARD): Out of committee report 22/06/18

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-321968-S4Q6L	University of Cambridge	24/05/18	<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. 	IGARD Members	Quorum of IGARD Members	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