Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 25 April 2019

Members: Joanne Bailey, Maria Clark, Kirsty Irvine (Chair), Geoffrey Schrecker, Maurice Smith.

In attendance: Stuart Blake, Dave Cronin, Louise Dunn, James Humphries-Hart, Karen Myers, Vicki Williams.

Apologies: Sarah Baalham, Anomika Bedi, Nicola Fear, Priscilla McGuire, Eve Sariyiannidou.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 11th April 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>NHS England (Quarry House): NHS England - DSfC - NCDR amendment 2019 (Presenter: James Humphries-Hart) NIC-139035-X4B7K</u> **Application:** This was an amendment application to add four new data products, Civil Registrations, Cancer Waiting Times DataSet (CWT), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs); and a renewal application for pseudonymised Children and Young People's Health Services (CYPHS), Secondary Use Service (SUS), Local Provider Flows, Community Services Data Set (CSDS), Mental Health Learning Disability Data Set (MHLDDS), Diagnostic Imaging Data Set (DIDs), Improving Access to Psychological Therapies (IAPT), Mental Health Minimum Data Set (MHMDS), Maternity Services Data Set (MSDS), Civil Registration, Mental Health Services Data Set (MHSDS), Cancer Waiting Times (CWT), National Diabetes Audit (NDA), Community Services Data Set (CSDS), Assuring Transformation (AT), Patient Reported Outcome Measures (PROMs) and Improving Access to Psychological Therapies (IAPT). The requested datasets are required to ensure that NHS England can meet its statutory duties (as per NHS Act 2006 and the Health and Social Care Act 2012) and to meet the requirements of the Five Year Forward View. **Discussion:** IGARD noted NHS England's request for CWT, and that the CWT was also being requested through NHS Digital by a number of Cancer Alliances with NHS England acting as Data Controller. IGARD agreed that the purpose of this application was distinct from the Cancer Alliance applications and were satisfied that there was no risk of duplication of effort or excessive processing. IGARD noted that the collection of datasets had previously been referred to as the 'temporary National Repository' and was now referred to as the 'National Commissioning Data Repository' (NCDR) and asked that the history of the name changes and the correct name was clear and consistent throughout the application. IGARD noted the standard wording in section 1 (Abstract) in respect of the Common Law Duty of Confidentiality and asked that this was updated to reflect current developments; and to also

	remove the reference to the ICO Code of Practice since it was no longer relevant and to insert suitable generic wording in line with NHS Digital IG advice. IGARD queried the specific access controls for each of the three Data Processors listed within the application and asked that the access controls were explicitly stated in section 5 (Purpose / Methods / Outputs) and that this was also replicated as a special condition in section 6 (Special Conditions). IGARD noted that information provided as part of the narrative in section 5 contained past activities and dates, and asked that this was updated and referred to the most recent data available, for example had previously projected savings been achieved and had the anticipated benefits been accrued. IGARD queried the reference in section 5(a) (Objective for Processing) that states "*Mortality is perhaps the ultimate measure of patient outcomes…*" and asked that this was re-phrased as it was agreed that mortality would only be an outcome measure if it was premature, it was not a useful measurable outcome in general. IGARD noted points 21 and 22 in section 5(c) (Specific Outputs Expected) that states (All datasets will be used to) "*Undertake budget reporting down to individual GP Practice level.*" and "*Produce GP Practice level dashboard reports, including high flyers*." and asked that careful consideration was given to review this information, in particular the measures and the language used (for example 'high flyers') and to ensure this reflected the nature of the data obtained. IGARD noted the benefits outlined in section 5(d) (Benefits) and asked that these were reviewed to ensure the appropriate language was being used and that these accurately reflected the level of data that was being accessed. **Outcome:** recommendation to approve The following amendments were requested: 1. To ensure that the history of name changes and current name of the National Commissioning Data Repository (NCDR) is clear and consistent throughout the application. 2. To update the Common Law Duty of Confidentiality section within the abstract to reflect current developments, including removing reference to the ICO Code of Practice and to insert suitable generic wording in line with IG advice. 3. To explicitly state within section 5 the specific access controls for each of the three Data Processors and to replicate this as a special condition in section 6. 4. To ensure the narrative in section 5 is up to date and refers to the most recent data available (for example, have the previously projected savings been achieved and anticipated benefits been accrued). 5. To rephrase the reference in section 5(a) to 'mortality being the ultimate measure of patient outcomes'. 6. To review points 21 and 22 within section 5(c) and to give careful consideration of these measures and the language used (for example 'high flyers') and to ensure this reflects the nature of the data obtained. 7. To review the benefits outlined in section 5(d) to ensure the appropriate language is used and that these accurately reflect the level of data that is being accessed.
2.2	<u>University of Leicester: MR1275 - The United Kingdom Aneurysm Growth Study (Presenter: Louise Dunn) NIC-148437-C9YSC</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) data for use in a study aiming to find out more about aortic aneurysms. The

