Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 13 December 2018

Members: Nicola Fear, Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance: Dave Cronin, Louise Dunn, Duncan Easton, James Humphries-Hart, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Apologies: Sarah Baalham, Joanne Bailey, Anomika Bedi.

Observers: Maria Clark, Stephen Elgar, Priscilla Maguire

1	**Declaration of interests:** Nicola Fear noted a professional link with staff involved with NIC-121483-R8P9F University Hospitals Birmingham NHS Foundation Trust and would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of this application. **Review of previous minutes and actions:** The outcomes of the 6th December 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting. The minutes of the 6th December 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. **Out of committee recommendations** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>Methods Analytics Ltd: Standard Extract Subscription – modification of section 5 (Presenter: Dickie Langley) NIC-09519-D5G0R</u> **Application:** This was an amendment application for pseudonymised Hospital Episode Statistics (HES), Secondary Use Service (SUS), Civil Registrations, Mental Health and Learning Disabilities Data Set (MHLDDS), Diagnostic Imaging Dataset (DIDs) and Mental Health Services Data Set (MHSDS). The data will be used to support the NHS either directly through the delivery of tools and bespoke analysis or indirectly through non-NHS organisations, where analytics are provided to the NHS as the end beneficiary via a non-NHS organisation. NHS Digital advised that this application had been re-submitted to IGARD due to the purpose of the application being revised. **Discussion:** IGARD noted the application had been updated since last presented to IGARD and requested that this made be made clear within section 1(a) (Abstract) to clearly set the scene regarding why the application had returned to IGARD and particularly how the application has been updated to reflect the change in purpose. IGARD noted that further information was required within section 5(a) (Objective for Processing) setting out an analysis using the Information Commissioners Office (ICO) guidance, explaining the Legitimate Interests relied on and asked that this be linked to the purposes outlined in the application. IGARD also noted that the application referenced Methods Analytics Ltd as having assessed the Legitimate Interest Assessment (LIA) and that this should be amended to correctly note that NHS Digital had assessed the LIA and deemed it satisfactory.

	Outcome: recommendation to approve subject to the following condition(s)
	1. To clearly set out an analysis within section 5(a) of the application explaining the Legitimate Interests relied on and linked to the purpose outlined.
	2. To update the abstract to reflect that NHS Digital, rather than Methods Analytics Ltd, has assessed the LIA and deemed it satisfactory.
	The following amendments were requested:
	1. To update the abstract to clearly set the scene with regard to why the application has returned to IGARD and how the application has been updated to reflect changes made, including the purpose.
	It was agreed the condition would be approved OOC by the IGARD Chair.
2.2	University Hospitals Birmingham NHS Foundation Trust: Baby Biome Study (Presenter: Dickie Langley) NIC-121483-R8P9F
	Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data and Civil Registrations Mortality data for a study of mother-infant pairs, which aims to address population level questions about infectious and immunological determinants of human health and disease. The overall aims of the study are to investigate the relationships between infant microbiota and the immune system, environment, clinical and feeding practices and subsequent health outcomes.
	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.
	IGARD queried why University Hospitals Birmingham NHS Foundation Trust (UHB) was not considered as a Data Controller and asked for further clarity on this in section 5 (Purpose / Methods / Outputs), and if not, to expressly note that UHB will be acting on the instruction of the Data Controllers (University College London and University of Birmingham) to manage and administer the study.
	IGARD noted that the Wellcome Trust Sanger Institute were referenced in the protocol as being part of the management team and carrying out substantial work and asked for further clarity on this and to also consider if they should be included as a Data Controller.
	IGARD queried the cohort numbers of 6800 individuals split into 3400 mothers and 3400 babies that indicate that only one baby for each mother will form part of the cohort and asked for further clarification that only singleton mother and babies will be used as part of the cohort, since the patient information provided suggested that multiple births would be included in the study.
	Outcome: unable to make a recommendation as there was not a quorum of members present but made a positive statement of advice subject to the following conditions:
	1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD.
	2. To update section 5 to clarify why University Hospitals Birmingham NHS Foundation Trust (UHB) is not considered a Data Controller and, if not, to expressly note that UHB will be acting on the instruction of the Data Controllers (University College London and University of Birmingham) to manage and administer the study.

	3. To provide further clarity on the Wellcome Trust Sanger Institute entity given that they are described within the protocol as being part of management team and carrying out substantial work, and to consider if they should be included as a Data Controller. 4. To clarify if only singleton mother and babies are being used as part of the cohort. It was agreed the response to the comments made would be reviewed OOC by IGARD Members.
2.3	<u>Imperial College London: Imperial College London/Dr Foster Limited Standard Extract Service Feed (HES Amendment, Renewal/Extension) (Presenter: Louise Dunn) NIC-12828-M0K2D</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data to identify measures of quality and safety in healthcare. Research themes are around developing and validating indicators of quality and safety of healthcare particularly by GP practice, consultant, and NHS Trust, showing variations in performance by unit, patient risk subgroups and risk prediction, risk adjustment and outlier detection for such indicators and variations and any other methodological aspects as they arise. **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. IGARD noted that section 1 (Summary) referenced IGARD having previously reviewed the application and that this should be amended to correctly reference IGARD's predecessor the Data Access Advisory Group (DAAG) for clarity. IGARD queried whether s251 support was in place for both the research database and the patient re-identification service for all Trusts and asked that the applicant provide documentary evidence, since it was noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) register had not been updated to reflect that the applicant had submitted their annual review 6 months ago. IGARD noted that the Data Protection Act (DPA) 2018 expiry date for Dr Foster Limited should be updated within the abstract to show the correct expiry date. **Outcome:** recommendation to approve subject to the following condition(s) 1. The applicant to provide documentary evidence that s251 support is in place for both the research database and the patient re-identification service for all Trusts. 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. To update the abstract to correctly reference DAAG as previously having reviewed the application, not IGARD. IGARD noted the utility of the work undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital was due to expire and, in light of this, it was suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to update the application. It was agreed the condition would be approved OOC by the IGARD Chair.

2.4	Dr Foster Limited: Dr Foster Standard Extract Service Feed (Presenter: Louise Dunn) NIC-68697-R6F1T
	Application: This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data to help healthcare organisations achieve sustainable improvements in their performance, to gain insight and to inform decision making. This is delivered in three strands; Dr Foster tools and services, bespoke analytics and research for publication.
	Discussion: IGARD noted that further information was required within section 5(a) (Objective for Processing) setting out an analysis using the Information Commissioners Office (ICO) guidance, explaining the Legitimate Interests relied on and asked that this be linked to the purposes outlined in the application.
	IGARD noted that the application references Dr Foster Ltd as having assessed the Legitimate Interest Assessment (LIA) and that this should be amended to correctly note that NHS Digital had assessed the LIA and deemed it satisfactory.
	IGARD noted that section 5(b) (Processing Activities) states "No record level data will be transferred outside of the EEA….." and that the territory of use should be amended to 'England and Wales'.
	IGARD queried if record level data will not be made available to Dr Foster Ltd parent company or group of companies except for Dr Foster Ltd except those outlined within the application / data sharing agreement and asked that this be expressly stated within section 5 (Purpose / Methods / Outputs).
	Outcome: The application was recommended for approval subject to the following conditions and (ii) subject to NIC-12828-M0K2D being recommended for approval and any conditions set out in NIC-12828-M0K2D being met**.**
	1. To clearly set out an analysis within section 5(a) of the application explaining the Legitimate Interests relied on and linked to the purpose outlined.
	2. To update the abstract to reflect that NHS Digital, rather than Dr Foster Limited, have assessed the LIA and deemed it satisfactory.
	The following amendment were requested:
	1. To amend the territory of use from 'EEA' to 'England / Wales'
	2. To expressly state within section 5 that Dr Foster will not to provide any record level data to its parent company or group of companies, except for those outlined within the application / data sharing agreement.
	It was agreed the condition would be approved OOC by the IGARD Chair.
2.5	Wolfson Institute of Preventive Medicine: MR39 – Smoking Study – Men attending BUPA Medical Centre (Presenter: Louise Dunn) NIC-148331-5F2FS
	Application: This was a renewal and extension application for pseudonymised Medical Research Information Service (MRIS) data for a study looking at risk factors for cancer and cause specific mortality, with an emphasis on the risks of smoking. The areas of research covered have included the health effects of active and passing smoking, screening, cancer and nutrition, cancer and infection, serum cholesterol in relation to ischaemic heart disease and cancer, apolipoproteins and IHD, blood pressure and stroke, cardiovascular screening and osteoporosis.