	UKAGS is a prospective cohort study of men attending the NHS aneurysm screening programmes in the UK, who are recruited to the study after they have been screened for abdominal aortic aneurysm (AAA) and are followed for up to five years. It is necessary to identify participants who have died during the follow up period to prevent questionnaires being sent to deceased individuals, it is also necessary to establish date and cause of death. The application was been previously considered on the 17th January 2019 when IGARD had been unable to recommend for approval pending; to separate the group of participants and the control group outlined in the application into (i) those who the applicant is in active contact with and recruited in last 5 years, and (ii) those who the applicant is not in contact with; in respect of those where the applicant is in contact with (group (i)), a number of steps should be taken with regard to setting out a clear timeline of the most recent consent forms with the most recent Patient Information Leaflets for the participants (cohort) and the control groups and to confirm how many were consented with the most recent consent form and Patient Information leaflet and a review should be undertaken of the materials to ascertain if the consent is either "incomplete" or "incompatible"; in respect of those where the applicant is NOT in contact with (group (ii)) suggest s251 support is sought for the use of their data; IGARD suggested that future steps would be to reconsent those participants and members of the control group who the applicant continues to be in contact (group (i)) with via an updated consent form along with the October 2017 Patient Information Sheet, depending on whether the consent was "incomplete" or "incompatible". **Discussion:** IGARD welcomed the application which came for advice on the consent materials and noted that the abstract had not been updated to include the relevant minute extract, as per process. There was a lengthy discussion on the cohort numbers and the consent materials provided, in particular around supporting document supporting document 30 (SD30), the supplementary consent form version 1 sent in October 2017 to cohort members that were under active follow up, and the information provided by NHS Digital in supporting document 99.3 (SD99.3), the review of the consent materials. IGARD queried the description of the cohort that was currently flagged with NHS Digital and was advised the total Cohort Size on system at start of Data Sharing Agreement (DSA) was 14,120 those already flagged with NHS Digital. IGARD queried the specific numbers involved in relation to the various cohorts and asked for further clarification of this IGARD queried reference in SD99.3 to case study groups 6 and 7, and control group 7 who were consented from 2016 to date, and were advised by NHS Digital that those who had not yet been recruited would not have been sent SD30 in Oct 2017 as they were not then part of the cohort. IGARD noted the reference in SD99.3 to some individuals not being in follow up and not being sent SD30 and asked for clarification of this and the approximate number of individuals who were not sent SD30. IGARD queried the cohort numbers who were sent SD30 and had **not** returned a signed copy and asked that NHS Digital investigate this further. IGARD members noted the data access outlined in the application appeared to be compatible with the consent materials but noted some insufficiencies in some of the historical consent materials and suggested further consideration was needed. NHS Digital noted that as the study would be closing over the next 6 months the applicant has submitted a letter for Health Research Approval (HRA) Confidentiality Advisory Group (CAG) approval and confirmed that this would be sent to all men in active follow-up to finalise their choices and clarify the consent.

	IGARD thanked NHS Digital for the comprehensive and supportive information provided in SD99.3. **Outcome:** IGARD welcomed the application which came for advice on the consent related materials and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. NHS Digital to investigate the specific numbers involved within the various cohorts outlined in the consent materials and application, particularly the cohort numbers who have been sent SD30 and had not returned a signed copy.
2.3	<u>University of Southampton: MR278 - Study of Birth Cohort from Hertfordshire (Presenter: Louise Dunn) NIC-148284-T2GPT</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) and Hospital Episode Statistics (HES) data for a study, which has been active since the late 1980's and has contributed to the understanding of lifecourse influences on health in later life. To test the hypothesis that chronic, non-communicable diseases of ageing had their roots in foetal and infant life 37,000 men and women born in Hertfordshire between 1911 and 1939, whose early health had been documented by health visitors, were flagged for continuous notification of death. Given the accrual of deaths over time and the increasing age of the cohort, a re-examination of early life influences on mortality is due. **Discussion:** IGARD welcomed the application and noted the importance of the long-running cohort study and the value they added to the research space. IGARD noted that section 1 (Abstract) should be updated to ensure that Article 6 of the General Data Protection Regulation (GDPR) reflects recent discussions between NHS Digital and IGARD including, updating reference to Article 6(1)(e) and removing the reference to the Higher Education Act 1992; and removing the paragraph starting "*Public Task: Section 8…*" relating to The University of Southampton. IGARD noted the reference to the Medical Research Council (MRC) Lifecourse Epidemiology Unit (LEU) was inconsistently referred to throughout section 1 and section 5(b) (Processing Activities) and asked that this was correctly updated throughout. IGARD also noted the reference to the MRC LEU at the end of section 5(b) in the context of employing staff and asked that this was updated to reference the correct legal entity. IGARD queried the information provided under the 'comments' section for Data Processor 1 in section 1(c) (Data Processor(s)) and asked that was updated to clarify the information provided was correct, including reference to the Academic Health Science Network (AHSN) and Foundation Trusts. NHS Digital noted that both a link to the applicant's fair processing notice and a draft fair processing notice, supporting document 7, had been provided. With reference to the supporting document 7, IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested they amend their current privacy notice including, but not limited to, stating that The University of Southampton as a joint Data Controller; removing reference to 'consent' as this was not relevant to the legal basis and to remove the reference to 'risk stratification'. IGARD noted that section 5(b) states ***"****This allows data to be linked as necessary to investigate emerging research questions. Any changes to the purpose would require an amendment to this agreement."* and asked that this was strengthened to be more robust and well defined.

	IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5(b) of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the abstract section on Article 6 of GDPR to reflect recent discussions between NHS Digital and IGARD including updating reference to Article 6(1)(e) and removing reference to the Higher Education Act 1992 and deleting the paragraph starting "Public Task: Section 8…" relating to The University of Southampton. 2. To ensure reference to the MRC LEU is consistent within the abstract and section 5(b). 3. To update section 5 to ensure the correct legal entity is referred to at the end of section 5(b) in the context of employing staff. 4. To update the description comments under Data Processor 1 in section 1(c) (including reference to AHSNs and Foundation Trusts). 5. The applicant should review their draft Privacy Notice to ensure it is GDPR compliant including (but not limited to) stating that the University of Southampton as a joint Data Controller; removing reference to 'consent' as this is not relevant to the legal basis and removing reference to 'risk stratification'. 6. To update section 5(b) to strengthen the wording relating to change of purpose in the context of 'emerging research questions'. 7. Confirmation within section 5(b) of the application that the applicant will not link the data further and the only data linkages are those permitted under this application.
2.4	Erasmus University Rotterdam: Synergy between PCI with TAXUS and Cardiac Surgery: SYNTAX Extended Survival (SYNTAXES) (Presenter: Louise Dunn) NIC-230360-H3Y3C **Application:** This was a new application for pseudonymised Civil Registrations data for a study that represents the extension to a 10-year of the planned final follow-up of the Synergy between PCI with TAXUS and Cardiac Surgery *(*SYNTAX) trail which was a multi-centre international investigation in which 1,800 patients were randomly assigned to drug-eluting stent-based percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). IGARD previously welcomed the application on the 4th April 2019 and provided the following advice: to provide the GDPR legal basis for the relevant data controller(s), since the data controller will process the data of individuals who may still be alive to establish the date of death; since the supporting documents provide overwhelmingly evidence that establishes UHS NHS FT as the data controller, to provide clarification to support the data controllership of the applicant (the medical centre of the Erasmus University); to provide an explanation why the other principal investigators are not joint data controllers with the chief investigator UHS NHS FT; what is the difference between the Erasmus University and Medical Centre and why Erasmus University is named as the Data Controller; since the s.251 is for the English cohort and permits the disclosure to and the processing of the data by the UHS NHS FT only, to provide evidence of a legal gateway under the Duty of Confidentiality for the applicant to receive the data; to update the abstract to be clear that the DPO requirement per organisation is specific to the Netherlands under Dutch Law; to clarify the percentage field of 12% outlined in the application and whether this relates just to the Date of Death or to more data; IGARD suggested the fair processing notice be updated to be more accessible to a lay reader; IGARD suggested that NHS Digital review the special conditions outlined in Section 6 to ensure obligation is on the applicant, not NHS Digital.