Discussion: IGARD noted that the Research Ethics Committee (REC) approval provided was from 2005 and asked for evidence that this was still ongoing or confirmation that it was no longer required.

IGARD noted that information had been provided of measurable and yielded benefits but asked for further examples of benefits to health and social care within section 5(d) (Benefits).

IGARD noted reference to 'collaborative working' within section 5 and suggested that it be explicitly explained what collaborative working was being undertaken by the applicant.

IGARD queried if the honorary professor's substantive employer agrees to be bound by and take action in line with the terms of the relevant honorary contract in the event of a breach and asked for confirmation from the substantive employer (by way of a letter of assurance or similar).

Outcome: recommendation to approve subject to the following condition(s)

1. To provide evidence that the original ethics approval is still ongoing or confirmation that it is no longer required.

2. To provide further examples of measurable and yielded benefits to health and social care within section 5(d).

3. To update section 5(d) to explicitly state what collaborative working is being undertaken as referenced in section 5(d).

4. To obtain confirmation from the substantive employer (by way of a letter of assurance or similar) of the honorary professor confirming that they agree to be bound by and take action in line with the terms of the relevant honorary contract in the event of a breach.

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

2.6	Birmingham City Council: LAPH HES (Presenter: Duncan Easton) NIC-25007-J9M9P

Application: This was an amendment application for pseudonymised Hospital Episode Statistics (HES) data to be used to support the Local Authority's fulfilment of its public health and commissioning functions.

The application was been previously considered on the 15th November 2018 when IGARD had deferred making a recommendation pending; to address whether for commissioning purposes the applicant should have access to a smaller subset of the national data provided and to set out the access controls in place OR to provide a justification of the provision of national data for commissioning purposes and address how the necessity test has been met, specifically for commissioning purposes; to update section 5 to clearly define how the outputs and benefits listed justify and reflect the use of national data; to update section 5 to justify the use of national data in relation to all the various processing being undertaken; to update section 5(b) to clearly state that NHS Digital data will not be transferred outside of England and Wales; to expressly state with the application that the necessity for the processing for the performance of task has been assessed by NHS Digital to ensure that only the minimum amount of data required is processed and consideration has been given to the whether the volume of data being requested is proportionate to the expected benefits and whether the task is itself necessary; 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) and justification of public task; the abstract should be updated to make specific reference to Article 9(2)(h) GDPR and the DPA 2018 and clearly describe how the schedule conditions are met; to update the abstract with reference to 9(2)(h) to expand the activities in addition to 'service evaluation', for example

including "public health" or similar; to update the abstract section on Article 9 to expressly refer to Article 9(3) GDPR and section 11(1) DPA 2018, to the conditions found therein and how these are met (for example naming the role of the relevant healthcare professional); to expressly state with in section 5(b) that the data held will be segregated from any identifiable data already held by the applicant.

Application: IGARD noted that the application had been updated to reflect all of the comments previously made.

IGARD and the presenter discussed the burden under General Data Protection Regulation (GDPR) to justify the use of national mental health data and it was agreed that, instead of national data, further data minimisation could be undertaken for the mental health dataset by geographical reduction to align with the smaller number of comparator geographies referenced in the application and supporting documentation.

IGARD also queried if the applicant had considered whether further data minimisation in respect of the mental health dataset had been considered via age, condition or health concern could be undertaken and, if not, to provide an explanation as to why not.

IGARD queried if the data held will be segregated from any identifying data already held by the applicant and that no attempt to re-identify will be undertaken by the applicant or any third party and asked that this be expressly stated within section 5(b) (Processing Activities).

IGARD noted that in section 5(e) the question is asked "Is the purpose of this application in anyway commercial" the answer is noted as 'yes' and that this should be amended to correctly state 'no'.

IGARD endorsed NHS Digital's review of that the applicant's privacy notice did not meet relevant criteria, including but not limited to reference to automated decision making.

Outcome: recommendation to approve subject to the following conditions:

1. To further minimise the data for the mental health dataset by geographical reduction to align with the smaller number of comparator geographies referenced in the application and supporting documentation.
2. To expressly state within section 5(b) that the data held will be segregated from any identifying data already held by the applicant and that no attempt to re-identify will be undertaken by the applicant or any third party.