	Discussion: IGARD noted the importance of the trial. IGARD queried how the data recipient handled the received data with the study ID since it also held study ID and the identifiers. NHS Digital confirmed that the University Hospitals Southampton (UHS) NHS Foundation Trust held the identifiers for the cohort as they recruited them initially and then sending identifiers to NHS Digital for linkage. UHS receive back from NHS Digital the mortality data and unique study ID. IGARD noted that the application did not detail how UHS would handle the returned data and if the direct identifiers were kept separate from the data returned and asked for confirmation that there will be no attempt to re-identify individuals. IGARD noted the reference to both randomised and registry patients within the application and queried if the s251 support extends to both, since the s251 support letter stated the support was for a 10 year follow up of patients who were enrolled on the trial, and asked that NHS Digital review the s251 support and provide written confirmation of this. IGARD queried what the official authority for Erasmus was under Article 6(1)(e) of the General Data Protection Regulation (GDPR) and asked that section 1 (Abstract) was updated to explicitly sett this out. IGARD noted that section 5(a) (Objective for Processing) summary of the research did not accurately reflect the purpose and suggested that key detail be added. IGARD noted that section 5(c) (Specific Outputs Expected) contained information on processing and asked that the relevant paragraphs be correctly moved into section 5(b) (Processing Activities); and that section 5(c) was updated to ensure it reflects actual outputs. IGARD also noted that section 5(c) did not reflect the data flows as set out in the data flow diagram provided as a supporting document and asked that section 5(c) was updated to include this information. IGARD noted that under the Common Law Duty of Confidentiality legal basis within section 1 (Abstract) there was reference to “in this case NHS Digital” and asked that this was removed. IGARD noted that supporting document 9, the draft privacy notice contained a number of clinical terms and asked that this was updated to be more accessible to a lay reader. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide confirmation that the direct identifiers are kept separate from the data returned and that there will be no attempt to re-identify individuals. 2. NHS Digital to review and provide written confirmation that the s251 support extends to both the randomised and registry patients. 3. To update the abstract to explicitly set out the official authority for Erasmus under Article 6(1)(e). The following amendments were requested: 1. To update section 5(a) to ensure the summary of the research accurately sets out the purpose. 2. To update section 5(c) to ensure it reflects actual outputs. 3. To update section 5(c) to ensure it accurately reflects the data flows as set out in the data flow diagram. 4. To move the paragraphs in section 5(c) relating to processing into section 5(b). 5. To amend the Duty of Confidentiality legal basis within the abstract to remove reference to ‘in this case NHS Digital’. 6. IGARD suggested the fair processing notice be updated to be more accessible to a lay reader.

	It was agreed the conditions be approved OOC by IGARD Members.
2.5	Royal College of Anaesthetists**:** MR1386 - National Emergency Laparotomy Audit (Stuart Blake) Presenter: NIC-355855-R4G6G **Application:** This was an amendment, extension and renewal application for identifiable Medical Research Information Service (MRIS) and Hospital Episode Statistics (HES) data for a national clinical audit commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical and Patient Outcomes Programme (NCAPOP) to enable the improvement of the quality of care of patients undergoing emergency laparotomy by providing high quality comparative information of the clinical practice and outcomes of all NHS providers of emergency laparotomy in England and Wales. The application was been previously considered on the 4th April 2019 when IGARD had been unable to recommended pending: HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis; To clarify why NHS England, Royal College of Surgeons of England (RCS) and The Royal College of Anaesthetists (RCoA) are not considered joint data controllers and, if they are, to amend the application throughout to reflect this; to clarify how HQIP's discretion and contribution to the purpose, design and execution of the audit is substantive to establish its role as a data controller; given the substantial amendments in this application are not reflected in the current s.251 support, an amendment application should be submitted to HRA CAG; to provide clarity on the role of the NIAA Health Services Research Centre as referred to in supporting document 18 and clarify its role in terms of supervising any subcontracted workers; to update the special condition in section 6 to amend the reference to 'contracted employees' to 'contracted workers'; to provide clarification if individuals are seconded into the Royal College of Anaesthetists or if the Royal College of Anaesthetists sub-contract this work to another organization; to update section 4 and insert a special condition in section 6 with the standard wording "Data processed under this application is pseudonymised and therefore is considered as personal data under the GDPR. All data controllers shall provide a privacy notice that is compliant with the GDPR notice requirements". **Discussion:** IGARD noted that the application had been updated to reflect the comments previously made with the exception that the Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task is the appropriate legal basis. Notwithstanding this, IGARD made a positive statement and were supportive of the application. **Outcome:** IGARD made a positive statement and were supportive of the application but were unable to recommend for approval. 1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis.
2.6	University of Oxford**:** 4CHILD - Four Counties Database of Cerebral Palsy, Vision Loss and Hearing Loss in Children (Berkshire, Buckinghamshire, Northamptonshire, Oxfordshire) (Presenter: Dave Cronin) NIC-148239-M8RTP **Application:** This was an extension application for pseudonymised Medical Research Information Service (MRIS) data for the purpose of a database established to collect information about children with cerebral palsy and / or severe vision loss and / or hearing loss. The register was set up against a background of uncertainty of the contribution of increased numbers of low birth weight survivors on the numbers of disabled children in the population. At the time, there were no routinely collected and easily accessible data on early childhood morbidity and so the register was set up as a framework to examine clinical associations of