The following amendments were requested:

1. To amend the section 5(e) with regard to commercial purpose from 'yes' to 'no'.
2. In respect of the mental health dataset to consider whether further data minimisation via age, condition or health concern could be undertaken and, if not, to provide an explanation why not.
3. IGARD endorsed NHS Digital's review of that the applicant's privacy notice did not meet relevant criteria, including but not limited to reference to automated decision making.

It was agreed the condition would be approved OOC by the IGARD Chair.

2.7	NHS Brighton and Hove CCG: DSfC Crawley CCG, Horsham and Mid Sussex CCG, Brighton and Hove CCG – Comm (Presenter: James Humphries-Hart) NIC-216638-L9N4N
	Application: This was a new application for pseudonymised Secondary Use Service (SUS) for Commissioners data for three CCG's to focus on Musculoskeletal (MSK) treatment for patients. The data is analysed so that health care provision can be planned to support the needs of the population within the geographical region of the CCGs.

	Discussion: IGARD queried if the data minimisation table in section 3(b) (Additional Data Access Requested) was limited to local data or national data and it was suggested that application be updated to clarify that the data was limited to local data only.
	IGARD queried if the data requested was just for the MSK Project and and asked that section 5 (Purpose / Methods / Outputs) be amended to reflect the clarification from NHS Digital that that the data will not just be used for the MSK Project.
	IGARD noted that the table in section 3(b) states that the frequency of dissemination will be 'ad-hoc' and asked that this updated to correctly state that it will be a 'monthly' dissemination.
	Outcome: recommendation to approve subject to the following condition(s)
	1. The application be updated to clarify that data minimisation table is limited to local data.
	The following amendments were requested:
	1. To amend section 5 to reflect that the data will not just be used for the MSK project. 2. To amend the application to correct reference that this was a monthly dissemination not an ad-hoc dissemination of data.
	It was agreed the condition would be approved OOC by the IGARD Chair.
2.8	University College London: Understanding excess child and adolescent mortality in the UK (Presenter: Kimberley Watson) NIC-141410-W6H4Y
	Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data to explore why the rate at which children and young people die in the United Kingdom is higher than in many other developed countries.
	Discussion: IGARD welcomed the application and noted the interesting work being undertaken.
	IGARD were not clear with regard to the study population and queried if the cohort encompassed individuals who died under the age of 25 and also accessed secondary care prior to their death and asked for further clarity on this within section 5.
	IGARD queried if the PhD study differed from the wider study outlined in the application and asked how the two studies fitted together and asked that this be clearly explained, along with clarification that the PhD student is a substantive employee of the University College London.
	IGARD noted that supporting document 6, the data flow diagram provided quite a lot of information that was not replicated within the application and asked that section 5(b) (Processing Activities) be updated to align with the data flow diagram.
	IGARD queried whether the applicant had ethics approval and asked that the application be updated to clearly state that the applicant does have ethical approval.
	IGARD noted that supporting document 2, the Research Ethics Committee (REC) favourable opinion letter, referenced that Health Research Authority Confidentiality Advisory Group (HRA CAG) approval is not required and asked that this be confirmed with the applicant for clarity.
	Outcome: recommendation to approve subject to the following conditions:
	1. To clarify that the cohort encompasses individuals who died under the age of 25 and also accessed secondary care prior to their death. 2. To clearly explain how the PhD study differs from the wider study, how the two studies fit together and to clarify that PhD student is substantive employee of the University College London.

	3. To include helpful extra detail from the data flow diagram provided (supporting document 6) in the narrative of section 5(b). The following amendments were requested: 1. To update the application to clearly state that the applicant does have ethical approval. 2. To check that the applicant does not need HRA CAG approval as referenced in supporting document 2, NHS REC favourable opinion letter. It was agreed the conditions be approved OOC by IGARD Members.
2.9	<u>Royal College of Anaesthetists: MR1477 - EPIdemiology of Critical Care After Surgery (EPICCS) (Presenter: Kimberley Watson) NIC-88623-F2H1Q</u> **Application:** This was a new application for identifiable and pseudonymised Hospital Episode Statistics (HES) and identifiable Medical Research Information Service (MRIS) data. The study is a one-week observational study including all patients who underwent inpatient surgery between March 21st - 27th 2017. This study uses patient information to help improve care for people undergoing surgery. All patients had prospective data collection on risk factors, surgical procedure and postoperative outcomes including the primary outcome of morbidity and secondary outcomes including length of stay and inpatient mortality. The admission of high- risk patients to critical care after surgery is a recommended standard of care, however poor compliance against this recommendation has been repeatedly demonstrated in large epidemiological studies. The application was been previously considered on the 4th October 2018 when IGARD were unable to recommend pending; section 5 of the application should be updated to provide a more detailed description of the study or studies and the cohorts which aligns with the information provided in the HRA CAG and Protocol supporting documents; provide clarification if the medical PhD referenced in supporting document 8 is the entire study or part of the study; to update the application to clarify why UCL, UCLH and NIAA-HSRC are not considered as joint data controllers; to clarify what the legal basis under common law extends to all cohorts and clinicians under this application; all data controllers to provide a fair processing notice and to ensure that it is compliant with the notice requirements under the GDPR; to provide a clearer justification why HES APC data is required for the entire cohort; to provide clarification in section 5 who is accessing the data and what data they are accessing and that this aligns with HRA CAG approval; to include reference to the NHS Act 2006 when first referencing section 251 in the application; to amend the legal basis in section 3(b) to refer to section 261(7) not section 261(2)(b)(ii). **Discussion:** IGARD noted that the application had been updated to address most of the comments previously made. IGARD noted that the application referred to "participating hospitals" and queried if this was all UK hospitals or just those hospitals who have patients in critical care during that one week outlined in the application and suggested that application be updated to clarify this and also who participated in the study. IGARD queried the study or studies outlined in the application and asked for a more detailed description within section 5 (Purpose / Methods / Outputs), along with further details of who was accessing the data and what data they are accessing. IGARD noted this should align with the information that has been provided in the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval and Protocol supporting documents provided. It was also suggested that the update regarding the data and access to data should also reflect the joint controllership outlined in the application.

IGARD noted that supporting document 8, the HRA CAG application form references a medical PhD and asked for further clarity in section 5 outlining how this fits with the wider study outlined in the application.

IGARD noted that section 1(a) (Abstract) states that the Royal College of Anaesthetists have assessed the Legitimate Interest Assessment (LIA) and asked that this be updated to correctly state that NHS Digital have assessed the LIA and deemed it satisfactory.

Outcome: recommendation to approve subject to the following condition(s)

1. To provide clarification of whether it is all UK hospitals or is it just those hospitals who have patients in critical care during that one week outlined in the application and who participated in the study.
2. Section 5 of the application should be updated to provide a more detailed description of the study or studies and the cohorts, details of who is accessing the data and what data they are accessing which aligns with the information provided in the HRA CAG approval and Protocol supporting documents. The update regarding the data and access to data should also reflect the joint controllership outlined in the application.
3. Provide clarification in section 5 of how the medical PhD referenced in supporting document 8 fits with the wider study outlined in the application.
4. To update the abstract to reflect that NHS Digital, rather than the Royal College of Anaesthetists, have assessed the LIA and deemed it satisfactory.

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

2.10	Clinical Practice Research Datalink (CPRD): Bowel Cancer Screening Programme – Data Linkage (Presenter: Kimberley Watson) NIC-108098-D2L3V
	Application: This was a new application for pseudonymised Medical Research Information Service (MRIS) data to support two separate research projects. The first project is looking at the non-responders to bowel cancer screening (cohort size: 66,275); and the second project is looking at the influence of negative result on the response of screening invitees and healthcare providers to symptoms of colorectal cancer (cohort size: 7,800).
	The application was been previously considered on the 20th September 2018 when IGARD had deferred making a recommendation pending; to remove any reference to NHS Digital owned data not being disseminated; to provide further clarity in the abstract on the selection criteria for the cohort for both studies and how they align with s.251 support; to clarify the nature of the project given the apparent inconsistencies in the supporting documentation; for example the REC approval describing an audit programme and other documents such as the Health Research Authority Confidentiality Advisory Group (HRA CAG) support referring to a research programme; to provide further details about and more robust routes to dissemination of the expected measurable benefits within section 5; to provide further clarification in the abstract the purpose of the cohorts; to amend section 3 to accurately reflect the cohorts. The following advice was given: IGARD advised that NHS Digital may wish to check with their legal team that the contractual arrangements in relation to this application are satisfactory for NHS Digital, considering that NHS Digital appear to be using the standard DSFC which assumes that NHS Digital is a Data Controller.
	Discussion: IGARD noted that the application had been updated to reflect all of the comments previously made.
	IGARD noted that the application stated that opt outs would be applied within the application and queried if the opt outs also include Public Health England (PHE) data and asked for further clarification on this.