	disabling conditions, to assess services, and to assess the effectiveness of perinatal intervention. **Discussion:** IGARD noted that the study page on the National Perinatal Epidemiology Unit (NPEU) website had not been updated in some time and did not reflect recent information and asked that the applicant update this, including but not limited to, that the data held was pseudonymised and being retained for possible future use. IGARD noted within section 4 (Privacy Notice) that the privacy notice did not meet the criteria set and asked that a special condition be inserted in section 6 (Special Conditions) that the applicant would provide a privacy notice that was compliant with the General Data Protection Regulation (GDPR) notice requirements and that it was published within one month of signing the Data Sharing Agreement (DSA). IGARD suggested that when this application returns the applicant should give due consideration to the narrative of the application, in particular (but not limited to) to put forward a compelling case for the value of continuing to hold the data and that the application give due consideration and sensitivity to the communities involved and current attitudes towards disability, to reflect current thinking. IGARD suggested that a 2-year timeframe was given for the data sharing agreement instead of the standard 5-years. IGARD advised that they would wish to review this application again when it comes up for renewal. IGARD noted and endorsed NHS Digital's request for an audit of the organisation in relation to this application / data sharing agreement. **Outcome:** recommendation to approve subject to the following condition: 1. To update the study page on the NPEU website. The following amendments were requested: 1. To insert a special condition in section 6 that the applicant will provide a privacy notice that is compliant with the GDPR notice requirements and that it is published within one month of signing the DSA. The following advice was given: 1. IGARD suggested that when this application returns the applicant should give due consideration to the narrative of the application, in particular (but not limited to) to put forward a compelling case for the value of continuing to hold the data and due consideration and sensitivity to the communities involved and current attitudes towards disability to reflect current thinking. 2. IGARD suggested that a 2-year timeframe was given for the data sharing agreement. 3. IGARD advised that they would wish to review this application again when it comes up for renewal. 4. IGARD noted and endorsed NHS Digital's request for an audit on the organisation in relation to this application / data sharing agreement It was agreed the condition be approved OOC by the IGARD Chair.
3	**AOB** **Joanne Bailey** IGARD noted that this was Joanne Bailey's final meeting and wished to extend their sincere thanks for her significant contribution over the last 7 years during her tenure on IGARD and its predecessor the Data Access Advisory Group (DAAG), as its Chair and former member, and

	General Practice Extract Service Independent Advisory Group (GPES IAG), as a former member.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 19/04/19

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-17824-V9F2B	Institute of Fiscal Studies	31/01/19	1. In respect of the Junior Doctor's strike project, to provide a more sensitive description of the project and include a clear and compelling case outlining the benefits to health and social care accruing from this study. 2. The applicant to justify the amount of data and years of data that needs to be processed for each project and to include a clear description of the data requested and the data minimisation efforts undertaken. 3. The applicant to describe the outputs and route to dissemination for each project (with the exception of the Sure Start Programme and the Waiting Time Projects) outlining how the data requested benefits health and social care.	IGARD Members	Quorum of IGARD Members 10.04.19	N/A
NIC-137864-T1P9B	University College London	28/02/19	1. The applicant should investigate whether it is necessary to update HRA CAG on the change in data processor and provide either (a) evidence that they have submitted an amendment application to HRA CAG detailing the change of the data processor, or (b) a satisfactory explanation to NHS	IGARD Chair	Acting IGARD Chair 11.04.19	N/A

			Digital as to why an amendment application to HRA CAG is not required.			

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

- None