Outcome: recommendation to approve subject to the following conditions:

1. To provide further clarification that the opt outs include Public Health England data.

It was agreed the condition would be approved OOC by the IGARD Chair.

2.11	<u>University of Sheffield: Emergency and Urgent Care System Demand in Yorkshire and Humber: A retrospective analysis of routine data (Presenter: Dickie Langley) NIC-14230-X7P9J</u> **Application:** This was an extension application for pseudonymised Hospital Episode Statistics (HES) data for a study analysing data for Yorkshire and Humber in order to identify specific patient groups with long-term conditions in whom improved emergency and urgent care system performance could reduce unnecessary variation in attendances and avoidable admissions. This will provide evidence for policy makers and commissioners to target appropriate interventions to manage patients with long-term conditions to reduce pressure on hospital services and improve patients' experiences of care. **Discussion:** IGARD queried what the expected measurable benefits were and when the evidence briefing would take place and in what form, and that further clarity be provided within section 5(d) (Benefits). IGARD also noted the following statement in section 5(d) "Publications detailing which patient groups will benefit most from interventions to reduce system variation will be in print in 2016/2017." and asked for further clarity on this. IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that the assessment within the section 1 (Abstract) and section 4 (Privacy Notice) be updated to clearly state that the application privacy notice 'does not' meet the criteria including (but not limited to) that individuals can contact the Information Commissioners Office (ICO) at any time, refer to automated decision making, and update the legal basis (since a different basis is noted in the application and the Fair Processing Notice). **Outcome:** recommendation to approve subject to the following condition(s) 1. To provide further clarity on the expected measurable benefits, especially when the evidence briefing will take place, and in what form and clarify the reference to 2016/17 in section 5(d). 2. To update the assessment in the abstract and section 4 to state that the Fair Processing Notice 'does not' meet the criteria, including (but not limited to) that individuals can contact the ICO at any time, refer to automated decision making, and update the legal basis (since a different basis is noted in the application and the Fair Processing Notice). It was agreed the conditions be approved OOC by IGARD Members.
2.12	<u>McKinsey & Company, Inc. United Kingdom: Standard Extract Subscription (Presenter: Dickie Langley) NIC-368233-L2N0W</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data to provide fact-based answers to NHS clients regarding identification, assessment and quantification of opportunities to improve the quality and efficiency of the NHS services that they deliver or are responsible for overseeing and regulating. **Discussion**: IGARD noted that the applicant was a branch of a USA company and queried if NHS Digital were content to disseminate the data under this application / data sharing agreement to a company that was a branch of a USA company and, as such, subject to a

foreign jurisdiction, and asked for written confirmation from NHS Digital confirming they were content.

IGARD noted that references were made to geographical restrictions and asked that this this be removed since the contracting party was a branch of a USA company and therefore the restrictions could not apply.

IGARD asked that further information be provided within section 5(a) (Objective for Processing) setting out the analysis using Information Commissioners Office (ICO) guidance, explaining the Legitimate Interests relied on and linked to the purpose outlined within the application.

IGARD noted that section 5 (Purpose / Methods / Outputs) set out the different types of processing and asked that section 1 (Abstract) be updated to align with the information provided.

IGARD noted that the applicant's fair processing notice did not meet the GDPR 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 including (but not limited to), specify that the applicant is a branch of a USA company; provide more information about the legitimate interest legal basis; to amend reference to data being transferred outside the EEA; confirm whether automated decision making is involved or not'; expressly describe the data subject rights and expressly state that these apply to data held by McKinsey and not NHS /NHS Digital; remove erroneous statements; that the applicant does not have a DPO based in the UK.

IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice.

Outcome: recommendation to approve subject to the following condition(s)

1. IGARD to receive written confirmation from NHS Digital that they are content to disseminate the data under this application / data sharing agreement to a company that is a branch of a USA company and, as such, subject to a foreign jurisdiction.
2. To remove any references in the application to geographical restrictions, since it is a branch of a USA company.
3. To clearly set out an analysis within section 5(a) of the application explaining the Legitimate Interests relied on and linked to the purpose outlined.

The following amendments were requested:

1. To amend section 4 to state that the Fair Processing Notice 'does not' meet the criteria and to update the abstract checklist to note the current shortcomings.

2. To align and update the abstract to reflect the different types of processing set out in section 5 of the application.

The following advice was given:

1. NHS Digital should work with the applicant to update their Fair Processing Notice.

IGARD noted the utility of the work undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital was due to expire, and in light of this it was suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to update the application.

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

2.13	Oxford University Hospitals NHS Foundation Trust: Outcomes in acute/general medical inpatients in the Hospital Episode Statistics (Presenter: Dave Cronin) NIC-07787-Z1W1X
	Application: This was an extension application for pseudonymised Hospital Episode Statistics (HES) data and Civil Registrations data to identify whether there is any evidence from existing electronic health record data to support the key prescriber concern that early antibiotic review leading to reduced antimicrobial usage will cause greater rates of treatment failure / mortality.
	Discussion: IGARD noted that supporting document 2, the National Institute for Health Research (NIHR) funding letter from 2015 stated that funding was for a period of 60 months subject to a satisfactory report on progress after 24 months and queried of this had been undertaken and if funding was still in place and that evidence be provided.
	IGARD queried the current position with the Fair Processing Notice and asked that this be clearly articulated in section 1 (Abstract) including what steps are being taken to produce a Fair Processing Notice that meets the criteria and clearly reflects the efforts undertaken by the applicant.
	IGARD noted that supporting document 8, the letter from the University of Oxford names individuals as part of the research and queried if these individuals were still in place and that the letter covers all the necessary individuals. IGARD asked that if any individuals have left or joined the study team, for the University of Oxford to provide a revised letter naming the relevant individuals involved.
	IGARD noted that their predecessor the Data Access Advisory Group (DAAG) asked to clearly define the routes to dissemination for the benefits and outputs outlined in the application and asked that this be updated in section 5 (Purpose / Methods / Outputs).
	IGARD noted that supporting document 3, the ARK Hospital Analysis Plan that Public Health England (PHE) and a number of NHS Foundation Trusts were referred to and asked for further clarity on the roles of these organisations in section 5.
	IGARD noted that the abstract should be amended to make clear that the applicant is a Foundation Trust and the relevant Article 6 and 9 of the General Data Protection Regulation (GDPR) be updated to reflect recent discussions between NHS Digital and IGARD including, but not limited to, reference to section 43(5) NHS Act 2006 in relation to the legal basis for Foundation Trusts.
	IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice.
	Outcome: recommendation to approve subject to the following condition(s)
	1. To provide evidence that funding is continuing.
	2. To update the abstract to clearly articulate the current situation and the steps being taken to produce a Fair Processing Notice that meets the criteria and reflects the efforts undertaken by the applicant.
	3. To provide confirmation that the named individuals in supporting document 8 (the letter from University of Oxford dated 10 June 2016 naming individuals as part of the research) are still in place and that the letter covers all the necessary individuals. If any individuals have left or joined the study team, for the University of Oxford to provide a revised letter naming the relevant individuals involved.
	4. To update section 5 to clearly define the routes to dissemination for the benefits and outputs outlined in the application and as noted by their predecessor DAAG.

	5. To clarify within section 5 the role of Public Health England (PHE) and the other Foundation Trusts referred to supporting document 3 the ARK Hospital Analysis Plan. The following amendments were requested: 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 section 43(5) NHS Act 2006 in relation to the legal basis for Foundation Trusts. The following advice was given: 1. IGARD suggested that the applicant continues to work with NHS Digital on their Fair Processing Notice. IGARD noted the importance of the research undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital was due to expire, and in light of this it was suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to update the application. It was agreed the conditions be approved OOC by IGARD Members.
2.14	Cardiff University: Building blocks Trial – Data Archive (Presenter: Dave Cronin) NIC-313754-G6X4Z The application was withdrawn by the presenter. IGARD noted the importance of the research undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital was due to expire, and in light of this it was suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to finalise the template and then update the application.
4	**AOB**
4.1	**NIC-292279-Z2S5T South London & Maudsley NHS Foundation Trust** IGARD noted that following the 29th November 2018 meeting, when IGARD had deferred making a recommendation. The relevant extract is as follows: "IGARD deferred making a recommendation, pending: 1 To update section 5 to clarify why Kings College London are not considered as joint data controllers (particularly considering various statements which would indicate otherwise in the supporting documents). 2 To send a letter of clarification to REC setting out, contrary to the earlier document provided to REC, that the applicant is dealing with pseudonymised data with direct identifiers removed and, in some cases, individuals may be re-identified on request. 3 To update the honorary contract to explicitly reference that substantive employers will be accountable for breaches of data protection laws and confidentiality. 4 To explicitly state in section 5 the identifiers sent to NHS Digital, to align with the s251 support. 5 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) the justification of public task for Foundation Trusts." NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.

4.2	**<u>NIC-08472-V9S6K UK Biobank</u>** IGARD noted that following the 29th November 2018 meeting, when IGARD had been unable to make a recommendation. The relevant extract is as follows: "IGARD were unable to recommend for approval. 1. To clearly outline the different purposes for which UK Biobank are processing data in the clinical setting and clearly identify the legal bases that relates to each separate purpose within a clinical setting. 2. To align the lawful basis for the applicant with the permissions listed under the Access Procedures supporting document (which appears to presume consent is the legal basis for processing)." NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.
4.3	**Automated Decision Making** IGARD noted that the Article 29 Data Protection Working Party had issued guidelines with regard to Automated Decision Making (WP251rev.01): *Guidelines on Automated individual decision-making and Profiling for the purposes of Regulations 2016/679.* IGARD also noted that the Information Commissioner's Office (ICO) had issued practical guidance for UK organisations on automated decision-making and profiling under General Data Protection Regulations (GDPR). It was noted that automated decision-making was the process of making a decision by automated means without any human involvement and that these decisions can be based on factual data, as well as on digitally created profiles or inferred data. Profiling analyses aspects of an individual's personality, behaviour, interests and habits to make predictions or decisions about them. Automated decision making and profiling can be useful for organisations and also benefits individuals in many sections include healthcare, however, there are number of risks and these are highlighted in in the ICO guidance.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 07/12/18

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-147941-XX4JP	The University of Manchester	04/10/18	1. To update the abstract of Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including (but not limited to) reference to the Royal Charter and public interest condition under the DPA 2018. 2. To clearly list the identifiers that are sent to NHS Digital. 3. To provide a clearer explanation and further examples of the proposed outputs and yielded benefits within section 5 of the application.	IGARD Members	Quorum of IGARD Members	N/A
NIC-147782-0D7TX	University of Oxford	01/11/18	1. To clarify in section 5(b) the data linkages and confirm that the applicant will not link the data further and the only data linkages are those permitted under this application 2. To provide evidence from the HRA CAG registry that the original 2015 s251 support (including any amendments subsequently made to the approval) is still in place. 3. To clarify the arrangements relating to the collection of data from the Renal Registry to specify who will collect the data and in this context to clarify further the statement within section 5(b) "The data from NHS Digital and UKRR will be collected separately so the data will only be linked to CTSU SHARP PFTU database through SHARP unique participant identifier…".	IGARD members	Quorum of IGARD Members	The request was "to clarify the **arrangements** relating to the **collection** of data from the Renal Registry **to specify who will collect the data**." For example, if it is the routinely collected data contained in the UKRR as set out in 5a perhaps that could be stated.

NIC-147907-MLK7R	Derbyshire Healthcare NHS Foundation Trust	22/11/18	1. To provide a detailed IG assessment that confirms that the duty of confidentiality has been met. 2. To provide evidence that ethics approval is not required.	IGARD Chair	IGARD Chair	Suggest that the IG assessment has a date (December 2018) inserted and it's a valuable document for future reference/an audit trail.
NIC-147957-4444C	University of Oxford	22/11/18	1. To provide evidence of confirmation that the study has ongoing ethics support	IGARD Chair	IGARD Chair	N/A

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

- None notified to IGARD